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Subject: Allegations of Anti-Competitive Practices by Radiopharma and Questions for the European Commission

1. Executive Summary

This report is based on our preliminary investigation. It focuses on alleged anti-competitive practices by entities operating under the name Radiopharma within the European Union's radiopharmaceuticals market. The CNMC's investigation into cartel behavior in Spain highlights the potential for competition issues in this sector across the EU. This report seeks to pose specific questions to the European Commission regarding its oversight of the radiopharmaceuticals market within the Union.

The analysis focuses on concerns regarding exploitative pricing of essential medicines, the implementation of agreements designed to stifle competition, and the alleged abuse of dominant market positions. This report will also critically examine the actions and inactions of the European Commission (EC) in addressing these alleged transgressions, particularly in light of its mandate to ensure fair competition within the EU's single market. The report will scrutinize the generic drug sector and the radiopharmaceutical industry, highlighting specific instances of alleged collusion and market manipulation that may have implications beyond the national borders of the UK and Spain. Ultimately, this analysis aims to provide a comprehensive overview of the alleged misconduct and to formulate pertinent questions for the EC regarding its role and effectiveness in ensuring a fair and competitive pharmaceutical market across the European Union.

The alleged anti-competitive practices by Radiopharma, along with questions surrounding the effectiveness of regulatory oversight, raise significant concerns about the functioning of the pharmaceutical market within the European Union. The European Commission has a crucial role to play in ensuring fair competition, protecting patient access to affordable medicines, and fostering innovation. A thorough investigation into the allegations outlined in this report, coupled with a reassessment of the EC's enforcement strategies and coordination with national authorities, is essential to safeguard the integrity of the EU's pharmaceutical market and protect the health and well-being of its citizens.

2. Alleged Exploitative Pricing with EU Implications

2.1. Radiopharma - Radiopharmaceutical Prices Compared to EU Averages

* Allegations suggest that radiopharmaceutical prices in the UK and Spain may be higher than EU averages. Given the essential nature of these medicines for diagnostics and treatment, particularly in oncology, the EC should investigate whether Radiopharma is engaging in exploitative pricing across the EU, potentially hindering access to vital healthcare and distorting competition within the single market. The reliance on imports in some member states further underscores the need for EU-level oversight to prevent price gouging.

3. Alleged Anti-Competitive Agreements with EU-Wide Impact

3.1. Radiopharma - Exclusive Agreements and Market Sharing

* The CNMC's findings of cartel behavior involving market sharing by radiopharmaceutical suppliers in Spain highlight the potential for anti-competitive agreements within the radiopharmaceuticals market across the EU. The EC should investigate whether similar exclusive agreements or market-sharing arrangements exist in other member states, potentially distorting competition and hindering patient access to essential radiopharmaceuticals.

4. Alleged Abuse of Dominance Affecting the EU Market

4.1. Radiopharma - Refusal to Supply Isotopes

* The UK's reliance on imported radioisotopes makes its radiopharmaceutical supply chain vulnerable. The EC should consider whether dominant players, potentially operating under the name "Radiopharma," are abusing their position by refusing to supply critical isotopes to competitors across the EU, thereby stifling innovation and limiting treatment options for patients .

5. Scrutiny of European Commission Actions

5.1. EC Oversight of National Competition Authorities: The EC should clarify its role in overseeing the actions of national competition authorities like the CMA and CNMC in the pharmaceutical sector.

6. Questions for the European Commission

1. * What is the EC's assessment of the alleged price discrepancies between the UK and Spain and the EU average for essential generic drugs and radiopharmaceuticals, and what steps could the EC take to address potential exploitative pricing within the single market?
2. * How does the EC monitor the effectiveness of its fines and decisions against pharmaceutical companies or groups like Radiopharma in preventing continued anti-competitive practices, such as pay-for-delay agreements and abuse of dominance, in member states?
3. * What is the EC's role in ensuring that national competition authorities adequately investigate and address issues with cross-border implications in the pharmaceutical sector, such as the alleged market sharing in Spain's radiopharmaceuticals market's activities in the UK?
4. What mechanisms are in place to ensure consistent and effective enforcement of EU competition law across member states, particularly in cases with cross-border implications such as those alleged in this report?
5. What mechanisms are in place to ensure consistent and effective coordination with national authorities to address potential regulatory capture or inertia that may hinder effective competition enforcement.?
6. * Given the UK's reliance on imported radioisotopes, what measures does the EC have in place to ensure a secure and competitive supply of these critical medicines across the EU, and to prevent dominant players from engaging in exclusionary practices?
7. * Can the EC provide details on the reasons for the closure of its 2020 investigation into Radiopharma's alleged collusion and explain whether pricing abuses were considered as part of that investigation?
8. * What specific steps will the EC take to align with its Directive 2014/104 to ensure that victims of anti-competitive practices in the pharmaceutical sector, such as national health services and consumers, are adequately compensated for damages incurred?
9. * How does the EC ensure transparency and prevent potential regulatory capture in its interactions with major pharmaceutical companies operating within the European Union?
10. * Given the CNMC's findings of a cartel involving market sharing by radiopharmaceutical suppliers in Spain , what is the EC's assessment of the risk of similar anti-competitive agreements, such as market sharing or price fixing, occurring in the radiopharmaceuticals market in other EU member states?
11. * The letter to the CNMC alleges that Radiopharma España engages in exploitative pricing of essential radiopharmaceuticals compared to EU averages. What is the EC's role in monitoring and addressing potential exploitative pricing of radiopharmaceuticals across the European Union, considering the essential nature of these medicines for diagnostics and treatment?
12. * Given the UK's reliance on imported radioisotopes , what measures does the EC have in place to ensure a secure and competitive supply of these critical medicines across the EU and to prevent potential abuses of dominance by single suppliers or a limited number of suppliers?
13. * The letter to the CNMC mentions potential exclusive agreements between Radiopharma España and hospital distributors . Does the EC have any concerns about the potential for such exclusive agreements to restrict competition in the radiopharmaceuticals market across the EU and limit patient access to a diverse range of products?
14. * Given the increasing importance of radiopharmaceuticals in cancer diagnosis and therapy , what is the EC's strategy for ensuring a competitive and innovative market for these vital medicines across the European Union?
15. * How does the EC coordinate with national health authorities and regulatory bodies in member states to ensure that pricing and reimbursement policies for radiopharmaceuticals do not inadvertently create barriers to competition or hinder patient access to necessary treatments?

7. Possible Violations of the EU Treaty by the European Commission

* Failure to Enforce Competition Law (Articles 101 and 102 TFEU): If the allegations of exploitative pricing, anti-competitive agreements, and abuse of dominance by Radiopharma are substantiated and have caused significant harm to competition and consumers across the EU, the EC's potential failure to take adequate and timely action could be considered a violation of its duty to enforce Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU).

* Failure to Ensure Proper Functioning of the Internal Market (Article 3 TEU): The alleged anti-competitive practices, particularly those leading to higher prices and restricted access to essential medicines in the UK and Spain compared to other EU member states, could be seen as hindering the proper functioning of the internal market. If the EC has not taken sufficient measures to address these issues, it could be argued that it has failed to uphold its duty under Article 3 of the Treaty on European Union (TEU) to ensure a competitive and undistorted internal market.

Atentamente,

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