Medicines for Europe Executive Committee
Rue d'Arlon 50 - 1000 Brussels

Brussels, 26 November 2019

Re: Open letter from Medicines for Europe Executive Committee members to the next European Commission on medicines shortages

Shortages of medicines are a concern in many Member States, affecting patient access to the treatments they need, when they need them. This situation is of great concern and our industry is doing everything possible to compensate for the market fluctuations causing shortages. However, this also requires a policy response to tackle the root causes so that we can prevent shortages in the first place.

Generic medicine manufacturers supply close to 70% of prescription medicines in Europe. With their cost efficiency, generic medicines have doubled access to medicines in Europe for the most prevalent chronic diseases over the last 12 years. However, cost containment, industrial factors and new regulatory requirements threaten that. We are therefore calling on the next European Commission to prioritise shortage prevention in pharmaceutical policy during its first 100 days.

- Following the 2009 financial crisis, European countries introduced cost-containment measures impacting generic and biosimilar medicines to reduce pharmaceutical expenditure or to finance new medicines. For many years, our association has warned that extreme cost-containment measures – such as mandated price cuts, clawbacks and procurement mechanisms focusing on cost only – are unsustainable and lead to withdrawals of products and companies from the market. These measures, when combined with major manufacturing and regulatory changes globally, are now clearly affecting the most vulnerable medicines.
- Recently, China has started to consolidate its active pharmaceutical ingredients (API) industry to improve environmental protection and supply for its internal market, with a major impact on API supply to Europe.
- The implementation of the EU serialisation rules against falsified medicines considerably impacted production cost, complexity and capacity. Manufacturers have also adapted to political shifts such as Brexit – transferring licences and laboratory testing procedures for thousands of medicines and stockpiling to maintain patient access in the UK and in Europe. These changes have not only consumed resources that could have been invested in manufacturing, they have also increased the cost of goods, reduced production capacity and complicated the supply chain – further exacerbating supply constraints.

Faced with concerns over shortages, countries across Europe are now introducing stockpiling requirements and severe penalties to ensure supply for their patients. While we can understand the concerns, abrupt, short-term requirements will further increase risks and complexity for manufacturers and ultimately lead to more shortages. In addition, there is a very real risk that these national requirements will divert stock to their market at the expense of their neighbours.

We are witnessing a perfect storm of market and regulatory policies with changing manufacturing dynamics globally that are increasing the risk of shortages and/or supply problems. We need EU leadership to reconnect manufacturers, regulators and payers or procurers of medicines (on behalf of national health services) to encourage investment in manufacturing by reducing regulatory complexity and costs, removing unsustainable cost-cutting measures in the off-patent sector and rewarding access rather than penalising it. National efforts to address the root causes of shortages require EU level coordination based on a similar format as the German *Pharmadialog*[1] to enable an action-oriented dialogue between industry, regulators, payers and policy makers.

To guarantee a stronger supply of essential medicines to patients, Europe should:

- Establish a cooperation mechanism to coordinate EU and national policies to reduce the risk of shortages and to avoid spill over effects through which one country's policy would create supply issues in another country.
- Engage ministries of health and industry to identify policies to stimulate investment in manufacturing including:
    - Guidelines on medicines procurement under the EU procurement directive including how to recognise investments in security of supply for Europe;
    - Industrial and competition policy measures that could stimulate more investment in manufacturing and supply for Europe.
- Introduce measures to reduce the complexity and cost of EU regulation in the off-patent sector and to facilitate shortage mitigation, including emergency variation and new application procedures and measures to increase the attractiveness of supplying medicines for smaller European markets.
- Engage with ministries of health on cost-containment measures that have clearly reduced competition in the generic medicines sector.

The security of essential medicines supply is critical for Europe. Europe should preserve a vibrant generic and biosimilar sector to ensure equitable and sustainable access to medicines for European patients. Jointly with ministries of health, regulators, payers or procurers, we can deliver effective solutions and we call on the next European Commission to prioritise this issue.

Yours faithfully,

James Burt
Accord

Warwick Smith
British Generic Manufacturers Association

György Thaler
Gedeon Richter

Michele Uda
Assogenerici

Marc Alexander Mahl
Fresenius Kabi

Joris Van Assche
Medaxes

[1] See, for example, the recommendations by the German Regulatory agency BfArM: Recommendations to improve the delivery excellence of relevant medicinal products in hospital

Ana Martí
Medichem

Bork Bretthauer
Pro Generika

Christoph Stoller
Teva

Artur Cwiok
Mylan

Rebecca Guntern
Sandoz

Nick Haggar
Zentiva

Markus Sieger
Polpharma

Neeraj Sharma
Sun Pharma

Adrian van den Hoven
Medicines for Europe

Beata Stepniewska
Medicines for Europe

Medicines for Europe Communications:
Kate O'Regan
koregan@medicinesforeurope.com