

European Union Ministers for Health

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Commissioner
Health and Food Safety
European Commission

Mr. Thierry BRETON
Commissioner
Internal Market
European Commission

Mr. Paolo GENTILONI
Commissioner
Economy
European Commission

Mr. Kadri SIMSON
Commissioner
Energy
European Commission

Brussels, 9th June 2022

SUBJECT: EPSCO (Health) Council - Open letter from Medicines for Europe Executive Committee to European Health Ministers and responsible European Commissioners on inflation impacting the supply of essential medicines

We, Medicines for Europe Executive Committee members, are writing to Health Council and the European Commission to express our concern over the impact of rampant inflation on the secure supply of essential medicines for European patients. Our industry supplies close to 70% of prescription medicines at very low cost to EU healthcare systems.

For the last decade, off-patent medicines have been subject to strict price regulation, budget austerity measures, and lowest-price tender rules, causing substantial price erosion and an unsustainable situation for manufacturers. This has been exacerbated by the Covid-19 crisis and the war in Ukraine, which has dramatically **increased general inflation, raw material and transportation costs.**

Inflation has risen in Europe to over 7% - a level not seen for decades, and this is combining with external factors exacerbating cost inflation for our sector:

- **Energy costs and supply:** The war in Ukraine has increased energy prices in the EU by 65% for gas and 30% for electricity¹ and some of our producers are at risk of having gas supplies rationed. This could directly and immediately impact the supply of medicines for Europe.
- **Logistics:** Transportation costs are increasing dramatically (up to 500%) due to the bottlenecks caused by the Covid-19 pandemic and the war in Ukraine. This impacts our production and delivery of medicines across Europe.
- **Inputs and raw materials:** Manufacturing input costs have risen by between 50-160%.
- **Skilled human resources:** General inflation is exacerbating human resource skill shortages for our specialist science-based industry.

Our industry operates in a highly regulated market where prices are set by national pricing and reimbursement authorities and subject to automatic price reduction measures known as reference pricing. Most Member States apply additional price reduction measures to our sector in the form of price freezes, clawback measures, mandatory rebates, rebate contracts and non-negotiable price reductions.

Our sector has a moral and a legal obligation to maintain the supply of essential medicines to Europe and we are fully committed to do so. However, our industry cannot operate in an environment combining rampant cost inflation with policies that continuously lower prices. We therefore call on the EU to help us tackle this challenging situation with sustainable policies that are aligned with European strategic autonomy.

- **Recognising the prescription medicines sector as critical in EU and national emergency plans for gas/oil supplies:** As medicines are essential goods, medicine manufacturing should be classified as essential in relation access to constrained energy supplies.
- **Warn of the potential risks for supply and availability:** Encourage Member States to address inflation under their Transparency Directive obligations related to availability and the efficiency of medicines production².
- **Adopt measures to mitigate the impact of inflation on cost of goods:** Companies should be able to adjust prices to the level of inflation.
- **Reform medicines procurement and pricing models:** the widely recognised link between medicine shortages and unreasonable tender practices³ and pricing systems must now be addressed as a high priority in EU law. Best practices such as multi-winner tenders and MEAT criteria should reward companies that invest in secure supply and the green and digital transition.

¹ (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022DC0138&qid=1649253932345>)

² The Transparency Directive aims to promote: “by ensuring the availability of adequate supplies of medicinal products at a reasonable cost; [and] (...) efficiency in the production of medicinal products.” <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32004L0109>

³ See Technopolis study on medicine shortages <https://op.europa.eu/en/publication-detail/-/publication/1f8185d5-5325-11ec-91ac-01aa75ed71a1/language-en/format-PDF/source-245338952>

- **Reduce the complexity and cost of regulatory compliance:** The Pharmaceutical Strategy⁴ includes a clear plan to improve the efficiency of pharmaceutical regulation by investing in digitalisation, such as e-leaflets, and reforming the variations regulation. These policies should be frontloaded to reduce the pressure on the availability of medicine.
- **Support EU manufacturing investment:** Given the huge disparity in energy and logistics costs between Europe and the competing regions, the EU must allow the generic industry to participate in EU resilience funded projects like the health Important Projects of Common European Interest (IPCEI)⁵.

Medicines for Europe has proven its commitment to medicines security of supply during the Covid-19 pandemic, its support to Ukraine and by re-investing in European medicines manufacturing. We stand ready to work together with the Commission and the Member States to ensure the current crisis does not undermine the access and availability of medicines.

Yours faithfully,

Signed

Medicines for Europe Executive Committee members

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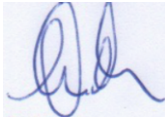
Artur CWIOK
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⁴ [A pharmaceutical strategy for Europe \(europa.eu\)](#)

⁵ [Launch of an IPCEI on Health Announced During the Ministerial Conference 'Towards an Independent, Competitive and Innovative European Healthcare Sector' - French Presidency of the Council of the European Union 2022 \(europa.eu\)](#)

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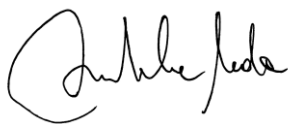
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