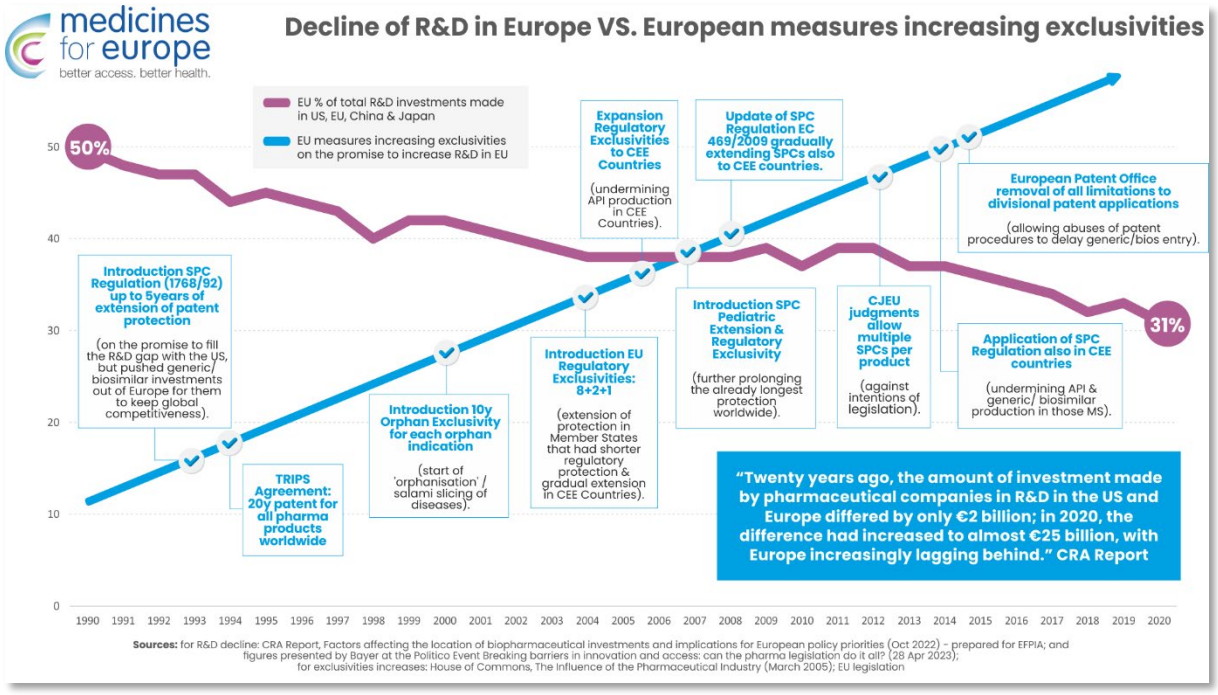
Brussels, 24th October 2023

OPEN LETTER: Members of the European Parliament and EU 27 Ministers of Health on the revision of the pharmaceutical legislation

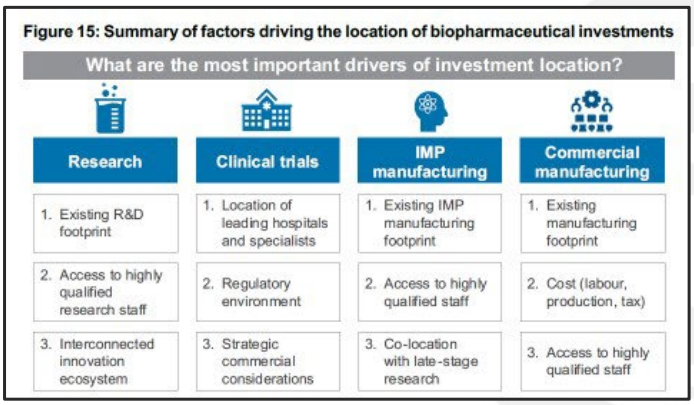
Medicines for Europe, the European association representing generic, biosimilar and valued added medicines manufacturing, is writing to underline the key principles that we support in relation to the reform of EU pharmaceutical legislation which is currently under review in the European Parliament and the Council. We globally support the initiative by the Commission to reform this legislation which needs to be adapted to the new realities of the EU pharmaceutical market. This legislation is critical to our industry and more importantly to public health. We should recall that the last 2004 pharmaceutical legislative reform, which improved generic medicine regulation and introduced biosimilar medicine regulation, led to a 100% increase in access to medicines from 2004-2014 thanks to generic medicines competition. In a similar vein, biosimilar medicines competition has saved EU healthcare systems over €30 billion and increased access for patients by 50%. We therefore urge you to pay particular attention to the sections of the legislation that encourage generic, biosimilar and value added medicines access in this legislative reform.

1) This first key principle of this reform is to ensure that the EU **foster more, not less, access to medicines**. We note with some surprise that the originator industry is claiming that the measures to support timely competition from generic and biosimilar medicines will undermine R&D investment in Europe. This could not be further from the truth. As the graphs below show, the EU has ratcheted up intellectual property and regulatory monopolies systematically since the 1990s. Yet, these increases in monopolies are correlated with a decline of R&D in Europe. This is because the evidence shows that the decline in R&D in Europe is related to other factors such as access to risk capital, cooperation between universities and industry and the consolidation of R&D activities, not to IP and other exclusivities.



Indeed, IP is not even mentioned among factors stimulating localization of R&D investments in the CRA report prepared for EFPIA

Figure 15: Summary of factors driving the location of biopharmaceutical investments



Sources CRA Report, Factors affecting the location of biopharmaceutical investments and implications for European policy priorities (Oct 2022)- prepared for EFPIA

On the other hand, there is clear evidence of the misuse of regulatory and pricing and reimbursement rules to delay competition from generic and biosimilar medicines across the EU. This is why it is fundamental to support a strong reform of the Bolar exemption (art. 85 of the Directive) that allows generic and biosimilar medicines development and approvals during the patent protection period. This measure will secure active pharmaceutical ingredients (API) manufacturing in Europe and to enable follow on competition on day 1 of patent/exclusivity expiry. The box below provides one illustration among so many of how misuse can cost healthcare systems dearly and undermine access to medicines for patients in need.

HIV medicines denied to patients

Truvada (Emtricitabine/Tenofovir): *Critical medicine for HIV prevention & treatment (reduce HIV transmission by 90%)*

Patent expiry: July 2017 **SPC expiry**: February 2020

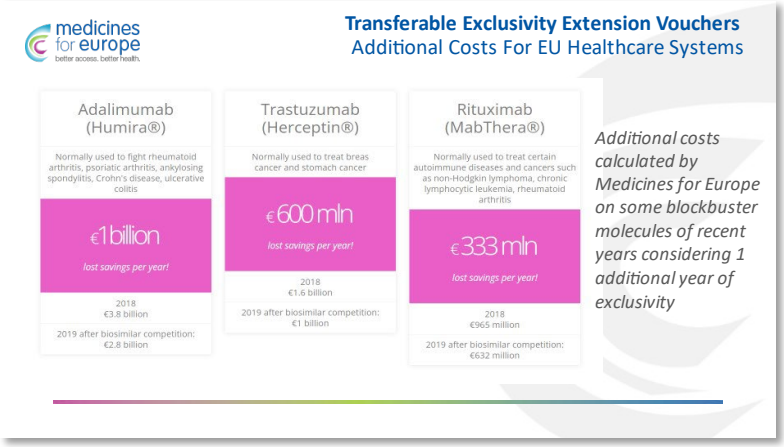
- The **SPC** invalidated in several EU national courts at different points in time & declared **illegitimate by the CJEU**
- Delayed national court decisions, **generics could NOT enter** those markets despite invalidating decision all around Europe

➢ Netherlands: generic reduced price for 30-day supply from €344,28 to €47,95

➢ Portugal: delay = **loss of €109 million** savings (1.1% of 2018 health budget), impacting treatment for **95.000 patients** !

We also strongly support a **balanced approach to incentivise R&D and repurposing of well-established (off-patent)** molecules regardless of whether the research is conducted by non-profit entities or by commercial companies like our members. Repurposing is an affordable way to address patient need and can complement the current model of relying solely on *de novo* drug discovery, contributing to the sustainability of the system. We strongly encourage making full use of this reform to stimulate innovation across a wide range of technologies: new indications, new formulations, and new combinations as this will affordably tackle many healthcare challenges such as ultra-rare diseases, availability of appropriate paediatric medicines, ensure better adherence for chronic conditions and reduce pressure on healthcare practitioners, particularly in the context of staff shortages.

We strongly encourage the Council to replace the current proposal for a transferable exclusivity voucher (TEV) for new antimicrobial drugs with an alternative, less costly solution to support access to reserve antibiotics. The TEV is nothing more than a coupon to extend monopolies on blockbuster drugs as the graph below shows. A better alternative would be an EU advanced purchase guarantee that would encourage innovation in antibiotic medicines.



2) Stronger together, which was the slogan for **EU solidarity** during the Covid-19 pandemic, is our second key principle for this legislation. The EU can no longer accept the huge differences in access to medicines between Western and Eastern or between big and small Member States. The conditional data exclusivity proposal does go some way to address this access gap, but it should be made more predictable for generic and biosimilar medicine developers so that we can play our role in bringing access when originators decide not to. The graph below shows the huge gaps in access to an important cancer medicine rituximab in Europe which has a direct impact on the health outcomes of patients.

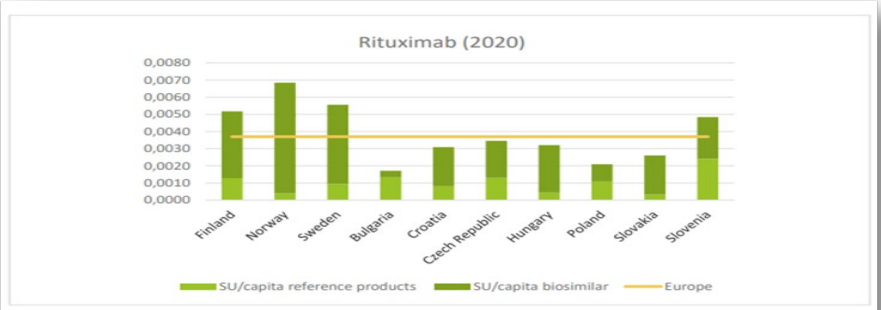


Chart 3: *Number of standard units per capita for rituximab in 2020. Source: IQVIA MIDAS MAT Q4 2020.*

We must also tackle some major problems in the EU Internal market that favour the richest European countries at the expense of the poorest countries. How can we accept, for example, that during last winter's surge in demand for antibiotic medicines, almost of the needed antibiotics in Romania were exported to the wealthiest EU countries? EU solidarity means that patients deserve access instead of market speculation. For this reason, we oppose the measures forcing our industry to supply wholesalers without any commitment from their side to supply patients in national markets.

3) Reducing medicine shortages is our third key principle for this reform. This reform needs to go further by ensuring more use of data to analyse and predict shortage risks – including the use of European medicines verification system (EMVS) data – for shortage prevention and mitigation, instead of a very burdensome reporting system difficult to manage/conclude on real risk. This is the only reliable data offering some overview of Member State supply and demand and it is shocking that we cannot advance this discussion with the EU.

We also call for a much clearer focus and harmonisation of shortage reporting requirements. Based on the new definitions of shortages and critical shortages, there should be harmonised, digital shortage reporting at national and EU level. Short risk management plans should be limited to critical medicines to avoid flooding medicines agencies with 400 000 documents that they do not have resources to manage. With targeted and digital reporting, we can facilitate close cooperation between manufacturers and medicine regulators to tackle this problem. We underline that the Commission communication, expected to be published in October, on a Critical Medicines Act (or something similar) is even more fundamental to encourage more investment in manufacturing and to stabilise generic medicine markets.

Finally, we must tackle the economic root causes of shortages, most notably, by including the reform of procurement with EU security of supply criteria and multi-award tenders.

4) Speeding up access to medicines through efficient regulation is our last key principle for this reform. Our industry accounts for 70% of prescription medicines and 80% of marketing authorisations. The efficient approval and maintenance of these 200 000-300 000 licensed medicines requires a new digital and more harmonised approach between the EMA and the network of national medicines agencies. Our regulatory network is confronted with shortages of staff and is therefore struggling to comply with legal deadlines for different regulatory procedures. We therefore urge the fast track of the measures to improve regulatory optimisation, for regulatory streamlining of biosimilar medicine approvals and global single development for complex generic medicines to avoid the duplication of studies and resources. We call for a flexibility through the scope of the Marketing Authorisation (MA) procedures to enable broader availability of medicines through the option of the centralised procedure while avoiding imposing the burden of the higher costs of the centralised procedure for smaller companies for whom the national routes might be more appropriate. We also call for a more coherent approach to the digitalisation of the medicine's agency network. Finally, the introduction of digital product information should be accelerated in the legislative proposal to reduce bottlenecks in the supply chain and improve the accessibility of information for patients and healthcare practitioners. Of course, we will work to find solutions for patients that may have limited access to digital tools.

Medicines for Europe is committed to ensure that this reform delivers better access to medicines, more EU solidarity, less medicine shortages and faster access to treatment. We look forward to working with you to deliver on these important principles throughout the legislative process.

Yours respectfully,

Elisabeth Stampa
President
Medicines for Europe