

TO:

Ms. Ursula von der Leyen
President
European Commission

Ms. Stella KYRIAKIDES
Commissioner Health and Food Safety
European Commission

Mr. Thierry BRETON
Commissioner Internal Market
European Commission

Brussels, 14 June 2023

Subject: Supporting Statement for the Council Non-paper on Improving the Security of Medicines Supply in Europe

Dear President von der Leyen,

On behalf of Medicines for Europe Executive Committee and European Fine Chemicals Group Board – a CEFCIC sector group -, we are writing to express our strong support for the [Non-paper on Improving the Security of Medicines Supply in Europe](#), as led by the Belgian delegation to the Council of the EU on 2 May 2023 and currently adhered by twenty-one EU Member States: [(BE, AT, NL, LU, HU, CZ, ES, FR, DE, EE, SI, RO, LV, LT, EL, MT, PL, IT, PT, DK, HR)].

As trade associations representing off-patent medicines and Active Pharmaceutical Ingredients (APIs) large, medium and small companies in Europe, directly providing highly skilled jobs, investing heavily in manufacturing R&D and accounting for 24% of API global production and 70% of prescription medicines supplied in Europe, this initiative demonstrates a comprehensive understanding of the complex challenges faced by the European pharmaceutical industry and addresses a pressing concern: the need for a coordinated and robust approach to safeguard the medicine supply chain in Europe. We commend Belgium and the Member States for taking the lead in addressing this critical issue and promoting measures that can strengthen the security of supply and availability of medicines across Europe.

The following key aspects of the non-paper resonate strongly with our industry:

1. Strengthened collaboration among stakeholders to alleviate medicine shortages: We appreciate the non-paper's focus on fostering collaboration among various stakeholders, including

Member States, API and medicines manufacturers and wholesalers sharing information on critical medicines stock levels and facilitating stock transfers between EU countries. The EU solidarity mechanism facilitates a cohesive approach that will ultimately benefit patients in situations of acute shortages where demand surges can be multiples of normal consumption¹ and thus provides a more rational response to potentially contradictory national stockpiling obligations. The solidarity mechanism should also be aligned with market realities to ensure that companies responding to a shortage are not inadvertently penalised if stock is shipped from another member state. Further, our members call for the fast-tracking of the regulatory optimisation measures put forward in the Pharmaceutical Directive and Regulation that facilitate production in the event of actual or anticipated supply tensions.

2. A European list of critical medicines: We support the need of accelerating the work on a harmonised EU list of critical medicines in the new pharmaceutical legislation (art.131), which is based on therapeutic criteria (criticality of the medical condition and existence of therapeutic alternatives) but also on industrial criteria (vulnerabilities of the value chain, mostly due to the consolidation of suppliers and to geopolitical risks, manufacturing technology constraints). Our members are committed to supporting these efforts by accelerating the implementation of the digitalisation of regulatory dossiers which would provide the EU with clear data to identify consolidation-linked vulnerabilities. Clearly, the EU should avoid placing unnecessary regulatory burdens on critical generic medicines that are subject to well-documented pricing policy pressure.
3. A Critical Medicines Act: The proposal to complement the EU pharmaceutical legislation with this Act could not be, in our opinion, more correct. Boosting investment in API and medicines production capacities and securing the long-term viability of our industrial facilities is a necessary and fundamental part of any reform to be undertaken in our sector to strengthen the European strategic autonomy in healthcare. It would also lead to the re-industrialisation of the EU in line with the New Industrial Strategy for Europe.² Moreover, the sustainability of our industry is only possible by adjusting current pricing and public procurement policies, particularly for mature products as documented in the recent study of the Commission³, which has led to aggressive price reductions and ultimately resulted in the consolidation and globalisation of API and medicines production. An EU guideline on the security of supply and green criteria for medicines procurement would go a long way to improving the sustainability of supplies across Europe.

In conclusion, EFCG and Medicines for Europe call on the Commission to fast-track the regulatory optimisation proposals of the Pharmaceutical Strategy, to initiate legislation to support manufacturing

¹ In 2020, the demand for ICU medicines during the Covid pandemic increased between 300-900%. In 2022-2023, the demand for paediatric antibiotic forms rose by 300-500%.

² eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0102

³ Study on best practices in public procurement of medicines (Gesundheit Österreich GmbH) <https://op.europa.eu/en/publication-detail/-/publication/ca856a7f-7c37-11ed-9887-01aa75ed71a1/language-en>

and to develop guidance for the security of supply in procurement in response to the Non-paper on Improving the Security of Medicines Supply in Europe as requested by twenty-one EU Member States and supported in multiple Parliamentary reports. We applaud the collaborative efforts of the Member States and urge the Commission and engaged stakeholders to work together to translate this crucial initiative into legislation and policy initiatives that complement the pharmaceutical legislation and thus effectively ensure the availability of medicines, reinforce patients' confidence and strengthen the competitiveness and future Europe's pharmaceutical sector.

Yours faithfully,



On behalf of Medicines for Europe

Elisabeth Stampa, President



[Steffen Denzinger \(Jun 12, 2023 14:26 GMT+2\)](#)

On behalf of EFCG

Steffen Denzinger, President

About Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value-added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information, please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.

About EFCG

EFCG, The European Fine Chemicals group, represents the European manufacturers of Fine Chemicals, Intermediates and Active Pharmaceutical Ingredients (APIs). Our members are the backbone of the pharmaceutical supply chain, supplying its essential building blocks and our vision is to help create a world where access to safe and good quality nutrients and innovative medicines is guaranteed for all. We promote a fairer and safer environment for future generations and we champion sustainable processes and enforced regulations that deliver safe products and enhance growth, employment and environmental performance. EFCG upholds the highest quality and safety standards in our industry and strongly advocates for all companies producing and selling in the EU to be held to the same high standard.

EFCG operates as a Sector Group within Cefic, the European Chemical Industry Council. Founded in 1972, Cefic is the voice of large, medium and small chemical companies across Europe, which provide 1.1 million jobs and account for 15% of world chemicals production. *EU Transparency Register n° 64879142323-90