8. GSPoA on PHIIP

Contents

In focus

The EB148/10 report has been submitted in response to the request made in WHA73(11) (2020) for a report on the progress made on implementing the decision. The Report also provides the implementation plan for further action on the prioritized recommendations of the review panel established at the request of WHA68.18 (2015) to conduct an overall programme review of the GSPOA PHI.

In the light of para 1 of decision WHA71(9) (2018) member states were also requested to respond to a questionnaire to gather information on the implementation of the recommendations of the review panel which were addressed to the member states. Secretariat has analysed the responses and will publish the findings in a report by end of January, 2021.

Paragraph 5 refers to an informal consultation between the secretariat and Member States on 3 December 2020 to discuss the recommendations of the review panel referred to in paragraph 2 of decision WHA71(9) (2018) as “not emanating from the global strategy and plan of action on public health, innovation and intellectual property” and the “recommendations of the review panel on promoting and monitoring transparency of medicines prices and actions to prevent shortages” (see note on typo by KEI here). Useful KEI piece here summarising the informal consultation report.

Background

The GSPOA was adopted in 2008 to *promote new thinking on innovation and access to medicines and to secure an enhanced and sustainable basis for needs driven essential health research and development relevant to diseases that disproportionately affect developing countries*. (See Tracker links to GSPOA, in particular WHA61 in 2008.)

An ‘Overall Program Review’ was appointed in 2015 and reported in 2017.

The Assembly’s most recent decision on GSPOA (WHA71(9) 2018) followed quite intense debate at EB142 (see M7 and M10) over the recommendations of the expert panel for the Overall Program Review of the GSPOA (summarised in EB142/14 Rev.1) and the draft decision

proposed by the Secretariat to “to take forward the recommendations of the review panel” (EB142/14 Add.1).

The US and Switzerland proposed revising the draft decision in EB142/14 Add.1 (supported by Japan), but strongly opposed by many countries (Brazil, Thailand, the Netherlands, Libya, Algeria (on behalf of the member states of the African Region), Sri Lanka, Pakistan, Vietnam, Colombia, the Dominican Republic, Burundi, the United Republic of Tanzania, Benin), who argued that delays to adopting the decision “could be construed as serving to protect the interests of the pharmaceutical industry.” Canada, France, Sweden and Italy proposed a drafting group restricted to ‘minor’ changes as a compromise.

While the drafting group reached a compromise, leaks from delegates participating in the drafting group (see "Member states clash as WHO mulls …”) suggested that not everyone was happy with the revised decision, and that it was a pragmatic choice “so as not to risk losing the whole report altogether.” The revised decision (EB142(4)) distinguished between recommendations “emanating from the GPSOA” (which were to be implemented) and recommendations “not emanating from the GSPOA” (which were to be further discussed) and was adopted at WHA71 (2018) as (WHA71(9), see four main components, listed above).

In October 2019 the WHO Secretariat circulated a questionnaire for member states to inform the further development of the draft Implementation Plan and the implementation of related resolutions such as WHA72.8 on medicines transparency.

The EB146(10) recommended the WHA73 to urge MS to implement the recommendations of the GSPOA. It called for the secretariat to hold further informal consultations with MS regarding the recommendations of the review panel referred to in paragraph 2 of decision WHA71(9) (the recommendations ‘not emanating from the GSPOA’ and the promotion and monitoring transparency of medicines prices and actions to prevent shortages. It reiterated the need for sufficient funding to ensure success of the implementation plan and requested an update from the DG including the paragraphic 2 discussions.

This was accepted at WHA73(11) through silent procedure.

See Tracker links to previous documents, debates and decisions on the GSPOA.

- For a prehistory of GSPOA, see PHM comment on EB136 item 10.5 (2015), which discusses the origins and report of the 2006 Commission on IP, Innovation and Public Health and the subsequent debates which led to the GSPOA.

- For a fuller analysis of the Overall Program Review’s 2017 report (including its recommendations) and a comparison with the Secretariat’s 2016 Comprehensive Evaluation see PHM comment on EB142 item 3.7 (2018).

See Secretariat index page for Medicines: innovation, access and use.

See also WHO informal consultation (3 December 2020) addressed concerns on price transparency and shortages by Thiru of KEI, posted on 12 Jan 2021

See Medicines and Intellectual Property: 10 Years of the WHO Global Strategy by Germán Velásquez, South Centre Research Paper 100, December 2019 for an insider perspective on the achievements and disappointments of the GSPOA.

Recent GB discussions of the GSPoA

Secretariat topic page on IP and Trade

PHM Comment

We welcome the report identifying the set of actions, indicators and deliverables for realisation of the elements of the GSPOA.

Member state accountability

It may be noted that the implementation plan annexed with the report will have to be read and revised in light of the findings of the Secretariat based on the responses of the member states to the questionnaire related to baseline information on national context of HIP. We look forward to reading the MS updates on their implementation of the GSPOA. However it is disappointing this wasn't made available in time for the EB148 to allow discussion and review, particularly given we are already almost half way into the implementation plan time period.

Promoting research and development

Steps responding to Recommendation 7 merely mirrors the submission of the DG in EB146/15 viz. "*by 2021 all research supported or published by WHO will be available for immediate access*". There is however no update on the extent to which such publication has been successful and the extent to which it has been available to MS. Nor is there information on specific steps taken by WHO secretariat to achieve this.

Improving research capacity

We urge that the efforts for strengthening the collaborative registration processes responding to Recommendation 9 be supplemented by developing pathways supporting public sharing of clinical trial results and any associated public funding for the same.

Innovation sharing and technology transfer

Recommendation 14 featured the next step of the Secretariat to produce a report on mechanisms to facilitate technology transfer. It is promising to read "Key actions to facilitate increased manufacturing capacity, voluntary sharing of intellectual property, data and

knowledge, and licensing, for example, through C-TAP, are essential to concretely bring results on implementation of the GSPA-PHI" was highlighted as a key action in the informal consultations held between the secretariat and the MS.

However, this sharing should also include technical know-how and should take a more obligatory framework as per the PIP framework, rather than voluntary. Furthermore, the success of innovation sharing and technology transfer is conditional upon the development of domestic manufacturing capacity which needs to be developed in tandem. We look forward to further discussions and concrete next steps on how this will be implemented by MS.

The steps to be taken in response to Recommendation 17 should include encouraging MS to publish all licenses with member states to support global collective bargaining in demand and prices.

The report, in response to Recommendation 18, suggests working with Medicines Patent Pool (MPP) and other organisations to promote further development of products and access to them. The recommended steps however fail to question the progress made in the five year strategy adopted in May 2018 by the MPP to expand its activities to cover all patented essential medicines, which requires engagement with many new stakeholders (and noted in EB 146/15). Examining progress on this strategy would help better recommend future action on expanding MPP's portfolio.

Delivery and access

In steps to be taken for supporting Recommendation 21 in promoting and monitoring transparency in medicine prices, we urge that in addition to the steps recommended by the report, the DG considers developing a mechanism that allows transparency of R&D costs.

Insufficient funding and approaching deadline

A recognised historical barrier to the successful implementation is insufficient funding. WHA73(11) requested the DG to reiterate the need to 'allocate the necessary resources'. However, MS should untie their funding to mitigate earmarking of fundings, allowing sustainable effective funding of the secretariat's work, including the implementation of the GSPOA implementation plan. The informal consultation summary report stated that USD 16.9 million is required for 2020 - 2022 but it's not clear if this has been fulfilled. The implementation plan is due to expire in 2022 as per the WHA68.18, therefore the DG and MS should consider the extension of the GSPOA beyond this time.

The overarching obstacle to the GSPOA

As we have highlighted in previous discussions of the GSPOA, there is one glaring omission - the paradox of harmonising public health with innovation and intellectual property within a system which is driven by private financial incentives. The full realisation of the vision of the

GSPOA would in due course require the disruption of pharmaceutical companies' business model.

Notes of discussion