TO:

Mr. Margaritis SCHINAS
Vice President
Promoting our European Way of Life
European Commission

Ms. Stella KYRIAKIDES
Commissioner
Health and Food Safety
European Commission

Mr. Thierry BRETON
Commissioner
Internal Market
European Commission

Ms. Margrethe VESTAGER
Commissioner for Competition
Executive Vice President
A Europe Fit for the Digital Age
European Commission

Ms. Ilze JUHANSONE
Secretary General
Secretariat General
European Commission

Cc:

Ursula VON DER LEYEN
President
European Commission

Brussels, 9 February 2023

Subject: Medicines for Europe letter on pharmaceutical legislation

Dear Vice Presidents, Dear Commissioners,

Medicines for Europe is committed to the medicines access and security of supply objectives set out in the Pharmaceutical Strategy for Europe. We note the progress in support of regulatory efficiency measures, in encouraging innovation on well-established molecules and clarifying certain important quality-related matters.

Specifically in relation to the Pharmaceutical Directive, we would like to underline two critical issues: encouraging competition and ensuring the availability of medicines.

1. **The importance of generic and biosimilar medicines competition for access**

The Pharmaceutical Directive plays a fundamental role in stimulating competition from generic and biosimilar medicines. This has doubled access to medicines across the EU and is the only driver of price competition and therefore of healthcare budget sustainability. We would encourage the following improvements to the legislation.

a. To ensure that originator manufacturers focus on unmet medical need and supply all markets, the legislation will make incentives conditional. The legislation should **modulate market rather than data exclusivity** as this will ensure predictability for generic and biosimilar developers who will be expected to launch when these conditions are not met. The current focus on regulatory data conditionality will lead to uncertainty and severely limit the effectiveness of the conditionality measures. The conditional extension of data exclusivity very late in the process would disrupt generic and biosimilar application procedures for manufacturers and regulatory authorities (as agency slots must be booked well in advance). In contrast, a fixed date for submitting generic and biosimilar medicine marketing authorisations applications 6 years after the reference product approval would align the EU with the international norm thus providing a level playing field with developers in non-EU countries. Originators would be unaffected as they would still benefit from market exclusivity with this change. These conditional incentives should be granted through a transparent process to provide predictability for follow-on manufacturers to bring competition at expiry of exclusivity.
b. The **Bolar exemption is a critical component** of the Pharmaceutical Directive to enable generic and biosimilar developers to plan and execute all aspects of the regulatory approval and administrative requirements for day-1 of expiry competition. However, there are many ways the originator industry can influence regulatory and administrative procedures to unduly delay competition. We have documented that many pricing and reimbursement registrations can easily be manipulated to significantly delay generic and biosimilar medicine competition, and hence increase Member State pharmaceutical budgets, regardless of effective patent validity or relevance. Therefore, the clarification of the Bolar should allow the necessary acts to place a product on the market (as per the objective of Bolar), this includes the submission of applications and grant of marketing authorisations as in the existing Bolar, pricing and reimbursement and procurement, and the possibility for API producers to supply and export. These clarifications are necessary to achieve encourage competition from generic and biosimilar medicines.
c. We **oppose the transferable exclusivity voucher** (TEV) for novel antibiotics. While we recognise the important clarifications made by the Commission, this delinks the reward from innovation and creates an incentive for any blockbuster drug to extend its monopoly on the EU market. As all studies show, the solution is to create an EU market for reserve antibiotic medicines through funding, regardless of their patent status.
d. Regarding changes to the **environmental risk assessment**, it is critical to avoid the unnecessary repetition of studies and to build on existing knowledge by allowing generic and biosimilar manufacturers to reference product data and to introduce a clear rule that this should **not unduly delay generic or biosimilar medicine competition** on the Internal Market. The current thinking could create opportunities

to 'discover' environmental concerns just as a generic or biosimilar developer is applying for a marketing authorisation. Without an exemption for delays to competition, this could easily be used to delay generic or biosimilar market entry by 1 or 2 years.

2. The availability of medicines

As the main driver of increased access to medicines, we want to work with the Commission to improve the availability of medicines across the EU. We have three issues to raise on this point.

a. Studies clearly indicate that packaging and labelling requirements restrict access to medicines and weaken the possibility to solve medicine shortages. The Commission can change this by enabling a vote on the **replacement of the paper leaflet with electronic patient information (ePI) as from 2030 across the EU**. Industry will work in that time to solve technical and digital accessibility issues together with medicine agencies and relevant partners. Similarly, the Directive should remove the requirement on generic and biosimilar medicine manufacturers to duplicate packaging and brand names multiple times to adapt to the patent evergreening strategies of the originator industry. This is a waste of resources and time for industry and medicine agencies and creates confusion for patients about their medicines. The legislation should end this requirement to multiply the number of duplicates for indication patents over which we have no control.
b. We are puzzled by the possibility for Member States to **opt-in to generic decentralised application procedures** with no consideration of the impact on the generic manufacturer. In contrast to the originator industry which will benefit from a billion-euro extra year of monopoly for supplying more markets, there is no incentive or reward for generic manufacturers through this measure. There are only obligations and costs including supplying countries where our members have no commercial operations. While we recognise the concern to help some national markets, there can be no regulatory delays, costs/burdens (fees, reporting, variations, supply obligations, etc) pertaining to those markets, and no market obligations (commercial establishment, registration for pricing and reimbursement lists or to procurement registries and procedures). As this measure aims to help some member states, they can take their responsibilities, and this should be explicit in the text of the Directive. Similarly, we would like it clarified that MAHs (Marketing Authorisation Holders) will have no additional national obligations (i.e., no obligation to remain in pricing and reimbursement lists, to participate in procurements and to contribute to clawback taxes that force the generic industry to subsidise the originator industry) related to the **extension the withdrawals to 12 months**. This should be explicit in the text of the Directive since your own studies and impact assessments show clearly that it is Member State market policies that are the root cause of withdrawals and since this legislation is clear that there should be no impact on the national competence for the organisation of markets.
c. Regarding the extension of **shortage notifications from 2 to 6 months**, the data from countries with such extensions shows, as cited in your own impact assessment, that this massively increases shortage "false alarms". Consequently, this 6-month reporting should be limited to major manufacturing changes such as the modernisation of production sites that require the plant to be shut down or to technology transfers as these are the only examples where a risk of shortage risk can be foreseen that far in advance. We are also disappointed that the Commission focuses exclusively on shortage reporting and not on

shortage prevention. Covid-19 and the recent shortages of antibiotics are clear examples of demand surge shortages. The use of EMVS (European Medicines Verification System) and harmonised, digital, shortage reporting systems would enable shortage prevention. We struggle to understand the Commission reasoning for consistently blocking efforts to **improve demand predictability using available data**.

d. We appreciate the effort to define critical shortages and critical medicines in the Directive. In line with that approach, we believe that **shortage prevention plans (SPP) should** focus on critical medicines or those at risk of a critical shortage. Extending this to all medicines will create unnecessary work for manufacturers and authorities with no benefit for public health.
e. It is important for generic, hybrid and fixed dose combination applications t**o have access to the Centralised and the Decentralised (national) Procedure,** to reflect the commercial realities of the off-patent industry. Restricting access to these procedures could reduce access for many smaller markets or certain regions with low access to medicines.

Medicines for Europe is committed to working constructively with the EU to improve the access and availability of medicine across Europe. Our proposals represent the pragmatic views of the sector to help streamline the registration and supply essential medicines. We support competition and regulations that improve medicines security in Europe.

Yours sincerely,

Adrian van den Hoven
Director General
Medicines for Europe