POSITION PAPER

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BUILDING A RESILIENT AND SUSTAINABLE EU HEALTH INDUSTRY

Europe's health sovereignty and the resilience of our pharma industry have been partially lost.

The unprecedented global health crisis caused by the Covid-19 pandemic has hit Europe particularly hard and has highlighted the weaknesses of our continent in terms of health autonomy. Europe was formerly the global hub for the synthesis of pharmaceutical ingredients but it has gradually lost its ability to **manufacture** critical molecules (not only APIs but also their precursors) that form the composition of essential medicines.

As a result, the European medicines supply chain depends for more than 74% on supplies sourced from Asia.

Europe's extreme dependence on other world regions poses an unacceptable risk for the European healthcare system**.** In recent years, increased occurrences of shortages of essential medicines in Europe not only constituted a health safety risk for patients but also placed a very heavy financial burden on healthcare systems.

Europe's health sovereignty will depend on its ability to maintain and develop its existing industrial base as well as investing in new technologies to selectively reshore essential medicines supply chains.

Other world regions have wasted no time in launching strong initiatives to ensure their health sovereignty. The United States administration has issued an "Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States" whilst China has its "Dual Circulation Model", India its "Self-Reliant India" Initiative and Japan its "Economic recovery plan for the pharmaceutical chain", to mention but a few.

Europe cannot afford to fall behind and must implement, as quickly as possible, robust measures that will ensure its own strategic autonomy and maintain its global competitiveness.

Our proposal

In order to address these problems, we propose a series of measures to be rapidly implemented at EU level within the framework of the Pharmaceutical strategy.

1. **Define, validate and regularly update a list of essential medicines, for which long-term supply must be guaranteed**
    - This list, to be coordinated centrally at EU level, should be based on objective criteria, such as (i) therapeutic interest; (ii) existing shortages; (iii) vulnerability of the value chain and especially the lack of or insufficiency of production capacity in Europe. It should also indicate the relevant quantities of essential medicines needed.

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- This will allow the continuous monitoring of and assessment of any risks of supply disruptions over the value chain in the short to medium term.

2. **Reinforce the requirements of health authorities in terms of security of supply of essential medicines**
   - Reduce to the strict minimum sourcing from producers who cannot guarantee reliability of supplies.
   - Develop an economic framework that promotes European-based manufacturers by ensuring that the EU demand of essential medicines be partially covered by medicines, active ingredients and precursors manufactured in the EU.

3. **Support existing European producers in the reshoring of critical technologies that guarantee the supply of essential medicines**
   - Provide targeted financial support for investment in capacity and innovation needed to manufacture essential medicines and their associated supply chain in Europe, allowing critical technologies to be reshored.
   - Ensure the rapid implementation at EU level of regulatory registration (CEP) when there is no existing European producer of the active substance.
   - Simplify regulatory procedures in order to accelerate registration of the active ingredient and its listing at national or European level.
   - Simplify the procedure for changing Registered Starting Materials (RSMs) and precursors suppliers.
   - Prioritise regulatory registration applications for molecules defined as strategic.

4. **Strengthen existing EU industrial base within high-performance facilities**
   - Target the reshoring of essential medicines supply chains to facilities that are deemed to be compliant with the strictest standards in terms of safety, quality and respect for the environment.
   - Maintain and encourage a dynamic and decentralised industrial base that will be the springboard for the development of future innovation.

5. **Accelerate research, development and sustainable industrialisation of innovative technologies.**
   - Support innovation and industrialisation of breakthrough technologies that combine competitiveness, sustainability, quality and respect for the environment.
   - Rationalise and focus incentives on a few strategic areas, improve the support system for research and innovation and simplify its access, opening it to small innovative companies.
   - Reinforce European excellence in the field of pharmaceutical synthesis (chemistry and biotechnology) while supporting research and education in this field at EU level. This can be done for instance through:
     i. promoting a European Network involving industry, academia and technology suppliers;

ii. stimulating association between industries for the application of innovative technologies;
iii. supporting the creation of multidisciplinary technological hubs;
iv. funding University courses and PhD programs to build strong skills in API synthesis and production processes.

- Improve mechanisms for assigning funds, incentivising the creation of spin-off and innovative startups.

6. **Impose for EU joint procurement and public tenders the implementation of sustainable supply practices that comply with European standards in terms of quality, safety and respect for the environment**.
   The purchase price cannot be the only criterion for the choice of a supplier in calls for tenders, particularly for public hospital contracts:
   - In addition to quality criteria (GMP), introduce environmental and safety criteria, as is common practice for private contracts;
   - Take into account the location of the production sites as well as the investments made in Europe;
   - Introduce an obligation to choose at least one supplier who produces in Europe. The impact of this measure on the cost of the final medicine would be minimal and not exceed 5%.

Existing European intermediates and APIs manufacturers represent around 600 sites all across Europe. They are the ultimate guarantees of Europe's health independence and provide critical molecules along the value chain of essential medicines and adapting their production to the needs of the Healthcare Industry, especially during medical crises.

EFCG members are part of the solution and they will provide a strong base on which to continue building a resilient and sustainable European pharmaceutical industry. Europe can rely on their existing facilities and their capabilities to maintain and develop their competences while ensuring full resilience of essential medicines value chains.

About EFCG

EFCG was formed in 2004 to be the focus, forum and voice of the European fine chemicals and Active Pharmaceutical Ingredients manufacturers. We are a non-profit international sector group within Cefic, the Brussels-based European Chemical Industry Council.

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