

European Union Ministers for Energy

c/c

European Union Ministers for Health

Mr. Kadri SIMSON
Commissioner
Energy
European Commission

Mrs. Stella KYRIAKIDES
Commissioner
Health and Food Safety
European Commission

Mr. Thierry BRETON
Commissioner
Internal Market
European Commission

Mr. Paolo GENTILONI
Commissioner
Economy
European Commission

Brussels, 27 September 2022

SUBJECT: Energy Council (TTE) – Medicines for Europe Open letter to European Energy Ministers and responsible European Commissioners on inflation and energy costs impacting the supply of essential generic medicines

For the last decade, off-patent medicines, which represent the 70% of dispensed medicines in the European Union, 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 (now over 9%), raw material costs** (risen by between 50-160%), **transportation costs** (up to 500%) **and energy prices**.

Gas and electricity prices have reached record levels in 2022 following the Russian invasion of Ukraine, and some of our producers are at risk of having gas supplies rationed or not being able to continue manufacturing activities due to the high prices. This is translating into electricity prices rising ten-fold for some of our factories in Europe. This threatens to undermine medicines supply and our industry's efforts to invest in manufacturing in Europe.

We welcome the work of the Council on gas storage and coordinated gas demand reduction which recognises the critical importance of maintaining medicines production operational. It is also imperative that the EU introduces measures to lower energy costs for the generic medicines sector which cannot legally increase prices anywhere in Europe due to reference pricing.

The recent Commission proposal¹ that will be discussed at the next Energy Council represents a positive step in this direction, but it should introduce **clear references to industrial sectors critical for the society**, to ensure that, regardless of the company size, they can benefit from the proposed derogation allowing Member States to apply interventions in price setting for the supply of electricity to SMEs (article 11).

In addition, it is essential that Member States **exclude the pharmaceutical industry from demand reduction measures** in their national gas security of supply emergency plans that should be updated by 31 October 2022, in line with the Commission "Safe gas for a safe winter" guidelines². We also request that the **off-patent medicines sector is included in the temporary crisis framework for State Aid measures** to support the economy following the aggression against Ukraine by Russia³.

These steps would be crucial to safeguard public health which relies on inexpensive off-patent medicines for pharmaceutical care. Any shutdown of production, even temporary, would have detrimental effects on the supply of medicines to patients and would demand a significant effort and long delays to resume operations. Several medicines (e.g. sterile, biological substances and antibiotics) are produced with highly specialized heating and cooling for their production and delivery to hospitals and clinics or require energy-intensive processes for active ingredient or formulation production. This requires a continuous supply of energy at affordable prices and, which enable European manufacturers to compete with China where industrial energy prices are controlled.

While all of our suppliers are increasing their costs, our sector cannot adjust prices for their products. We operates in a highly regulated market where medicine 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 medicines in the form of price freezes, clawback measures, mandatory rebates, rebate contracts and non-negotiable price reductions. This combination of cost inflation and price control policies threatens the availability of medicines and makes EU manufacturing unsustainable.

¹ (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0473>)

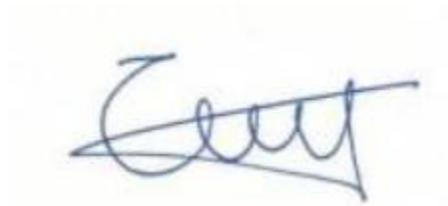
² (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022DC0360&qid=1658479881117#document2>)

³ (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02022XC0324%2810%29-20220720>)

Our sector has a moral and a legal obligation to maintain the supply of medicines to Europe and we are fully committed to do so. However, we 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.

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,



Elisabeth Stampa
President
Medicines for Europe