Medicines for Europe

Contribution to DG Competition Consultation on New Competition tool

September 2020

General Comment:

Medicines for Europe welcomes this initiative, which complements the general objective of the European Commission to ensure that competition works properly in the market, especially in cases, as stressed in the latest DG Competition Report on "Competition enforcement in the pharmaceutical sector" (2019): "*Authorities must remain vigilant and pro-active in investigating potentially anti-competitive situations, including where new practices used by companies or new trends in the industry are concerned, such as the growing relevance of biosimilars*."

Both Option 1 and 3 described in the inception impact assessment seem relevant for the generic, biosimilar and value added medicines industries.

Competition issues for which the new competition tool may be relevant:

- **Denigration of competitors & Misinformation to reduce competition:**
  - Use of the power on the market to denigrate upcoming or current competitors (esp. biosimilars).

- **Patent linkage**
  - The "*unlawful*" linkage between status of patents & decisions on MA/P&R is still in place in several EU countries: CZ, DE, FR, IT, NL, PL, PT, (RO).

    In the Pharma Sector Inquiry of 2009[1], the Commission committed to act against all forms of patent linkage. Given the clear delay to competition generated by such practice at national level, we see the need for the EU to take action and "*strictly enforce the applicable rules [and] act against patent linkage*", as stated in the 2009 Sector Inquiry.

    → Need for an EU ban of patent linkage
    → Meanwhile, the new tool should allow the EU to request Member States to change their legislation/practice that allow patent linkage in Europe and delay generic/biosimilar entry beyond IP expiries.

[1] Sector Inquiry Report: part 1 - part 2

- **Delayed competition & Damages**
  - To healthcare systems

    → Need for mechanism allowing national authorities to systematically claim damages caused to the national healthcare systems, in compensation for overpaying for the medicine due to the lack of competition caused by the conduct of dominant companies that delay off-patent entry.

  - To competitors:

    While having an impact on public expenditure, practices delaying generic competition also create significant economic damages to generic companies. This is particularly the case for sham or vexatious litigation. A particularly problematic issue is the level of damages caused by unduly granted preliminary injunctions (PI) based on later invalidated patents. For instance, in the Central-Eastern EU region, patentees can achieve (PI) relatively easily, irrespective of the strength of the patent. Such PI can only be challenged via invalidation of the patent which may take several years, in the meantime the PI is still in force and the defendant is prevented from entering the market with the generic product. After a successful invalidation – and consequently removal of the PI – the damages caused by the PI based on an invalid patent are significant, but most regrettably in CEE jurisdictions these are extremely difficult to claim. Such outcome goes directly against the Enforcement directive (Art. 9.) and impacts negatively the competition on the internal market. A clear example is Case C-688/17. National legislations regarding damages in case of an overturned PI is not as harmonized as it should be across Europe.

    → Need for EU harmonization of legislation on damages to be paid to companies suffering from practices delaying competition

- **Procurement**
  - Any form of discrimination of biosimilars vs the originator, which may take the form of slots reserved for originators, with long litigation and subsequent loss of the market for the biosimilar.
  - Cases similar to the Roche in Romania 2017-2019: Competition authority sanctioned Roche for anticompetitive behavior: 128mln Euro – in order to delay the access to the market of biosimilar products, Roche sold to partner distributors the product for a higher price than its bids in public procurements, making it impossible for competitors to win the procurement, overruling an existing law to prevent monopolizing the market for the distribution of a certain medicine, securing a monopoly of distribution ahead of biosimilar entry.

- **Market strategies**
  - Cases in which the originator, by using their position of power on the market, changes formulation or presentation (*e.g.* intramuscular, cutaneous/transdermal, sub-cutaneous,

etc.) of its product in order to shift patients to the new version with little significant clinical improvements. This results in *de facto* reduction of the accessible market for new entrants by making use of protections acquired for follow-on version and preventing head-to-head competition of similar products.

- **Pricing strategies**
  - Aggressive price cuts to make the market unattractive or even unprofitable for upcoming competitors. The effect of such practice may be a reduction of competition, since new entrant will struggle to penetrate the market. Due to reduced or absent competition, it is expected that in the medium-long term prices of that product increase. With blockbuster products marketed for several years in a monopolistic situation, such pricing strategy can be sustained by the originator to warrant potential competitor of the market, securing a longer *de facto* monopoly position or, at the very least, a larger market share based on dominant position. This behavior is particularly apparent for biosimilar medicines, where due to relatively high cost of development (vis-à-vis generic medicines) it endangers the business continuity and development of future biosimilar versions.
    Pricing strategies are also widely addressed in the DG COMP Sector Inquiry of 2009, where it states that in countries where there is *price linkage* between originator and generic "*The originator company may, for instance, force down the prices of generic competitors to a level where it is no longer profitable for them to sell the generic version. Of course, price reductions are in any case to be expected once generic versions enter the market. It is therefore difficult to identify the exact reasons behind sharp price reductions by the originator company, particularly if they are not sustainable*." P.496

- **Clawback and payback**
  - The application of an undifferentiated clawback or payback to the pharmaceutical industry, effectively transfers part of the overspending with protected medicines to the off-patent industry, indirectly supporting monopolies at the expense of competition. These practices disproportionately impact off-patent medicines, that typically operate with lower margins, creating unsustainable conditions for manufacturers that end withdrawing products from the market, reducing the competition and supply diversity.