

LAPORAN PERJALANAN DINAS

SEARN Assembly Meeting

15-16 Juli 2025 di Thimphu, Bhutan



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BADAN PENGAWAS OBAT DAN MAKANAN REPUBLIK INDONESIA TAHUN 2024

BAB I PENDAHULUAN

A. Latar Belakang

South-East Asia Regulatory Network (SEARN) telah dibentuk untuk mengembangkan dan memperkuat kolaborasi, konvergensi, dan ketergantungan regulasi di Wilayah Asia Tenggara. Pertemuan pertama diadakan pada tahun 2017 dengan semua Otoritas Regulasi Nasional (NRA) di wilayah Asia Tenggara yang bertanggung jawab atas regulasi produk medis sebagai anggotanya. SEARN telah berkembang menjadi jaringan dinamis yang melibatkan lebih dari 100 ahli dari NRA yang bertemu sepanjang tahun untuk memajukan rencana kerja yang disepakati. Hingga April 2025, lebih dari 60 pertemuan telah diorganisir sebagai bagian dari work plan 2024-2025 yang sedang berjalan, yang mencakup 13 *action points*. Hal ini memungkinkan kemajuan signifikan dalam beberapa tahun terakhir di berbagai area pekerjaan SEARN, termasuk pelaksanaan strategi berbagi informasi SEARN (dari tidak ada SEARN safety alerts, telah ada 3 alerts pada 2023-2024, dan 14 alerts pada workplan 2024-2025 yang sedang berlangsung), pengembangan mekanisme kesiapan regulasi yang pertama kali pada Agustus 2024 untuk mpox, atau pengembangan domain kerangka kompetensi untuk mendukung NRA dan strategi pembangunan kapasitas SEARN.

Assembly ini akan menjadi kesempatan untuk meninjau kemajuan pada workplan 2024-2025 dan sesuai dengan Monitoring and Evaluation Framework, mengadopsi workplan untuk tahun berikutnya, mendiskusikan dan menyepakati arah strategis network. Ini termasuk meninjau pilot dari strategi capacity building, menyelesaikan Memorandum of Understanding (MoU) SEARN untuk memfasilitasi kolaborasi dan berbagi informasi, meninjau pencapaian dari WG3 vigilance yang dibuka untuk 15 ahli eksternal, atau berinteraksi dengan network internasional seperti ASEAN dan International Medical Device Regulators Forum (IMDRF), serta meninjau pencapaian respons SEARN terhadap Mpox, serta membentuk working group khusus untuk produk obat tradisional. Coalition of Interested Parties(CIP) yang dibentuk pada Juli 2023, dan memulai diskusi dengan mitra potensial lainnya (Jepang, ADB, dan US FDA).

Pertemuan ini akan diikuti oleh pertemuan virtual dari working group SEARN dan Steering Group

B. Tujuan

Misi SEARN adalah untuk mengembangkan dan memperkuat kolaborasi, konvergensi, dan ketergantungan regulasi di wilayah Asia Tenggara terkait isu dan tantangan regulasi yang sama, yang akan membangun kepercayaan dan kapasitas, serta memungkinkan Otoritas Regulasi Nasional (NRA) untuk melaksanakan mandat mereka dalam melindungi kesehatan masyarakat.

Tujuan Khusus

1. Menyimpulkan kemajuan workplan SEARN 2024-2025 dan network sesuai dengan the Monitoring and Evaluation Framework (termasuk kemajuan terhadap

Global Benchmarking Tool), serta mendiskusikan dan mengadopsi workplan SEARN 2025-2026.

2. Mengadopsi dokumen dan strategi yang dikembangkan oleh working group serta mendiskusikan cara lebih lanjut untuk meningkatkan berbagi informasi, reliance, kolaborasi, dan capacity building.
3. Mendiskusikan dan mengadopsi TOR.
4. Mendiskusikan cara untuk memperkuat keberlanjutan network.
5. Berdiskusi dengan *public procurement agencies* tentang bagaimana mencapai keseimbangan yang memadai antara kualitas dan aksesibilitas produk medis bagi semua, serta membuat deklarasi bersama antara *public procurement agencies* dan anggota SEARN untuk mendukung tujuan ini.
6. Memfinalkan SEARN Memorandum of Understanding.
7. Berdiskusi tentang potensi kolaborasi dengan jaringan regulasi lainnya (misalnya ASEAN, Western Pacific Regional Alliance of NRAs for Medical Products).
8. Memfinalkan aplikasi SEARN untuk International Medical Device Regulators Forum (IMDRF).
9. Memfinalkan SEARN intra-action review of the Network's response to Mpox
10. Berdiskusi dan mengoptimalkan kolaborasi yang ada dengan Coalition of Interested Parties (CIP) dan mitra potensial lainnya.
11. Mengambil keputusan mengenai nominasi chair Working Groups, rotasi member Steering group dan host Assembly 2026

C. Pelaksanaan

Tempat : Thimphu, Bhutan
Waktu : 15-16 July 2025

D. Penyelenggara

WHO SEARO

E. Peserta

Kepala otoritas regulatori obat atau perwakilan, Chair Working Group, perwakilan dari WHO HQ, SEARO, WPRO, WCO, perwakilan dari public procurement agencies, anggota Coalition of Interested Parties (TGA, ADB, CEPI, Duke Nus Centre of Regulatory Excellence (CoRE), ISOP (International Society of Pharmacovigilance), Swissmedic, US FDA (U.S. Food and Drug Administration) dan USP (United-States Pharmacopoeia).

BAB II KEGIATAN

A. AGENDA

14 July		
Time (Thimphu)	Agenda item	Lead

14:00	Preparatory Meeting	WHO Closed meeting
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15 July		
Time (Thimphu)	Agenda item	Lead

08:30	Arrival of guests and invitees	Lead
09:00	1. Opening addresses	Chair Assembly Regional Director WHO SEARO
09:00	1.1. Arrival of chief guest (HE Health Minister)	Bhutan
09:10	1.2. Marchang ceremony	Bhutan
09:20	1.3. Welcome remarks	Director, BFDA
09:40	1.4. Remarks	Regional Director/WHO Representative, WHO
10:00	1.5. Keynote Address	Honorable Minister, MoH
10:20	1.6. Opening of the Assembly	All
10:30	1.7. Vote of Thanks	Chief, MPD, BFDA
10:40	Group photo and High Tea	

11:00	2. Introduction of the participants, update on countries not participating in this meeting, and Indonesia's departure from SEARN	Chair and Secretariat
11:10	3. Latest global developments in medical products regulation	WHO HQ
11:40	4. Introductions to the U.S. FDA in India and FDA's International Offices	US FDA India Office Mr. Gregory Smith
12:00	5. Introduction to ADB and its regulatory system strengthening activities	ADB Dr Jae Kyoung Kim
12:15	6. Feedback from the Steering Group	Chair Steering Group
12:25	7. SEARN Monitoring and evaluation framework	SEARN Secretariat
12:35	8. Work plan outputs § Discussion and adoption of working groups' outputs, including SEARN MoU	Rapporteurs and WG Chairs

13:00	<i>Lunch Break</i>
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14:00	9. Regulatory excellence: Achieving Balance of quality and accessibility to medical products for all – Session 1	SEARN and public procurement agencies (virtual)
14:00	9.1. Introduction and objectives	SEARN secretariat
14:05	9.2. Streamlining Access: Enhancing collaboration between regulatory authority and procurement agencies for timely access to quality and affordable medicines	WHO SEARO Uhjin Kim
14:25	9.3. Key challenges: Perspectives from Public Procurement Agencies · Bhutan (5 mins) · Maldives (5 mins) · Discussion	Bhutan, Maldives
14:45	9.4. Perspectives from the Industry	Bhutan
14:55	9.5. Issues around small volume products	WHO SEARO

		Anil Chawla
15:05	9.6. Open discussion on Interplay between NRA and PPA	WHO SEARO Adrien Inoubli
15:15	9.7. SEARN work on facilitating access (shortages, reliance)	SEARN Secretariat
15:25	9.8. Online Poll and discussion: Fostering collaboration	WHO SEARO Gereltuya Dorj
15:40	9.9. Draft Joint Declaration – Presentation and first discussion	SEARN secretariat
15:55	9.10. Conclusion of the first session on Regulatory excellence: Achieving Balance of quality and accessibility to medical products for all	SEARN secretariat

16:00	Coffee Break	
16:30	10. Work plan outputs (Continued) § Discussion and adoption of working groups' outputs, including SEARN MoU	Rapporteurs and WG Chairs
18:00	End of the meeting	
18:30	Dinner hosted by His Excellency the Health Minister of Bhutan	
16 July		
Time (Thimphu)	Agenda item	Lead
09:00	11. Work plan outputs (Continued) § Discussion and adoption of working groups' outputs, including SEARN MoU	Rapporteurs and WG Chairs
10:15	12. Sustainability of SEARN	Secretariat
10:30	Coffee Break	
11:00	13. Draft declaration of Members of SEARN and public procurement agencies on Enhancing Convergence and Collaboration for Access to Quality-Assured Medical Products	SEARN and public procurement agencies (virtual)
12:00	14. 2025-2026 Workplan § Discussion and adoption of the 2025-2026 Workplan § Discussion and adoption of the Nominations of Chairs, Rapporteurs and drafting group members	Chair Assembly

12:45	15. Other decisions § Creation of WG6 Traditional Medical Products § Proposed revised ToR, Discussion and Adoption § New SEARN logo § Application for SEARN to join IMDRF § Host of the next SEARN meeting – Discussion and Adoption § Rotation members of the Steering group – Discussion and Adoption	Chair Assembly
13:15	16. Summary of the decisions made	Secretariat
13:30	<i>Lunch Break</i>	
14:00	17. Roundtable discussion with regulatory networks and partners: strengthening collaboration within SEARN and beyond SEARN – the way forward	ASEAN, WPRA, ADB, CIP and SEARN Secretariat
15:25	18. Conclusions of the meeting	Chair Assembly
15:30	Networking between National Regulatory Authorities	Bhutan
18:00	<i>End of the SEARN Assembly meeting</i> <i>Social event</i>	
18:00	Closed Meeting of the CIP regional Steering group	CIP members, other partners, SEARN secretariat
19:00	<i>End of the Meeting of the CIP regional Steering group</i>	

B. Hasil Pertemuan (DISINI YA NOTULENNYA):

1. Opening addresses by Chair Assembly (Patrice)

English	Bahasa
• Your Excellency, the Honorable Minister, Ministry of Health • Dr. Upendo Olak, WHO representative, means WHO Country Office, TMPO. Distinguished delegates from member states. • Represented from the visual and UN agencies. • Esteemed guests, ladies and gentlemen, a very good morning, and kudos Ambula. • It's both a privilege and a great pleasure for me, on behalf of the	• Tema pertemuan tahun 2025: "<i>Mercury to Excellence</i>," yang menekankan keseimbangan antara mutu dan ketersediaan obat serta tantangan yang harus dihadapi oleh regulator. Pertemuan ini diharapkan tidak hanya menghasilkan keluaran teknis, tetapi juga mempererat hubungan kemitraan di antara negara-negara anggota. • Negara-negara di kawasan Asia Tenggara dihadapkan pada berbagai tantangan kesehatan

Royal Government of Bhutan and the Bhutan Food and Drug Authority, Ministry of Health. To welcome each one of you to the South East Asian Regulatory Network assembly. We are... Absolutely thrilled to have this significant event.

- I'm sure with you the beauty and human spirit of our country.
- All populations in the Southeast Asia region faces diverse health challenges compounded by complex supply chains and growing demands.
- For new therapeutic technologies. Regulatory authorities carry the critical responsibility of safeguarding public health.
- Yet, we must ensure that the regulatory processes do not become barriers.
- That is life-saving medicines, vaccines, and medical devices. From reaching those who need them the most.
- Ensuring timely access to safe, effective, and quality-assured medical products is not just a technical goal.
- In fact, it is a fundamental pillar of public health and human dignity.
- This year's meeting theme... That we have selected is Mercury to Excellence.
- That is, achieving a balance between quality and excess of medical products for all.
- Speaks of a challenge that resonates. Deeply across all our missions gathered here today.
- As regulators in the region, we play a pivotal role as public health gatekeepers.
- Safeguarding populations against substandard falsified and unsafe medical products. Yet, we also face increasing pressure to accelerate approvals. As they did innovation and responded rapidly to health emergencies, all while

yang semakin kompleks, diperburuk oleh struktur rantai pasok yang rumit serta meningkatnya permintaan terhadap teknologi terapeutik terbaru. Dalam konteks ini, otoritas regulatori memegang peranan penting dalam melindungi kesehatan masyarakat, seraya memastikan bahwa proses regulasi tidak menjadi hambatan dalam penyediaan obat-obatan, vaksin, dan alat kesehatan.

- Akses yang tepat waktu terhadap produk obat yang aman, berkhasiat, dan bermutu tidak hanya merupakan aspek teknis, tetapi juga merupakan pilar mendasar dalam sistem kesehatan masyarakat.
- Dalam menjalankan fungsinya, otoritas regulatori di kawasan Asia Tenggara dituntut untuk menjaga masyarakat dari paparan obat yang tidak memenuhi standar, dan menghadapi tekanan untuk mempercepat proses persetujuan terhadap produk inovatif dan merespons situasi darurat kesehatan secara cepat, tanpa mengabaikan integritas standar ilmiah yang berlaku.
- SEARN berperan sebagai platform kolaboratif yang vital bagi negara-negara anggota, termasuk Bangladesh, Bhutan, India, Indonesia, dan lainnya, dalam memperkuat kapasitas sistem regulasi nasional. Sejauh ini, SEARN telah menunjukkan kemajuan nyata dalam mendorong konvergensi regulasi dan pembangunan kapasitas, meskipun upaya lebih lanjut masih diperlukan untuk mempertahankan momentum serta mengatasi tantangan yang terus berkembang.
- Pertemuan ini menjadi wadah

maintaining rigorous standards, which is not very easy. ● Striking the right balance between quality assurance and accessibility is no simple task. It requires constant learning, innovation, and collaboration. ● But the urgency couldn't be cleared. People can't afford to wait, and we must do what we have to do. ● The South East Asia Regulatory Network, which we, in short form, would call as SEARN. ● Serves as a vital platform for member states. Consisting of Bangladesh, Bhutan, GPR Korea, India, Indonesia, Maldives. ● Here, to collaborate harmonized approaches, and also strengthen the virtual system. ● SEARN, I believe, has made significant progress in promoting regulatory convergence, whereas practices, and capacity building. ● But for the action, it is required to sustain momentum and address emerging challenges. ● This assembly of SEARN 2025 held in Thimphu Bhutan is an opportunity to spark wider dialogue and build strong partnership among our regulatory authorities. ● Together, in this assembly, we aim to conclude the progress of Serum 2425. ● And adults 25, 26 would plan. Share experiences in managing emergencies without compromising our standards. ● Finalize the third MOU and chart the network's strategic direction, including sustainability of the network. ● We also would engage with public procurement agencies to strike the right balance between quality and accessibility of medical products for all.	strategis untuk memperluas dialog, memperkuat kemitraan antar-otoritas regulatori, serta berbagi pengalaman dalam merespons keadaan darurat kesehatan tanpa menurunkan standar mutu. Selain itu, pembahasan diarahkan pada penyusunan rencana strategis SEARN, serta penajakan potensi kolaborasi dengan jejaring regulasi lainnya, seperti ASEAN. ● Diperlukan komitmen bersama untuk menghadapi tantangan kesehatan lintas negara dan memastikan bahwa kepentingan pasien serta masyarakat tetap menjadi prioritas utama dalam proses pengambilan <i>regulatory action</i>. ● Indonesia sebagai anggota tetap dalam SEARN, dijadwalkan akan mengakhiri keanggotaannya setelah pertemuan tahun ini. Chair Assembly menyampaikan apresiasi atas kontribusi yang signifikan selama masa keanggotaan. Kehadiran Indonesia telah memberikan perspektif yang berharga, dan peluang kerja sama lanjutan di masa mendatang tetap terbuka untuk Indonesia.
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| <ul style="list-style-type: none">• And jointly explore a declaration to support this group. We will also be discussing potential collaboration with other regulatory networks, such as ASEAN and the Western Pacific Regional Alliance of the Inawi.• Last, but not the least, strengthen regional cooperation to tackle cross-border health challenges and ensure that patients and community.• Remaining at the very heart of our regulatory decisions.• The Bhutan Food and Drug Authority is proud to be part of this network, and even more proud to host this year's assembly.• I hope this meeting proves not only technically enriching. But it also offers everyone a chance to build meaningful connections, explore fresh ideas, and leave inspired to take bold, collaborative steps forward.• And while we engage in this vital discussion. I also wish for you to experience Bhutan's unique culture, warm hospitality, and the pristine natural environment.• Now, as Indonesia, who is one of the permanent members of the steering group prepares to leave this SEARN following this year's meeting. I think it's with, everyone feels, we all are feeling a profound mix of sadness as well as gratitude. We are deeply thankful for all that Indonesia has given to this shared journey. Their unwavering dedication, invaluable insights, and the generous spirit of collaboration that has touched us all. Indonesia has not only enriched the hope of the SEARN, but also, we have strong bonds across the region. We will miss their presence.• And the unique perspective they have all along throughout the discussions. | |
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• From all of us, we extend our warmest wishes to Indonesia. • And the delegations who are present here for success and fulfillment. • In all future endeavors, and we sincerely hope that we will cross paths again for more opportunities to work together. • So, I look forward to maintaining strong ties and exploring ways to work together in the future with Indonesia. • Once again, I want to welcome each one of you to Bhutan, and we look forward to a successful and fruitful assembly. • Together, thank you, and touch it.	
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2. WG Representative (Dr. Olak)

- Your Excellency, the Honorable Minister of Health, Royal Government of Bhutan. - Important in Wangchuk. Mrs. Gaimbidha? - Chair of this assembly. Distinguished representatives of member states and heads of national regulatory authorities. Development partners - Representatives from ADB, U.S. Food and Drug Administration, Western Region Pacific. - Western Pacific Regional Alliance of National. Regulatory authority? - My colleagues from WHO Regional Office, Country Office, Development Partners. Ladies and gentlemen, and a warm welcome. - To this annual assembly of the Southeast Asia Regional Regulatory Network. - Let me begin by extending my sincere appreciation to the	• Komitmen Bhutan dalam SEARN 1. Bhutan telah menunjukkan komitmen yang luar biasa dalam jaringan regulasi di Asia Tenggara (SEARN) dan berperan aktif dalam penguatan kapasitas regulasi di regional ini. 2. Bhutan telah secara konsisten berpartisipasi dalam <i>steering group</i> dan berbagai <i>working group</i>, serta menyumbangkan kontribusi signifikan dalam pengembangan sistem regulasi yang lebih baik. 3. Bhutan juga telah berinisiatif untuk memulai pusat regulasi regional pertama yang berfokus pada sistem manajemen kualitas regulasi (<i>Regulatory Quality Management System</i>), yang merupakan pencapaian besar bagi regional ini. • Tema Pertemuan dan Tujuan
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Royal Government of Bhutan and the Ministry of Health, in particular, for graciously hosting this important meeting in the Kingdom of Bhutan.

- Which is known for its commitment to gross national happiness and equity in health.
- Bhutan has been committed and a proactive member of this member state-led network.
- And has consistently demonstrated leadership. Actively participated in steering committees.
- And has contributed to multiple drafting groups. And volunteered to pilot the first-ever regional center of regulatory excellence.
- Focusing on the regulatory quality management system, and this is both commendable and inspiring.
- The theme for this assembly is regulatory excellence achieving a balance between quality.
- And accessibility to medical products for all. Which underscores the pivotal role.
- That robust regulatory systems can play in enabling timely access to safety.
- Effective quality assured, and affordable medical products, which is a cornerstone for achieving universal health coverage.
- I would like to respectfully urge all delegates and member states to consider.
- The importance of pool procurement mechanisms. For smaller countries, the lack of such collaborative arrangements presents significant challenges.
- And ensuring sustainable and equitable access to essential medical products. At a reasonable price.

Kolaborasi

1. Tema pertemuan "*Regulatory Excellence*" menekankan pencapaian keseimbangan antara kualitas dan aksesibilitas obat.
2. Tema ini mencerminkan tantangan besar yang dihadapi negara-negara di kawasan *South East Asia*, di mana peningkatan kapasitas regulasi yang kuat sangat dibutuhkan untuk memastikan akses tepat waktu terhadap obat yang aman, berkeadilan, dan bermutu
3. Tujuan utama adalah menciptakan kolaborasi regional untuk memastikan bahwa obat yang disetujui memenuhi standar kualitas yang tinggi dan dapat diakses oleh seluruh populasi, tanpa mengorbankan kecepatan dalam proses persetujuan.

• Tantangan di Kawasan Global Selatan:

1. Negara-negara di kawasan Global Selatan, termasuk Asia Tenggara, menghadapi tantangan besar terkait fragmentasi regulasi dan kapasitas yang bervariasi di masing-masing negara.
2. Tantangan ini diperburuk dengan kompleksitas rantai pasokan dan meningkatnya permintaan untuk teknologi medis baru yang terus berkembang.
3. Meskipun banyak kemajuan telah dicapai, perbedaan dalam kapasitas dan sistem regulasi antar negara masih menjadi hambatan utama dalam memastikan akses yang adil dan berkelanjutan

- And pool procurement offers a practical path. Towards leveraging collective bargaining power, enhancing affordability, reducing supply vulnerabilities and aligning with the spirit and ambition of. - This year's assembly. Since the last assembly was held in Dhaka. In July 2024. SEARN has made impressive strides. - Let me highlight some of the milestones. A mature SEARN Memorandum of Understanding is underway now which will lead to collaboration among national regulatory authorities. National Quality Control Laboratories have now access to our database. - Characterizing their capacity to enable collaboration and facilitate training. The SEARN competency-based training catalog is currently under development. - And a new training program for good storage and distribution practices, inspectors have been launched. - Working Group 3 on vigilance. Has now benefited from the support of 15 independent experts. - And the first safety signal and issue are under review. Sound safety alerts are now being actively shared between NRAs. - Strengthening post-market surveillance. The preparedness strategy has successfully been piloted with MPOX. - And that is, I have benefited from a forum to discuss. Regulatory issues and centralized supporting resources. - Many NRAs have initiated self-assessments using global benchmark tools for medical	terhadap obat di kawasan ini. • Pentingnya Kolaborasi Regional: 1. SEARN telah menunjukkan kemajuan signifikan dalam mempromosikan konvergensi regulasi antar negara, di mana negara anggota dapat saling berbagi keahlian teknis, sumber daya, dan pengalaman. 2. Kerjasama ini tidak hanya memperkuat kapasitas regulasi, tetapi juga memungkinkan negara-negara untuk merespon lebih efektif terhadap tantangan kesehatan masyarakat yang muncul di region ini. 3. SEARN juga berfokus pada peningkatan pengawasan pasar pasca-produksi dan berbagi informasi terkait keamanan obat yang sangat penting untuk melindungi kesehatan masyarakat. • Tantangan Keberlanjutan SEARN: 1. Meskipun banyak kemajuan telah dicapai, SEARN tetap menghadapi tantangan besar terkait keberlanjutan jangka panjang, khususnya dengan terbatasnya sumber daya keuangan dan manusia. 2. Untuk mempertahankan momentum SEARN, diperlukan upaya lebih dalam menggali dukungan finansial, baik dari anggota SEARN, mitra eksternal, maupun lembaga internasional yang mendukung penguatan kapasitas regulasi regional.
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devices regulation. - SEARN is now in the final stage for applying to the membership in the International Medical Device Regulators Forum. - These achievements are a testament. To your collective commitment, technical leadership, and growing maturity of SEARN in our region. - But however, we are not free from challenges that lie ahead. - The sustainability of SEARN remains a pressing concern, especially. With the growing constrained financial and human resources. - To sustain and grow this vital network. We must explore innovative ways to mobilize support from member NRAs, partners, and stakeholders. - I encourage you to have an open solution-oriented discussion on this matter. - I also sincerely thank our partners from the Coalition of Interested Partners. - For their invaluable contribution throughout this. Work plan. Over the next two days, you are here. - And I'm sure of your deliberations. Will be quite pivotal in paving the path for a robust SEARN Network. I encourage you to actively participate in these discussions, ensure that the time. - Invested by you, benefits your own national regulatory authority, and serves the interests of your country. - But while you're here, don't miss to enjoy the beauty and serenity of this beautiful country of Bhutan. - And make most of the time	● Pentingnya Kerjasama dengan Public Procurement Agencies: 1. Untuk menjaga keseimbangan antara mutu dan ketersediaan obat, SEARN mengusulkan agar kerjasama dengan <i>Public Procurement Agencies</i> diperkuat. 2. Kolaborasi ini akan memungkinkan negara-negara anggota untuk memastikan akses yang lebih baik terhadap obat yang aman dan bermutu, sekaligus memastikan bahwa biaya produk tetap terjangkau bagi seluruh masyarakat. ● Rencana Kolaborasi dengan Jaringan Regulasi Lain: 1. SEARN juga berencana untuk menjajaki kemungkinan kolaborasi dengan jaringan regulasi internasional lainnya seperti ASEAN dan <i>Western Pacific Regional Alliance</i> untuk memperkuat kerjasama dalam mengatasi tantangan kesehatan lintas negara. 2. Kolaborasi ini diharapkan dapat menghasilkan pendekatan yang lebih harmonis dalam hal regulasi dan aksesibilitas obat di tingkat global. ● Tujuan dari Pertemuan Ini: 1. Pertemuan ini diharapkan dapat membuka dialog yang lebih luas dan membangun kemitraan yang lebih kuat di antara otoritas regulasi negara anggota. 2. Dalam pertemuan ini, SEARN berencana untuk mengevaluasi kemajuan yang telah dicapai selama periode 2024–2025, serta
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here. This is the best season to visit Bhutan, and I'm sure this weather will also add to your. - To make your meeting more productive. Thank you, Natashi Delhi.	merencanakan langkah-langkah untuk tahun 2025–2026, termasuk berbagi pengalaman dalam mengelola situasi darurat tanpa mengorbankan standar yang sudah ditetapkan. 3. Selain itu, pertemuan ini juga bertujuan untuk menyelesaikan perjanjian MoU ketiga dan merencanakan arah strategis SEARN, termasuk keberlanjutan network ini di masa depan.
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3. Keynote Address Honorable Health Minister, MoH Bhutan

• Distinguish delegates from member states. Representative from the World Health Organization. Development partners, and Colleagues. • And a very warm welcome to Bhutan. It is my great honor and privilege to address you today. • At the inaugural session of the South East Asia Regulatory Network Assembly meeting. On behalf of the Royal Government of Bhutan and the Ministry of Health. I extend a warm welcome to the distinguished delegates of the Southeast Asia Region, and collaborating partners. • I would like to extend our heartfelt gratitude to the World Health Organization. For its continued support in fostering regulatory collaboration and capacity building across the region. • We are truly honored to host this important gathering here in Bhutan. The health of our	• Dalam konteks global yang semakin terintegrasi, pemastian khasiat, keamanan dan mutu obat telah menjadi prioritas bersama. Tidak hanya pada tingkat nasional, tetapi juga regional dan internasional. Berbagai platform kerja sama regional yang telah terbentuk menjadi bukti nyata dari komitmen bersama untuk memperkuat kapasitas regulasi, mendorong pertukaran keahlian teknis, serta harmonisasi dengan standar global. • Sejak awal berdiri, SEARN telah mencatat kemajuan signifikan dalam meningkatkan kolaborasi regional dan memperkuat kesiapan negara anggota dalam merespons tantangan kesehatan masyarakat. Misalnya, pandemi COVID-19 yang menjadi pengingat akan urgensi sistem kesehatan yang tangguh serta kesiapan regulatori yang efektif. Pengalaman selama beberapa tahun terakhir semakin menegaskan nilai strategis dari
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people depends significantly. ● On the stand and efficiency of our regulatory system in an increasingly interconnected world. Our ability to safeguard the quality, safety, and efficacy of medical products is not only a national responsibility, but a shared regional and global priority. Different platforms stand as a testament to our collective commitment to strengthen regulatory capacity, sharing technical expertise and aligning practices with international standards. Since its inception. ● SEARN has made commendable progress in enhancing regional cooperation, and enabling countries to respond more effectively to public health challenges. ● This assembly convinced at a critical moment. The COVID-19 pandemic has powerfully reminded us how essential resilient health systems are. And how critical it is to be prepared from a regulatory standpoint. The lessons of recent years have been highlighted. The immense value of strong regulatory networks. ● Certain information sharing and harmonized strategies. To ensure access to safety, high-quality medical products. ● As we come together for this SEARN assembly. I urge all delegates to reflect not only on how far we have come. But also on the challenges that remain and the opportunities before us. Let us commit to strengthening our regulatory authorities. ● Investing in the development of our workforce. Harnessing the	jejaring regulasi yang kuat, mekanisme pertukaran informasi yang andal, dan penerapan strategi yang terkoordinasi untuk menjamin akses terhadap obat yang aman, berkhasiat, dan bermutu. ● Pertemuan SEARN kali ini menjadi momentum penting untuk merefleksikan pencapaian yang telah diraih sekaligus mengidentifikasi tantangan yang masih dihadapi serta peluang kolaborasi yang dapat dioptimalkan. Penguatan kelembagaan otoritas regulatori, pengembangan kapasitas sumber daya manusia, pemanfaatan inovasi digital, serta pembangunan sistem pengakuan dan kepercayaan lintas negara menjadi agenda utama dalam menciptakan sistem regulasi yang tangguh dan terpercaya. ● Bhutan terus menunjukkan komitmen yang kuat dalam menjalin kerja sama dengan mitra regional, organisasi global, serta WHO untuk mendorong konvergensi regulasi dan memperkuat sistem pengawasan obat. Namun demikian, penguatan sistem regulasi tidak dapat dilakukan secara terpisah. Diperlukan solidaritas dan tanggung jawab bersama untuk memastikan tidak ada negara yang tertinggal dalam pengembangan kapasitas regulatori. ● Melalui kerja sama dan kolaborasi yang erat, setiap negara, tanpa memandang skala maupun keterbatasan sumber daya, diharapkan mampu melindungi kesehatan dan kesejahteraan masyarakatnya secara optimal. ● Pertemuan ini diharapkan dapat menghasilkan diskusi yang
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potential of digital innovations and building mutual recognition and trust across our region. • Together, we can shape a future where every person has family access to safe, effective and quality assured medical products. • Bhutan stands steadfast. In our commitment to working alongside our partners in the region, globally, and with the World Health Organization. To drive regulatory convergence and build stronger systems. • But we know we cannot do this alone. Now, more than ever. • We must nurture true solidarity. And embrace our shared responsibility. • It is imperative that no country is left behind. In advancing, it is regulatory capabilities. • Together, through unity and cooperation. We can ensure that every nation, regardless of its size or resources can protect the health and well-being of its people. • And I conclude. I would like to acknowledge the dedicated efforts of the Bhutan Food and Drug Authority. World Health Organization country office in Bhutan and the World Health Organization Regional Office. For making this assembly possible. • I am confident that devaluable discussions will have a meaningful insight. And concrete actions. That will help us move closer to our shared goals. • I once again welcome you all to Bhutan. And I wish the SEARN Assembly meeting every success. • Enjoy your stay in Bhutan. Thank you, and Tashid Lake.	konstruktif, wawasan strategis, serta tindakan nyata dalam mewujudkan tujuan bersama di bidang penguatan sistem regulasi kesehatan.
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4. Mr. Jigme Tenzin, Chief Regulatory Officer, Medical Product Division, Bhutan Food and Drug Authority

English	Indonesia
• The inaugural session of the Assembly of members of Southeast Asia Regulatory Network 2025. • I would like to sincerely thank all for gracing us with your presence and thoughtful participation. The health of our population depends profoundly on the strength and efficiency of the regulatory system. • The Global South is not only a hub for the manufacturing and consumption of medical products, but also a region of diverse health systems and regulatory capacity. • This diversity brings challenges, particularly regulatory fragmentation and varying levels of capacity, but it has an equal presence or opportunity for collaboration, shared learning, and regional integration. • On behalf of the Bhutan Food and Drug Authority and the organizing team. I wish to express special gratitude to Your Excellency, Honorable Health Minister for your gracious presence and for your steadfast commitment to strengthen the regulatory system in Bhutan, and contributing to the broader regulatory landscaping. • Allow me to once again reaffirm. As emphasized during the integral address. • Ensuring timely access to a safe, effective and quality-assured medical product. Because it is not only a national effort. But a	• Wilayah <i>Global South</i> saat ini tidak hanya berperan sebagai pusat utama produksi dan konsumsi obat, tetapi juga mencerminkan keragaman sistem kesehatan dan kapasitas regulatori di antara negara-negara di dalamnya. Tingginya variasi kapasitas ini menimbulkan tantangan tersendiri, khususnya dalam menghadapi fragmentasi regulasi serta kesenjangan dalam kemampuan institusional. Meskipun demikian, kondisi tersebut juga membuka peluang besar bagi kolaborasi lintas negara, <i>sharing knowledge</i>, serta penguatan integrasi regulasi di tingkat regional. • Sesi pembukaan pada pertemuan ini menandai langkah penting menuju peningkatan konvergensi regulatori dan kolaborasi yang lebih erat di antara negara-negara anggota SEARN. Rangkaian diskusi teknis yang akan berlangsung selama pertemuan diharapkan dapat memperkuat fondasi kerja sama yang telah terbentuk serta menghasilkan langkah-langkah konkret yang mendekatkan seluruh pihak pada pencapaian visi bersama di bidang regulasi kesehatan.

collective regional commitment and good in solidarity, trust, and mutual recognition. • I also wish to extend our heartfelt appreciation to WHO Country Office and WHO Southeast Asia Regional Office, specifically Dr. Adrien and Anil. For your enduring partnership and invaluable support. Your guidance and collaboration has been instrumental in bringing the Assembly to life. And advancing our shared goals of regulatory capacity building and public health protection. Today's opening marks an important step towards deeper. Regulatory convergence and collaboration among SEARN member states. • I'm confident that discussion and exchange in the days ahead will build on this foundation leading to concrete actions that bring us closer to our common vision. • Thank you once again for your engagement and contribution. • Every success. Thank you. • With that, we conclude the inaugural session for this important gathering. On behalf of the Bhutan Food and Drug Authority, I extend our heartfelt gratitude to all our distinguished guests. • For their presence today, we now look forward to the technical discussions, where we will delve deeper into the key themes and opportunities for collaboration. • Thank you once again, and let us carry this spirit of partnership and purpose into the next	
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5. Regulatory excellence: Achieving Balance of quality and accessibility to medical products for all - Secretariat

• Thank you. Okay, so, participants online, I understand, also, that right now we have a little bit of connectivity issues, not directly from the meeting, but from the telecom company, so apologies for that. And, we hope that you can nevertheless follow this meeting adequately. • Just to remind you that this meeting adheres to the WHO Code of Conduct to Prevent Harassment. You can access the document through that QR code. • A copy of the document was also put in the shared folder. • This is the code of conduct. The key message is that if any participants would like to report, you can do it with any member of WHO or to the relevant authorities. • Just to let you know also that we have some colleagues from the national media that are in the room just for a few minutes, and they will exit after the presentation of the objectives and the agenda. • It's just to make some images. So, for the objectives of this meeting, which are the same as in the concept note, we'll conclude on the progress of the SEARN work plan, and especially the monitoring and evaluation framework. • We received some late responses, so the final version is now available in the shared folder. It was finalized today, early in the morning. So if you want to have the latest detailed version, you can go there. • We just discussed highlights during this meeting, but if you want to go back to any of this in	Tujuan pertemuan: 1. Meninjau Capaian Rencana Kerja SEARN 2024–2025 dan <i>progress networking</i> berdasarkan Monitoring and Evaluation Framework, termasuk <i>progress</i> terhadap <i>Global Benchmarking Tool</i> (GBT) 2. Membahas dan mengesahkan rencana kerja (<i>Workplan</i>) SEARN 2025–2026 3. Mengesahkan dokumen dan strategi yang dikembangkan oleh <i>Working Group</i>, serta membahas upaya meningkatkan sharing knowledge, reliance, kolaborasi, dan penguatan kapasitas 4. Membahas dan mengesahkan <i>Terms of Reference</i> (ToR) terbaru untuk <i>networking</i>. 5. Membahas upaya memperkuat keberlanjutan SEARN. 6. Diskusi dengan <i>Procurement Public Agencies</i> mengenai keseimbangan antara mutu dan ketersediaan obat, serta Deklarasi Bersama antara Badan Pengadaan dan Anggota SEARN 7. Finalisasi <i>Memorandum of Understanding</i>/MoU SEARN. 8. Membahas potensi kolaborasi dengan networking Regulasi Lain (misalnya ASEAN, <i>Western Pacific Regional Alliance of NRAs for Medical Products</i>). 9. Finalisasi Aplikasi SEARN ke <i>International Medical Device Regulators Forum</i> (IMDRF) 10. Finalisasi review intra-aksi (<i>Intra-Action Review</i>) atas respon SEARN terhadap wabah Mpox 11. Membahas dan mengoptimalkan kolaborasi yang ada dengan anggota <i>Coalition of Interested Parties</i> (CIP) serta mitra potensial lainnya. 12. Mengambil keputusan terkait nominasi: <i>Chair Working Group</i>, <i>rotation member</i> untuk <i>Steering Group</i>, dan tuan rumah Assembly
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more detail, we can do that. • Will adopt the documents and strategies, the 13 ones that have been developed during this year. • Discuss proposed changes in the terms of reference. We'll discuss the sustainability of the network. It will be a short discussion, but it's still important to have this discussion, although we agreed that we would work on this during the next work plan. One of the key sessions to be aligned with the team that was chosen by the Bhutanese presidency is, we have two sessions that have been planned with public procurement agencies. To achieve adequate balance between quality and accessibility. • And we hope that we can agree on a common declaration, but it's not mandatory either. So I know, for example, that many of you have not yet provided feedback, so I have to say that I don't know where we're standing right now on that declaration. • We will also see what colleagues from public procurement agencies think about it. • And, if it's not feasible during this meeting, we'll still find a way to continue to work on that common declaration. But let's try to at least have a good discussion on this during this meeting. • We will discuss more about the SEARN Memorandum of Understanding, so you know from the meeting in April that we agreed to have a new target towards, early 2026. So we will	SEARN 2026 Partisipasi Anggota dalam Pertemuan Assembly SEARN 2025 • Pertemuan Assembly SEARN 2025 dihadiri oleh mayoritas negara anggota SEARN, yang menunjukkan komitmen berkelanjutan terhadap penguatan sistem regulatori regional Asia Tenggara. Para peserta terdiri dari perwakilan <i>National Regulatory Authorities</i> (NRAs), <i>Procurement Public Agencies</i>, serta mitra teknis dan pembangunan. Sebagian besar anggota hadir secara langsung, sementara sebagian lainnya berpartisipasi secara daring melalui skema pertemuan hybrid. • DPR Korea tidak dapat berpartisipasi dalam pertemuan tahun ini. Selain itu, WHO selaku sekretariat SEARN belum dapat melakukan komunikasi resmi dengan Myanmar, sejalan dengan aturan keterlibatan Perserikatan Bangsa-Bangsa saat ini terhadap otoritas negara tersebut. • Sebagai bagian dari penguatan kolaborasi teknis dan cakupan kerja SEARN, Assembly juga menyambut baik usulan pembentukan Working Group 6 (WG6) yang akan membuka ruang kolaborasi baru dengan regulator tradisional dan pengobatan komplementer. Sehubungan dengan hal ini, apabila WG6 disahkan, dua otoritas regulatori nasional akan bergabung sebagai anggota baru SEARN, yaitu: Ministry of Health and Family Welfare (India) dan Department of Ayurveda (Sri Lanka)
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not finalize it now, but we'll discuss it. And, if you decide to expand also with the creation of the working group 6.

- On traditional medical products. One thing to keep in mind is that we will also have two new authorities, one from Sri Lanka and one from India joining, and I suppose they will also need to be associated with that process related to the SEARN memory, and double understanding.
- So, I think probably the target of. Early 2026 is good but we will also further discuss with the colleagues.
- We'll discuss potential collaboration with other regulatory networks and new potential partners, finalize the application to IMDRF, finalize also the report on the interaction review, on the network's response to MPOX.
- Optimize the partner from the collaboration with partners, and take all decisions related to required nominations.
- Please already have a look at the work plan. We cannot finish this meeting without having chairs, reporters, and drafting group members for all the action points and it's best when it's voluntary. So, have a look at the work plan just to already see where you would like your countries to participate.
- That's also especially the case for traditional medical products, because it's a new work plan. So we would need to have trusting group members and reporters there.
- So, this is the agenda. We finished the opening.
- First, an update on members' participation in these meetings. So, from DPR Korea, we received a letter indicating that

they were not able to participate this year. • And WH secretariat Toussain, uh, is not able. At the moment, to liaise with Myanmar due to the current UN rules of engagement with its authorities. • With respect to national regulatory authorities, provided Working Group 6 is created, the meaning would also be that we would welcome two new NRAs in SEARN • The Ministry of Ayush from India and the Department of Ayurfah from Sri Lanka. And if the colleagues from these institutions would also like to have more discussions about what it involves and so on, we can also do that during the meeting.	
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Statement of Representative of Indonesia about Departure from SEARN

• Indonesia notified the Secretariat on 1st of July its decision to leave SEARN in the context of its wider decision to join the WHO Western Pacific region. • I think the chair of the student group already expressed the sentiment of the assembly just to highlight to all colleagues that you have a document called the SEARN Contingency Plan related to Indonesia's departure, in which you may find many responses to possible questions that you may have. If not, now would also be the right moment to raise these questions, and I would also like to invite Indonesia, if you'd like to say a few words. I think now would	• Indonesia telah memberitahukan pada tanggal 1 Juli keputusannya untuk keluar dari SEARN, sehubungan dengan keputusan yang lebih luas untuk bergabung ke dalam kawasan WHO Regional Western Pacific. • Indonesia telah bergabung sebagai member SEARN dari tahun 2017. Indonesia secara tulus berterima kasih untuk semua kesempatan <i>networking</i> dan bantuan dari semua member dan Sekretariat. Indonesia tetap terus terbuka dengan kesempatan kerja sama lain di masa yang akan datang. • Terhadap keputusan Indonesia tersebut, Chair of Assembly menyampaikan rasa terima kasih yang tulus atas segala kontribusi yang telah diberikan Indonesia
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also be a good time.

Mulai dari sini Remarks from Indonesia (Bu Togi)

- Okay, thank you Adrian, Honorable Chair, distinguished Delegates, certain secretariat, and esteemed colleagues.
- On behalf of the Government of Indonesia.
- It is with mixed emotions that we address you today as a member of the Southeast Asia Regulatory Network (SEARN).
- Indonesia has been an active and committed member since 2017. And during this time, we have had the honor of surfing on the steering group and various working groups. Contributing to the growth and success of this valuable network.
- As a member of the steering group, Indonesia has worked alongside many of you to ensure the smooth functioning of SEARN, endorse key decisions and promote collaboration across our region. We are particularly grateful for the support and cooperation of the SEARN Secretariat and all member countries. The sharing of knowledge and expertise has significantly enhanced our regulatory practices and strengthened our shared commitment to improving the quality, safety, and efficacy of medical products in the region.
- However, as you are aware, Indonesia made the decision to transition to the Western Pacific Regional Office.
- We extend our heartfelt thanks.

dalam perjalanan bersama, dedikasi yang tak tergoyahkan, wawasan yang sangat berharga, serta semangat kolaborasi yang hangat dan inspiratif, yang telah meninggalkan jejak mendalam. Indonesia tidak hanya memperkaya semangat dan harapan SEARN, tetapi juga telah membangun ikatan yang kuat di seluruh kawasan. SEARN terus berharap akan kesempatan bertemu kembali dan kerja sama dalam berbagai bentuk di masa yang akan datang.

- Selain itu, WHO Secretariat, Adrien, juga menyampaikan bahwa BPOM (Indonesia) telah melalui perjalanan panjang bersama SEARO. Bahkan, saat SEARN dibentuk, Indonesia menjadi contoh dengan kehadiran 100% dalam setiap pertemuan, yang menunjukkan komitmen besar Indonesia. Sekretariat merasa sangat sedih karena Indonesia adalah salah satu negara pertama yang mengajukan otoritas yang terdaftar di WHO dari kawasan Asia Tenggara dan sudah sangat maju dalam hal ini. Meskipun tidak melalui SEARN dan SEARO, diskusi bilateral dengan Indonesia diyakini sangat bermanfaat dan Indonesia akan terus bergerak maju.
- Secretariat juga menampilkan pilihan logo baru SEARN (4 pilihan) untuk di voting oleh representatif yang hadir.

To each and every one of you for your support, your collaboration, and your dedication to regulatory excellence. We are very proud of the accomplishments we have achieved together. And we look forward to continued cooperation in the future, but in a new context.

- We express our sincere gratitude to the Chair, the steering group, the working group, and of course, the SEARN secretariat. For their tireless efforts in advancing the network's mission.
- Indonesia is confident that SEARN will continue to thrive and evolve. And we remain hopeful that our paths will cross again in the future.
- Thank you, and we will soon continue success in all its endeavors.
- And I have also to thank you for having stayed very active up to now. And to have actively participated also still in some of the drafting groups, in the working groups, and so on, so that's very much appreciated.

Ini mulai lagi Adrien's part (ini kalimat dari Dr. Anil ternyata)

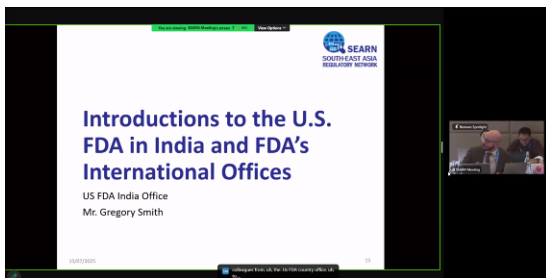
Actually, Indonesia was one of the first few countries where the SEARO started working on strengthening national regulatory authority.

Starting from the workshop, myself and Togi did together in 2003. We did an array assessment together. So, Togi's retired, I'm still to retire in 5, 8 years or so.

The whole Indonesian BPOM actually has taken the whole journey with

SEARO. And of course, when SEARN was born. They created an example. I can tell you the example was, 100% attendance there with other NRAs. So that shows their commitment, and we feel very sad, actually. One of the first countries who applied for WHO-listed authority from The Southeast Asia region, and they are quite ahead in that. So, we were thinking that we will have a lot of learnings from this experience. I'm very sure, if not through SEARN, not through SEARO, but on a bilateral basis when you are having a discussion with them, please. Nobody stops you doing bilateral exchanges. And you must visit sometime, you know, what they have created there in Jakarta, as well as around. We are all together. We were all together, and of course, they're moving toward us. WIPRO will not stop us.	
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6. Introductions to the U.S. FDA in India and FDA's International Offices - US FDA India Office, Mr. Gregory Smith

 Excellent. Thank you, Adriene. Good morning, greetings to you from the US FDA. We are thankful for the opportunity to meet His Excellency, the Minister of Health. It's truly an honor to be here in	Kantor FDA India yang berlokasi di Kedutaan Besar Amerika Serikat di New Delhi memiliki peran strategis sebagai titik kontak bagi kolaborasi bilateral dan pertukaran informasi di kawasan Asia Selatan dan Asia Tenggara. Sejak dibuka pada tahun 2009, kantor ini bertugas untuk melindungi kesehatan masyarakat Amerika dengan memastikan bahwa produk-produk yang masuk ke AS aman dan memenuhi standar kualitas yang ketat. Kantor ini juga menjadi perpanjangan tangan FDA di kawasan ini, berfungsi sebagai "mata dan telinga" untuk memantau dan berbagi informasi mengenai isu-isu regulatori
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beautiful Tempu with such a distinguished group of regulatory leaders from across Southeast Asia. I want to begin by thanking the Assembly of the members of the Southeast Asia Regulatory Network, or SEARN, for the invitation for us to engage.

In this annual meeting under the Kingdom of Bhutan's SEARN presidency.

We congratulate the Kingdom of Bhutan on the achievement, and look forward to the discussions under this year's theme. Of regulatory excellence Achieving Balance of Quality and Accessibility. To medical products for all. So, I'm Greg Smith. I'm the director of the FDA India office.

And I sit within FDA's Office of Global Policy and Strategy, or OGPS.

We're based in the U.S. Embassy in New Delhi. And my office advances, FDA's mission to promote and protect American public health by ensuring global considerations are fully integrated into FDA policies and operations.

I've personally worked for FDA for 14 years now, and I joined the FDA India office in 2022, so I've spent the last 3 years of my life in New Delhi. It's been a great experience for me to be able to witness firsthand.

How regulatory partnerships. Can strengthen public health protection for all of our citizens.

As part of the larger family of FDA international offices, Europe, Latin America, China and soon to be in Africa. The India office functions as the point of contact for many of FDA's bilateral exchange and regional partnerships.

yang berkembang.

Sebagai bagian dari jaringan global FDA, kantor ini bekerja sama erat dengan regulator nasional di India, seperti **CDSCO (Central Drugs Standard Control Organization)**, dan berperan dalam memperkuat sistem regulasi di kawasan tersebut. Sejak 2019, FDA India telah melakukan lebih dari 1.700 inspeksi terhadap fasilitas pengolahan pangan, alat kesehatan, dan obat di kawasan Asia Tenggara. Dalam konteks ini, India memainkan peran penting sebagai pemasok utama obat-obatan generik dan produk medis ke AS, di mana sekitar 40% dari produk obat bebas dan resep yang beredar di pasar AS berasal dari India.

FDA India berperan aktif dalam berbagai forum internasional, seperti **International Medical Device Regulatory Forum (IMDRF)** dan **International Conference of Drug Regulatory Authorities (ICDRA)**. Mereka juga mengadakan kunjungan dan pertemuan dengan negara-negara di Asia Selatan, termasuk Sri Lanka, Bangladesh, Bhutan, dan Nepal, untuk mengeksplorasi peluang kolaborasi lebih lanjut dalam pengawasan dan regulasi produk medis. Melalui keterlibatannya di platform seperti **SEARN** (Southeast Asia Regulatory Network), FDA terus mendorong upaya konvergensi regulasi dan berbagi informasi untuk meningkatkan perlindungan kesehatan masyarakat secara global.

FDA memiliki sejumlah prioritas strategis untuk mendukung misi utamanya, yaitu memastikan **keamanan, efektivitas, dan kualitas produk medis** yang mencapai konsumen. Beberapa prioritas utama termasuk meningkatkan **inspeksi internasional** untuk memperkuat

It is at the forefront of collection, analysis, and sharing of high-quality information.

Including inspectional data to advance FDA's public health mission. Complex global supply chains fundamentally altered our economic and security landscape. And demanded a major change in the way FDA fulfills its mission to promote and protect the health of American people. Just as public health leaders have long recognized the disease knows no borders, the FDA also recognizes that product safety and quality no longer begin or end at the border.

Thus, in 2009, the agency opened an office in New Delhi after concluding that having boots on the ground would best protect Americans from unsafe and ineffective exports. And then also help us collaborate with the regulators and industry in the region to best meet U.S. Regulatory expectations. India and the surrounding region represent vital sources for medicines and foods for the United States.

India, as you know, supplies approximately 40% of the over-the-counter and generic prescription drugs used in the U.S. Similarly, it may not be known by all, but close to 40% of the shrimp consumed by the United States comes from India as well.

Since 2019, FDA has conducted over 1,700 inspections of food, medical devices and drug manufacturing facility inspections across Southeast Asia. Since the opening, FDA India has fulfilled a critical role, functioning as the FDA's eyes and ears in the country and the region.

Our staff conducts inspections. Follows regulatory and market developments. Tracks biomedical

pengawasan terhadap rantai pasokan global, memperkenalkan **modernisasi uji klinik** untuk mengurangi ketergantungan pada pengujian hewan dan meningkatkan infrastruktur uji klinik, serta mendorong **harmonisasi regulasi** global melalui kerjasama internasional, seperti di **ICH (International Council for Harmonisation)**. FDA juga berfokus pada **keamanan rantai pasok**, dengan memperkuat praktik pengawasan untuk mencegah peredaran produk substandar dan palsu.

Secara keseluruhan, FDA berkomitmen untuk **berbagi pengalaman dan pengetahuan** dengan negara-negara mitra guna mengatasi tantangan regulatori yang semakin kompleks. Dalam kesempatan ini, FDA juga mengungkapkan keinginannya untuk melanjutkan **kerja sama yang lebih erat**, dengan harapan dapat membangun jaringan yang lebih kuat dalam melindungi kesehatan masyarakat global, mempercepat akses ke produk medis berkualitas, dan mendukung upaya mitigasi pandemi di masa depan.

research trends, assesses manufacturing, product safety and quality, and meets with industry and government to share information.

On FDA's regulatory requirements, practices, and perspectives. We work with governments, including national regulatory authorities, industry, and academia within India, FDA has fostered a close and growing relationship with CDSCO. As well as relations with the regulators at the state level, and we acknowledge and celebrate Dr. Ranga being here with us here today.

As a testimony to our collaboration, for example, we are proud to have worked with CDSCO.

On the International Medical Device Regulatory Forum, and we congratulate them on achieving affiliate membership last year. Within the South Asia region, we've been privileged to have conducted regulatory visits to Sri Lanka, to Bangladesh and Butan to meet with government and industry stakeholders in different forums.

And settings to learn more about the opportunities for FDA engagements and collaborations.

We also had the privilege of holding a virtual introductory meeting with the Drug Regulatory Authority of Nepal. And interacted during their visit to Washington, D.C. last year. And last but not least, FDA representatives were glad to have met other regional counterparts in person at the 19th International Conference of Drug Regulatory Authorities, or ICDRA, held in Delhi last year. Counterparts we recognize are here in the room today.

It's platforms like ICDRA and SEARN that help us advance shared Public

health. It's really an amazing opportunity for us to be here in a setting like this, in a small group regulator to regulator, to talk about our shared interest, to talk about our learnings and experiences, and then hopefully to implement and work together on the challenges ahead.

Looking forward, the U.S. Food and Drug Administration remains steadfast in its mission to protect and promote public health.

By ensuring the safety, efficacy, and security of medical products that reach American patients, FDA has identified several priorities that will inform some of our foreign office efforts.

First is inspections. FDA is increasing our foreign inspections, not particularly unannounced inspections, to strengthen oversight of global supply chains.

Secondly, we're a clinical trial modernization. FDA is seeking to modernize oversight of clinical trials. Good laboratory practices to encourage studies that are representative of the U.S. populations.

Reduce dependence on animal testing methods. And reinvigorate clinical trial infrastructure in the United States.

Thirdly, regulatory harmonization. Through ongoing regulatory harmonization efforts, FDA will continue to promote alignment of regulatory standards and practices to maintain consistent quality and improve access to innovations.

For example, as a founding member of the regulatory. A regulatory member of ICH.

The FDA will continue to actively

participate in its activities to promote. Global harmonization of technical requirements for pharmaceutical products.

Lastly, supply chain security. Through various platforms, including the Asia-Pacific Economic Cooperation, or APAC, FDA continues our work to improve supply chain security. An integrity supply chain practices, which can reduce instances of substandard, falsified, or counterfeit products.

Reaching consumers. In closing, I want to affirm our shared commitment to protecting and promoting public health. We are here to share our experiences and learn from one another.

The complexity of today's regulatory challenges calls for deeper and growing dialogue.

Thank you in advance for the engagement, your insights, and your willingness to work with us going forward.

Thank you very much. Any questions from some members?

Yes, please do Dr. Greg, thank you for coming over here, and then participating in this tight group.

1. "One question I would like to ask the USFDA is whether the FDA is open to collaborating with SEARN in any area to further common interests and those you have already mentioned in your speech. Thank you."

Yeah, that's a very good question.

Traditionally, the FDA has not been a financial provider of funds to our regulatory counterparts. It has been more on information sharing and technical assistance that our role has

been, so that has been the traditional opportunities for cooperative agreements. There are certain circumstances where FDA has worked within countries and regions on cooperative agreements.

And those can be investigated. Sri Lanka, we would like to have collaborative work, especially in the section of medical devices.

The FDA, so that we can use their Regulatory measures and the poorest number registration. So we'd like to work closely with the FDA.

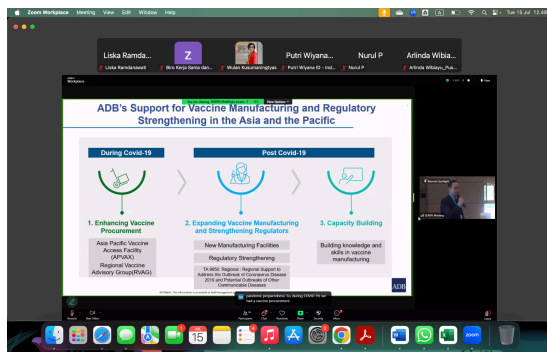
2. "And another question I would like to ask from the Indian FT office is that we know, we understand that you do regular inspection of manufacturing plants for the safety of the American people, but I wonder whether you can share the findings of your information with us also, because we also get a lot of products from India, and maybe other countries also. Is that..."

We can just quickly respond. We'd be glad to further our conversations with Sri Lanka, we're pleased to have visited there, in 2023. And look forward to future visits. I do think there's an opportunity for us to have some technical information exchanges on medical devices, and I believe, as well, USFDA exists for that purpose, and we'd be glad to discuss that further with you.

3. "Thank you, thank you. I would like to pose a question as far as traditional medicine is concerned whether USFDA has any plan or proposal to have engaged with The national regulatory authorities. So I remember that recently,

USFDA team came to the Ministry of Ayush, and visited certain facilities, manufacturing facilities also. So, how to go forward in that respect? FDA looks forward to working with the Ministry of Ayush and with the NRAs represented here as well. We do have teams of experts. Back at headquarters that are looking at applications that are based on botanical or natural medicine. And, we do look forward to providing opportunities where they're virtual in person, for some technical exchanges on those topics. We find those very, very beneficial, and we look forward to doing that in the coming year. And we do see that as a growing priority and area of discussion in the international forum that Ayush and Natural Medicines is a priority. So we look forward to maybe defining some topics together that we could potentially have some formal collaboration with and in terms of bilateral discussions, just remember that there is a calendar that you can use, including for Sri Lanka, to book a session with our colleagues from the US FDA.	

7. Introduction to ADB and its regulatory system strengthening activities - ADB, Dr. Jae Kyoun Kim



So, good morning again, everyone. My name is Jake and Kim. I'm a health specialist working at the Asian Development Bank.

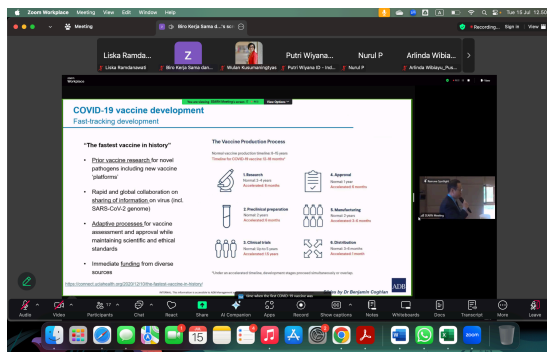
And first of all, I would like to thank the Secretariat WHO for inviting ADB to this very important meeting. So, I would like to share this morning about some of the regulatory system strengthening activities we are doing at the Asian Development Bank.

ADB has supported a lot of activities on regulatory system strengthening during COVID. I will be going more into the details, but we see regulatory systems strengthening. As in the lens of pandemic preparedness. So, during COVID-19, we had a vaccine procurement facility called The Asia-Pacific vaccine access facility, which is called APVAX. It's, like, very similar to COVAX, but in a different modality.

And we had a reasonable vaccine advisory group. I remember Australia TGA was a member also, WHO, of course. And after post-COVID-19.

We had activities supporting the countries and strengthening regulatory systems. It was one of the core activities as well. We also did capacity building.

Asian Development Bank (ADB) telah mendukung berbagai kegiatan penguatan sistem regulatori, khususnya selama masa pandemi COVID-19, sebagai bagian dari upaya kesiapsiagaan menghadapi pandemi. Salah satu inisiatif utama adalah Asia-Pacific Vaccine Access Facility (APVAX), sebuah skema pengadaan vaksin yang mirip dengan COVAX namun dengan pendekatan berbeda. Dalam pelaksanaannya, ADB membentuk kelompok penasihat vaksin yang melibatkan TGA Australia, WHO, dan mitra lainnya. Pasca pandemi, ADB terus melanjutkan dukungan kepada negara-negara melalui program penguatan sistem regulatori dan pengembangan kapasitas sebagai komponen utama.



How this became one of the major areas that we are discussing in ADB.

So, I would like to suggest taking time back in December 2020. Would there be anyone who remembered what happened in December 2020? We call it the era of hope and despair, because it was the time when the first COVID-19 vaccine was developed.

So, from the scientists, from researchers, from the development partners, government agencies.

It was the fastest vaccine in history, so everyone was really excited. Everyone thought It'll be the end of the pandemic.

And it wasn't just one vaccine. There are a lot of vaccines that have been developed.

And just looking at the supply forecast. It looked like you'll be having enough for the whole entire world, because they were expecting about 20 billion doses.

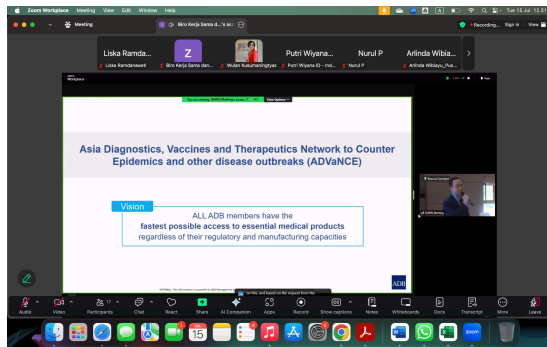
But if we see the reality. It wasn't happening. For the high-income countries, for the upper-middle-income countries, the vaccine procurement was kind of enough. But if you see the lower middle-income countries, low-income countries, that wasn't the situation. And I remember a lot of frustrations coming from the countries. That they

Selama masa awal pengembangan vaksin COVID-19, antusiasme global sangat tinggi. Para ilmuwan, peneliti, mitra pembangunan, dan lembaga pemerintah menyambut vaksin sebagai harapan untuk mengakhiri pandemi. Berbagai jenis vaksin dikembangkan dalam waktu singkat, dan berdasarkan proyeksi suplai saat itu, diperkirakan akan tersedia hingga 20 miliar dosis—cukup untuk seluruh populasi dunia.

Namun, kenyataannya tidak demikian. Negara-negara berpenghasilan tinggi dan menengah atas berhasil mengamankan vaksin dalam jumlah memadai, sementara negara-negara berpenghasilan menengah bawah dan rendah menghadapi kesulitan besar dalam pengadaan obat esensial untuk penduduknya. Hal ini menimbulkan kekecewaan yang luas di banyak negara.

Merespons situasi tersebut dan permintaan dari negara-negara anggotanya, ADB meluncurkan inisiatif baru bernama **ADVANCE** (*Asia Diagnostics, Vaccines, and Therapeutics Network to Encounter Epidemics and Other Diseases*). Tujuan utama ADVANCE adalah memastikan seluruh negara anggota ADB memperoleh akses secepat mungkin terhadap obat esensial. Inisiatif ini mencakup semua negara anggota ADB yang hadir, kecuali DPR Korea yang bukan anggota ADB.

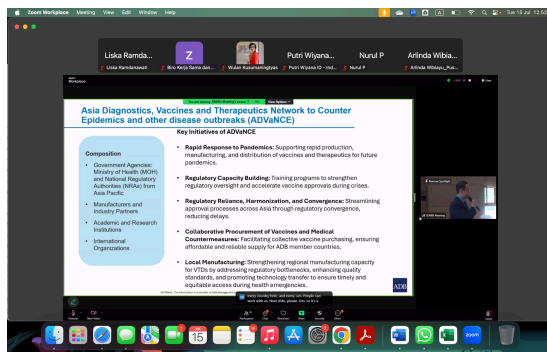
can't procure essential medical countermeasures for their own population.



So, based on this, and based on the request from the countries, ATP has recently launched an initiative called ADVANCE. It stands for Asia Diagnostics Vaccines and Therapeutics Network to encounter epidemics. And other diseases.

And our vision is to all ADB members. At the fastest possible access to essential medical products. And Adrien asked me to define all the members.

It's all members in this room. So, for the CIO member countries, except DPR Korea, because they are not our member. Everyone, every country here, and everyone who can work with us.



It's the composition of the government agencies, including the Ministry of Health and the National Regulatory Authorities. Manufacturers, private industry partners, academia, research institutions and also development partners. We are working very closely with WHO, like USP, also RVMC, ZP, and a lot of others.

And I hope we could build some more potential partners here.

Especially Australia, the TGA was our very close partner. We hope we can continue our discussion.

Like, US FDA, the points I mentioned on clinical trial ecosystems.

Regulatory harmonization is in our focus areas. So we hope you could discuss it further.

It's really for the rapid response for pandemics and to go for each component, the regulatory capacity building.

We saw during the COVID-19, it was really a bottleneck and a barrier for a lot of countries.

So, we are really prioritizing regulatory capacity building. Also, regulatory reliance, harmonization, conversions.

It's our focus area. And, poor procurement with collaborative procurement is one of the modalities

ADVANCE (Asia Diagnostics, Vaccines, and Therapeutics Network to Counter Epidemics and Other Disease Outbreaks) merupakan inisiatif dari Asian Development Bank (ADB) yang bertujuan untuk memperkuat kapasitas negara-negara Asia dan Pasifik dalam menghadapi pandemi dan wabah penyakit lainnya melalui pendekatan kolaboratif lintas sektor.

Komposisi ADVANCE:

Inisiatif ini melibatkan:

- Lembaga pemerintah, khususnya Kementerian Kesehatan dan Otoritas Regulasi Nasional dari negara-negara Asia dan Pasifik,
- Produsen dan produsen bahan,
- Lembaga akademik dan penelitian,
- Organisasi internasional.

Lima Inisiatif Utama ADVANCE:

1. **Rapid Response to Pandemics**
Mendukung produksi cepat, manufaktur, dan distribusi vaksin serta terapi untuk pandemi saat ini maupun masa depan.
2. **Regulatory Capacity Building**
Menyelenggarakan program pelatihan untuk memperkuat pengawasan regulatori dan mempercepat proses persetujuan selama krisis.
3. **Regulatory Reliance, Harmonization, and Convergence**
Menyederhanakan proses persetujuan di seluruh kawasan melalui mekanisme reliance dan harmonisasi regulasi, serta pengurangan keterlambatan.
4. **Collaborative Procurement of**

we're looking at. In the local manufacturing.

I think some of the people made here might have been attending the World Local Production Forum, which happened in Abu Dhabi earlier this year. And there's a lot of focus on and the testimonials saying that.

For the countries which had local manufacturing capacity. They were much more, capacitated to respond to pandemics, so we are looking closely at this, too. And this also includes traditional medicine products.

To be honest, traditional medicine is not in our portfolio yet.

But we have increasing requests from other countries. Like, when we visited people, I remember that there was a staff member asking for traditional medicine products. Also, you know, countries like the Philippines, the minister, was also asking for it then.

I'm hearing a lot of it. So, closely, having discussion with the VPRO,, traditional medicine unit on how it could work.

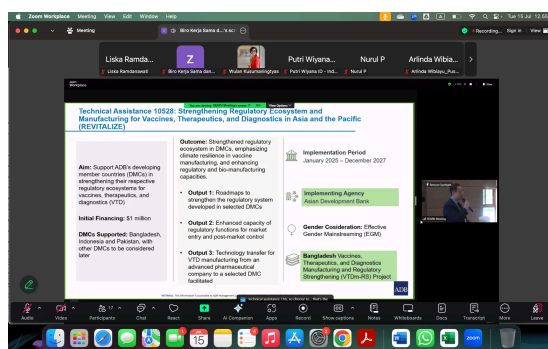
In **Sierra**, I was really glad to see the working group on traditional medicine products, so we are interested to discuss further on how we could work together.

Vaccines and Medical Countermeasures

Memfasilitasi pengadaan kolektif vaksin dan obat untuk negara anggota ADB, dengan fokus pada keterjangkauan dan keberlanjutan suplai.

5. Local Manufacturing

Meningkatkan kapasitas manufaktur regional untuk produk biologik (VDTs), mengatasi hambatan teknis, meningkatkan standar mutu, serta mendukung alih teknologi agar akses terhadap produk kesehatan darurat lebih cepat dan merata.

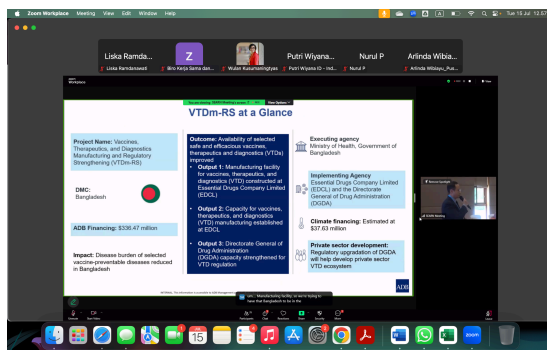


Technical Assistance 10528: Strengthening Regulatory Ecosystem and Manufacturing for Vaccines, Therapeutics, and Diagnostics in Asia and the Pacific (REVITALIZE)

Tujuan Utama:

Mendukung negara-negara berkembang anggota ADB

So, currently, we have technical assistance. So choose that's the term you use in ADB, it's a grant money, it's a grant project for around 1 million US dollars. So it's mainly focusing on strengthening regulatory ecosystems and manufacturing for vaccine therapeutics and diagnostics. So the major focus country right now is Bangladesh, very glad to see our DCDA colleagues in the HIV bomb. Pakistan, which is not a member of SEARN. We are interested to have further discussions with the countries that we haven't discussed before, like, good time, Baldi, Sri Lanka, and all the others. Throughout these two days. So, actually, when I saw the timesheet, I was very tempted. To book all the time, but I thought maybe there will be some new partners, new countries that I might meet, so I just intentionally left it all blank. So if any countries are interested in doing these activities with us. Please let me know. So if we see the output, it's mainly on, so the output one is strengthening the regulatory system on the roadmaps, and output 2 is on the capacity building. So we are doing capacity buildings for the NRAs. But also with biomanufacturing, mainly partnering with the Korean agencies called KNIBERT. And a global training hub for biomanufacturing. So that's or so in the area. We are supporting technology transfer for DTDs also.	(Developing Member Countries / DMCs) dalam memperkuat sistem regulatori mereka, khususnya di bidang vaksin, terapeutik, dan diagnostik (VTD). Pendanaan awal: USD 1 juta Negara sasaran: Bangladesh, Indonesia, Pakistan, dan negara DMC lainnya yang akan ditentukan kemudian. Hasil yang Diharapkan (Outcome): Penguatan ekosistem regulatori di negara-negara sasaran, dengan peningkatan ketahanan terhadap krisis kesehatan melalui penguatan pengawasan regulatori, manufaktur vaksin, dan kapasitas produksi. Tiga Output Utama: • Pengembangan roadmap sistem regulatori di negara-negara sasaran. • Peningkatan Kapasitas Fungsi Regulasi: • Alih Teknologi: Transfer teknologi manufaktur VTD ke negara DMC terpilih guna mendukung produksi produk farmasi tingkat lanjut. Periode Implementasi: Januari 2025 – Desember 2027 Lembaga Pelaksana: Asian Development Bank (ADB) Pertimbangan Gender: Mengarusutamakan kesetaraan gender secara efektif (Effective Gender Mainstreaming – EGM) Contoh Proyek Terkait: Bangladesh Vaccines, Therapeutics, and Diagnostics Manufacturing and Regulatory Ecosystem Strengthening (VTDnR-BS Project)
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And for this, Bangladesh, we have a main project. It's called Vaccine Therapeutic Diagnostic Manufacturing Regulatory Strengthening.

So, we are partnering with DGDA, of course. To increase their maturity level, to up to maturity level 3.

Also, we are partnering with EDCL, Essential Drugs Company Limited. It's a government-owned, manufacturing facility.

So, you're trying to have Bangladesh to be in the independence of procuring their medical countermeasures, including vaccines.

And other therapeutics and diagnostics as well.

Yep, that's the end of my presentation. And I would like to discuss further on. And you have the questions or comments you would have.

Proyek lainnya bernama *Vaccine Therapeutic Diagnostic Manufacturing Regulatory Strengthening*.

Informasi Proyek:

- **Nama Proyek:** *Vaccines, Therapeutics, and Diagnostics Manufacturing and Regulatory Strengthening (VTDm-RS)*
- **Negara Pelaksana:** Bangladesh
- **Pendanaan ADB:** USD 336,47 juta
- **Dampak yang Diharapkan:** Mengurangi beban penyakit yang dapat dicegah dengan vaksin di Bangladesh

Output Utama:

1. **Fasilitas Manufaktur Baru:** Pembangunan fasilitas manufaktur vaksin, terapeutik, dan diagnostik di *Essential Drugs Company Limited (EDCL)*.
2. **Peningkatan Kapasitas Produksi:** Meningkatkan kapasitas produksi VTD di EDCL agar berkelanjutan.
3. **Penguatan Fungsi Regulasi:** Memperkuat Direktorat Jenderal Pengawasan Obat (DGDA) untuk mendukung fungsi regulasi VTD.

Lembaga Pelaksana:

- **Executing Agency:** Kementerian Kesehatan, Pemerintah Bangladesh
- **Implementing Agency:** *Essential Drugs Company Limited (EDCL)* dan *Directorate General of Drug Administration (DGDA)*

Aspek Tambahan:

- **Perkiraan Pembiayaan untuk**

	Adaptasi Iklim: USD 37,6 juta • Pengembangan Sektor Swasta: Penguatan kapasitas regulasi DGDA juga akan mendukung sektor swasta dalam membangun ekosistem VTD nasional. ADB bermitra dengan DGDA untuk meningkatkan tingkat maturitas sistem regulatori mereka hingga Level 3. ADB juga bekerja sama dengan EDCL (Essential Drugs Company Limited), yaitu fasilitas manufaktur milik pemerintah. Tujuannya adalah mendukung Bangladesh agar dapat mandiri dalam pengadaan produk medis, termasuk vaksin, terapeutik, dan diagnostik lainnya.
QnA	
Any questions? 1. Yeah, thank you, Kim. I mean Good to know. When this information is not, Been to our knowledge. Is your program limited to only capacity building of those countries which want to develop, or is it open to all other countries, like India? Yeah, we are all open to other countries, but just the restriction is you need to be an ADB member country. Which, everyone's illegible here. So, I hope, I presume India is an ADV member. yes, of course, of course. Thank you. I think that's very good. I think of the contribution you have made. 2. (Mangula) My question is whether this is an industry-led request, or	

how we can just actually cater that. Funding, number one, number two is whether you have a Certain priority of ADV itself. In this category of actions. Nepal also wants to explore this area, because we are not, Vaccine manufacturing country so far. So, people are, industries are interested to conduct. and opened some facilities. So in this sense, I think ADP could be a good option, because funding is very scarce. And ADV is always full of funding, you know? They have very good money. So, how does that mean to support a country like Nepal. Oh, yes, absolutely. I would be happy to discuss. I'm the project leader of the technical assistance on regulatory System Strengthening Local Manufacturing, so you can just talk, and you can happen. And, yeah, so we'll be happy to discuss it further. I assume, again, the \$1 million. Could be a little small for such a huge group. Dr. Hasn's ticket won't come up. So if there is any possibility of increasing based on the number of countries that are approaching you, and I also have the information, maybe it's correct, that when a country wants to approach ADB with a concrete proposal, there is a possibility of huge loans also, soft loans also. Which can be triggered by this. Small grant, which is 1 million grant, and then thereafter, the country can discuss the loans, soft loans also. For a full system. As I understand. Bangladesh was granted around 500	
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million US dollars, for strengthening. Vaccine production, as well as \$50 million to strengthen. So, I think this information is correct.

Oh, yes, that's very correct, and it's also correct that 1 million US dollars is not enough.

So we started small, we didn't think that it would be expanding a lot, so it was mainly for the three countries, Bangladesh, Indonesia, and Pakistan.

But since we are getting a lot of requests, and just last week.

We had a symposium on pandemic preparedness, which was initiated.

Initiated by our vice president. So it's quite a high level within ADB.

And in every session, everyone was talking about regulations. So, I envisioned that we'll be getting more funds, and I'm currently applying.

For other trust funds to get additional financing for us, so I'm pretty sure the amount of the whole TA will be increasing and also, you're correct about the loan project. If we could get a loan project agreement, that would be great, like the Bangladesh project is about 340 million US dollars. The initial plan was 500, but I think it has been shrunk a little bit.

So, we can use a similar modality with. Other countries as well.

Right? Yeah, I just want to share, take the opportunity, and thank you very much for your nice presentation. But now, this year has really benefited from their health.

And we are going to establish it. Vaccine management history planned for the government sector.

Now we have, but all our private sectors. But with their help, we are going to develop in the government sector and also, we are going to develop one laboratory complex. That will be for a 12th Street building. Which will have one-stop service for. All that is, except, tests involving minimal studies. So I think this is really wonderful, and if other countries can also benefit from you. So, countries in the region. May be very strong in other NCLs and besides, I want to request that you have one program. Training of officials of NRA, and in sales in the courier. And it can be applied to other countries also. We recently heard the very good news, that now the site has been decided within Dhaka, so you'll be moving much faster and we got your request for collaboration with the Korea MFDS, that's Korea FDA. So they said that we can do it this year, but in December, so we are trying to arrange with them on the study tour, and capacity-building training. I think the capacity-building training from their side, and also the opportunity for study tours.	
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8. Paparan dari WHO/RSS team lead (Ali Reza) dengan judul WHO Regulatory Systems Strengthening Updates:

- a. Adanya kesenjangan besar dalam sistem regulasi global (hanya 30-31% yang memiliki kapasitas yang cukup untuk memastikan kualitas dan keamanan obat).
- b. Regulatory systems' maturity level of WHO Member States dan tantangan terbesar:
 - Membangun kapasitas anggota yang konsisten dengan GRP.
 - Mendorong kerja sama regulatory, konvergensi dan transparansi melalui work-sharing and reliance.
- c. Mandat WHO berasal dari resolusi yang disahkan oleh Majelis Pekerja pada tahun 2014 (Resolusi 6720) yang menekankan pentingnya penguatan sistem regulasi.
- d. Berdasarkan data base WHO RSS Feb 2025, sebanyak 31 % (61 negara) berada pada ML 3, ML 4, sebanyak 19% (36 negara) berda pada ML 2 dan sebanyak 50% (97 negara) pada ML 1. Mulai dari tahun 2016 sd 2024, jumlah negara anggota yang dilakukan benchmark melalui GBT semakin meningkat,

- e. Global status of national regulatory systems (medicines and vaccines regulation as of Feb 2025):
 - Vaksin yang diproduksi oleh negara dengan ML 3 atau 4 memenuhi syarat untuk EUL atau prekualifikasi.
 - NRAs dengan ML3/ML4 memenuhi syarat untuk proses WLA PE.
- f. Tujuan dari inisiatif WL adalah:
 - Untuk menyediakan jalur yang transparan dan berbasis bukti bagi RAs untuk diakui secara global.
 - Untuk mempromosikan akses dan pasokan obat yang aman, efektif, dan berkualitas.
 - Untuk mengoptimalkan penggunaan sumber daya yang terbatas dengan memfasilitasi reliance.
- g. Berbagai dokumen telah disiapkan untuk mendukung inisiatif ini, termasuk penerbitan dokumen kebijakan pada tahun 2021. Pada tahun 2022, WHO mengeluarkan panduan operasional dan manual untuk evaluasi kinerja.
- h. Sebanyak 33 Negara Anggota dan 36 Otoritas Regulasi dievaluasi dan terdaftar pada 2023-2024.
- i. Milestones dan outlook untuk WHO Listed Authorities (WLAs) ke depan: Tahun 2024-1027 memastikan bahwa NRAs pada tWLA list menjadi WLAs atau ML3/ML4 serta computerization dari indikator PE indicators atau tools
- j. Berdasarkan the 19th ICDRA recommendations, WHO dalam proses memperluas ruang lingkup dari WLA MD + IVDs
- k. WHO Workshop on GRP in the regulation of medical products:
 - telah dikembangkan pada tahun 2023-2024
 - menargetkan regulator dan pembuat kebijakan
 - 2,5 Hari termasuk sesi teori singkat dan analisis ekstensif dari studi kasus nyata dari BM dan latihan praktis
- l. WHO workshop on regulatory performance indicators (RPI):
 - Telah dikembangkan pada tahun 2024 untuk memberikan panduan praktis tentang pengembangan, pelaksanaan, dan pemeliharaan RPI.
 - Menargetkan regulator dari QMS, regulasi teknis, dan fungsi administratif yang relevan.
 - Lokakarya selama 3 hari yang terdiri dari 8 modul.
- m. Complementary to the GBT – A Global Competency Framework for regulators of medicines, 2022:
- n. WHO Coalition of Interested Parties (CIP) Network:
 - terdiri dari 29 anggota CIP network dengan 25 partisipan dan 4 observer.
 - bertujuan untuk membangun dan mempromosikan pendekatan strategis dan terkoordinasi yang terpadu dalam memperkuat sistem regulasi nasional dan regional.
- o. Kunci dari partnership dari CIP Network:
 - merupakan network strategis yang dipimpin WHO untuk mengoordinasikan penguatan sistem regulasi (RSS) secara global.
 - Network yang bersifat sukarela yang diluncurkan pada tahun 2021, dengan 29 anggota organisasi hingga saat ini.
 - 38 negara di 6 Wilayah mendapat manfaat dari dukungan terkoordinasi pada tahun 2024 (investasi lebih dari 125 juta USD): percepatan pelaksanaan IDP dan progres kematangan.
 - Key milestones: Global Steering Group meetings, Regional Steering Groups in South-East Asia and Africa, 19th ICDRA endorsement for expanding scope to medical devices & IVDs.

9. Feedback from steering group

- a. Pada saat *Assembly* telah diinformasikan mengenai kehadiran dan kegiatan SEARN sejak pertemuan *Assembly* terakhir (Juli 2024), yakni kegiatan SERAN telah dilaksanakan sebanyak: 3 kali *meeting Steering Group*, 16 kali *meeting* dari total 5 *Working Group* (dengan penambahan 1 kali *meeting* pada WG 2 dengan melibatkan Industri untuk membahas mekanisme *convergence*), 2 kali *meeting* untuk pembentukan WG 6 - Obat Tradisional, 47 kali *meeting* dari total 13 *drafting group* yang aktif. Sedangkan untuk Mpox telah dilaksanakan 1 kali *meeting Steering Group*, 4 kali *meeting*

Mpox ad hoc working group, dan 2 kali *meeting* untuk berkonsultasi dengan *stakeholders* sebagai bagian dari tinjauan *intra-action* SEARN terhadap tanggapannya terhadap *Mpox*.

- b. Selain itu telah dilaksanakan 5 kali *workshops* dengan diantaranya 3 kali *workshop* dengan *stakeholders* terkait peningkatan pelaporan vigilans di setiap wilayah, 1 kali *workshop* terkait *Regulatory Information Management Systems* (RIMS) oleh MTaps, dan 1 kali *workshop* terkait penguatan regulasi alat kesehatan.
- c. Dalam rangka finalisasi SEARN MoU juga telah dilaksanakan 2 kali *meeting*. Selain itu, juga telah dilaksanakan 9 kali survei untuk mendukung berbagai strategi yang berbeda, diantaranya pada: WG1 (*Needs for biological reference standards* (AP8), *NQCL Capabilities* (AP8 dan AP9), dan *Prioritisation of NQCL in-person trainings* (AP9)), WG2 (*Needs for GSDP workshops* (AP1) dan *AMR capacity of NRAs* (AP19)), WG3 (*Valproate* (AP15), *National strategies for information sharing* (AP3)), WG4 (*Shortages* (AP20)), dan WG5 (*Potential RCOEs for medical devices*)
- d. Selain itu, sejak Assembly, Juli 2024, terdapat 3 SOP yang telah dikembangkan dan disetujui, yaitu:
 - i. SOP.01 *Document Control SOP*
 - ii. SOP.02 *Management of participation in SEARN*
 - iii. SOP.03 *Management of confidentiality and links of interest*
- e. Dan terdapat 2 *Work Instructions* yang sedang dalam penyusunan, yaitu:
 - i. WI.01 *Management of participation in SEARN*
 - ii. WI.02 *Management of confidentiality and links of interest*

10. SEARN Monitoring and evaluation framework

- a. Adapun ringkasan tingkat keberhasilan dari setiap *Action Point* (AP) yang dilaksanakan selama 2024-2025 adalah sebagai berikut:
 - Untuk AP yang mempunyai tingkat keberhasilan yang sangat baik, yakni memiliki dampak positif dan signifikan adalah AP 4. *Public website and internal platform*.
 - Sedangkan untuk AP yang mempunyai tingkat keberhasilan yang baik, yakni memiliki dampak positif selama berlangsungnya kegiatan SEARN adalah AP3. *Information Sharing*, AP5. *Reliance*, AP6. *Sustainability of the Network*, AP10, *Increase the number of reports*, AP11. *Integration of vigilance*, AP12. *Preparedness against public health emergencies*, AP14. *Integrity of excipients*, AP15. *Risk management*, dan AP16. *Regional safety signals*.
- b. Pada WG 1 - *Quality*, terdapat 3 AP yang mana 2 diantaranya mempunyai tingkat keberhasilan yang cukup, karena tidak terdapat dampak yang bisa diukur, misal untuk AP8. *Reference standards*, tujuan dari bentuknya AP tersebut adalah untuk memfasilitasi pengadaan *reference standards* yang mana sampai saat ini belum diimplementasikan karena programnya baru akan dimulai, begitu juga dengan AP9. *Collaboration between NQCL*, AP ini juga baru akan membentuk MoU dan *database* untuk kedepannya dapat berkolaborasi antar laboratorium sehingga tidak terdapat dampak yang bisa terukur. Namun, untuk AP 14. *Integrity of excipient*, 8 dari 9 negara anggota SEARN telah mengimplementasikan pengujian metode ED-DEG sejak tahun 2023, sehingga AP 14 termasuk mempunyai tingkat keberhasilan yang sangat baik.
- c. Selanjutnya untuk WG2 - *Regulatory Strengthening*, untuk AP1. *Capacity building* telah terdapat beberapa kali *meeting* untuk membahas AP ini, namun baru pada tahap awal implementasi sehingga dampaknya belum dapat terukur, sedangkan untuk AP. 5 *Reliance* mempunyai tingkat keberhasilan yang baik.
- d. Dari WG3 - *Vigilance*, seperti AP.10 *Increasing the number of report*, beberapa negara sudah mengembangkan strategi untuk mengatasi situasi ini, namun pelaporan umumnya masih rendah. Variasi yang signifikan di dalam negara anggota tergantung pada *channel* pelaporan, yang menunjukkan kurang adanya integrasi. Untuk AP 11. *Vigilans*, sudah terdapat peningkatan progresif di negara-negara yang telah mengembangkan strategi untuk mengatasi integrasi tersebut. Untuk AP 15. *Risk management*, sedang dilakukan *pilot project* pada produk valproat, sedangkan untuk AP. 16 *Safety signal* juga sedang *on going pilot project* dengan produk minoxidil.
- e. Untuk WG4 - *Information sharing*, mempunyai tingkat keberhasilan yang sangat baik karena terdapat dampak yang sangat positif, yakni dari AP 4. *Internal platform and public website* yang mana user pengunjung platform meningkat dan akan dilakukan perbaikan berkelanjutan

- f. Untuk WG 5 - *Medical devices*, baik untuk AP17. *Capacity building for medical devices* dan AP. 18 *Facilitate reliance for medical devices* termasuk dalam tingkat keberhasilan yang cukup, karena belum terdapat dampak yang dapat terukur.
- g. Dari semua *SEARN Monitoring and Evaluation Framework* yang disampaikan pada Assembly, *dokumen tersebut disetujui dan diadopsi* pada Assembly tersebut.

11. Work plan outputs

a. SEARN MoU

b. Mpox ad hoc Working Group

- i.
- ii. Adapun outcomes dari SEARN Mpox Intra-Action review yang telah disetujui adalah sebagai berikut:
 - 1.

c. WG 1 - Quality

- i. Assembly telah mengadopsi output WG 1 dan aksi yang direkomendasikan dalam workplan tahun 2025–2026 dan setuju untuk mempublikasikan public summary di situs web SEARN.
- ii. Untuk AP9 tentang Kolaborasi antara NQCL, Assembly merekomendasikan penambahan satu poin aksi tambahan: “Uji coba sistem untuk memfasilitasi berbagi dan pengujian sampel antar NQCL anggota SEARN.”
- iii. Diusulkan agar Thailand mempresentasikan green book-nya dalam WG4 untuk mendiskusikan bagaimana informasi tersebut, beserta informasi serupa dari anggota negara lainnya sehingga dapat dimanfaatkan oleh network di masa mendatang.

d. WG 2 - Regulatory Strengthening:

i. Thailand: mengusulkan:

rencana aksi AMR SEARN diselaraskan oleh rencana aksi nasional masing-masing negara sehingga tidak duplikasi. Rencana aksi akan dishare ke seluruh negara anggota.
melakukan pilot bersama SEARN

-
- diselar Seahrusnya align sehingga tidak ada duplikasi.
- harus belajar detail AP.1. PPT hanya konsep. Harus diskusi untuk bagaimana implemtasinya.
- Next step: develop detailed resquest proposal. akan dishare dengan
- IT contract. di thailand melakukan preparasi sejenis mekanisme ini, kami bisa pilot dan sharing dengan SEARN. GBT< WLA for vaccine. Next year: maturity level for medicine. Traing metric akan sangat bernamfaar, KIta ada 4 proposal finasnsial dari suplier yang ebrbeda,
- SeARN akan punya sort of training katalof
- Meskipun Indonesia keluar dari SEARN, pakar eksternal yang telah dicalonkan oleh Indonesia tetap dapat melanjutkan mandatnya karena pakar tersebut dinominasikan secara individu oleh anggota SEARN. Namun, ke depan hanya negara anggota SESRN yang bisa mencalonkan anggota baru.

e. WG 3 - Vigilance

- i. Telah dilakukan proses seleksi *external expert* dengan hasil sebagai berikut:
 1. Dari 48 *expressions of interest* yang telah diterima dari 8 negara (2 diantaranya berasal dari Industri Farmasi) diseleksi berdasarkan CV sehingga didapatkan 15 *experet* dari anggota SEARN.
 2. Selain itu untuk mendukung aktivitas WG3 telah dibuat SOP *For Managing Confidentiality And Links Of Interest*.
 3. Terhadap *external expert* dari Indonesia akan tetap berlaku meskipun adanya kepergian Indonesia dari SEARN

- ii. *Assembly* mengadopsi output yang diusulkan yang disampaikan oleh *Chair Working Group*. *Assembly* juga menyetujui dalam mempublikasikan ringkasan publik di situs web SEARN serta mengadopsi tindakan yang disarankan dalam *workplan* 2025-2026, yakni:
 - 1. AP.15 - *Develop the capacity to assess and manage risks associated with medical products*.
 - a. Melakukan survei untuk mengumpulkan informasi tentang *legal provision* dalam mengelola risiko;
 - b. Mengembangkan rekomendasi untuk mendukung negara anggota SEARN dalam mengelola risiko sesuai dengan kapasitasnya;
 - c. Mengembangkan kapasitas negara anggota SEARN dalam mengelola risiko (termasuk penilaian RMP);
 - d. Melakukan *pilot project* pembentukan pusat regional untuk farmakovigilans;
 - e. Mengembangkan mekanisme untuk memfasilitasi *reliance* pada manajemen risiko di negara anggota SEARN; dan
 - f. Menangani setiap isu yang muncul terkait dengan strategi ini.
 - 2. AP 16 - *Strategy to develop a regional mechanism to detect and review safety signals*.
 - a. Eksplorasi ekspansi obat prioritas ke vaksin dan produk biologis;
 - b. Finalisasi publikasi pemetaan variabel dalam formulir pelaporan ADR yang berlaku secara nasional;
 - c. Berinteraksi dengan pembuat kebijakan tentang cara memperkuat farmakovigilans;
 - d. *Pilot project* pendirian pusat keunggulan regional untuk farmakovigilans;
 - e. Mengembangkan mekanisme untuk memfasilitasi *reliance* terkait *safety signals* di SEARN;
 - f. Menangani masalah baru yang muncul terkait dengan strategi ini.
- iii. Selain itu, pada saat *Assembly* diminta agar semua anggota SEARN dapat secara aktif berbagi informasi terkait kegiatan farmakovigilans dengan pusat kolaborasi IPC untuk memfasilitasi pengembangan buletin *pharmacovigilance newsletter*.

f. WG 4 - Information sharing

g. WG 6 - Traditional Medicines

- i. *Assembly* menyambut partisipasi NRA baru dari India dan Sri Lanka dalam *Assembly of the Members of SEARN*.
- ii. *Assembly* mengadopsi usulan pembentukan *working group* 6 (WG6) Produk Obat Tradisional beserta usulan terms of reference-nya.
- iii. *Assembly* juga mengadopsi tindakan yang direkomendasikan dalam rencana kerja tahun 2025–2026 melalui dua poin aksi baru:
 - AP22: Peningkatan kapasitas untuk produk obat tradisional
 - AP23: Konvergensi regulasi produk obat tradisional
- iv. *Assembly* juga meminta agar informasi lebih lanjut mengenai cakupan *working group* serta penggunaan terminologi internasional untuk produk obat “tradisional” disediakan di situs web publik SEARN.
- v. Terkait pemilihan *chair* untuk *working group* yang baru dibentuk, *Assembly* mempertimbangkan satu pernyataan minat yang diterima dari Dr. A. Raghu (India).
- vi. Dr. A. Raghu terpilih secara mufakat sebagai Ketua WG6 Produk Obat Tradisional.

h. National Information Sharing

- i. *Assembly* 2022-2023 telah mengadopsi strategi untuk memfasilitasi pertukaran informasi. Telah terdapat deklarasi dari setiap negara anggota SEARN untuk memfasilitasi pertukaran informasi dan komitmen untuk memperkuat pertukaran informasi tersebut. Selain itu, telah disepakati template *Confidential Disclosure Agreement* untuk memfasilitasi pertukaran informasi yang bersifat rahasia secara bilateral. Pedoman juga telah disusun, khususnya dalam hal pertukaran informasi mendesak dari SEARN.
- ii. Sedangkan *Assembly* 2023–2024, telah menetapkan format untuk pertukaran informasi yang mendesak. *Platform internal* juga telah dikembangkan dalam rangka pemantauan dan evaluasi yang dapat diakses oleh setiap negara anggota SEARN, misal dapat digunakan untuk pemantauan WLA/GBT dan

memfasilitasi adanya *issue* tertentu. *Cover letters* juga telah dikembangkan sebagai sarana bagi NRA dalam memberikan informasi. Selain itu juga telah dilakukan survei mengenai pembatasan informasi dari setiap negara anggota SEARN.

- iii. Assembly 2025, telah mencatat mengenai perkembangan status strategi nasional dalam hal *information Sharing* dan membahas langkah-langkah yang perlu dilakukan selanjutnya. Para anggota sepakat untuk mengambil pendekatan yang menggabungkan beberapa hal, yaitu finalisasi MoU SEARN, memperkuat SEARN *legacy* beserta strategi *information sharing* yang telah dibangun, serta menggunakan pendekatan yang pragmatis untuk mengatasi tantangan yang masih ada. Selain itu, *information sharing* dianggap sebagai sarana penting untuk mencapai berbagai tujuan yang telah ditetapkan.

1. Draft declaration of Members of SEARN and public procurement agencies on Enhancing Convergence and Collaboration for Access to Quality-Assured Medical Products:

INDONESIA:

pengalaman. suplier fenobarbital hanya ada 1 IF yng legal. Produk memenuhi syarat, dan kit minta stop produksi tapi setiap orang protes. oleh karena itu perlu implement quality risk management.

so, I dd QRM, forecastring, IT tools, central bidding, local procurmenet, public procurement design

Komen Draft declaration →

Bangladesh:

2. National Information Sharing:

- a. Information sharing: sesuai dengan komitmen pada GBT. information sharing bukan akhir tapi permulaan

3. Sustainability:

4. Rapporteur W2 : Thailand.

WG 4= srilanka

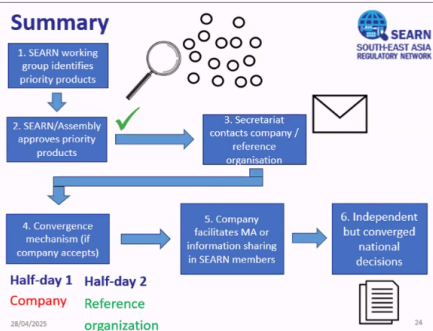
WG 6. Chari India

4. TOR:

2024-2025 Highlights from the SEARN reliance strategy



Proposition of a SEARN convergence mechanism:



16/07/2025

28/04/2025

24

18

2024-2025 Highlights from the SEARN shortages strategy



Scoping review:

- Summarizing prior work on definitions
 - 2016 WHO work on definition of shortages: 56 definitions identified
 - 2 definitions and a definition framework were drafted, and several criteria were identified for refining definitions
- EU developed a comprehensive system to prevent, detect, monitor and minimize shortages
- USP studied economic factors of shortages in the US

Survey conducted on shortages:

- Mapping of NRA roles
- Challenging areas: identification/monitoring of shortages
- Limitations: lack of legal provisions/clear responsibility and tools, and insufficient number of staff
- Paediatric medicines most quoted for shortages, but also chemotherapy, antibiotics, medical devices/IVDs and vaccines

16/07/2025

19

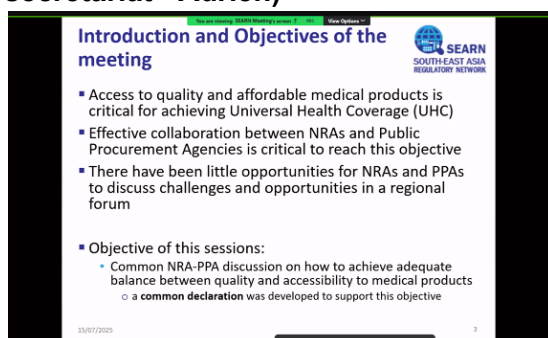
Recommended actions in the 2025-2026 workplan



Action point	Lead	Support	Need	Action*
20	4	5	Strengthen the capacity of SEARN Members to monitor and address shortages	1. To conduct a survey to collect current definitions related to shortages and existing mechanisms to address these in SEARN members 2. To develop a system to compile, analyse and share information related to shortages at SEARN level to support Members in forecasting, reducing and averting shortages/stockouts 3. To learn from the experience and best practices of SEARN members and other regions / organizations in addressing shortages, including public procurement agencies (e.g. ICAPS) 4. To develop collaboration with public procurement agencies to support the development and implementation of the SEARN strategy 5. To support SEARN Members in addressing shortages through capacity building, including at the organizational level (e.g. legal provisions, clear responsibilities, tools)

12. Regulatory excellence: Achieving Balance of quality and accessibility to medical products for all – Session 1 (SEARN and Public Procurement Agencies (virtual))

Introduction and objectives (SEARN secretariat - Adrien)



Okay, so, uh, just to introduce a little bit why we're having this, uh, session today.

Uh, the first thing is ... well, actually, it's not on this slide, it is if we come back to the previous slide.

Sorry? Yes. So Every year, when we organize the meeting of the Assembly of SEARN, we ask the host country.

To let us know what. Theme they would be interested in to, uh, address the specific, uh, issues that they face.

And, uh, this year, colleagues from Bhutan chose this theme, Regulatory Excellence, Achieving Balance of Quality and Accessibility to Medical Products for All.

Next slide. So, in this context.

Um, discussing with colleagues from BFDA. Uh, and also based on experience from, uh, several countries in the region.

What we could, uh, highlight is that, in general. Uh, I think

All from PPA and from national regulatory authority agree that access to quality and affordable medical products is critical for achieving.

Universal health coverage. In this context. Effective collaboration between NRAs and PPAs is extremely important, but what we can see also is that there have been little opportunities for NRAs and public procurement agencies.

To discuss together challenge and opportunities in a regional forum. So very often, it's done at the national level, but it stays there, and there are independent activity, but it's not so common that.

A. Pengantar dan Latar Belakang Sesi (Disampaikan Oleh Adrien)

1. Sesi ini diadakan sebagai bagian dari pertemuan Assembly SEARN tahunan. Setiap tahun, negara tuan rumah diminta untuk mengusulkan tema yang relevan dengan isu-isu spesifik yang mereka hadapi.
2. Tahun ini, Bhutan memilih tema: **"Keunggulan Regulasi: Mencapai Keseimbangan antara Mutu dan Aksesibilitas obat untuk Semua."**

B. Tujuan Sesi

1. Dalam diskusi bersama BFDA dan berdasarkan pengalaman berbagai negara di kawasan:
 - o Diakui bahwa akses terhadap obat yang bermutu dan terjangkau sangat penting untuk mencapai cakupan kesehatan semesta (Universal Health Coverage).
 - o Kolaborasi efektif antara otoritas regulatori nasional (NRA) dan badan pengadaan publik (PPA) sangat krusial.

Namun, kesempatan untuk dialog antara NRA dan PPA di forum regional masih sangat terbatas; biasanya hanya berlangsung di tingkat nasional dan berjalan sendiri-sendiri.

2. Sesi ini bertujuan membuka ruang diskusi bersama antara dua lembaga penting tersebut, guna mencapai keseimbangan antara mutu dan akses obat. Relevansi diskusi bisa berbeda-beda tergantung situasi masing-masing negara. Harapannya semua negara dapat memperoleh manfaat, meskipun terdapat isu-isu spesifik di beberapa negara.
3. Topik diskusi dapat diperluas sesuai kebutuhan dan masukan peserta, terutama jika ada aspek yang belum terakomodasi secara memadai.
4. Salah satu hasil yang diharapkan dari dua sesi ini adalah **penyusunan deklarasi bersama** antara otoritas regulatori nasional dan badan pengadaan publik.

C. Agenda Singkat Sesi

1. Presentasi utama akan disampaikan

In a regional framework, there is the possibility to have both.

Regulatory authorities and public procurement agencies. So the objective of this session is to have a common discussion between these two important organizations on how to achieve this, uh, balance.

So, depending on the countries, it may be more or less relevant, because there are also some issues that can be quite specific.

To some countries, but we still hope that all countries can benefit from these sessions, and this is not also a limit, uh Through the declaration and through the discussions that we will be having, we can also expand, if you feel that some aspects are not sufficiently covered. One of the things that we hope to achieve during these two sessions, but that remains to be discussed, is the possibility for a common declaration between national regulatory authorities and public procurement agencies.

Next slide.

So, very quickly, this is the, uh, agenda. So, right after, uh, my colleague Gene will provide a keynote presentation.

Uh, on, uh, how to streamline access. We will hear about key challenges, uh In general, related to access from public document agencies, but we will also hear from Timor-Leste from DNFM.

And in addition to the colleagues here, we will also hear from the public procurement Agency of Bhuta, which is participating in person, um, in this session.

We will also hear later on some perspectives from the industry in Bhutan, so the goal is also to understand what are the specificities of the challenges that could be faced in a country like Bhutan, uh, which is likely quite different from the challenges that industry, for example, in India or in Bangladesh may be facing. So some aspects, also, it's a new common, but there may be also certain specificities, so we wanted also to capture that as part of this discussion, just to make sure that we're not missing anything.

We will hear later on from Dr. Anil Chola on the challenges around the ... specifically the procurement of small

oleh Uhjin mengenai "**Streamlining access**" (penyederhanaan akses), akan disampaikan tantangan utama yang dihadapi badan pengadaan publik terkait akses obat.

2. Kemudian, dilanjutkan dengan presentasi dari Timor-Leste (DNFM) dan Badan Pengadaan Publik Bhutan (hadir secara langsung). Perspektif dari industri Bhutan juga akan dibahas, untuk melihat tantangan spesifik yang mereka hadapi – yang mungkin berbeda dari tantangan di India atau Bangladesh.
3. Pemaparan oleh Dr. Anil Chola mengenai tantangan pengadaan obat dalam jumlah kecil akan relevan terutama untuk negara berpenduduk kecil, namun juga bisa dialami oleh negara besar untuk produk tertentu seperti:
 - Obat penyakit langka (orphan drugs)
 - Produk dengan tantangan pengadaan khusus
4. Pada sesi ini juga akan dilakukan diskusi terbuka mengenai hubungan dan dinamika antara NRA dan PPA dalam kerangka SEARN. Topik ini sudah mulai disentuh dalam dua poin aksi SEARN:
 - Isu kelangkaan (shortages)
 - Mekanisme konvergensi berbasis reliance

Tujuan: memperkenalkan inisiatif ini ke kolega dari badan pengadaan publik.

5. Diskusi lanjutan akan didukung dengan **polling daring** untuk menggali cara memperkuat kolaborasi antara NRA dan PPA.
6. Peninjauan awal atas **draft deklarasi bersama** bergantung pada hasil diskusi.
7. Sesi lanjutan besok pagi (1 jam) akan digunakan untuk:
 - Melanjutkan pembahasan deklarasi jika masih ada tantangan
 - Membahas isu tambahan yang mungkin muncul dari diskusi hari ini
 - Menyusun solusi praktis untuk permasalahan yang muncul

quantities of medical products that is something that is relevant, actually, for any countries.

It's an issue that is more often faced by countries with small population, but depending on the products that we're discussing, even large country can also face challenges. Uh, when it comes, for example, to, I don't know, some orphan disease, or some particular products that, uh, are facing, uh.

A lot of tension in terms of procurement, so that can also speak to all of you.

Uh, we will then have some discussions on, in general, quite open discussion on the interplay between national regulatory authorities and PPAs, Um, from SEARN, so you're already aware that we're touching on some of these issues, especially through two action points, one, uh, which was just initiated last year, which is around shortages, another one which is around reliance in the proposed convergence mechanism, but the idea is also to present this to the colleague from Public Procurement agencies, so that they're also aware of these activities.

Uh, we'll then have some further discussion that will be supported by an online poll on how to foster collaboration between NRAs and PPAs. And we'll have a first review of what is proposed as a draft joint declaration.

The idea is then to, depending on the discussion, to have another session tomorrow.

It can still be on the drop declaration, that depends on how challenging the discussions are.

On this draft. And, um, we can also use, uh, so this is a one-hour session tomorrow morning.

Some of the time related to it can also be, uh, used if there was some particular issue that we did not necessarily foresee, but that would come out of this discussion today, so we can use some time tomorrow to come back to this issue and try to perhaps, uh, come with some practical, uh, solutions to it. So, that's it for the agenda.

Streamlining Access: Enhancing collaboration between regulatory authority and procurement agencies for timely access to quality and affordable medicines (WHO SEARO-Uhjin Kim)

If we can have this one, I think it's under 9.2.

Thank you, colleagues. And over to Uhjin. Shall I share it from my end? You can also, but I think colleagues are uh, it's blocked. Maybe then you can yep. It's coming, don't worry. Meanwhile, you can introduce yourself if you wish.

Great, thank you. Good afternoon and good evening to all regulators and focal points from public procurement agencies. It's wonderful to see both regulatory authorities and procurement agencies come together. For this important joint meeting. Right. Next slide, please. uh, we are united by a common goal to achieve a sustainable development goal 3.8, which is universal health coverage, which calls for access to safe, effective, quality, and affordable essential medicines and vaccines for all. Regulators and procurers are both vital stakeholders in ensuring the health of our population's your collaboration determines not only. The quality and safety of medicines, but also their affordability and timely access to those who need them most. Next slide, please.

As we begin, let's look at the unique and complementary roles. Each of us play along the medicine's life cycle. Understanding the life cycle of a pharmaceutical product is crucial for regulators. Procurement agencies, manufacturers, and other stakeholders. The cycle can be divided into, uh, three phases. Pre-launch, Peri-launch and post-launch. That is from research and development

Streamlining Access: Enhancing collaboration between regulatory authority and procurement agencies for timely access to quality and affordable medicines (WHO SEARO-Uhjin Kim)

1. Tujuan Umum

- a. Mewujudkan SDG 3.8: akses universal terhadap obat dan vaksin yang aman, efektif, bermutu, dan terjangkau.
- b. Memperkuat kolaborasi antara otoritas regulatori (NRA) dan lembaga pengadaan publik (PPA) untuk meningkatkan ketersediaan dan efisiensi distribusi obat.

2. Peran Komplementer NRA dan PPA dalam Siklus Obat

- a. *Stakeholders* dan NRA berperan dalam siklus obat dari mulai pre-market, selama peredaran, dan pasca peredaran obat.
 - Pre-market : R&D, evaluasi, otorisasi.
 - Selama peredaran : pengadaan, registrasi, distribusi.
 - Post-market: pemantauan pasca-pasar (farmakovigilans, dll)
- b. Sepanjang siklus obat tersebut, NRA fokus pada keamanan, mutu, dan efektivitas obat, sedangkan PPA berperan memastikan pengadaan dan distribusi obat yang telah memiliki izin edar dan bermutu.

3. Kesenjangan Produk di Pasar Publik vs Swasta

- a. Pasar swasta: hingga 15.000 produk teregistrasi (beragam dan luas).
- b. Pasar publik: fokus pada *National Essential Medicines List* (NEML), 200–830 produk tergantung negara.
- c. Namun, di pasar publik, PPA juga mengadakan produk non-NEML (hingga 3.000 produk).

4. Tantangan di Pasar Generik & Produksi Lokal

- a. Asia Tenggara didominasi oleh produk generik multisumber.
- b. Registrasi berulang untuk molekul generik yang sama membebani kapasitas NRA.
- c. Menyebabkan:
 - Fragmentasi volume pasar.
 - Berkurangnya skala ekonomi
 - Beban pada sistem asuransi kesehatan.
 - Kesulitan manajemen stok dan pengadaan.
- d. Contoh fragmentasi pasar:
 - Glucometer dan strip glukosa: terlalu banyak jenis

to market entry until it reaches a patient, and we monitor its use. Regulators safeguard public health by evaluating, authorizing, and monitoring the quality, safety, and efficacy of medicines from registration through post-market surveillance. You can see public procurement agencies in the middle, where they ensure that registered and quality assured medicines are sourced efficiently, affordably, and properly delivered to healthcare facilities.

Next slide, please. So when we look at the products in the market, and what, uh, what are the products that we deal with as regulators and procurers. Uh, it is said that there are more than 20,000 products out there in the world registered. None of our ... I mean, probably most of our member states do not have 20,000 products in the market, but if we look at the public health sector and the private health sector, the private health sector market is often larger, where there could be a range of 4,000 to 15,000 products that are registered in the market, covering inpatient, outpatient, and over-the-counter medicines. It is often paid by a social health insurance schemes, or private health insurance schemes, or by individuals and families. But if we move to the public sector, uh, the public sector procurement is done by public procurement agencies, whether it is at a national level, state level, or a facility level. What is the range of products that we deal with? We focus much smaller. Uh, therapeutic groups. Uh, I mean, we ... we ... we'll ... that are essential. So, we focus on procurement of products that are on the National Essential Medicines list (NEML)

In Southeast Asia region, some countries have the smallest number, ranging around 200 medicines to the largest number, around 830, that would be Thailand. But public procurement agencies not only procure medicines that are in the

menyebabkan masalah stok dan pengadaan.

- Kapsul Amoxicillin 500 mg: ratusan produk dari berbagai produsen menghambat efisiensi pengadaan dan manajemen inventori.

5. Duplikasi Proses *Quality Assurance*

- a. Dalam hal ini, baik NRA dan PPA meminta dokumen QA yang sama, seperti sertifikat GMP, sertifikat produk farmasi, CoA, pengujian bets, inspeksi, dsb. Hal ini menyebabkan inefisiensi sumber daya, dan potensi standar QA yang tidak konsisten.
- b. Solusi:
 - Pengakuan bersama (*mutual recognition*) dan sharing informasi hasil QA seperti PPA dapat mengacu pada hasil registrasi dan inspeksi NRA, hasil inspeksi visual PPA dibagi ke NRA.
 - Pengembangan bersama (*joint development*) dokumen QA, inspeksi, dan pengujian bets.

6. Tantangan di Negara dengan Populasi Kecil

- a. Kapasitas produksi lokal dan NRA terbatas.
- b. Ketergantungan pada produk impor melalui distributor.
- c. Tantangan:
 - Produk tender belum teregistrasi saat pengadaan.
 - Siklus registrasi dan pengadaan tidak sinkron.
 - Biaya tinggi akibat margin distributor.

7. Rekomendasi Strategis:

- a. Penyelarasan kebijakan & proses antara NRA dan PPA.
- b. Peningkatan berbagi data & perencanaan bersama.
- c. Pemanfaatan alat digital & sistem informasi untuk transparansi, efisiensi QA, dan dialog regulatori-pengadaan secara *real-time*.

National Essential Medicines list, because the list is sort of a mix of products that are required at primary healthcare level, and at Tertiary healthcare level as well. So, after many of the procurement agencies also procure, non-NEML product, which could range between 400 to 3,000 products.

So, um, while we have national regulatory authorities trying to ensure, evaluate, and authorized entry of many of these products, what is needed by the public procurement agencies is a much smaller set of products. Next slide, please.

However, the Southeast Asia region is largely dominated by multi-source generic. It's a generic market and the local production, where we have countries with large pharmaceutical production capacity, but mainly focuses producing off-patent generic medicines. So, what the situation leads to is a unique challenge where we have.

A lot of, um, challenges around repeated registration of the same. Generic molecules. So, the National Regulatory authorities are often overburdened by repetitive registration of the same generic molecules and these generic registration taking out most of the workload. Uh, hence, there could be a delay, um, of market entry of much-needed medicines. And, of course, there could be some issues around ensuring consistent quality across multi-source products from different manufacturers, which could constrain regulatory resources. But these situation is also a challenge for public procurement agencies, because too many of the same molecules could fragment the volume. Reduced economies of scale, and result in inefficient procurement and stock management. It also constrains. Uh, the capacity of the social health insurance schemes where they need to set up the prices of the each generic

molecule. So they're often overburdened by setting up reimbursement prices of the numerous generic molecules.

Next slide, please. So, we could end up a situation like this. One example, though it's not always the same, but a good example from a medical device, which is a glucometer. As you know, the glucose strips are specific to the glucometers that are produced, so it is sort of brand-specific. I have seen in many countries where there's an overflow of different types of glucometers and strips. Even in the public sector, which inevitably fragments the volume, and it makes stock management and forecasting extremely difficult. So, even if there are many, uh, if there is availability of, uh, a particular glucometer and the strips, but then, if there is a stock out of another brand, which still leads to stockouts and unavailability for the patients that are using that particular product. And the situation is probably even worse when it comes to medical products, medicines, and amoxicillin, which is most widely used products probably alongside paracetamol is a good example.

And I've only just listed a few photos, but there could be hundreds of amoxicillin 500 mg capsules from thousands of manufacturers around the world. So what does That situation leads to.

So the procurement and consumption is split across same generics from different manufacturers. So, which would result in loss of economies of scale, resulting in reduced bargaining power. So, that leads to difficulty in inventory management due to fragmented supplies, because even if you have the stock availability of one particular brand amoxicillin, you might not have stock available for another, which is still a stock out. And, um, especiallywhen generic substitution is not allowed, this leads to serious stock-out issue problem, because, uh,

you know, it's still unavailable, and these are the results of market fragmentation due to potentially a lot of the same generics available in the country.

Next slide, please.

And another area where there's quite a lot of duplication is duplicated quality assurance mechanisms. So there could be overlapping processes. So, um Often NRAs and public procurement agencies requesting the same quality assurance documents from the same suppliers. For example, GMP certificates.

Certificate of Pharmaceutical Products, Certificate of analysis, which is not only required when it comes to marketing authorization or product registration, but for public procurement agencies, when they tender, and part of quality assurance checks.

There could be batch testing, duplications. There could be separate quality audits and inspections, all resulting in resource inefficiency and risk of inconsistent standards.

However, there's not only a negative side, there could be a ... both agencies could supplement the QA process.

If there's a mutual recognition and information sharing of quality assurance findings, so the public procurement agencies relying on the NRA registration and inspection outcomes. PPAs, the Public Procurement agencies, could also provide limited but vital information regarding the results of the visual inspection of the products, especially when there is uh, per shipment or post-shipment inspections, and there could be a joint development of quality assurance document requirements, inspections, and batch testing.

So, one case study, although my colleague Anil, would discuss a little bit more in depth about small country situation, where there is small volume.

So, we have several countries in a region where we have small population countries, uh,

resulting in small volume or small demand and often, there is no local production capacity, or there is limited local production capacity. So there is heavy reliance on imports, and often, uh, the National Regulatory authorities are small and limited capacity for marketing authorization review and inspection capacity, and there is no or little incentive for manufacturers to seek marketing authorization in that particular country, and public procurement agencies are tendering imported medicines, often not directly with the manufacturers, but through importers and wholesalers, the intermediaries.

So what does that lead to? So the tendering within registered products unfortunately, made limit choices or led to shortages and supply chain vulnerabilities, and the tender product may not be registered in the country sometimes if the small NRAs are struggling to catch up with the product registration of what's already in the market, and there could be misalignment of procurement and registration cycles, where the tendering process happens first, and the registration happens later. Or if the registration process takes a lot of time, and there is all, you know, resulting in delay and the multiple intermediaries adds margin and increases the cost of the products once it reaches the countries.

Next slide, please. So, we have discussed some of the challenges, uh, and issues around quality products, affordable prices, and timely access, where our shared goal is to provide quality products at affordable prices, in a timely manner, to a patient in need. We can only achieve this when we work together and complement each other's work, as regulators and procurers.

Next slide, please. So, strengthening collaboration and alignment is what we like to discuss a bit more in depth

later on. But I think there are three key factors. One would be streamlining policy and process. Second would be enhancing data sharing and joint planning between national regulatory authorities and public procurement agencies. And lastly, leveraging digital health tools for transparency and efficiency. Especially if we could, uh, use some digital health tools to share data and facilitate timely dialogue. so that is just an introduction of the session today, and thank you very much. Over to you, Adrien	
Key challenges: Perspectives from Public Procurement Agencies • Bhutan (5 mins) • Maldives (5 mins) Discussion 1. Ministry of Health Maldives  Okay, hi, um, you can go to the next slide. Uh, hi, my name is Mirza, and I just want to give an idea on how we are managing in motors. So, just to give you a country overview, we are a country, uh with a population less than, uh 500 went ... about 520,000, about 1,200 islands, and people live in 187 island. And it is actually quite scattered. Uh, I mean, uh, it ... we golike, this, like, uh, in the middle of the ocean. And only about 1% of the country economic area is, uh, land and, uh, geographically, we are distributed into,	Perspektif Negara dalam Tantangan Pengadaan Publik 1. Maldives (Mirza-Ministry of Health) - Maladewa: negara kepulauan kecil dengan populasi sekitar 520.000 jiwa yang tersebar di 1.200 pulau (187 berpenghuni). - Sistem jaminan kesehatan <i>Universal Health Coverage (UHC)</i> diberlakukan untuk seluruh warga negara. Tidak ada biaya langsung (<i>out-of-pocket</i>), kecuali untuk layanan komersial. - Pengelola jaminan: <i>National Social Protection Agency</i> dan perusahaan jaminan kesehatan negara: Asanda. - Sistem pengadaan obat dan alur distribusi - Pengadaan sebagian besar dilakukan oleh Kementerian Kesehatan untuk RS dan fasilitas kesehatan. - Beberapa rumah sakit besar dan pusat thalassemia memiliki anggaran mandiri dan melakukan pengadaan sendiri. - Obat program nasional dikelola oleh <i>Health Protection Agency</i> bekerja sama dengan WHO. - Tantangan utama - Tantangan Pengadaan Volume pengadaan yang kecil membuat sulit membeli langsung dari produsen, harus lewat reseller sehingga harga lebih mahal dan dokumen pendukung sering tidak sesuai regulasi

uh, 21 atolls. In some metals, there are 5 items, uh And, uh, in some of the islands, there's a population which is, uh, less than Um, let's say 200 people. And, uh, with interest of this meeting, I would like to say that, uh, uh Right now, the country, uh, government is practicing. Universal healthcare coverage for all the local people.

And, uh, out ... there's no out-of-pocket ... any out-of-pocket expense, too. It has to be borne by any of the local people. Of course, if you're going for a commercial, uhplace, I mean, you will have to, uh, pay something. and, uhAll the tests and everything is there, and if it is something which is not covered in the, uh health coverage. I mean, uh, then you can reimburse it through ... through a national setup. We have one, uh, for health coverage and social welfare. Things we ... we have a government entity name, uh, National Social Protection Agency. Under them, of course, there's, uh, health coverage company, which we name as Asanda where the ... all the medical expenses will be, uh, managed by them.

You can go to the next slide. Okay. Basically, this is how we manage our medical supplies for our pharmaceuticals, uh, we have only hospital use items, which most of those things will be procured by, uh, Ministry of Health for the Health Facilities and us, of course, independently, we have our national hospital, which is located in Mali. And, uh, there are a few major health facilities, like, uh, an two or three hospitals and National Thalassemia Center, also under them in urban primary healthcare centers, which is located in the capital, will also go under them.

They have a separate budget. They will be, uh, doing some of the procurements independently and also, um, in Uh, other, uh, islands. Some of the major hospitals, they are also

nasional.

- Tantangan Distribusi
 - Distribusi antar pulau sangat menantang dan mahal.
 - Dikelola oleh STO (*State Trading Organization*), perusahaan milik negara yang mengatur logistik masuk dan keluar sejak 2010.
- e. Regulasi dan standar obat
 - Semua obat harus sesuai standar NRA nasional (MFTA).
 - Dokumen wajib: CoPP (*Certificates of Pharmaceutical Products*), sertifikat GMP, informasi dalam bahasa Inggris.
 - Dalam kedaruratan kesehatan nasional, beberapa persyaratan regulasi bisa dikecualikan, asal obat masuk dalam daftar WHO
 - Jika kejadian tidak sampai ditetapkan sebagai darurat nasional, regulasi tetap harus dipenuhi. Hal ini menghambat respons cepat terhadap kejadian luar biasa berskala kecil (misalnya *outbreak* musiman).
- f. Permasalahan volume dan ketergantungan
 - Kebutuhan obat rendah, sulit memenuhi *minimum order quantity* (MOQ) dari pabrikan. Akibatnya:
 - Persediaan bisa kehabisan.
 - Harus mencari bantuan WHO atau negara tetangga.
 - Harus membeli dari reseller dengan kualitas dan dokumen tidak selalu sesuai.

Kesimpulan: Maladewa menghadapi tantangan signifikan dalam pengadaan dan distribusi obat akibat lokasi geografis yang terpencar dan volume kebutuhan yang kecil. Kolaborasi lintas lembaga, fleksibilitas regulasi pada kondisi darurat, serta dukungan internasional menjadi kunci solusi.

Uh, managing the, umbudget independently. Of course, they'll be doing their procurements separately. And, of course, we have ... if it is any medicine which is prescribed by the doctors or registered doctors, you will get it, uh, on prescription, over-the-counter medicines are there, and, of course, we have some national program medicines. We have programs which is uh, conducted by our, uh, health protection agency in collaboration with, uh who we are doing procurement for them as well, and of course, there are contracts. And most of the Um, just like the ... in the presentation that Jin mentioned. We also wanted to do procurement independently. But we were faced a lot of challenges. Actually, we have two challenges here in our country. First, it's inbound challenge. Okay? That is, uh, procuring. And, uh, second challenge is, after we procure, how we are going to distribute.

As I mentioned, I mean, number of locations may not be high. In terms, uh, if we make comparison to another country. But the challenge for us is that we have to deliver everything. So, about 10 Um, it was in 2013, so about 14 years back, government made the decision that Uh, the work we are doing, inbound logistic and outbound logistics, will be managed by a state-owned enterprise, which is named STO. So, generally uh, all the hospitals and all the places I mentioned, uh, the general items which is procured.

For, uh, hospital use. Uh, things which is, I mean, uh, up to the standard, which is, uh, mentioned by us. Of course, we are going up to the standard of our quality commissioner here. The medicine standards will be, of course, given by our MFTA, which is the NRA. e did, uh, approves the medicine and things. And, um, we ... we have ... so we ... what ... how we are going to do ... we do is that. We give, uh, place order to

state-rating organization to procure the items and deliver the items. Of course, it has to be up to the standards, uh, which is, uh, given by MFTA, and we assume all the, uh, medicines, which they import into the country will be in. I mean, they have to abide all the standards which is set by our MFT, like, uh, they have to provide proper certification, registration has to be completed. And, um, minimum documents will be, like, the documents that Jin has mentioned all the prescription, all the information on the medicine has to be in English. That is one. Other thing is, uh, COPP has to be there, and GMP has a good administration practice. GMP must be submitted. And, uh, with regards to health emergencies. Um, first, it is actually two layers. One is, if a health emergency is declared nationally. The importer, STO, they will not have to submit any documents. But, of course, these medicines has to be mentioned in WHO emergency list. Then, uh, they can bypass all the, uh ... regulatory requirements. But on the other hand, there's another issue. Not everything is in unforeseen circumstances. Just a, uh We ... in our country, we have, um Let's say due to seasonal change and things. Um, sometimes there'll be outbreak of certain diseases. Not actually the outbreak which goes out of control, or number of cases increase. And, uh, sometimes, um, of course, these, uh, actually things which is not unforeseen. But, um, it is more ... more related to how much we are prepared.

Uh, the issue here is that, uh, number of cases we have to attend, uh. Okay, there might be an estimate, but it will vary. And, uh, how we manage our stock. Stockpiling, that is the issue. So, for this, uh, situations. We ... we are not able to, um, bypass any of the, uh, regulatory requirements. Of course, sometimes there is a challenge because, uh, what

happens in our country is that because the quantity we order is quite less. And the, uh, the interval will be generally longer than other countries. So, uh, let's say, for example, if we ... if we take some medicine, for example, let's say adrenaline. Um, we ... if we take it from a factory, or direct manufacturer. The amount we procure from them will be more than, I mean, minimum order quantity, is actually more than what we need for 2 years. But, um, I mean ... so, uh, in these kind of situations. In case we run out of stock, we usually seek help from WHO. We try to source it from a country nearby. If, uh, it is not there, then we Uh, we do, uh, face, uh, difficulties because how STO manages is that since the quantity is small. We are ... they are not able to get it directly from a manufacturer. They actually have to get it from resellers. So, in case of resellers, sometimes, as per their requirement, the documents they have to, uh, sell in their territory, and what we seek is a bit different. So, uh, that is, uh, one of the main challenges, actually, uh, we face. And, uh, regarding, uh, health, uh, emergency. If it is an outbreak, if it is an ... if it doesn't go to a national level, usually it is not declared here is in a health emergency. In that case, we will not be able to bypass any of the regulatory requirements. It's a ... generally, that is how we manage it here. I mean, if there's any questions, of course, I'll be happy to take it. Thank you.	
2. Timor Leste (MoH)	2. Timor Leste (Delfim- <i>National Director of Pharmacy and Medicine- Ministry of Health</i>) a. Sistem kesehatan & pengadaan • Layanan kesehatan gratis dari tingkat primer hingga tersier, termasuk obat-obatan. • Timor-Leste sepenuhnya bergantung pada impor obat dari negara seperti



Thank you, Adrian. Madam Chair, Adrien, W2 expert.

Partners, ladies and gentlemen, let me share with you the procurement challenges from Timor-Leste. Even though I'm not from a procurement agency, but from the Ministry of Health, we work together daily on this issue.

Next slide, please.

I'll be covering at least five components here. I'll first explain a little about our procurement agency in Timor-Leste and my directorate, which is not a regulatory function, but involved in procurement methods and legal frameworks, along with the key challenges.

First, our healthcare system is free of charge from primary up to tertiary care, including medicines and other pharmaceuticals, based on our constitution. All Timorese people are entitled to free healthcare.

Secondly, Timor-Leste depends on imported medicines from overseas, so we face challenges in accessing essential medicines. We receive funding from the state budget every year, and also have donor support such as Global Fund, UN agencies like UNFPA for family planning commodities, UNICEF, and others.

Most of our suppliers are from Indonesia, Southeast Asia, India, Bangladesh, a few from Australia and Europe. We don't have vaccines and anti-cancer medicines locally. We receive technical support from DFAT through TCA to strengthen our national regulatory functions. For supply chain management, we get support from DFAT via their implementing partner (called PHD), including through mSupply. They are also helping us develop our procurement manual, which is currently

Indonesia, India, Bangladesh, Australia, dan Eropa.

b. Struktur Kelembagaan

- **Direktorat Nasional Farmasi (DNF)** bertanggung jawab atas kebijakan, perencanaan kebutuhan (kuantifikasi), dan pemutakhiran data stok.
- **UNFPA** menangani pengadaan, pergudangan, dan distribusi.
- **Badan pengadaan nasional** bersifat otonom dan terpisah dari Kemenkes.

c. Metode Pengadaan

- **Utama:** pengadaan tahunan melalui anggaran negara.
- **Lainnya:** tender terbuka, tender terbatas, dan pengadaan darurat jika stok habis di tengah tahun.

d. Kerangka Regulasi dan Panduan Teknis

- **Kebijakan Obat Nasional**
- **Essential Medicines List (EML)** dan **Panduan Terapi Standar** telah disusun
- **Manual Bisnis Farmasi**
- **Manual pengadaan** difinalisasi dengan dukungan DFAT, menunggu persetujuan resmi.

e. Tantangan Utama dalam Pengadaan

- **Keterlambatan dalam Siklus Pengadaan:** Proses bidding hingga kedatangan stok memakan waktu 3–6 bulan.
- **Keterbatasan Anggaran:** Proposal anggaran sering tidak disetujui penuh (misalnya hanya disetujui 50% dari pengajuan).
- **Kelemahan Sistem Stok dan Pelaporan:** Kuantifikasi berbasis data konsumsi, namun kualitas data masih rendah di tingkat fasilitas/distrik. WHO sedang bantu perkenalkan kuantifikasi berbasis morbiditas.

f. Dokumentasi dan Standar Produk

- **Tidak semua produk** pengadaan DNF harus teregistrasi.
- **Persyaratan dokumen** seperti sertifikat GMP sering tidak lengkap atau tidak sesuai.

g. Perubahan Program Kesehatan di Tengah Tahun

- **Perubahan tiba-tiba** dalam program obat (contoh: ganti captopril ke benazepril) menyulitkan pengadaan—butuh waktu 3 bulan hingga 1 tahun.

Kesimpulan: Timor-Leste menghadapi tantangan signifikan dalam pengadaan obat karena ketergantungan pada impor, proses pengadaan yang lambat, dan sistem logistik

awaiting approval.

The National Directorate of Pharmacy under the Ministry of Health is separate from the government procurement agency, which is an autonomous body. DNFN only handles quantification—planning the need for medicines annually and submitting that to the minister for approval. UNFPA is responsible for procurement, warehousing, and distribution. At the health facilities level, local teams monitor and supervise health service delivery and dispensing of medicines.

Next, please.

This is our main role at NFM: policy development, technical guidelines, ensuring the essential medicine list is implemented, updating stock situations, quantification every year, and coordinating with UNFPA for procurement to ensure availability of stock in warehouses.

Next, please.

Regarding procurement methods, we use annual procurement funded mostly by the state budget. Other methods include public tender, restricted tender, and emergency purchasing—especially when items run out mid-year, which requires urgent replacement either locally or from overseas to keep stock available.

Next.

These are our legal frameworks, policies, technical guidelines, and platforms. Our national medicine policy was approved in February, the standard treatment guideline for primary health care is awaiting approval, and the revised essential medicines list was also approved in February. The Pharmaceutical Business Manual is already approved and will be launched this month.

Let me now share key procurement challenges:

We experience frequent delays in the procurement cycle—from bidding documents, assessments, announcements, responses from companies, to complaints—taking 3 to 6 months before stock becomes available. DFAT has supported us in finalizing our procurement manual, which is now waiting

serta pelaporan data yang belum matang. Kolaborasi dengan mitra internasional dan penguatan kapasitas nasional sedang diupayakan untuk mengatasi hal ini.

for formal approval.

Most of our medicines are generic—100% generic—currently containing 331 active ingredients and 426 preparations. We also face budget constraints; for example, when we propose a 16 million budget, we only get half approved.

Our quantification method is based on consumption data. With WHO support, we are introducing morbidity-based quantification, starting this year with programs like communicable diseases.

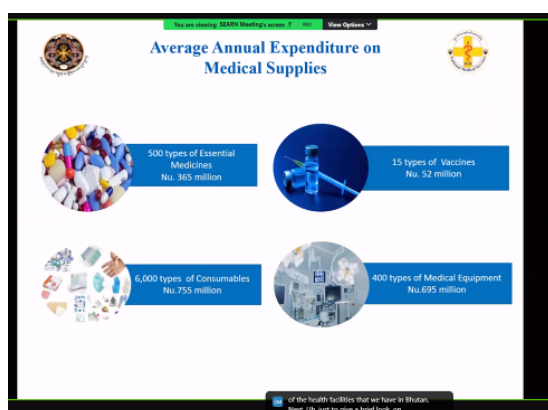
However, some facilities and districts are weak in reporting consumption data, so we can't fully trust the reports—indicating that our stock control system is still weak.

Another challenge is access to correct information and quality product documents such as GMP certificates. NFM does not require product registration for all items it procures—unlike private sector which must apply for registration. We instead apply for full dossiers or use reliance mechanisms.

A further challenge is the introduction of new programs mid-year. For example, after the essential medicine list is finalized, new medicines may be introduced, like switching from captopril to benazepril. It's difficult to find substitute products immediately—sometimes taking 3 months to 1 year.

That's what I can share with you. Thank you very much.

3. Bhutan



A very good afternoon. My name is Rinjan

3. Bhutan (Rinjan Doji-National Medical Services)

- Sistem Kesehatan dan Pengadaan
 - Layanan medis di Bhutan gratis untuk seluruh penduduk (± 700.000 jiwa).
 - Pengadaan dilakukan secara terpusat oleh Departemen Produk Medis.
 - Hanya pemasok lokal terdaftar yang boleh ikut tender.
- Cakupan dan Skala Pengadaan Tahunan
 - ± 500 jenis obat esensial (termasuk obat tradisional): USD 365 juta.
 - 15 jenis vaksin (kebanyakan lewat UNICEF): USD 52 juta.
 - ± 6.000 item habis pakai medis: USD 755 juta.
 - ± 400 alat medis (penggantian): USD

Doji, and I work for the Department of Medical Products. As requested, I will be giving a snapshot of our improvement process. Regarding the key issues and challenges, I believe they have been comprehensively captured by Ms. Woo Jin Kim. Next slide, please. As per our Constitution, medical and healthcare services in the country are free of charge. The procurement of medical supplies is centrally carried out by the Department of Medical Products, in line with procurement rules and regulations. Currently, only locally registered suppliers are permitted to participate. The procured medical supplies are distributed to 924 facilities spread across the country. Next. These are the details of the health facilities we have in Bhutan. Next. To give a brief overview: on average, we procure around 500 different types of essential medicines, including traditional medicines. Our average annual spending is USD 365 million. We procure 15 types of vaccines annually, most through UNICEF, with an average spending of USD 52 million. We also procure around 6,000 different types of consumables with an average spending of USD 755 million. As for medical equipment, we procure 400 types—mostly for replacing old equipment—with an average spending of USD 695 million per year. We procure 213 types of lab reagents, spending around USD 166 million annually. For traditional medicines, the spending is around USD 75 million. For medical gas refilling, USD 35 million, and for distribution, USD 9.5 million. Next slide. As mentioned earlier, most of the issues	695 juta. • 213 jenis reagen laboratorium: USD 166 juta. • Obat tradisional: USD 75 juta. • Pengisian gas medis: USD 35 juta. • Distribusi: USD 9,5 juta. c. Tantangan Utama • Ketergantungan impor hampir total, hanya satu pabrik obat tradisional dan satu manufaktur baru di Bhutan. • Volume pengadaan rendah → harga lebih mahal dan sering tidak menarik bagi pemasok → tidak ada penawar. • Logistik mahal dan lambat, kadang biaya kirim > nilai barang. • Tantangan saat darurat kesehatan, terutama jika produk tidak ada dalam Daftar Obat Esensial Nasional (NEML). • Manajemen stok lemah, terutama untuk produk dengan masa simpan pendek. • Stok darurat tetap dibutuhkan (contoh: rabies, gigitan ular), tapi sulit diseimbangkan agar tidak mubazir. Kesimpulan: Bhutan menghadapi tantangan besar dalam pengadaan karena ketergantungan impor, volume kecil, dan keterbatasan sistem distribusi dan stok. Inisiatif untuk mencari alternatif pengadaan global belum berhasil sepenuhnya karena biaya logistik tinggi dan ketidaksesuaian kebutuhan lokal.
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have been already covered. We import almost all medical supplies, except those produced by one pharmaceutical management company for traditional medicines and one recently established manufacturing unit in eastern Bhutan.

We do not have domestic pharmaceutical companies. Through our annual tender, we secure 92% of supplies from registered suppliers, while the remaining 8% is secured through direct procurement—mostly from abroad.

We face challenges related to the economy of scale. Many of our procurement needs are low in volume, which increases the cost of medical supplies. Sometimes we receive no bidders for certain low-volume items because they are not profitable for local suppliers. This forces us to import, often leading to delays and high logistics costs that sometimes exceed the value of the goods themselves.

Another major challenge is procurement during health emergencies—especially when the required medicines or products are not listed in the National Essential Medicines List.

Inventory management is also a challenge, especially for medicines with short shelf lives. Our small population (just over 700,000) still requires stockpiling for emergency situations such as rabies or snake bites. We struggle to balance between avoiding wastage and meeting oversight expectations.

Next.

This is the final slide. Some of the interventions we have initiated include sourcing through alternative platforms.

For example, we explored Bamboo Walk, which offers competitive prices and delivery times that match our procurement and budgeting cycle.

We also explored the Amrit platform (Affordable Medicine and Reliable Implants for Treatment), an initiative of the Indian Ministry of Health and Family Welfare. However, we found that only 29 out of 9,129 items were actually cheaper. Even then, pack sizes did not align with our facility needs, increasing risk of wastage.

Third, we tried sourcing from the UNDP

Global Health Procurement Services. We requested 199 medicines, but only 10 were cheaper than local options. The remaining 187 had much higher costs. Our estimate was USD 255.97 million, whereas UNDP's estimate for the same was USD 1.5 billion. The high cost difference was mostly due to logistics, low volume, pack size mismatch, and delivery timelines that didn't align with our procurement cycle. In a nutshell, these are the major procurement issues we are currently facing. Thank you.	
Diskusi: 1. Sri Lanka Thank you very much. In fact, the problems highlighted—especially in Uhjin's presentation—are common to us as well. I would like to mention a couple of additional points. One such problem we face is that sometimes we have registered suppliers, but they don't participate in tenders floated by the procurement agency due to various reasons. However, they still supply to the private market. As a result, the government has to procure from unregistered suppliers, whose product quality is not assured. That is one issue. Another issue is for orphan drugs and small-quantity-needed drugs—we often don't have registered suppliers for these either. So again, we end up getting certain drugs from external sources. For example, we were receiving some products from GFMDA, and TB drugs from GHPMTA. But starting next year, we will have to procure antiretroviral drugs domestically, and we're facing a problem because there are no registered suppliers for these. Also, clinicians are very strict in requiring that the supply comes only from WHO-prequalified manufacturers, which adds another layer of difficulty.	Sesi Diskusi: 1. Sri Lanka Sri Lanka menghadapi dua tantangan utama tambahan dalam pengadaan obat: - Pemasok terdaftar tidak mengikuti tender, tetapi tetap memasok pasar swasta, pemerintah akhirnya membeli dari pemasok tidak terdaftar dengan mutu yang tidak terjamin. - Untuk obat untuk penyakit langka atau kebutuhan volume kecil, termasuk obat antiretroviral, TB, tidak tersedia pemasok terdaftar, sehingga harus impor, sulit menjamin ketersediaan dan kualitas, apalagi dengan persyaratan dari klinisi agar produk berasal dari pabrikaan pre-kualifikasi WHO. 2. Thailand a. Thailand menghadapi kekurangan obat esensial kritis bervolume rendah, seperti obat kardiovaskular darurat dan kemoterapi. Obat ini termasuk standar terapi namun hanya menerima sedikit dalam siklus pengadaan. b. Untuk mengatasi ini, mereka telah memulai pendekatan berkelanjutan untuk obat esensial prioritas tinggi, seperti baru-baru ini membentuk program penanggulangan kekurangan antidot dengan tujuan memasok antidot nasional yang juga mendukung negara tetangga (seperti Malaysia) secara cepat dan efisien. c. Impor dan produksi lokal dilakukan untuk beberapa produk seperti antivenom dan antidot biologis lainnya. d. Tantangan termasuk stok mati, tidak memiliki WHO PQ karena biaya tinggi. Mereka mendorong kolaborasi

Those are the two main additional problems I wanted to highlight. 2. Thailand In my country, we have the problem of certain critical essential medicines being in shortage due to small volume demands. For example, cardiovascular medicines that are life-saving in emergency rooms, and chemotherapy medicines for cancer patients—these are standard treatments, but currently we receive very few applications in the procurement cycle. I believe this is a common issue that many of us might be facing, and it could be an important topic for discussion. Actually, in my country, we are also trying to implement sustainable approaches for high-priority essential medicines. We have recently established an antidote shortage program, aiming to supply antidotes domestically and help neighboring countries as well. We both import and attempt to produce some of these medicines ourselves. This includes products like anti-venom and other biological antidotes which we are now producing locally. However, we don't have WHO prequalification, as the cost to apply for the full WHO PQ program is quite high for us. But we are open to sharing and supporting other countries if needed. I believe we need more collaboration in this area—so that we can exchange knowledge on regulatory approaches and supply mechanisms for these low-volume but high-impact medicines. For instance, in our system, we often face dead stock because we stockpile these medicines annually, but actual usage is low. Then we need to replace them again the following year. So, perhaps we can also share experiences about managing medicines like room and detox agents. We imported one recently, and now we're starting local production. There are other examples, such as cyanide poisoning antidotes and similar rare or	regional untuk berbagi sumber daya, pengetahuan, dan sistem distribusi untuk obat langka dan berdampak tinggi seperti antidot dan detox agents. 3. Nepal (Narayan) - Sistem Desentralisasi - Pengadaan obat dilakukan oleh pemerintah lokal, provinsi, dan pusat sesuai kewenangan konstitusional. - Hal ini menyebabkan masalah kualitas dan harga tinggi, karena tidak ada skala ekonomi (setiap daerah membeli sendiri-sendiri). - Usulan Solusi: Nepal sedang merancang sistem "central bidding, local procurement", namun implementasinya sulit karena tiap tingkat pemerintahan memiliki otonomi → perlu kerangka kerja bersama (<i>framework agreement</i>). - Keterbatasan Obat Esensial Kritis: Obat untuk penyakit langka (thalassemia, sickle cell), antidot, imunoglobulin, dan obat emergency care sering langka karena volume kebutuhan rendah → tidak menarik bagi sektor swasta. - Potensi Regional: - Meski Nepal dikelilingi oleh pemasok besar (India, China, Bangladesh), akses belum optimal karena isu volume dan harga. - Mendukung ide Thailand untuk membentuk platform regional bersama untuk pengadaan antidot dan obat kritis ber-volume rendah. - Isu Tata Kelola: - Korupsi dan ketidaktepatan waktu pengadaan menjadi perhatian publik. - Perlu kehati-hatian dalam memilih mitra sektor swasta → banyak yang hanya mengejar keuntungan dengan mengorbankan kualitas. - Regulasi Nasional: Semua pemasok dan produsen yang terdaftar di Nepal dapat ikut serta dalam pengadaan → tetapi perlu pengawasan ketat terhadap mutu dan akuntabilitas. 4. Bangladesh (Tauhid Ahmed) - Sistem Pengadaan dan Regulasi Sudah Matang - Bangladesh memiliki jalur
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orphan medicines. We believe these kinds of products can be shared across the region.

Actually, Mahidol University, Thai FDA, and other organizations have been involved in developing the antidote program, in collaboration with the WHO Collaborative Center.

We hope to expand this collaboration, and one of the first steps could be regional sharing and mutual support.

For example, this year we supported Malaysia by supplying botulinum antidote for three emergency cases. It was done very quickly and informally, through coordination between the Thai Ministry of Public Health and Malaysian counterparts.

We were able to advise them on treatment protocols, proper use, and ensured the antidote was dispatched at the right time to the patients.

This could be a model for other countries in the region.

And yes, I believe you were referring to ICAPs, right?

Especially. So, Narayan?

3. Nepal (Narayan)

I think the presentation was basically based on public sector procurement, yes.

Nepal's experience is a little bit, uh, different, because we have get a bit brave, etc. And of course, essential medicine program is under public sector, and since fertilization, pre-essential emergencies are given to the local bodies, so they process themselves and some of the medicines are also procured by the provinces. And mainly program items is a family-led program directions. And equipment are procured by the Federal government. So, my experience, uh, is that there are issues of quality.

Fundraised by the local body procurement, currently. So we are thinking about to devise some kind of, uh. methods so that we can address this issue. And also, there is issue of high price, uh. of expenses for recruiting at the local label, because we ... there is no economy of scale.

pengadaan dan regulasi yang sudah mapan selama lebih dari dua dekade, dengan standar internasional dan prosedur pengujian mutu yang ketat.

- Semua obat dalam pengadaan pemerintah harus melalui uji laboratorium sebelum pembayaran dilakukan → kualitas obat di jalur pemerintah relatif terjamin.
 - b. Masalah Mutu Ada di Sektor Swasta
 - Di sektor swasta, pengawasan mutu kurang kuat karena keterbatasan SDM, anggaran, dan kapasitas laboratorium dari otoritas regulatori.
 - Distribusi di daerah terpencil menjadi tantangan karena kurangnya pengawasan.
 - c. Ketersediaan Obat Tidak Jadi Masalah Utama
 - Obat secara umum tersedia di pasaran, namun akses menjadi masalah utama bagi masyarakat miskin karena sistem *out-of-pocket* → pasien harus membayar sendiri.
 - Jadi, isu akses lebih terkait kemampuan membayar, bukan stok atau ketersediaan produk.
 - d. Kondisi Bangladesh tidak sama dengan negara Lain, tantangan di Bangladesh berbeda dengan negara seperti Nepal, Maladewa, atau Timor-Leste.
 - e. Bangladesh mengikuti regulasi pengadaan publik yang jelas, yaitu Public Procurement Act 2006 dan Public Procurement Rule 2008.
 - f. Jaminan mutu obat dilakukan melalui pengujian di National Drug Control Laboratory (NDCL).
 - g. Diakui bahwa kapasitas laboratorium masih terbatas, seperti juga terjadi di banyak negara lain.
 - h. Namun, otoritas regulatori (DGDA) terus berupaya memberikan dukungan terbaik untuk menjamin mutu, baik dalam pengadaan pemerintah maupun swasta.
 - i. Komitmen Bangladesh adalah untuk memastikan kualitas obat setinggi mungkin, terlepas dari jalur distribusinya.
5. India (Dr. Runga)
- a. Situasi Khusus India
 - India memiliki jumlah industri obat yang sangat banyak, sehingga kompetisi harga sangat tinggi.
 - Namun, persaingan ini dapat

Uh, since, uh, every local body purchases, same edition. And that is often in a higher price. that is one big issue we are currently, uh, struggling. So, we are Let's say, projecting a kind of, uh. Central bidding, local procurement. Concept that is being discussed at the moment, that is on the table. Since a different level of government have their own constitutional right. Thickener, we cannot force any authority, any level of government to actually do. Uh, there's certain things, so we have to have an agreement. So we are working on to develop some kind of framework agreement between the distribution level of government. So that is really a challenge for us. So, we also like to listen from other. Prince, uh, if they have any, any pursuit. Good, uh, announcements in this particular. Also, then. Second thing is, uh, as you see into theOverall market, uh, scenario. We are facing, uh, mostly, I think, like other countries. Immunoglobulins, anti-dots. And for medicines for rare diseases. Like, for example, thalassemia and sickle cell anemia. And, of course, some of the critical gear medicines. An often found scarce, because they are not being very much, uh, used in. In large quantity because of that. Even private sectors are also not very much interested to procure, because of the Preditability, as well as, uh. What do you call the ... I mean, uh, incentive out of that. So, uh, we are struggling to really address that. We are also lucky because we are being surrounded by almost 20,000 companies around. Nepal, because India do have more than 10,000 companies. And Bangladesh is also there nearby. So we have China also on the other side. So, we have several	mengorbankan fokus pada kualitas, karena tekanan harga. b. Tantangan dalam Akses Pasar Ekspor • Banyak negara hanya membuka tender untuk produsen domestik, sehingga produsen India tidak bisa ikut serta. • Padahal, India memiliki banyak produsen yang sudah terdaftar di WHO-PQ, FDA, EMA, dan badan pengadaan besar lainnya → potensi besar untuk diekspor jika akses dibuka. c. Hambatan Utama bagi Produsen India dalam Menyediakan Obat ke Negara Lain • Proses registrasi yang lama: Di banyak negara, waktu registrasi bisa 1–3 tahun, membuat produsen enggan mendaftar. • Biaya registrasi tinggi: Biaya pendaftaran yang mahal membuat produsen tidak tertarik, terutama jika tidak ada kepastian memenangkan tender. d. Proses inspeksi yang rumit dan lambat • Inspeksi fasilitas oleh otoritas negara tujuan sering memakan waktu lama, bahkan sebelum ada kepastian pesanan. e. Dampaknya terhadap Ketersediaan Obat Global • Meski India memiliki kapasitas produksi dan stok, produsen enggan masuk pasar negara lain karena hambatan administratif dan biaya tinggi. • Ini menjadi salah satu penyebab kelangkaan obat di berbagai negara, terutama untuk kebutuhan volume kecil. • Penerapan mekanisme reliance/regulatory reliance antar negara menjadi penting, agar registrasi dan inspeksi tidak perlu diulang, cukup mengandalkan hasil dari badan regulatori terpercaya seperti WHO, FDA, atau EMA. 6. Indonesia (Tri Asti Isnariani) a. Kolaborasi Multipihak • Sistem pengadaan melibatkan berbagai pihak, termasuk otoritas registrasi (<i>marketing authorization</i>), lembaga pengadaan nasional, dan
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suppliers. So, particularly, accessibility would have been very easy for Nepal, but Thing is that, because of the quantity. Certain antidotes. As I mentioned before, immunologics. These products, I think, is, uh, Thailand has raised recently. I mean, that's a very good idea for antidote, I think. We can kind of develop. One common kind of supply, um. Forum where any country can access in a cheaper and better price. So that can ... we can work on that area. I also. Uh, really like that idea, so Every country should work in this. Um, this is, uh, one thing I said. Um, other thing is what Nepal is doing, actually, uh, is that We have a public procurement, uh, different entities there. Uh, there is a different authority to look after this public procurement activities, developing laws, policies, and other things. Also overlooking those procurement? And procurements are often discussed, and they are very much raised by the public. Very interesting thing. A lot of corruption issues are also raised in this particular thing. So if you are even going for a very good process, following the process, you're not getting in right time. That's a big issue. Getting ready in the right time. I don't know about other countries, and our colleague from India also, they suggest to. Use their facility out of that, uh. But I don't know, it's Bangladesh and Bhutan's experience was, they are very highly priced. Definitely, there is a challenge again. And then there is accountability issue again, so we have to really address that. I can see if we do have a What responsible private sector.	Kementerian Kesehatan. b. Penggunaan Sistem Digital ● Indonesia mengembangkan sistem e-katalog dan e-purchasing untuk pengadaan obat secara elektronik. ● e-Katalog dikelola oleh Kemenkes, sementara proses pembelian dijalankan oleh dinas kesehatan di tingkat daerah dan fasilitas pelayanan kesehatan. c. Kebijakan Maksimal 3 Pemenang per Molekul ● Setiap jenis obat di e-katalog dibatasi maksimal 3 pemenang tender untuk meningkatkan efisiensi dan pemerataan distribusi. ● Namun, tantangan muncul jika hanya 1 pemenang tersedia → risiko kekosongan stok jika produk dibekukan karena masalah mutu. d. Sistem Freeze-Unfreeze: Jika obat tidak memenuhi standar mutu, Kemenkes dapat membekukan (freeze) produk tersebut dalam sistem. e. Dukungan Produk Lokal dan Inovatif: Sistem ini juga mendukung pengembangan produk dalam negeri dan inovasi obat nasional melalui kebijakan prioritas bagi produk lokal di e-katalog. Usulan Kolaborasi Thailand untuk Negara Kecil 1. Thailand menghadapi tantangan serupa dengan negara kecil lainnya, seperti jumlah pasien yang sedikit tetapi memiliki daftar obat esensial nasional yang luas. 2. Usulan Thailand: ○ Mengajak negara-negara kecil untuk berbagi daftar kebutuhan obat esensial. ○ Thailand bersedia membantu melalui pengadaan terpusat dan regional, serta bernegosiasi harga untuk negara kecil. ○ Biaya transportasi ditanggung oleh negara penerima, sementara Thailand bantu pengadaan dengan harga terbaik. 3. Tidak ada keharusan membeli dari produsen lokal di Thailand → memungkinkan fleksibilitas dalam pengadaan. 4. Thailand siap berbagi spesifikasi
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We can manage all this, but private sector. In, uh, gun adjustments world. I'm not blaming them, but because of this, uh Variety of, uh, interests, you know? They don't supply good quality, they go for low quality medicine where they ... wherever they find a kind of, uh, you know. That's what management or government is ... you're really not able to really manage that. so we have to be very cautious about selecting the private sector people. In Nepal, anysupplier who is registered in Nepal can supply. or manufacturer can directly supply also. These are the two options available. Thank you. 4. Bangladesh (Tauhid Ahmed) The various presentations. My observation is actually the situation is a bit diverse. In comparison to the Picture of Bangladesh, that picture ofMaldiv, or Timor-Leste is actually. I'm not very much similar. The picture is very diverse. So, putting them in common. Platform or metrics is a bit difficult. In our country. We actually have oil-developed pathways. For procurement, there are goodguidelines, obviously international standard. Or more than To decade about ... two decades, they are in place. Regulatory bodies are also present, the procurement pathways are. More and less oil- defined. We have our own problems, which are probably not very much similar with their problem. Like just the Speaker just who spoke just before me, from Nepal, they are facing difficulty ensuring control ... quality. In our country. The procurement process, I'm actually not working in the regulatory body, I am working in the procuring as NCC. My office is actually the central procuring. Office, or supply chain management in the health sector. So, I am less involved with regulation,	produk jadi, laporan stabilitas, dan stok antidot atau obat tertentu yang masih tersedia. 5. Usulan pilot project: Mulai dengan beberapa obat esensial yang sangat dibutuhkan negara lain, secara sukarela dan terkoordinasi. Thailand mendorong kolaborasi regional secara sukarela, efisien, dan fleksibel untuk mengatasi tantangan volume kecil dalam pengadaan obat.
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more involved with supply chain management.

But for every procurement, we have to ensure quality, so We are closely related. We have testing methods, and we'll develop a design pathways how to ensure quality of the rats that we are going to procure. We fixed standards, and after receiving supply. We go through standard testing in the standard labs. So, actually, there is little scope of supplying poor quality drugs, because if they supply the suppliers deliver poor quality goods. The ... in one hand. Are supplying the goods, but on the other end are not going to receive the .Uh, payment, their investment will be Within, andIn addition to that, there will be punitive measurements. So, the standard of drugs in government supply chain is not a problem in Bangladesh. In Bangladesh, the. Another problem of standard? Is in the private sector. Because in the private sector. They are rarely involved in standard testing. Ensuring standard. Because theoretically, all drugs available in the market are produced after receiving license and certificate from the regulatory bodies?

So, in theory, any Normal frygen. Having a prescription, going to a pharmacy. Can conveniently buy any drug.

But in that sector, actually. There is gaps. Because the regulatory bodies in Bangladesh. They have manpower shortage, budget shortages.

The laboratory capacity is Not that much extended.

So in the farthest corners, in the rural areas, in the Uh, restricted areas and the sub-district areas. Quality is a challenge. Supply

If we put A2 in the According to the time frame, that whether the people gets it in appropriate time.

This is also not ... the condition is not similar to Nepal or Bhutan or Aliphar.

Everything is government paid for. As in Bangladesh.

A significant portion of the drugs consumed by the patients. The cost goes from out-of-the-pocket.

So there is actually no shortage in the drugs in the market.

But for the poor people. For practical reasons, they don't have the access, because they cannot pay for it. So in Bangladesh, the Issue of availability of the drugs is less related with.

Amount of drugs available in the stores, but it more relates with the personalizing ability of the patients.

So these things are not totally similar. I went through the draft motion also.

Before joining. There are 7 points in that raft.

May I comment it? Now, or should you go through it at the end of the session?

5. DGDA

About finding ways to, um Collaborate on solving some of these issues. I don't know if colleagues from DGDA would like to are there anything? I think it's really ... we should not extend discussion much, but to actually summarize, as he rightly mentioned, we follow public procurement Act. 2006, and public pretty much ruled, 2008. For procurement, and he also rightly said their quality is ensured.

Through testing in our laboratory, that's in the sale, National Drug Control Laboratory.

Uh, as he was telling about the capacity, yes, capacity is actually no ... nobody in the world has the sufficient capacity.

Everybody has these shortfalls. But we are trying our best to provide the support to spread to the procurement, whether the government or private. So, actually, we are ensuring highest level of quality for the drugs, whether it is coming through private or public machine.

6. India (Dr. Runga)

Thank you, Adrien. I mean, I heard the various perspectives. Situation in India is, uh So, we have too many manufacturers.

Where, in one of the slides. The PPP who Who has presented, they say. Uh, when the manufacturers are many.

So, there's a lot of competition because of that. And they will not be in a situation to focus more on the quality.
And there's a lot of pressure on the prices because of competition.

So, that's a different situation. So, uh, coming ... heard various views. But I understand, moose. So, I have been, uh, part of the procurement process in the sense of policymaking at various changes in the government of India. So, what I have ... we have seen is that, eh. In many countries. The public procurement is limited to their own manufacturers.

So, it is ... it is rather than they have ... the countries, each of them have to introspect themselves. Of course, a very small countries where, like, Bhutan, where don't have manufacturing.

So that's a different issue. But those countries where manufacturing is ... manufacturers are available.

So, their first preference goes to the domestic manufacturer. There is a reservation.

And we, as CDSCO, national regulators. And also, our Ministry of External Affairs, though they have been interacting with various countries to allow the Indian manufacturers to compete in the tendering process.

So, if that is made, so we ... that country has a large pool of manufacturers who are, uh, registered with, say, uh, WHO-listed authorities, like FDA,

EMA, or any other authorities.

Our WHO-PQ register. Or UN agencies' procurements registration, or in any of the major procurement agencies, so they are registered.

So, India has a pool of manufacturers who are registered with all of these things.

And that will open a big opportunity to them, and because the number is more. So, the competition also will be high.

The second one is the registration process itself takes a long time. In many countries, so it often extends to. Average not less than 1 year exceeds 2 to 3 years.

And because of which, so those who have capacities, who Are benchmarked by any major agencies. So, they are not interested to register because of this. Long, uh.

Uh, and by the time they register, this opportunity is lost.

That is two. Third one is The registration cost itself, they are very, very expensive.

So, the first step to supply to any country would be registration.

And without knowing whether, uh In case those manufacturers who want to supply only to government procurement.

So, they have only one opportunity, say, during the tender process, and they are not sure whether they would be.

Awarded the tender or not? So, without having any confidence on getting the orders. They have to register. And the restoration process

and cost is highly expensive and not affordable.

The third one is, after this comes the inspections by the NRA.

Which themselves take a Long time.

So, these are the major issues that have been flagged by the Indian manufacturers.

So when we ask them, uh Even during the shortages, because

I heard, like, many countries have said there are drug shortages.

Whether in small quantities or whether in larger quantities. So, when we asked them why you do ... because you have capacities, you have drugs available, why don't you go and register? So, they say these are the points that, uh. Prevent them from registration.

And the inspection process itself will take long time. And they have to ... the inspectors from that country have to come.

And, uh, audit the facilities. So, I would take up this matter of regulatory, even Ali, Dr. Ali has raised this issue regarding good, uh, reliance

7. Indonesia

Yeah, thank you, Dr. Adrien. Uh, we are from Indonesia, would like to share some, the system that we already established in our country, in procurement system for medicines, uh. There is some parties that collaborate in this, uh, system.

The MA Marketing Authorization that is One of the important things as a requirement.

The priority, uh, requirement. So, uh, there is situation or issue that the medicine that's being used has no marketing authorization. The other one, uh There is a procurement agency who developed the system, we call it a e-catalog and e-purchasing. The e-catalog and e-purchasing is developed by our procurement agency, but managed by Ministry of Health.

Minister of Health, for e-catalog. And a purchasing, running, or manage, uh, sorry, operate by our regular or district health office and health services who need the medicine and, uh Plan to buy the medicine from e-katalog. And in this system, We, uh, established there is a system that, uh, maximum 3 winners.

So, uh, we tried to make, uh, effective and efficient, medicines that are being used and may ... being Distributed in all of our countries, so So, we call it e-katalog, and there is, uh, etalase that only .But, uh, every molecule only have maximum 3 winners. The challenge is sometimes, uh, there is only one winner.

So, if, uh, we also have the freeze and unfreeze system in this e-catalog. So, if there is a medicine that, uh, not fulfill the standard the medicine, quality of medicine. So sometimes they, they are, uh ... The Ministry of Health will freeze the medicine.

But the challenge is, if there is only one winner, so it could be happened the shortage, but it It is, uh, real, yeah. And then, uh, only TB medicines, only one producer, only manufacturer that can, uh, produce, uh, the Product. And the other one, we also, uh, has a policy to prioritize the local product. So, this one is a disk e-catalog, also, uh, one of the tools to, uh, support the development of local product, t he development of innovative medicine in our country. Maybe that, uh, all

There is, uh, there are all five, uh, systems that can be summarized, but for specific, uh, complete information, maybe, uh, we suggest this forum.

In fact, our Ministry of Health, especially for the procurement Bureau, yeah.

Procurement Bureau in Ministry of Health. Thank you. Thank you very much, yes.

8. Thailand

I like to, uh, have some proposal. For, um, the small country.

And Thailand is facing the same, uh, we have limited small population.

Actually, however, we have. A large list of national essential list of medicines.

So, um, I think that we like to maybe sharing, uh, our goal, uh, together to have the plan.

What is the essential medicine that you really need in your country?

And if we're going to Tokyo as our government procurement. We have, like, the centralized and also regional procurement of the public organization.

So we're going to coordinate this. And see whether the price is okay for your small country.

And then the transportation cost will be covered by your country. So, we're gonna negotiate for the ... for the price. Actually, in Thailand, we do not have.

The rule that we have to procure for local manufacturer early.

So we used to send us in the price. And then we can

discuss into the details.

Whether or not this will be helpful for your country.

And I think that we like to ... also can share with you on the ... also the, uh, our, um.

Our finished product specification and stability inspection report. Uh, if anything that we need.

And for certain medicines, like antidote, or some medicine that. We already procure, and then we have their stock.

This will be maybe Tokyo, uh, by exact cost to your country.

So I think that we need to plan for this, and we share the essential medicine, and then, uh, whether or not we have the procurement on this.

Make this scene, and do we have the production, or we imported already?

So we have to do everything, you know, import and produce ourselves.

And we still have something left. So maybe we can share with this, and to move forward, um, on this.

Issues. So, uh, I think that, uh, we can, like, understand your country, and because I, uh, I also have the problem on.

Minimum order. Yes, and we don't have enough patients to do that, but I have to buy.

Yeah, this is the things that I would like to share, and then maybe we can start with certain medicines.

That Lily, uh, needed by your country. So, this is, uh, like, voluntarily, so maybe we have the pilot project

for this. I think that we can move forward, really, efficiently, whatever that voluntarily to coordinate.	
Perspectives from the Industry (Bhutan) Hello. Hello. Yeah, good afternoon, uh, regulatory bodies and, uh. I would like to say thanks to Mr. Jigni to invite me for this session. So, we are the, uh, Ajister Bhutan Healthcare, uh, Limited. So, which is located in Bhutan, so it is a first kind of, uh. Pharmaceutical manufacturing company in Bhutan. Next slide, please. So, uh, we came with only 3 slides, uh, because of the limited time, so. I would like to understand about the harmonization of GMP certification. So, since some countries are near about 9 countries are there. So, once any, uh, origin country, and along with that, through Eveati. Other country, uh, come and audit our facility. If they are okay with that, uh, with respect to the GMB aspects. So, remaining certain countries can accept our regime practices, so apart from the product registrations.	Perspektif dari Industri di Bhutan 1. Azista Bhutan Healthcare adalah perusahaan manufaktur farmasi pertama di Bhutan, dengan kapasitas besar dan orientasi ekspor. 2. Usulan Harmonisasi Sertifikasi GMP Mengusulkan pengakuan bersama (mutual recognition) antar negara untuk hasil audit GMP agar tidak perlu registrasi dan inspeksi ulang di tiap negara. 3. Dorongan untuk Ekspor Regional - o Produk yang sudah terdaftar di Bhutan sebaiknya dapat digunakan sebagai dasar untuk registrasi di negara lain. - o Target ekspor ke negara-negara anggota SEARN (dengan proses registrasi yang lebih sederhana. 4. Masukan terhadap Kebijakan Pengadaan - o Menyoroti bahwa fokus pengadaan hanya pada harga terendah sering mengabaikan aspek kualitas. - o Meminta agar produk dalam negeri Bhutan yang sudah teregistrasi diberi prioritas dalam pengadaan nasional. 5. Usulan Skema Pengadaan Berkala Mengusulkan pengadaan tiga atau empat kali dalam setahun (bukan tahunan) untuk mengurangi beban keuangan pemerintah, meningkatkan manajemen stok, dan menghindari kedaluwarsa produk 6. Solusi untuk Produk Volume Kecil - o Produk dengan kebutuhan volume kecil yang sama antar negara bisa digabungkan dalam sistem regional, sehingga lebih efisien dan ekonomis. - o Industri Bhutan mendorong kolaborasi regional, harmonisasi regulasi, dan pengakuan produk domestik untuk memperkuat ketahanan obat di kawasan.

So, this is, uh, I would like to, uh. Bring to your kind notice. Uh, so, second thing is that, so, uh, mutually.

So, this is, again, mutual recognition and trust among the regulatory across the certain countries.

And so, for the ... this ... once it is approved by, uh, Sun Kanti, so we can export to, uh, any other Sun countries.

By registering our products. So, next slide, please.

So, coming to the export and, uh, import initiatives, so I would like to bring to your kind notice about the. I export and the import point of view, because you know the population of Bhutan, it is only, uh.

Uh, bind 8 to 5 million, nah. So, since we are having a huge capacity to manufacture here.

So, once it is completed, so we'd like to export to certain countries, uh, based on their, uh, needs. So, products we would like to register in other countries also in the same.

And secondly, once we registered in origin of country, so say, uh, document will be submitted to other countries.

For the registration. So, this is one aspect we would like to bring to your notice.

So, last slides. So, this is something, uh, regarding about the Bhutan-registered products, particularly.

So, now, uh, everybody's, uh, discussing about the procurement policies. So, in procurement policy, I would like to inform you all, so everybody's looking for ... L1 is a destination. There's a low-cost prices at a destination. So, they're not looking for any quality of the aspect for the product procurement, because of the financial aspect from the Minister of Health or Government.

So, instead of looking at L1 price, so look into the quality aspects also, where we are going to supply for the products.

And so, it is already, uh, mentioned for the A duplication of the registration process.

And the second thing is there, so since we are only the manufacturing company in Bhutan.

So, we'd like to request to the, uh, procurement, uh. Department. So, whatever product we registered in Bhutan, we would like to supply those products.

Uh, through Tinder process or through, uh, negotiation process to the, uh.

Button. So, that will give more, uh. Benefit to the origin of countries, and second thing I would like to propose here for all the Sun members. origin of countries, and second thing I would like to propose here for all the Sun members.

So, instead of going for annual procurement, so we have proposed it to the government for the, uh.

Four quarters or three times in a year. Since we are only the manufacturer here, that will be reduced the burden on, uh.

Government with respect to the finance. And stock management, and Xperia of the products. These three are advantages for the government.

So that, I would like to propose to the Bhutan, uh.

Procurement agency. And so, uh, once it is clear that, so then it will be easy for us to.

Export to the other Sun countries. And so, as, uh

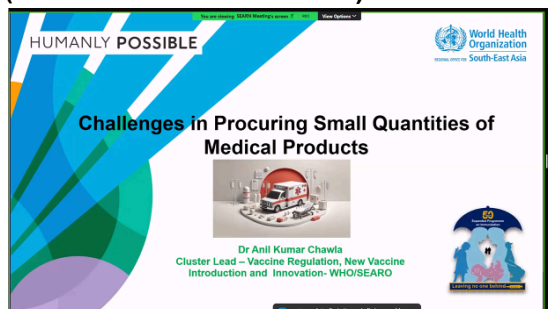
There is one problem with respect to the low volume of the products. So, if some countries are having same products.

Uh, same products, and once it is registered in, uh.

Put on. So, same products can be supplied to other countries also, so that will give

Solution for the lower volume products. This is all about my presentation. Thank you so much.

Issues around small volume products (WHO SEARO-Anil Chawla)



So, I will start with a very simple

Issues around small volume products (WHO SEARO-Anil Chawla)

1. Masalah kelangkaan obat bukan semata karena volume kecil, tapi lebih pada rantai pasok yang tidak efisien dan kurangnya kepercayaan antara produsen dan pembeli.
2. Negara besar pun mengalami kelangkaan, contohnya India dan Indonesia untuk vaksin hepatitis B → menandakan bahwa masalah ini bersifat sistemik, bukan hanya karena daya beli atau jumlah pasien.

statement. Sun rises in the east. And it sets in the list. All of you agree, maybe? But it's very wrong. It's absolutely incorrect statement, no? It does not. It stays there. It's rotating. And sun appears, or becomes visible in the morning. And it is not visible in the evening. Actually, you'll remember the whole concept of shortages, small volumes. Et cetera, et cetera, from this sentence. Actually. Let's see. India is a very big manufacturer, so is Indonesia for vaccines. India supplies 50% of. Global demand. Barry Farma. His 100-year-old manufacturers, they have participated in a very big way. In polio eradication program and eradication of many more diseases. But India is having shortages. Co-hepatitis B vaccine. Indonesia is having shortages of hepatitis B vaccine. How much volume? 50,000 doses, which is kind of Import for Bhutan, 25 million doses you want. India wants some time. 100 million doses, but there is a shortage. So basically. The issue is Not small volumes. Issue is one of our friends from Bangladesh. Mr. Dr. Ahmad mentioned, it's supply chain.	3. Pengadaan tidak bisa dipisahkan dari regulasi dan manufaktur. - o Perlu sistem pooled procurement dan pooled regulation (pengadaan & regulasi bersama). - o Komitmen jangka panjang (multi-year contracts) akan membangun kepercayaan dengan pemasok. 4. Pentingnya kolaborasi dan inovasi - o Gunakan kecerdasan buatan (AI) untuk prediksi permintaan. - o Publikasikan kebutuhan secara terbuka agar lebih banyak pemasok bisa merespons. 5. Perlu insentif bagi produsen kecil dan lokal - o Fokus bukan hanya pada standar internasional (misalnya WHO GMP), tapi beri masa transisi bagi industri lokal agar bisa beradaptasi tanpa harus ditutup. - o Produksi lokal penting untuk ketahanan akses, terutama di negara kecil seperti Bhutan, Sri Lanka, Nepal. 6. Usulan konkret: - o Pusat regional untuk pengujian dan pengembangan, termasuk laboratorium rujukan bersama. - o Stok darurat regional untuk produk penting berdampak tinggi seperti antidot, vaksin, dan obat untuk penyakit langka. Kesimpulan: masalah akses terhadap produk ber-volume kecil harus diatasi melalui pendekatan kolaboratif regional, penguatan produksi lokal, dan komitmen pengadaan jangka panjang.
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It's a very big issue of supply chain.
And of course,
we have to be very careful as a
regulator.

That We have actually

We are the key stakeholders in making
sure that
access is available.

If we register every Tom, Nick, and
Harry, and the
company disappears after 6 months or
1 year.

They are unable to supply, then we are
actually
wasting our energies as a regulator.

I will give example from the region,
actually. There
are three state drug controllers. India
has excellent.

Not full procurement, pooled
regulation. System in place. There is a
federal thing, there is a state drug
authority.
So they manage the whole structure of
supply. Very
carefully the access.

And the same is visible. Also, in
Europe.

It's not reliance-only. It is Pooled
regulation. So,
pooled

Procurement cannot be successful
until unless we
have. Pooled regulation. And maybe
pooled
manufacturing also for the region.

So these are a few simple things we
have to
understand.

Uh, can you ... can we ever see
shortage of ice
cream?

In a retailer shop, do we have L1 issues there? No, ice creams are only, always available in the shops. They don't have problems. So, and I'm Give you an example of iStream, because it's a cold chain-managed product. These are very simple things which we have to understand. As procurement agencies, as well as regulator. India also, again, giving an example, because I know the system very well. They were very closely knitted, actually. Once upon a time, the Directorate Journal of Health Service, which is more like a procurement agency. Was very closely associated with regulator. Excellent systems in place. And similarly, these systems were working very well after. Somewhere else also. Now, coming back to the regulator. If we think that we want to buy a product with peanuts. Or we want to ... these are a very expensive product. And we can't afford as small countries. Bhutan's GDP is around \$3,000 US dollars. They have, of course, problem of shortages. Luxembourg. 130,000 US dollar GDP. They also have problems, like Thailand was talking about. For anti-cancer product? Antidotes, etc, etc.	
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So, this is not linked with How rich the country is, how much affordability is there.

The issue is deeper. Very deep. So I'll go to some of the slides. I'm not going to go through the whole presentation, don't put it, yeah?

Okay, let's go to the few of the slides. Next one.

So Of course, I will touch here one point, disparity in supplies.

What happens? A manufacturing country has full control on the manufacturer.

Very strong control. So the government agency, for example, a producing country.

As they have the generation that they will give orders to the local supply.

So they float tenders for 50 million rupees. And now they will put a clause. That 20 million doses can be procured immediately, additionally. So, the manufacturer ends up.

Forbidding or foregoing his commitment for international supply, they supply to the local one.

So there is a problem. So, there is a always

Fight between procurement agencies. So, until unless we sort it out, we'll keep facing this problem.

So, what are the issues? Next slide, please. So, we have to very carefully focus on.

Market dynamics. The market dynamics can be

controlled by what? You know why the ice cream is available always in the retail shop?

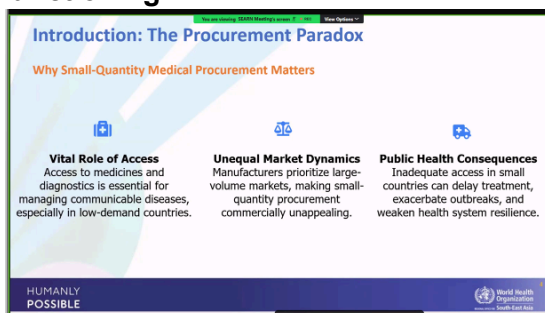
Why there is no shortage of bread?
Because there is a trust existing.
Between the buyer and the supplier.
This trust is absolutely missing.

In procurement agency. They cannot assure the distributor or the manufacturer that they will buy so much of product over the year.

And, uh, one of our colleagues was saying that I procure very small volume.

And this volume is not Equaling the minimum binding quantities. But if you give long-term commitments.

You can always get your orders, and this is how the big procurement agencies are functioning.



Unicef is successful because they give multi-year contract. So, if your procurement agencies, even if they are buying 10,000 or.

\$10,000 equipment. If you can give long-term contracts. You can assure the supplier.

That here is the contract, we'll certainly buy, irrespective what is the price rate contract, etc.

These issues of Gaps won't happen. So, you have to be in

Very innovative in using artificial intelligence, forecasting your demand, making it sure that minimum is always purchased.

It'll start off keeping your stock. Next, please.

So, one of the more next Slide. So, one of the biggest problems is, of course, for diagnostics and therapeutic bottlenecks.

It's not only the kids, etc, you buy. For a small country like Bhutan or Maldives, it is how to use them, especially the equipments are very expensive.

So there are more complex issues here. Where you have to go and pool your use.

It's possible, and that is why we are thinking to have a regional center of excellence.

Which can work like a, you know, testing development method, or center for excellence, but they can also.

Conduct testing. You know, the labs which are there in Bangladesh also, India also, many other countries.

They pull the samples around, and they go to a single place, and they get tested.

So, we have to pool like this. Next, please.

Uh, so As I told you, actually.

Uh, the larger buyer. They are

Really the smaller buyers. So, huge global demands.

They are interfering in the process of. Smaller procurement agencies. So, until you sit together.

So you went to UNOWs, or etc, etc, they said, or UNICEF, or UNAIDS, that please.

Buy this for us. But did you publish your demand. On the internet, that we want this much, and this is our price. Anybody else can give us?

Lower than this, there will be, I think, 5-6 more people.

To offer you these prices. And now, coming back to the Uh, last one. Next, please. So, uh

The pooled procurement models have to be there. There have to be emergency stockpiles, and

One of the most important things is you have to. Give lots of incentives to the manufacturer and supplier. And it's a good thing we have a.

Uh, manufacturers sitting here, probable manufacturer, or maybe they are already producing.

Until unless you will give incentives to them. Long-term buying arrangements, they are not going to trust you. So.

These are very, very important things. And now

Something very important for a

country like
Bangladesh, which is coming into.

Vaccine procurement or vaccine
manufacturing, and
also Bhutan. A small manufacturer
starting.

You know, production here. And they
are already
targeting global supplies. I'm not
saying that.

You dilute the GMP guidelines. So the
focus need
not to be international supplies.

The focus by the regulator that we
have the
minimum standards in place.

So we were talking about, you know,
the supplier
with. A lot of quality issues, etc. But if
we can have
let's say, if we try to implement.

The ANX2 now. Many of the companies
will close
down in injectable.

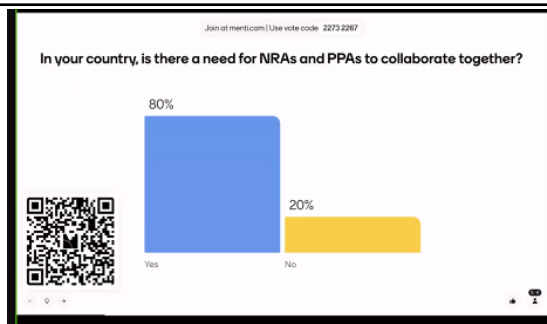
For example, 5 years back, a
manufacturer has
constructed an industry.

And you start applying the standard
which was
published last year.
And you will close them. So this is not
possible. So
you make it sure that you lessen these
manufacturers for a period of time, 5
years or 10
years.

So that they, at least, whatever they
have built. They
are able to recover the cost of older
facilities, or the
legacy facilities, and they can
establish new plant.

I have manufactured billions of doses
with my own
hand. And I used to cap the wires with
my hand.

Using a flame. There were no laminar flows available. We were using cabinets, so at that time also, we were manufacturing. Products injectable? And now also, of course, we have to upgrade the standards. As much as possible, but it is important that you maintain the legal SC facility with a lot of strong. Regulatory, you know. Oversight, and let them. Continue the local production. So, local production is something which is very, very important, and it taught. Actually, the small country like Sri Lanka, Nepal. That we must have local production. Otherwise, there'll be. Access issue. So that's it.	
Open discussion on Interplay between NRA and PPA (WHO SEARO-Adrien Inoubli)	Tidak ada, masuk ke diskusi negara2 diatas
SEARN work on facilitating access (shortages, reliance) (SEARN Secretariat)	Tidak ada, masuk ke diskusi negara2 diatas
Online Poll and discussion: Fostering collaboration (WHO SEARO-Gereltuya Dorj)	1. Pertanyaan pertama yang ingin kami ajukan adalah apakah Anda merasa perlu adanya kolaborasi antara otoritas regulasi nasional dan lembaga pengadaan publik? Mayoritas responden menjawab "ya",



Yep, so that's The first question, um

Thank you very much. Apologies for the mis Um, yeah, I ... we have received responses. The first question we are interested in.

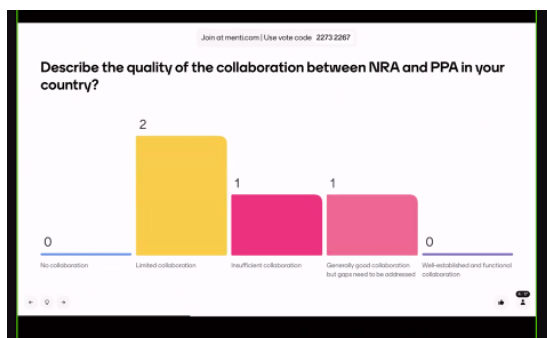
To get your responses on would be if you have a, um ... if you think that you need a, um

Collaboration between the national regulatory authorities and the public procurement agencies.

So we can see that majority of the respondents are saying yes.

So we have to collaborate together. That's nice. I'll give maybe One more second So we can see the majority of the participants are

Um, of the opinion that we have to collaborate together. So we can move to the next



yang menunjukkan bahwa kolaborasi memang dianggap perlu. Sangat baik. Mari kita lanjut ke pertanyaan berikutnya.

- Pertanyaan kedua berkaitan dengan kualitas kolaborasi antara otoritas regulasi nasional (NRA) dan lembaga pengadaan publik di negara Anda. Pilihan jawaban meliputi: tidak ada kolaborasi sama sekali; kolaborasi terbatas; kolaborasi tidak memadai; kolaborasi umumnya baik tetapi masih ada celah; dan kolaborasi yang sudah mapan dan fungsional.

Sebagian besar responden menyatakan bahwa kolaborasi yang ada masih terbatas atau tidak memadai.

- Pertanyaan berikutnya berfokus pada pengadaan dan distribusi obat serta vaksin. Kami ingin mengetahui apakah produk-produk tersebut telah terdaftar di otoritas regulasi nasional di negara Anda?

Jawaban yang masuk cukup bervariasi, namun mayoritas responden menyatakan bahwa produk-produk tersebut sudah terdaftar. Itu sangat baik. Sebagian besar produk telah terdaftar, diadakan, dan didistribusikan.

- Tantangan terbesar dalam menyelaraskan proses antara NRA dan lembaga pemerintah publik untuk memastikan akses obat yang tepat waktu. Apakah tantangan utamanya adalah kurangnya saluran komunikasi, tidak adanya pertemuan rutin, kurangnya pertimbangan terhadap persyaratan teknis masing-masing pihak, atau kurangnya berbagi data?

Responden juga dapat menyampaikan alasan lain di kolom chat. Sebagian besar responden menyatakan bahwa berbagi data masih tidak memadai dan kurangnya perhatian terhadap aspek teknis masing-masing pihak. Beberapa juga menyebutkan tidak adanya pertemuan rutin untuk berbagi tantangan.

- Pertanyaan berikutnya adalah informasi apa yang paling berguna untuk diterima secara rutin oleh lembaga pengadaan publik dari NRA. Apakah itu pembaruan terkait perubahan proses dan jadwal registrasi, status registrasi produk, pipeline produk yang sedang ditinjau, peringatan keamanan atau kualitas,

Yep. So the second question Yeah, so the second question would be if you can describe the quality of the collaboration between the NRAs and PPAs, the public procurement agencies in your country. Um, option, um, number one would be there's no collaboration at all. Um, number two, we have some sort of collaboration, but it's limited. Um, number 3 would be insufficient collaboration. Number four, um, we have generally good collaboration, but gaps need to be addressed. And then, the last option is we have a well-established and functional. Collaboration. So we can see that, you know, um, most people have indicated that the collaboration is limited between the, um. Nras and the public procurement agencies are insufficient. Thank you very much, so we move to the next question. Um, so this one, um, focuses on the procurement and, um. Supply of medicines and vaccines. And, namely, we are interested in if these products are. Um, registered within the National Regulatory authorities in your countries. We can see that, um Yeah, um Sort of, um Yeah, it's quite dynamic. I can see that, you know, some people responded yes.	deteksi kekurangan, atau informasi tentang kelompok terapi yang memiliki terlalu banyak atau terlalu sedikit produk? Sebagian besar responden menilai bahwa informasi mengenai status registrasi produk, informasi kekurangan, serta peringatan keamanan dan kualitas adalah yang paling berguna. 6. Apa yang dapat membantu memperkuat kolaborasi antara NRA dan lembaga pengadaan publik? Apakah itu peninjauan bersama atas proses masing-masing untuk menyelaraskan jadwal dan persyaratan, pertemuan bersama, platform digital bersama, kejelasan peran masing-masing, atau proses dan template yang terintegrasi? Mayoritas responden mendukung penggunaan platform digital bersama, peninjauan proses secara terkoordinasi, pertemuan bersama, serta format yang terintegrasi dan seragam. Kesimpulan: - Sebagian besar peserta menilai kolaborasi antara otoritas regulasi nasional (NRA) dan lembaga pengadaan publik penting, meskipun saat ini masih terbatas atau belum optimal. - Tantangan utama meliputi kurangnya komunikasi, tidak adanya pertemuan rutin, dan minimnya berbagi data teknis. Informasi paling dibutuhkan oleh pengadaan publik adalah status registrasi produk, potensi kekurangan, dan peringatan mutu/keamanan. - Untuk memperkuat kerja sama, disarankan penggunaan platform digital bersama, pertemuan rutin, dan format kerja yang terintegrasi.
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So, so, uh, the bars are sort of, like, jumping up and down, but yeah, most, most respondents have indicated yes to this question, thank you very much.

So, most of the products are registered, um, um, and procured and supplied to your country. That's perfect.

Um, I think this is the last one, if not the second, for the last.
Um, and this is, uh, around, um, if you could indicate, um, according to your opinion, what would ... what is the biggest challenge in aligning processes between the NRAs and the public government agencies.

Um, to ensure timely access to medical products. Do you think that it's, um, the main challenges around the lack of communication channels, or we have no regular meetings to address the, um, issues that we share?

Or do you think that there's a lack of consideration of respective technical requirements in each?

Um, other processes, um, or, um, we ... you think that, um, the ... the data sharing is not sufficient, insufficient.

Or, um, do you think there are other reasons, uh, and if you could just, you know, type it in in the chat box.

So we can have some analysis on it, and then have some further discussion. So, most of the

respondents are.

Saying that, um, the data sharing is not enough, and there's a lack of concentration of respective.

Um, technicalities, um And also, we have some respondents saying that we have no regular meetings.

Um. To share our, um Challenges. Okay, oh, yeah, another question. So, um, for the information, uh, what information do you think, uh, would be the most useful for the public procurement agencies to regularly receive.

From the NRAs, the National Regulatory authorities, do you think the information would be useful and must, um, beneficial for, uh.

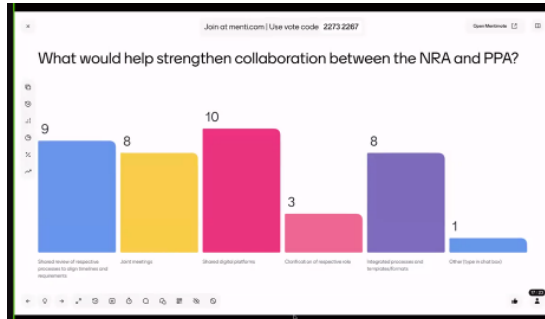
Uh, in regards with changes in registration processes and timelines. Product registration status.

Pipeline of products under review. Safety or quality alerts, information to detect shortages.

Or do you think that, um, information around therapeutic groups, uh, with too many or too few products registered? This could be too much of generic products registered. And you have lots of, um, product availability in the market. Or do you think there are other reasons? Not reasons, other information that would be most useful, according to your opinion?

And if you could type it in, that would be very useful. So we see that product registration status is very useful.

Uh, followed by the information to identify these shortages and. Safety and quality alerts are very useful.



Um, so what, um, would ... what do you think would help to strengthen the collaboration between the NRAs and the public procurement agencies? Do you think.

Shared review of respective processes to align timelines and requirements, joint meetings.

Um, do you think shared, um, digital platforms, electronic, um. Uh, databases would be useful. Uh, or do you think, um, clarifications on respective roles would be?

Helpful or integrated processes and templates and formats would be also useful to strengthen our collaboration.

Or do you think there are, um Other reasons, um, that would help strengthen the collaboration between the NRAs and PPAs.

So yeah, I can't see my chat box. But I will have a look at it straight away after when I minimize the window.

Um, yeah, so we see that, um, most of the

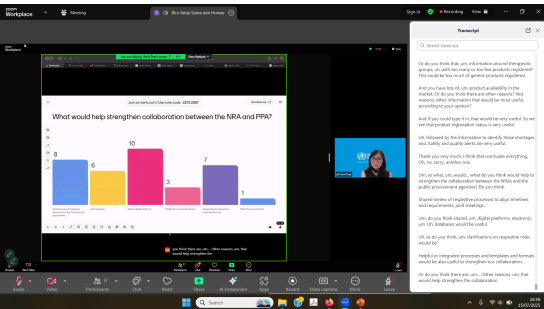
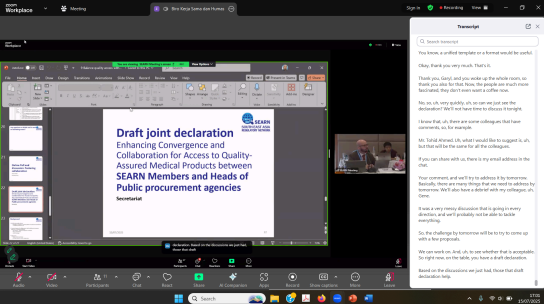
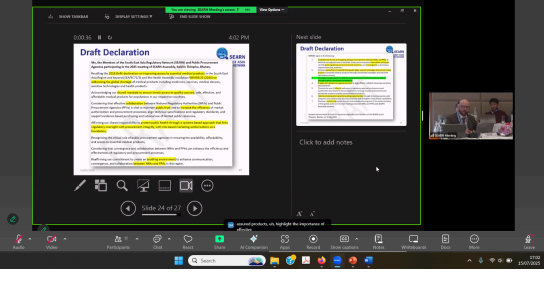
respondents, um, indicate that the shared platforms in digital form would be useful. Shared review of respective processes to align timelines and requirements would be also useful. As well as joint meetings and, um, integrated, consolidated processes with, um. You know, a unified template or a format would be useful. thats it Thank you very much. Apologies for the misunderstanding. We have received responses. The first question we're interested in is whether you think there's a need for collaboration between national regulatory authorities and public procurement agencies. The majority of respondents answered yes, indicating that collaboration is necessary. That's great. Let's proceed to the next question. The second question is about the quality of collaboration between the NRAs and the public procurement agencies in your country. The options are: no collaboration at all; limited collaboration; insufficient collaboration; generally good collaboration with some gaps; and well-established and functional collaboration. Most people indicated that the collaboration is either limited or insufficient. Thank you. Moving to the next question. This question focuses on the procurement and supply of medicines and vaccines. We're interested in whether these products are registered	
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within the national regulatory authorities in your countries. The responses are dynamic, but most respondents indicated yes. That's excellent. Most of the products are registered, procured, and supplied.

Next, we ask about the biggest challenge in aligning processes between NRAs and public government agencies to ensure timely access to medical products. Is the main challenge the lack of communication channels, absence of regular meetings, lack of consideration of respective technical requirements, or insufficient data sharing? You may also suggest other reasons in the chat box. Most respondents indicated that data sharing is insufficient and there's a lack of attention to respective technicalities. Some mentioned the absence of regular meetings to share challenges.

The next question is about what information would be most useful for public procurement agencies to regularly receive from NRAs. Is it updates on registration process changes and timelines, product registration status, pipeline of products under review, safety or quality alerts, shortage detection, or information on therapeutic groups with too many or too few products? Most respondents found product registration status, shortage information, and safety alerts to be the most useful.

Lastly, what would help strengthen collaboration between NRAs and public procurement agencies? Shared review of processes, joint meetings, shared digital platforms, clarification of respective roles, or integrated processes and templates? Most respondents supported shared digital

platforms, aligned process reviews, joint meetings, and unified formats.	
	
	
	

13. Draft Joint Declaration – Presentation and first discussion:

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14. Conclusion of the first session on Regulatory excellence: Achieving Balance of quality and accessibility to medical products for all:

15. Work plan outputs-Discussion and adoption of working groups' outputs, including SEARN MoU

16. Roundtable discussion with regulatory networks and partners: strengthening collaboration within SEARN and beyond SEARN – the way forward

The session is aimed at discussing how to strengthen collaboration within SEARN and beyond. It is proposed to organize this session into three parts. The first part focuses on how to anchor SEARN within existing political organizations. There is a proposal for your consideration, which will serve as the basis for the first discussion. The second part will discuss how to support SEARN from both existing and potential partners. The third part will focus on strengthening collaboration beyond SEARN. In particular, we will discuss ASEAN and the Western Pacific Region Alliance of NRAs. I see that my colleague Jean Ho has already joined. Thank you for joining again. Now, we will start with the first proposal, which actually came from a discussion with Bhutan in the past. This proposal focuses on Beamstack, which already exists, and whether this framework could serve as a basis for some of SEARN's activities. Beamstack refers to the Bay of Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation. As far as I understand, this organization has clear economic objectives. What I would like to highlight is that when looking at other regulatory networks in different regions, particularly in the EU, we see a highly integrated market for medical regulation. This integration exists because the pharmaceutical industry pushed for it, seeking a unified market for products. However, the limitation of this framework is that Maldives and Timor-Leste are not members. But perhaps in future discussions, we can explore how these countries could still be associated with this specific project or simply through the general SEARN framework. The core principle of SEARN remains the same:	• Diskusi kali ini bertujuan untuk membahas bagaimana memperkuat kolaborasi dalam SEARN dan juga di luar SEARN. Disarankan agar sesi ini dibagi dalam tiga bagian. Bagian pertama akan membahas bagaimana mengintegrasikan SEARN ke dalam organisasi politik yang sudah ada. Terkait hal ini, telah disiapkan sebuah usulan awal untuk dipertimbangkan dan didiskusikan bersama. Bagian kedua akan membahas bagaimana mendukung SEARN melalui kemitraan dengan pihak-pihak yang sudah ada maupun yang potensial. Bagian ketiga difokuskan pada penguatan kolaborasi di luar SEARN. Kita akan secara khusus membahas kerja sama dengan ASEAN dan Aliansi Otoritas Regulasi Nasional (NRA) di wilayah Pasifik Barat. Saya melihat kolega kami, Jean Ho, telah terhubung. Terima kasih telah bergabung kembali. Slide selanjutnya, mohon ditayangkan. Kita akan memulai dengan usulan awal yang sebenarnya berasal dari diskusi dengan Bhutan beberapa waktu lalu. Isu yang diangkat adalah mengenai <i>Beamstack</i>, sebuah kerangka kerja yang telah ada. Pertanyaannya adalah apakah kerangka ini relevan untuk beberapa aktivitas SEARN. Beamstack merupakan inisiatif dari negara-negara di kawasan Teluk Benggala yang mencakup kerja sama teknis dan ekonomi lintas sektor. Sejauh yang saya pahami, organisasi ini memiliki tujuan ekonomi yang jelas. Saya ingin menyoroti bahwa ketika kita melihat jaringan regulasi di wilayah lain, misalnya Uni Eropa, kita melihat adanya pasar yang terintegrasi dalam hal regulasi medis. Hal ini terjadi karena industri farmasi mendorong integrasi tersebut.
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every activity should benefit all members. If it's not possible to include Maldives and Timor-Leste, the initiative will not work effectively.

Beamstack, which some of you may be more familiar with, focuses on specific cooperation projects to support rapid economic development. We're discussing the convergence workshop, which may not happen immediately and could take years. For example, we could consider work sharing on marketing authorization. Perhaps in the future, regional pathways for marketing authorization could be one of the frameworks we could attach this initiative to.

Currently, SEARN remains a voluntary network of NRAs. To make it more structured, it might be beneficial to link it to existing regional frameworks. So far, Beamstack is the only one we have identified.

The question we would like to explore from the assembly is whether you think it is worth investigating this option. Do you have any concerns? If any of you have prior experience with Beamstack, your input would be valuable to help us understand it better.

I reviewed the website quickly, and from what I understand, medical products are not a central area of focus for Beamstack, but they are not outside its scope either. I also found discussions related to traditional medical products in Beamstack, which suggests that it could be an entry point. It may not need to be limited to that.

I'll stop here and open the floor for discussion. Later, we can hear from each of you.

Yes, we don't have any experience with Beamstack, and I haven't studied it thoroughly, so I can't comment. But it might be worth exploring, as it's a broader economic alliance, so the possibility of partnership could be worth considering. Mr. Delphin?

I think, if I look at this, most of the

Namun, keterbatasan dari kerangka seperti *Busticle* adalah bahwa negara seperti Maladewa dan Timor-Leste bukan merupakan anggotanya. Oleh karena itu, dalam diskusi mendatang, kita perlu mengeksplorasi bagaimana mereka tetap dapat dikaitkan dengan proyek tertentu, atau paling tidak melalui kerangka umum yang disebut *SUN*.

Prinsip dari *SUN* tetap sama: setiap kegiatan dari SEARN seharusnya membawa manfaat bagi semua anggotanya. Jika Maladewa dan Timor-Leste tidak dapat diikutsertakan, maka inisiatif ini mungkin tidak berjalan efektif.

Fokus awal berasal dari Beamstack, namun beberapa di antara Anda mungkin lebih memahami kerangka ini.

Diskusi ini berkaitan dengan proyek kerja sama yang mendukung percepatan pembangunan ekonomi. Misalnya, berbagi pekerjaan dalam otorisasi pemasaran, atau pembentukan jalur regional untuk otorisasi tersebut di masa depan.

Apakah hal ini dapat menjadi salah satu kerangka kerja tempat inisiatif ini dapat melekat?

Saat ini, SEARN merupakan jaringan sukarela dari NRA. Jika kita ingin memberikan dasar dan struktur yang lebih kuat, maka menghubungkannya dengan kerangka yang sudah ada di kawasan ini adalah pilihan yang layak.

Pertanyaan yang ingin kami ajukan kepada majelis adalah:

Apakah Anda merasa hal ini layak untuk dijabari?

Apakah ada kekhawatiran atau pengalaman yang bisa dibagikan terkait Beamstack?

Saya mencoba menelusuri situsnya dan dari pemahaman saya, produk medis bukan merupakan fokus utama Beamstack, namun juga tidak berada di luar cakupannya. Saya menemukan bahwa terdapat sejumlah diskusi terkait produk medis tradisional dalam kerangka

members of this organization are already integrating Asian countries. So, most of them, including Timor-Leste, are soon to be part of ASEAN. It has already been announced that Timor-Leste will become an ASEAN member in October. After this, we can have further discussions, particularly with line ministries, like Foreign Affairs, to understand their position. But for the meantime, we can observe the situation.

Thank you. From Thailand. So, acknowledging that this is a surprise discussion, perhaps some of you are not prepared or are unfamiliar with this framework, and that's okay. We can highlight this for now, but what we need to focus on right now is whether you think it is worth exploring, and we can discuss next steps.

For the BIMSTEC discussion, we haven't had direct discussions with our policymakers yet. However, if there are any points for discussion, we can accept them and provide feedback later since we are not part of top management.

Maldives, is it worth exploring since many SEARN countries are members? However, I am also not familiar with this organization, so we need to explore further. I understand that there is an ongoing process for traditional medicine under BIMSTEC, but I'm not deeply involved in whether this can be integrated into SEARN. I don't think so because there are different perspectives, and we are more aligned with WHO's system. BIMSTEC is primarily an economic forum, aiming to improve trade and transportation within the region. While it could benefit the movement of medicines, I don't think regulatory aspects would fit well here.

However, it's always good to associate with any political grouping. For sectors like pharmaceutical regulation, it's useful to align with such frameworks. I have experience with the BRICS countries, where we had an MOU and cooperation for specific product regulation. I have also gone through BIMSTEC, and health is one of their subjects of cooperation, with

Beamstack, yang menunjukkan bahwa mungkin hal ini dapat menjadi titik masuk awal.

Namun, tentu saja ini tidak perlu dibatasi hanya pada kerangka tersebut. Untuk sementara, kami akan berhenti di sini dan membuka sesi untuk mendengarkan pandangan dari Bapak/Ibu sekalian.

Beberapa negara menyatakan bahwa mereka belum memiliki pengalaman langsung atau belum mempelajari kerangka ini lebih lanjut.

Namun demikian, karena Beamstack bersifat ekonomi dan merupakan aliansi yang lebih luas, mungkin ada potensi untuk mengeksplorasi kerja sama yang relevan.

Diskusi ini juga menyebutkan bahwa sebagian besar negara anggota telah berintegrasi dengan negara-negara Asia, dan bahwa Malaysia telah ditunjuk untuk memimpin inisiatif ini. Diumumkan bahwa pada bulan Oktober, Timor-Leste akan menjadi anggota Asia.

Setelah menjadi anggota resmi, pembahasan lanjutan dapat dilakukan bersama kementerian terkait, seperti Kementerian Luar Negeri, untuk memahami posisi masing-masing negara.

Sementara itu, kita dapat terus memantau dan mengamati perkembangan ini.

Diskusi ini mungkin datang secara tiba-tiba, namun tidak masalah jika Bapak/Ibu belum siap atau belum mengenal kerangka ini. Kami ingin tahu apakah hal ini layak untuk dijajaki, dan jika iya, kita dapat mendiskusikan langkah selanjutnya.

Bagi negara yang belum melakukan pembahasan dengan pembuat kebijakan, kami memahami bahwa diskusi internal perlu dilakukan terlebih dahulu. Jika ada hal yang dapat diterima dan menjadi dasar diskusi lebih lanjut, silakan disampaikan nanti.

Sebagian negara ASEAN sudah menjadi anggota. Namun demikian, beberapa

trade also included. So, if the remaining two countries, Maldives and Timor-Leste, have no objections, we can explore this further. Thank you very much. Bangladesh is already a member of BIMSTEC. Regarding the involvement with the pharmaceutical sector, we need to explore further. We can discuss and decide. I think for Bhutan, it could also be a good opportunity to explore. However, looking at all the ongoing discussions, we don't have enough information to make a decision. We agree that it's good to explore, but more detailed information and clearances from the respective countries are required before we take further action. Yes, that was the intent before starting the work. Excuse me? Thank you. I just wanted to share some background on why this issue came up during Working Group 2 discussions. Basically, there is no legal binding or formal structure, and even creating an MOU has been a struggle. We are exploring whether there is any regional collaboration or cooperation, and it seems that ASEAN does have a strong regional framework. Similarly, in the European Union, you can see regional collaboration. Regulatory frameworks do not have borders, and we truly need regulatory collaboration with a legally structured framework. Beamstack was one platform we identified, where there is at least a charter agreement among the prime ministers of the countries. As mentioned by the counterpart from India, there is also sector collaboration, especially in science and technology. Leveraging science and technology is key, and from that angle, I think it's definitely beneficial to have market authorization or joint evaluations initiated. Ultimately, these are the basic ideas, and information sharing can also come into play at a later stage. So, in terms of next steps, I see two possibilities. The first is to	pihak menyatakan belum memahami keuntungan kerangka ini untuk negara seperti Maladewa. Ada juga proses yang sedang berlangsung terkait pengobatan tradisional di bawah kerangka lain. Namun belum diketahui apakah hal tersebut bisa terintegrasi ke dalam Beamstack. Beberapa pihak menyatakan bahwa pendekatan WHO lebih sesuai karena struktur dan sistemnya sudah terbentuk, meskipun Beamstack lebih merupakan forum ekonomi. Diskusi juga menyebutkan adanya manfaat dalam mempermudah ekspor-impor barang, transportasi, dan kerja sama lainnya di kawasan ini. Kerangka ini mungkin berguna untuk pergerakan produk medis, namun untuk aspek regulasi, masih diragukan apakah bisa digunakan. Tetap ada manfaat bergabung dalam aliansi politik atau kerja sama sektoral, seperti yang telah dilakukan dalam kerangka BRICS untuk regulasi produk tertentu. Pengalaman terdahulu menunjukkan bahwa kesehatan dan perdagangan bisa menjadi bagian dari kerja sama ini. Apabila Maladewa dan Timor-Leste tidak berkeberatan, maka inisiatif ini bisa terus dijajaki. Sebagai penutup, kami mengakui bahwa masih dibutuhkan informasi yang lebih rinci dan persetujuan resmi dari masing-masing negara. Langkah selanjutnya yang dapat diambil ada dua kemungkinan: 1. Negara-negara anggota membawa isu ini untuk dibahas lebih lanjut dengan pemerintah masing-masing setelah kembali ke negara asal. 2. Kita dapat menjadwalkan diskusi
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take time, and when you return home, discuss these initiatives further with your respective governments. We can then plan for another discussion.	lanjutan di masa mendatang untuk mengevaluasi kembali kemungkinan kolaborasi ini.
There is no point in going forward, so the next steps would be for the assembly to mandate India to contact His Excellency Indra Manipande, the Secretary-General of Beamstack. Thank you. Just being mindful of the colleagues connected online, since we started late, I would propose we move directly to the part related to WIPRA. I want to double-check if Gino and Geraldine are connected and if they have any time constraints. Thanks, Adrian. Sorry, can you hear me? I need to leave in 5 minutes for another meeting, but I can rejoin afterward, if possible. So for your convenience, we can have another 30-minute session and then start the discussion, or we can start it now — whatever you prefer. I'm happy to stick with Jinhao, who's also online. If we could start the WIPRA discussion in about 30 minutes, that would be very helpful, as we both have another meeting in 5 minutes. Okay, do you agree to start in 30 minutes? Yes, that would be perfect. Thank you. Let's move to the next slide. The second axis of the discussion is about supporting SEARN through existing and potential partners. The questions we'd like to ask are directed to existing partners (those participating in this meeting), as some partners are not represented at the moment, and to potential partners to hear from them about what future support or collaboration	

with SEARN might look like.

We can start with existing partners, as you may be more familiar with this exercise. I suppose Paul will be first?

Thank you, Adrian. From TGA's perspective, as most of the member states in the room are aware, we have an Indo-Pacific Regulatory Strengthening Program funded by our Department of Foreign Affairs and Trade. This program involves member states such as Timor-Leste, Thailand, and Indonesia. Our broad focus is on regulatory systems strengthening, which allows flexibility in the specific activities we can undertake with those member states. At the regional level, we can participate in regional activities, such as workshops, training, and being part of SEARN's working and drafting groups. From our side, we're open to proposals, and we will continue this collaboration as long as the Member States want it.

Thank you very much. I propose we go through the different partners and return to the questions afterward. Matthew, are you connected online for CEPI? Over to you.

I am indeed. For next year, it would be an honor to continue supporting SEARN, similar to how we supported it last year. We have involvement with both individual regulators and the global ecosystem. We propose to continue in the same way by providing subject matter experts for working parties. I also have a few additional potential experts to support the working parties, which I will email out later today. We can also provide expertise in training activities and facilitate connections between different regulatory authorities, both within SEARN and through other regulatory strengthening activities we're involved in. Another area we're focusing on this coming year is strengthening the inspectorate, so if there are specific requirements related to regulatory inspections, we'd be happy to discuss that further. Lastly, we are working on securing funding for Good Distribution Practice training and GMP training, which I'd like to help fund,

pending approval. We are also open to discussing other funding activities within the CEPI remit.

Thank you very much, Matt.

I don't think anyone from CORE or ICE is connected, and I'm not sure about Jean-Christoff either, as it may be the middle of the night for him. Hopefully, they'll join later for the CIP meeting.

Now, I'd like to hear from colleagues at the US FDA and the ADB, to get your feedback on the meeting and thoughts on future support or collaboration with SEARN.

Sure, I can go first. We've had very good discussions over the past 1.5 days. The areas covered are highly relevant to our focus as well. We have two criteria for collaboration: first, the country must be a member of the Asian Development Bank, which I believe everyone in the room is eligible for. Secondly, if the activity relates to regulatory capacity building, regulatory reliance, harmonization, convergence, collaborative procurement, or local manufacturing, it's very easy for us to engage. If there are other suggestions, we can be flexible. We are very interested in further discussions with the countries and institutions like Australia, TGA, WHO, and US FDA.

Thank you. I greatly appreciate the opportunity to be here. This type of engagement is incredibly valuable. We're involved in numerous conferences, but this kind of concentrated, small-group discussion, where conversations continue during coffee breaks and lunch, is uniquely beneficial. We plan to take our suggestions back to our headquarters as a proposal and share them with the Secretariat for feedback. We see many points where the FDA can provide technical expertise to support SEARN's work.

Thank you, very clear.

Any questions or comments from the assembly regarding support from partners

or potential collaboration?

I have a comment. If you're looking for additional partners, PMDA might be a good one. PMDA has an office in Asia and focuses on training and capacity building in Asian countries, which includes our region. They've done virtual and on-site training, so perhaps we can explore further with them to see if they can provide support. PMDA participated in the February workshop on medical device regulation. If you have close ties with PMDA, perhaps a meeting with PMDA colleagues and Thai FDA would be helpful to present SEARN's activities and explore how PMDA could be involved in the future. I can coordinate with PMDA's office in Bangkok to start the conversation.

Thank you very much.

Yes, please?

I have a general question for SEARN membership. How would SEARN receive funding from a third party? Who is the fiduciary agent? There are three ways: the first is through WHO and the Secretariat, as Matthew is working on. The second is through conducting activities with another organization under the Secretariat. Basically, we have a work plan, and we want that plan to be implemented.

So, it doesn't matter whether the funding comes from WHO or not. The third possibility would be to completely outsource the entire activity to another organization. For example, we did this with a virtual workshop on minimum common standards for regulatory information management systems, which was completely outsourced to MTTAPS, USP, and PQM+. Our role was just to facilitate by obtaining the contacts of the working group so they could invite members. These are, I believe, the three main options available.

Recently, we've been working on a new mechanism through which WHO can receive funding, especially for entities that are not from the private sector. There's a

lot of potential for funds to come through WHO directly or through WHO/CRO, and then we can conduct the activities with partners who are funding specific activities or long-term goals. So, we are open to this.

In addition to what Adrian mentioned, we have also discussed the funding gap. I would like to request that partners fill this gap if possible, in a tangible manner. We are open and continuing discussions together, and our mission is clear. I would request partners to consider supporting the activities so that the network can move forward. Without funding, everything becomes uncertain and unclear. We need clear activities and funding moving forward to ensure we can continue working comfortably and efficiently with the necessary staff.

I would again raise the point that these partners have their own approval systems and processes, but let's see if there's a way to move forward and find some light at the end of the tunnel.

Thank you.

In addition to the Thai colleague's point about PMDA, I also heard that JICA is doing a lot of work in Bhutan. Perhaps we can discuss this together, with the working group, JICA, and PMDA, and explore how the Japanese government is supporting member states. We can work together on this, including with the Thai FDA.

Okay, I think that was a good discussion. If I were to summarize, existing partners have expressed their intention to continue supporting SEARN in similar ways. When it comes to potential partners, there's general appreciation for the work conducted this week, and there is interest in exploring potential collaboration with SEARN. Additionally, the Assembly has proposed further exploration of potential collaboration with the government of Japan, through various channels, including PMDA, with support from Thai FDA.

Okay, moving on.

Next, we have the main discussion: ASEAN PPWG. These are the ASEAN members who are also members of SEARN. Currently, only Thailand is an active member of ASEAN in this regard. Myanmar is marginally involved. At the moment, Indonesia and Thailand are in control, but we're trying to list potential areas where SEARN is already working and where collaboration might be possible, particularly related to information sharing. One particular example is alerts for substandard and falsified products, as both regions have mechanisms for this. Another area is regulatory convergence, which could also be approached more broadly. This ties back to our previous discussions on regulatory information management and the minimum common standards for RIMS.

There has been very little adherence to the existing standards, and even the format of marketing authorization dossiers already represents some form of convergence. Regulatory convergence, in a very broad sense, already exists in regions like ASEAN, with the ASEAN Joint Assessment procedure, but perhaps something different, or softer, could be explored to cover both regions. This could be of interest to the pharmaceutical industry in both regions, and they may support this effort to avoid unnecessary duplication in the application process.

On my end, I'm not familiar with what PPWG has been doing in terms of capacity building, but based on the activities already in place in SEARN's capacity building, I think ASEAN could also benefit from some of these activities. For example, the capacity building platform being developed by SEARN could be of interest to ASEAN members with little adaptation, particularly for GSDP in-country training and its organization. This concept could easily be replicated or merged between the two regions.

It's difficult to pre-plan the areas of collaboration because that would require

detailed discussion. The idea is to start these discussions. Initially, there was an intention to invite ASEAN as part of this meeting, but the process has been difficult and somewhat confusing. After informal discussions with colleagues from Indonesia and Thailand, we propose that for the time being, we focus on PPWG and send a letter from the chair of the steering group, using the usual SEARN template, along with a concept note explaining what SEARN is and the activities we've done. Thai and Indonesian colleagues can review the proposed activities to see if anything is missing or needs to be adjusted.

The letter would request the opportunity to present SEARN to PPWG and its activities, and have a direct discussion with PPWG. The target outcome of this discussion could be to form mixed PPWG-SEARN informal drafting groups to look at each other's activities, identify areas for collaboration, and come up with a proposal for future collaboration between PPWG and SEARN.

I'd like to hear from colleagues in Thailand and Indonesia whether they think this approach makes sense based on their experience with PPWG. We can then hear from other members.

In summary, the proposal is to have further collaboration between PPWG and SEARN, but it may take some time to develop. The approach is supported, but it will need patience, and we will continue processing the steps accordingly.

So, perhaps, you can also expand this among the member states. Thank you.

Hearing the discussions, how do other non-ASEAN SEARN members feel about this? Does this seem like a good way forward to you?

Let's start with you, Mr. Truman.

Vietnam, I'm not sure about this aspect, but I think it's likely related to Beamstack, which has a broader economic focus. It seems like the scope is more aligned with that. However, the pharmaceutical

industry is growing, and the needs are also increasing. I believe this is becoming an important part of the economic landscape. So, I think it's worth exploring the possibility of learning and further collaboration.

Mr. Delphim:

I think the issue is that we can't directly give a mandate to Indonesia for communication with ASEAN. It's difficult because the assembly of SEARN members should give the mandate to other members. For us, we have to assess proposals from partners to strengthen the PPWG or member states. Typically, proposals from partners or other organizations would be evaluated for whether we should accept that support or not.

Regarding ASEAN participation, each country must fund its own participation in meetings. The structure of SEARN and why PPWG is attractive is because it operates under the economic pillar of ASEAN, focusing on the harmonization of pharmaceutical products. The communication and involvement of the industry can also be facilitated through the Implementation Working Group. The structure of ASEAN PPWG or AACSQ is similar to ICH, with sponsors and regulators collaborating on activities. Working groups can propose technical requirements for development.

I think SEARN can manage potential conflicts of interest and industry influence, which is a common challenge in both ASEAN and ICH. Partners support our activities, but SEARN needs to think about how to link up with ASEAN and other partners. However, this is a long process, and there are many layers of bureaucracy involved. The proposal must go through high-level political approval, such as from prime ministers and the high-level committees, before it reaches the working group. This is the structure of ASEAN, with both economic and social pillars involved in these processes.

So, to be completely clear, are you suggesting that this could be a way forward, but it will take a long time? Or

are you not very supportive of the proposed way forward?

Mr. Truman:

If I were in your position, I would hesitate to proceed as proposed. The policy level must be engaged first because the table follows policy directives from above. If you want to reach out, the fastest way is through the policy-level devices, which will provide the mandate needed to proceed.

Mr. Delphim:

Absolutely. For BIMSTEC, as well as for SEARN, we may request collaboration. However, it's essential to clarify whether the mandate for these organizations is in place, as they are high-level political bodies approved by member states or governance bodies. We need clarity on whether it is possible to proceed this way.

If we can explore it, why not? It would be important to push forward with these proposals because SEARN and its hard work are crucial. Everyone's efforts — the partners and our team — are vital, and we should share this work and get mandates from other organizations. It's essential to explore these possibilities for greater reach, resources, and impact. The larger the team, the better it will be.

The difficulty I see with this proposal is that we need some clarity on the activities happening within PPWG and compare them to SEARN's activities. Once we identify areas of collaboration, we can move forward with a concept and present it at the policy level. Until we have that clarity, we can't proceed with the proposal.

Mr. Delphim:

My comment is that, from my experience, I think harmonization between SEARN and ASEAN will be key. If we are going to focus on economic integration, harmonization, and common technical documents and guidelines, this is something that SEARN could work on and then expand to ASEAN. These activities would be a good starting point and would help ensure the sustainability of SEARN's activities while also receiving

support from many organizations.

Currently, all governments are concerned about economic issues, but they still need to maintain independence. However, they must also support economic growth. So, for this to work, we need to think about how we can incorporate both economic aspects and SEARN's objectives. It's not just about ASEAN; it's about creating a larger market together. This includes work-sharing and reliance mechanisms.

The unmet needs of manufacturers should be addressed, and efficiency in these areas should be a focus. I think if we move forward like this, we'll be successful. However, if we only focus on training, like with ASEAN, it might not be the best approach. Instead, we could discuss with agencies whether they would be willing to support SEARN by including certain members in their training programs. This might be a quicker route, but we should think about the bigger picture.

I think the proposal would be stronger if it also has an economic dimension, as Beamstack is considering economic aspects, including collaboration on products and innovations. While Beamstack does focus on food products and non-healthcare items, we should explore how SEARN can also link with the economic side of things.

So, if I understand you correctly, you're saying that this could be a way forward, but it may take a very long time, and you're not entirely supportive of the proposed way forward?

Exactly. It's important to know the mandate for these organizations. These are high-level political bodies approved by member states. If it is possible to proceed, then we should explore it. But it's critical to ensure that we have clarity on what the activities are and how SEARN can align with these initiatives. Once we understand the activities, we can present a clearer proposal to the

policy level.

So, to summarize, we should first focus on areas of mutual interest, and then, if successful, expand to other areas of collaboration. The key is to ensure that the activities we choose align with the objectives of all parties involved.

Yes, and as you said, the key is to start with the areas of mutual interest and gradually expand. This approach is more feasible and productive.

I don't have anything to add. I agree with the proposal. We can go ahead with this approach and see where it leads.

My question is: when we talk about collaboration, there are two parties involved. How do we define the responsibilities and commitments of both parties moving forward?

Collaboration requires at least two parties. If we're talking about the ASEAN process, it's entirely political. The working group operates under a larger umbrella, and the process flows from the base through the pillars up to the high levels. How we approach this and determine the contact point is crucial. Once we identify the contact point, we need to be sure that the response we receive is valid and supported by ASEAN's mandate. These things should be clarified from the beginning when pursuing collaboration.

ASEAN's information is open and available on their website, and we can refer to documents and implement them. In some cases, we've used ASEAN's GMP guidelines even before formal collaboration. But we couldn't formalize a collaborative framework. Now, if SEARN is going to formalize a collaboration, we need to ask: where is the contact point, and is there a clear response from ASEAN?

I'm not sure if we are clear on how this would proceed. My focus is on

strengthening our network and reliance culture within SEARN first, and then ASEAN can start looking at us. SEARN can say, "Here's what we're doing," and ASEAN can consider how to collaborate, but we need to think about how we can make this work.

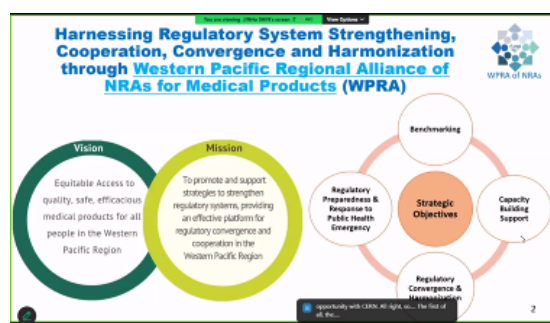
At this point, ASEAN is self-funded, and while they may have supporting agencies, they are busy with their own processes. SEARN can learn from ASEAN's technical know-how and engage with them on common practices. Let's first identify what we can ask from ASEAN and explore how they can attach to SEARN's activities. We need to figure out how SEARN can approach ASEAN and the working group to find a connection. Let's first clarify this and then move forward.

This is a very interesting topic, and I believe a lot of discussions have been made. From what I'm hearing, SEARN is not very attractive to ASEAN at this stage. We need to acknowledge that. First, we need to strengthen SEARN and then approach ASEAN. At the same time, we can show our interest to ASEAN. I think sending a letter could highlight that SEARN is interested in learning from ASEAN.

Additionally, we should request support in identifying common areas between PPWG and SEARN. It's important that the letter we send is not too general. If we identify areas of common interest, it will make the letter more impactful and increase the chances of a response. So, we need support, especially for drafting the letter and identifying those commonalities.

I agree with what has been said. The letter should focus on presenting SEARN's activities and build awareness. We should not expect too much from this first contact. This will primarily be an informational action to raise awareness of SEARN's existence and activities. We should also explore mechanisms to stay informed about ASEAN's activities, so we don't duplicate what's already been done.

To summarize: the proposal is to send a letter with clear and achievable goals, such as presenting SEARN's activities without expecting much in return. It's about building awareness of SEARN, learning about ASEAN's activities, and finding ways to stay informed about ASEAN's ongoing work so we can either build on it or avoid duplicating it. Does that sound like a good way forward?



The National Regulatory Authorities (NRAs) in the Western Pacific region, particularly after the H1N1 pandemic in 2011, began calling for a collaboration mechanism. The first meeting was held in Korea, and over time, vision and mission objectives were defined. These documents have been published multiple times, and the members have visited and confirmed these strategic objectives, which are the vision and mission for both pillars.

The vision is to ensure that NRAs in the region can provide quality, safety, and efficacy in medical products to the people of the Western Pacific. The mission is to support strategies to strengthen national regulatory systems and to provide an

effective platform for regulatory convergence and cooperation in the region. I believe SEARN shares a similar vision and ambition.

There are four strategic objectives in place. The regional office has received significant support from the headquarters, particularly in strengthening regulatory systems. The core strategy focuses on benchmarking, and after that, the Institutional Development Plan is developed. Capacity-building support, training, coaching, and engaging other NRAs are emphasized. Regulatory convergence and harmonization are also key goals, along with regulatory preparedness to respond to public health emergencies.

The impact of the Webra Alliance Network can be seen in two main areas. First, the alliance has contributed significantly to elevating regulatory maturity. It has enabled 14+ countries to advance their regulatory capabilities through WHO benchmarking. For example, Singapore and the Republic of Korea went through this benchmarking process and achieved a status that was announced a couple of years ago. Other countries such as China, Vietnam, Brunei, Cambodia, Fiji, Papua New Guinea, Laos, and Mongolia also followed suit with self-benchmarking, while Malaysia and the Philippines are awaiting final results.

Second, the alliance made a significant impact in the pandemic response. Many NRAs built trust and collaborated quickly through the network, especially in emergency authorizations for diagnostics, vaccines, and therapeutics during COVID-19. This was a positive outcome and highlights the alliance's effectiveness in facilitating rapid action.

However, there are key challenges, especially in resource-limited countries. The prevalence of substandard and falsified medical products remains a significant threat. There is also a lack of customer awareness about these products, as well as complex supply chains, many of which involve illegal online sales. Limited access to affordable

medicines, high prices, and insufficient regulatory oversight, particularly in lower-resource countries and small island developing nations, are other critical issues.

To overcome these challenges, collaboration can improve opportunities in the region. During the two-day meeting, I've noticed the importance of this cooperation and the potential for growth.

The discussion has been very insightful, and I've learned a lot. It's encouraging to see the comprehensive nature of the work you're doing, and it's motivating to think about joint working groups and shared training workshops. For example, we've had regulatory performance indicator workshops and quality management system workshops in the past, and it would be great to continue these efforts. Cross-regional emergency simulations, mutual review, and reliance are also areas where we could collaborate.

In our region, we have support from partners like TGA Australia through the Regulatory Strengthening Program (RSP), and Japan's ATC and RCL Training Center programs. Recently, Korea launched the Global Harmonization Center initiative, which complements long-term support for vaccine lot release and testing training. Additionally, Korea is working with WHO on regional training centers, with candidates from China undergoing selection.

This collaboration offers a good opportunity, and there are also initiatives like global manufacturing hubs, which are supported by the Korean government. China has applied for this and is currently undergoing the selection process. So, there is an opportunity to work together with the SEARN network.

Jinho:

Regarding the joint working group, I think there's a need for further study on how SEARN working groups operate, as I am somewhat unfamiliar with that. The regional alliance has discussed creating a working group, but this proposal has not yet materialized. It may be due to

language barriers or other issues, but I believe reliance recognition is an important aspect, and this could be a good foundation for a joint working group.

Jinho (continued):

In particular, countries like Japan, Korea, and China, which have more advanced NRAs, may have a keen interest in collaborating. In the past, there has been informal collaboration among these countries, even without a formal framework. We could work together on common regulatory functions, such as harmonizing technical requirements, which is where SEARN and ASEAN could collaborate more closely.

One area that I feel is currently lacking is the work on diagnostics. ASEAN countries have been working on establishing a National Essential Diagnostics List (NEDL) with support from the Economic Research Institute in Jakarta. This could be an area for potential collaboration as well.

There's also an ongoing initiative on AI in health, which is evolving rapidly. The WHO and the Ministry of Food and Drug Safety organized an international symposium last year, and many regulatory authorities participated to share experiences on AI. This could be an area where we can engage further, as it is developing at a fast pace.

Jinho (continued):

Perhaps we could start by sharing our work plans with each other. SEARN could present its plans to WIPRA, especially focusing on capacity building. If there are overlapping areas in our plans, we can collaborate to optimize resources. Another possibility is cross-regional emergency simulations, which could be a simple yet effective collaboration. After your meeting, WIPRA could also share feedback with SEARN members about their activities, allowing us to explore collaboration opportunities.

Discussion on Collaboration:

I think these two steps—sharing work plans and engaging in cross-regional simulations—are easy and practical ways

to begin collaborating. I'd like to check with the members of SEARN to see if this makes sense, starting with Sri Lanka.

Sri Lanka:

I think these suggestions are practical and realistic. We can definitely collaborate as our objectives align. There's a lot of overlapping work, and I'm sure we can work together effectively.

Timor-Leste:

Yes, I agree.

Thailand:

Yes, collaborating on this program will make it more visible, and I think it's a good opportunity.

Maldives:

I agree. This is a good opportunity for collaboration.

Bangladesh:

I second the comments from my colleagues. I believe this is a low-hanging fruit, and we should take advantage of it.

Discussion on Collaboration and Platforms:

The members of the WIPRA group are diverse, consisting of large countries. So, the question arises: is the offer coming from that group, or are we the ones asking for it? I believe it's both ways. We share our work plan, they share theirs, and we identify areas where we can collaborate.

However, it's important to note that BIMSTEC is a different type of organization. It's a long-term political organization, whereas our focus is more on technical collaboration. If the WIPRA members are agreeable to this collaboration, that's fine, but there needs to be a clear understanding of the support we are expecting from them. Particularly, it would be interesting to hear from Indonesia's perspective.

Indonesia's Response:

Yes, we would be happy to have

collaboration between SEARN and WIPRA.

Anil's Question:

Could you guide us on the kind of collaboration you have with platforms like ASEAN or others in your region? I was going through the WIPRA website, but I was unable to log in. What kind of information can be shared between the NRAs? It would be interesting to understand how both open and closed platforms operate, and how we can work together to share information. Since we are both WHO-led, how can we collaborate, and how will your members perceive this?

Response:

Thank you, Anil. To clarify, we provide a voluntary cooperation mechanism with a diverse group of countries. Half of them are located in the Pacific Islands, and we prioritize support for those countries. There's an ongoing discussion about forming a sub-regional platform to support the Pacific Islands, as many of them don't have fully developed national regulatory authorities. Some countries only have pharmacists handling procurement and supply chain oversight.

WIPRA faces similar challenges, and ASEAN is seen as an important political organization. However, collaboration with ASEAN has not been formalized yet because the WHO Secretariat, which supports this network, represents both regions. This makes it a bit complex. However, if we can collaborate with SEARN, there might be more opportunities, especially since some countries share similar regulatory issues.

Regarding the platform, the WIPRA website, created with support from the Korean government, is still dependent on their funding to maintain it. Currently, we use the WHO SharePoint more often due to IT limitations. However, we can explore better collaboration to create a more effective information-sharing platform in the future.

Closing Remarks:

Thank you, Jinho. We heard the room

and the consensus is to collaborate. We will keep you informed about our work plan, and we would appreciate it if you could share your work plan with us as well. If it's helpful, we would be happy to have you present at future meetings. Thank you very much for taking the time to connect with us and share more about your activities over the past two days. Chair's Final Remark: With that, we conclude the meeting. Just before we end, I'd like to mention that the speed dating session for organizations is starting now. The times have been adjusted to make it easier for everyone, so no need to reorganize. Over to the chair for the final conclusion of the meeting. Thank you very much.	
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17. Conclusions of the meeting

Thank you, Adrian. Indeed, two long days. Now, as we come to the close of the CERN assembly, I would like to express my deepest appreciation to each one of you for your valuable contribution. Thoughtful engagement and shared commitment to strengthening the regulatory system in the Southeast Asia. Over the past two days, we have clearly demonstrated that by working together with trust, transparency, and technical collaboration.	
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We are making meaningful progress, although not at the speed at which we would desire.

So that means... so we may want to put a little more concerted effort, especially a coordinated approach as member states.

To ensure that all intended objective, expectation, aspiration of CERN, especially in terms of.

Reaching out or collaboration beyond CERN is required, so we may have to put a little effort there.

I would also like to acknowledge the outstanding efforts of the Technical Working Group, the regional partners, and the Secretariat, and.

All the participants who are participating virtually, as well as in person, everyone's dedication is key to turning shared vision into tangible results.

Special appreciation to our, uh, CRO, I mean. Sun Secret, especially Adrian, I mean, who has been doing the heavyweight lifting for this assembly and the network as a whole.

Special appreciation to our, uh, CRO, I mean. Sun Secret, especially Adrian, I mean, who has been doing the heavyweight lifting for this assembly and the network as a whole.

We truly value your efforts and your contribution, and hope you'll keep the momentum going. Further, I would like to extend this opportunity to thank the existing international partners for their continued support.

And, um, commitment. And also, the new potential partners, ADB and US FDA, for their interest shown to support CERN and the member countries.

As the chair of the staging group, I'm proud of the momentum that we have built so far.

And I'm... I'm hopeful about what lies ahead, let us carry the spirit of

collaboration that defines CERN, not just as a network, but also as a. Shared commitment to of public health and patient safety. And finally, Indonesia. Like I said in the welcome address, you will be missed, and we all wish you the very best in your future endeavor. Please remember us, and stay connected. Cern looks forward to maintaining strong ties and exploring ways to work together. So, once again, thank you all for your presence, your insights, and your partnership. I look forward to a continued journey together, wishing everyone a safe journey back home. Thank you, and Testila.	
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18. Networking between National Regulatory Authorities

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C. Anggaran Pembiayaan peserta

Pembiayaan keikutsertaan konferensi ini sebagai berikut:

BAB IV

KESIMPULAN DAN TINDAK LANJUT

A. Kesimpulan

B. Tindak Lanjut

Sebagai bagian dari ,, usulan tindak lanjut yang dapat diupayakan antara lain:

BAB V DOKUMENTASI

Members participation in this meeting

Countries:

- DPR Korea was not able to participate this year
- WHO, as secretariat of SEARN, was not able to liaise with Myanmar due to the current UN rules of engagement with its authorities

National Regulatory Authorities:

- Provided WG6 is created, SEARN will welcome two new NRAs in SEARN:
 - Ministry of Ayush (India)
 - Department of Ayurveda (Sri Lanka)

