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11 April 2025

TO THE EUROPEAN COMMISSION

Subject: Allegations of Anti-Competitive Practices by Teva Pharmaceutical Industries Limited and Questions for the European Commission

Dear EC Team,

Preliminary Report to the European Commission on Alleged Anti-Competitive Practices by Teva and Scrutiny of EC Actions

1. Executive Summary: This report addresses alleged anti-competitive practices by Teva Pharmaceutical Industries Limited (including its subsidiaries Teva UK Limited and Teva España) within the European Union's pharmaceutical market. The EC has previously taken enforcement action against Teva for pay-for-delay agreements and abuse of dominance. This report seeks to pose further questions to the European Commission regarding its ongoing oversight of Teva's activities across the EU. 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.

2. Alleged Exploitative Pricing with EU Implications : Teva - Generic Drug Prices Compared to EU Averages: While research suggests that generic medicine prices in the UK are generally lower than the EU average, the EC should consider whether Teva's pricing strategies in other EU member states exhibit exploitative characteristics. The significant price variations across European countries warrant scrutiny to ensure Teva is not leveraging market power unfairly in specific regions, potentially undermining the goals of a unified and competitive EU pharmaceutical market.

3. Alleged Anti-Competitive Agreements with EU-Wide Impact: Teva - Pay-for-Delay Agreements and Blocking Generic Entry: Evidence indicates Teva's involvement in pay-for-delay agreements, including those sanctioned by the EC. These practices, aimed at delaying the entry of cheaper generics, have a direct impact on healthcare costs and patient access across the EU. The EC should assess whether its previous actions have been sufficient to deter Teva from continuing such anti-competitive behavior in various member states. Allegations of blocking generic entry in Spain also raise concerns about potential infringements of EU competition law.

4. Scrutiny of European Commission Actions

* 4.1. EC Investigations and Enforcement Regarding Teva: The EC has previously investigated and fined Teva for anti-competitive practices, including pay-for-delay agreements and abuse of dominance related to its multiple sclerosis drug Copaxone. The EC should provide further information on the scope and findings of its 2020 investigation into Teva's alleged collusion and explain why it did not address pricing abuses or compel disclosure of key agreements at that time. Furthermore, the EC should detail the measures it has taken to ensure that Teva complies with EU competition law following these enforcement actions and whether there is ongoing monitoring of Teva's activities across the Union.

* 4.2. 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. 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? The EC should also outline how it coordinates with national authorities to address potential regulatory capture or inertia that may hinder effective competition enforcement.

5. 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 like Teva 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 and Teva's activities in the UK?
4. * 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?
5. * Can the EC provide details on the reasons for the closure of its 2020 investigation into Teva's alleged collusion and explain whether pricing abuses were considered as part of that investigation?
6. * 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?
7. * How does the EC ensure transparency and prevent potential regulatory capture in its interactions with major pharmaceutical companies operating within the European Union?
8. * The EC has already fined Teva for pay-for-delay agreements concerning Modafinil and for abuse of dominance related to Copaxone. What specific mechanisms does the EC have in place to monitor Teva's compliance with EU competition law following these decisions and to prevent future infringements across the Union?
9. * Given the allegations of Teva España potentially blocking generic entry through agreements in Spain, what is the EC's role in ensuring that national market practices do not undermine the principles of a competitive single market for pharmaceuticals within the EU?
10. * The letter to the CMA mentions a closed 2020 investigation into Teva's alleged collusion. While the research material does not provide details of a closed CMA investigation in 2020, the EC also reportedly sanctioned Teva and Cephalon in November 2020. Can the EC clarify the scope and findings of any investigations into Teva around this period, particularly concerning potential collusion or pricing abuses across the EU?
11. * What is the EC's assessment of the potential for Teva to engage in "evergreening" or other strategies to extend patent protection for its drugs across the EU, and what measures does the EC take to ensure that such strategies do not unfairly delay the entry of generic medicines into the market?
12. * How does the EC ensure that national competition authorities within the EU, such as the CMA and CNMC, are adequately addressing potential anti-competitive practices by pharmaceutical companies like Teva that have cross-border implications?
13. * In light of the significant impact of pharmaceutical pricing on public health budgets across the EU, what specific steps does the EC take to monitor and address potential instances of exploitative pricing of essential medicines by companies like Teva in different member states?

6. 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 Teva and 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.

7. Conclusion

The alleged anti-competitive practices by Teva , 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.

We look forward to your prompt and detailed response,

Sincerely

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