A STRONG EUROPEAN API INDUSTRY CAN ACHIEVE STRATEGIC AUTONOMY OF THE EU HEALTH SYSTEM

November 2022

The COVID-19 pandemic highlighted the vulnerability of the EU health system and accelerated the need for a new and radical strategy to strengthen its autonomy.

The EU pharmaceutical supply chain is fully committed to improving the security of supply of medicines, innovating and upgrading manufacturing technology and processes, reducing environmental footprint and creating growth and jobs, all of which will help achieve the EU goal of an **Open Strategic Autonomy** of our Health Industry. Industry is also committed to increasing availability and access to affordable medicines.

Europe's Active Pharmaceutical Ingredient (API) production must be at the centre of any journey towards strategic autonomy. APIs are the key components of pharmaceuticals, responsible for their therapeutic effects. Producing APIs safely and sustainably requires cutting-edge Research & Development facilities, enabling the transition from laboratory scale to pilot plant and then to full industrial scale.

Today, API Production in Europe is in a worrying decline. From a global production share of 53% in 2000, the 2020 share tumbled to 25%. Europe has become dependent on other regions for APIs: 56% currently originate from India and China[1]. Many critical APIs are no longer produced in Europe as illustrated with the striking example of Metoprolol, used for high blood pressure. Formerly produced in the EU, it is currently produced mainly in China and India as 16 of these EU sites have stopped producing it. Similarly, Gabapentin, a treatment for epilepsy, now comes mainly from India after 10 EU producers stopped the product. These are just two examples of the many molecules for which Europe is dependent on other regions, creating a risk for the security of supply.

If we take into account key raw materials and intermediates, this dependency becomes even more critical as the EU relies for 74% on other world regions for the manufacturing of its APIs. The decline is exacerbated by the offshoring to these regions of key technologies and processes.

There are multiple reasons for the shift of API production to other regions. At their source is the extremely low price imposed on the finished drug which in turn requires low-priced APIs. Other reasons include:

1. **The impact of the cost of compliance with EU social and environmental standards on manufacturing costs.** While they are pillars of our European way of life, such standards imply additional costs for API production – up to 30% of expenditure - that other world

[1] Source: APIs facts & figures infographic, https://efcg.cefic.org/library/infographics/

regions do not bear**.** These costs have favoured the relocation of production capacities to Asia.

2. **Public procurement that focuses on price alone as a decision factor** to the detriment of other values such as social responsibility, security of supply and environmental footprint.
3. **Lack of dedicated investment, support and incentives to stimulate European API production and innovation in greener manufacturing processes**. For example, manufacturers in India can benefit from a 2021 PLI scheme that rolled out manufacturing incentives.
4. **Heavy administrative burdens and slow analogue processes** that unnecessarily suck up valuable time and financial resources.

Turning the tide: Recommendations to increase Europe's API production

Financial, policy and administrative support mechanisms are necessary to maintain API production in Europe and to drive relocation.

1. Investment enhancement

National governments and the EU must support investments that stimulate the construction or modernisation of production facilities, as well as in cutting-edge manufacturing technologies. From a mainly SME base, API production involves bespoke technology and dedicated production lines with investments of between €50 and 180million per infrastructure and a completion time frame of three to six years. Elaboration of a financial - legislative framework for API investment in Europe would accelerate the re-location of production and prevent the extinction of current activities.

2. Support for competitive pricing

Public funding schemes from member states and at EU level can bring about a competitive environment using, for example, mechanisms modelled on agricultural policy subsidies. Public funding schemes should also be available for hiring staff and for training in the skills needed for high quality European API production.

3. Environmental protection

By financially incentivising and rewarding expenditure on environmentally friendly manufacturing, the EU would encourage industry to accelerate investment in Europe and will facilitate the Green Transition.

The EU should also talk to other regions to ensure that all work cooperatively to minimise environmental impact and climate change.

4. Lighter and faster administrative procedures

These should include:

- **Fast-tracking approval** for sustainable processing technologies such as new environmentally-friendly synthesis routes.
- **Digitalisation of regulatory processes** such as processes for registration and filing of changes in substances and procedures.

5. Non legislative support measures – levelling the playing field

Authorities in reimbursement and procurement policy should move towards using **non-price related criteria**, such as backward integration of raw materials and intermediates, process innnovations and improvements and social and environmental factors to reward the production of APIs in Europe.

Reimbursement decision makers should recognise that the pressure on the price of mature molecules and the successive price cuts have their limitations. Price erosion should not be allowed to go beyond the point where production is no longer financially viable.

The **pricing doctrine** for mature drugs **should be adapted to reflect their industrial, environmental and social benefits** and to reflect their role in maintaining **security of supply and increase access to medicines**.

A threshold price for mature medicines which takes into consideration the over-consolidation of API production must be introduced**.** Where this is demonstrated, payers could introduce changes to the generic reference price system – similar to the Canadian "ladder" model.

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.

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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