

# MEMO

## Patient access to medicines: how to prevent medicine shortages? *European Parliament, 6 December 2017*

The sustainability of healthcare budgets in Europe has been intensely pressured by multiple factors, such as a growing and ageing population, an increased disease burden, the introduction and increased cost of new innovative medicines<sup>[1],[2],[3]</sup>. To overcome these challenges, several national authorities have adopted austerity measures and applied short-term cost-containment measures to pharmaceuticals, including to generic medicines despite their low cost (around 4% of total healthcare expenditure in Europe) and their relevance for care (62% of medicines dispensed today in Europe are generic medicines).

Short-term cost-cutting measures, such as *ad-hoc* price cuts, external reference pricing, payback, tendering, etc. have driven the prices of some off-patent medicines to unsustainably low levels. This causes manufacturers of generic medicines to withdraw from the market, resulting in the increased risk of medicine shortages<sup>[4],[5],[6]</sup>. The [evidence](#) now shows that many national markets across Europe are relying on too few suppliers for essential life-saving medicines in both the hospital and ambulatory sectors.

Tackling medicines shortages in a multi-source context, requires an approach that addresses both the root causes of medicines shortages and mitigates medicine shortages once they occur. Addressing the economic causes of shortages to ensure market predictability and competition, improving regulatory efficiency, improving transparency in supply chain and a proper and controlled communication are important measures to tackle medicine shortages. Please find more information on Medicines for Europe key recommendations to tackle medicines shortages [here](#) and the Economist Intelligence Unit report on medicine shortages [here](#).

The ALDE Group and Medicines for Europe gathered several stakeholders in the European Parliament to discuss the topic of [medicines shortages](#). The event was attended by representatives of the industry, the European Commission, the European Parliament, permanent representations, pharmacists, patients and academics. The discussion, led by Marc-Alexander Mahl, Medicines for Europe President, focused on unravelling the root causes for medicines shortages in Europe to better tackle the problem that affects all Member States.

It was noted by Lieve Wierinck, MEP ALDE, that Medicines shortages have a great impact on patients and their families. The causes are complex that can be tied to economic, regulatory and manufacturing issues. Long-term solutions need to be pursued by all involved to ensure access to essential medicines for patients.

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<sup>[1]</sup> [The Parliament Magazine. 2015.](#)

<sup>[2]</sup> [Eurostat Population Statistics](#)

<sup>[3]</sup> OECD, Fiscal Sustainability of Health Systems: Bridging Health and Finance Perspectives. 2015.

<sup>[4]</sup> SFK (Foundation for Pharmaceutical Statistics), Pharmaceutisch Weekblad. 2014.

<sup>[5]</sup> APM Health 2015. Available at: <http://www.apmhealthurope.com/home.php>.

<sup>[6]</sup> QuintilesIMS Health. An International Comparison of Best Practice Approaches to Drug Shortages. 2015.

Agnes Mathieu, Deputy Head of Unit, European Commission, shared the legal tools Member States have at their disposal to avoid and tackle medicines shortages, such as waiving some of the labelling requirements to mitigate a shortage. In addition, the European Commission is encouraging sharing of best practices among Member States and working closely with EMA/HMA taskforce on Availability of Medicines Products. Ms Mathieu agreed that fostering competition is important to maintain several manufacturers in the market and noted economic reasons as one of the drivers of Medicines Shortages.

The economic issues were further stressed by Cristian-Silviu Buşoi, MEP EPP, that mentioned the issue with the clawback tax in Romania and stressed that the innovative budget should be differentiated from the off-patent budget as the price decreases of generic medicines are linked with the increased spending on new innovative medicines.

Eddy Gilissen, VP Supplier Alliances, IQVIA, distinguished between short-term and long-term shortages, mentioning whilst the former are typically local and linked to distribution issues, the last are mostly related with economic issues, namely price drops. He also noted that manufacturers may leave the market for economic reasons and the lack of competition can make markets more susceptible to shortages. He concluded that when prices drop so low that the number of providers becomes very limited, this has implications on the sustainability of our healthcare system and the provision of pharmaceuticals and that dependence on non-EU imports can increase risk of supply issues.

These statements were corroborated with the example of Romania provided by Vlad Voiculescu, member of Romanian Health Observatory, who declared shortages in Romania to be due economic reasons, in particular the fierce pricing policies that led to several drugs being provided by a single supplier or even withdrawn from the market.

Eddy Gilissen, PhD-researcher, KU Leuven, stressed that pricing procedures and quality requirements seem to strengthen each other in causing drug shortages and, notwithstanding companies wanting to deliver high quality drugs, manufacturers will leave markets when profit-margins for generic drugs decrease and are too low, calling for a balance between quality requirements and prices of drugs.

Closing the event, Marc-Alexander Mahl observed that more predictability for manufacturers is needed in terms of what they will need to produce. He then stressed that to avoid shortages a multi-source market should be maintained and markets should avoid relying on a small number of manufacturers. Price-cuts, poorly designed tenders, reference pricing systems and disproportionate penalties have a negative impact on the number of manufacturers remaining on a certain market.