Ms. Ursula VON DER LEYEN
President
European Commission

c/c

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

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

Ms. Stella KYRIAKIDES
Commissioner
Health and Food Safety

Mr. Thierry BRETON
Commissioner
Internal Market

Ms. Ilze JUHANSONE
Secretary General
Secretariat General

Brussels, 4 April 2023

Subject: Importance of revising EU pharmaceutical legislation

Dear President von der Leyen

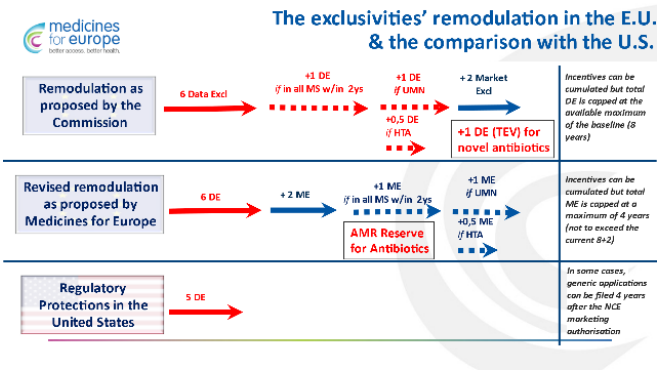
We are disappointed at the slow pace of progress in implementing the Pharmaceutical Strategy for Europe. Medicines for Europe played a critical role during the COVID-pandemic when many promises were made about EU solidarity, reliable drug supply chains and European strategic autonomy. For more than two years our manufacturers and the EU institutions have been working hard to understand each other's perspective. The latest delay is highly regrettable considering how long it will take for this reform to apply in EU member states and to deliver tangible results for patients facing medicines access and availability problems. We therefore call on the Commission to rapidly introduce the legislation based on these commitments. Specifically, the proposal should improve equitable access through competition and security of supply through shortage prevention.

Predictability and timely competition to deliver on timely access

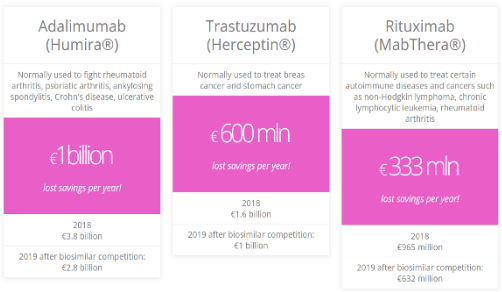
The EU intellectual property and regulatory exclusivity system is the longest in the world, comprising market and data exclusivities, patents and supplementary protection certificates, orphan and paediatric exclusivities, to stimulate innovation during the exclusivity period and to guarantee timely access to off-patent competitor

medicines at expiry. While the support for innovation has been clear, the assurance of competition at expiry has been mired by legal uncertainty for our sector which supplies around 70% of prescriptions. The new legislation should **correct this imbalance.**

- To deliver equitable access, the modulation of incentives should **adjust market rather than data protection**. In this way, if the originator manufacturer does not fulfil the requirement to place their products on all EU markets, the generic or biosimilar medicines would be licenced to supply. **Considering the impact of the EU's long exclusivity period on access, affordability and availability, data exclusivity and market exclusivity cumulated should not go beyond the current maximum level of protection.**



- The proposal should not include transferable **exclusivity vouchers (TEV) for novel antimicrobials which would massively increase costs for healthcare budgets and delay access to medicines in critical therapy areas, like oncology.** TEVs also undermine the fundamental tenant of EU innovation policy by delinking the reward from innovation and research and by effectively creating a market to purchase monopoly extensions for the most expensive blockbuster drugs. For equitable access to novel and established reserve antibiotics, the EU should instead develop a solidarity-based market like the Swedish subscription model combined with the transferable *regulatory* market review voucher as exists in the US. [*Please find here Medicines for Europe position as well as existing alternatives to TEV. The figure shows additional costs calculated by Medicines for Europe on some blockbuster molecules of recent years considering 1 additional year of exclusivity*.]



- Many Commission studies[1] and Parliament reports provide ample evidence of the delays to generic and biosimilar medicines that have hindered equitable access to medicines across the EU. **The legislation should finally remove these artificial and unlawful barriers to the day-1 entry** of generic and biosimilar medicines by **clarifying the Bolar provision in the Pharmaceutical Directive.** This should clearly include the supply of EU produced active pharmaceutical ingredients (APIs) for obtaining marketing authorisations, for conducting studies and for pricing and reimbursement administrative procedures (more information here).

Security of medicines supply

In addition to the efforts of our industry to invest in more resilient supply chains, the pharmaceutical legislation should dramatically improve the **prevention and mitigation of medicines shortages for patients**. To achieve this, the proposal should**:**

[1] Single Market Strategy of 2015, Charles Rivers Associates 2016, EC Roadmap to optimise the IP legal framework 2017, Max Plank institute study 2018, Pharmaceutical strategy 2020.

- **Harness the digital revolution for medicines supply and demand predictability and** to enable pre-emptive measures against shortages. National regulatory authorities and the EMA (European Medicines Agency) should be allowed to use **existing IT systems such as the European Medicines Verification System (EMVS) to forecast demand and supply.** The recently initiated dialogue between HERA, EMA and manufacturers of antibiotic medicines is a good starting point for such a policy. There should be a rapid (2030 at the latest) **replacement of cumbersome and out of date paper leaflets with electronic product information** to support rapid and more equitable supply allocation across EU member states when medicines shortages occur while avoiding duplication of paper/digital versions for manufacturers.

- **Prioritise an EU list of critical medicines with shortage prevention plans (SPP) that will enable manufacturers and authorities to focus resources.** This would avoid unnecessary duplications and administrative burdensome reports and submissions with no benefit for public health while facilitating prevention and mitigation actions by manufacturers and regulatory authorities. We underline that the compilation of different regulatory requirements on generic medicines which have very low capped pricing across Europe is a major risk of medicine shortages or unavailability.

- Similarly, **the extension of shortages notifications from 2 to 6 months would massively increase shortage "false alarms"** as happened in Italy and in Canada. **Notification of 6 months should be limited to major manufacturing changes** that present a risk such as the modernisation of production sites or technology transfers whereas unpredictable shortage risks should be notified as soon as the manufacturer is aware.

- While we s**upport efforts to improve the environment,** requirements in the Pharmaceutical Directive should **not duplicate already existing legislations regulating medicines manufacturing**.

Although outside of the scope of the Pharmaceutical Directive, it is also important that the EU engages in a coherent industrial strategy, a *Medicines Security Act*, that supports greater investment and market sustainability in medicines and API (Active Pharmaceutical Ingredient) manufacturing.

We consider this legislation to be critical for improving patient access, availability and security of supply of medicines and we remain at your disposal for any clarification you may need.

Yours respectfully

Elisabeth Stampa,
President of Medicines for Europe