C/2024/1568

5.3.2024

Opinion of the European Economic and Social Committee on Securing Europe's medicine supply: envisioning a Critical Medicines Act

(exploratory opinion requested by the Belgian Presidency)

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Referral	Request by the Belgian Presidency of the Council 10.7.2023
Legal basis	Article 304 of the Treaty on the Functioning of the European Union
Bureau decision	19.9.2023
Section responsible	Consultative Commission on Industrial Change
Adopted in section	9.11.2023
Adopted at plenary	13.12.2023
Plenary session No	583
Outcome of vote (for/against/abstentions)	169/0/1

1. Conclusions and recommendations

1.1. The Committee calls for an urgent and robust action plan to attract the production of active pharmaceutical ingredients (APIs) and finished medicines to the European Union. It urges the European Commission to set up a new, comprehensive EU mechanism to support the production of APIs, the API market and finished medicines in the EU. The main advantage of this new potential framework is that it has to lead to relevant EU legislation which takes into account the specific nature of the production of, and trade in, active substances.

1.2. The European Economic and Social Committee (EESC) highlights the importance of mitigating dependencies and at the same time strengthening the resilience and the strategic autonomy of the EU. It therefore recommends introducing suitable legislative measures to enhance the existing production of pharmaceuticals in the EU Member States and support European pharmaceutical production capacities with regard to the entire supply chain. In this respect, the European Commission, together with the Member States, should introduce appropriate administrative and financial incentives to favour already existing pharmaceutical manufacturers in the EU and encourage the relocation of production from third countries in order to strengthen our resilience in terms of access to medicines.

1.3. The planned activities will also have a positive impact on research and development (R & D) activities, the labour market, the development of new market branches and restoring the EU's image as an attractive place to work.

1.4. Access to active substances and essential medicines becomes a 'weapon' in geopolitical games, which is why the EU must be independent in the production of these strategic resources. Compensating for the difference in production costs between the EU and Asia is a necessary cost of strengthening the security of EU citizens and must come from new, dedicated EU funds. In order to ensure the highest possible availability of these strategic resources, urgent action by the European Commission is necessary to restore and rebuild the production of these products in various geographical regions of the EU.

1.5. Current challenges facing the pharmaceutical industry include dependence on Asia for the production of active substances and population medicines, i.e. generics, and rising production costs, including expenditure on materials and energy. However, there are growing concerns that further increases in energy prices could lead to problems in this supply chain as an increasing number of companies reduce their production capacity, which could impact pharmaceutical production.

1.6. To strengthen the European pharmaceutical industry, we need to reduce dependence on Asia and the USA, increase investment attractiveness, stimulate research and development efforts and review pricing policy, and create financial and institutional support in order to restore the production of active substances and essential medicines, i.e. generics, in the EU. Action must be taken with the European Health Data Space in mind. The European Health Data Space will help the EU achieve a quantum leap forward in the way it delivers healthcare to citizens across Europe. It will enable citizens to control and use their health data in their home country or in other Member States.

1.7. One of the challenges we face as patients and EU healthcare systems is medicine waste. Therefore, the European Commission should consider actions to counteract this phenomenon. Taking into account the above and the phenomenon of drug shortages, actions should be taken to better manage the availability of pharmaceuticals. In this perspective, it is worth promoting the idea of pharmaceutical care and the pharmacy as a place of coordinated patient care.

1.8. In order to maintain patients' access to affordable therapies, the intellectual property (IP) framework should not hamper the development and market launch of generics/biosimilars and hence price competition. The debate on fair pricing as well as transparency of R & D costs for medicines is therefore strongly supported by the EESC.

1.9. The European Commission should also consider increasing independence for the medical use of personal protective equipment and medical devices.

1.10. A Critical Medicines Act, which should take the form of an EU regulation, would provide an overarching regulatory framework for the following:

1) a legislative framework setting out the process for choosing which APIs are to be reshored in Europe;

2) a financing mechanism to develop industrial infrastructure for producing APIs and finished medicines in Europe (R & D, investment in infrastructure and technology and operating costs during the financing period);

3) relevant EU guidelines on pricing in the European market for finished products, and on reimbursement so that APIs and finished medicines produced in Europe can be competitive.

2. **Background to the opinion**

2.1. The European Commission communication on a *Pharmaceutical Strategy for Europe* describes the EU's pharmaceutical industry as 'strong and competitive', providing 800 000 direct jobs, a trade surplus of EUR 109,4 billion and a major contribution to investment in research (more than EUR 37 billion in 2019) ([1]). The EU is the world's second largest pharmaceutical market ([2]). Unfortunately, the EU has experienced a decline in competitiveness in recent years, resulting in the relocation of production, jobs and clinical research and development to Asia and the USA. Over the past two decades, the investment gap between the US and the EU has grown from EUR 2 billion to a staggering EUR 25 billion, representing a thousand percent increase in the disparity. Consequently, Europe has witnessed a loss of vital pharmaceutical know-how and an increasing dependence on other regions, particularly Asia, while grappling with supply chain challenges in the pharmaceutical product sector.

2.2. The health and life of European patients should not depend on the import of APIs and essential medicines from other regions of the world. In order to ensure the highest possible availability of these strategic resources, urgent action by the European Commission is necessary to restore and rebuild the production of these products in various geographical regions of the EU.

([1]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a *Pharmaceutical Strategy for Europe* (COM(2020) 761 final, 25 November 2020).
([2]) COM(2020) 761 final.

2.3. The EESC is particularly concerned about the EU's current dependence on the supply of active substances from third countries. Medicine shortages have increased in European countries over the last decade, with the situation worsening during the COVID-19 pandemic. Concerns have been raised that outsourcing production of active pharmaceutical ingredients (API) and finished medicinal products to Asia may have led to more disruptions in the pharmaceutical supply chain. The experience of the COVID-19 pandemic has shown that, in the event of a crisis, countries with a strong local pharmaceutical industry tend to concentrate the production of their domestic players in the national market, thereby driving down foreign demand. In reality, complex, globalised but insufficiently diversified pharmaceutical production and supply chains are already having an adverse effect on Europe and are likely to do so in future unless remedial action is taken. The increasing instability of international relations can only make this threat worse.

2.4. Growing dependence on raw materials for production of medicines imported from Asia has led to a partial loss of own production capacity. Until the mid-1990s, Europe and the United States supplied 90 % of the substances used in worldwide pharmaceutical manufacturing. Today this figure is only 20 %. What is more, non-European manufacturing capacity for API and API-related materials is concentrated in a single region and in only a few production facilities. In 2019, 40 % of the world's APIs were imported from China, and over 50 % of the world's API were produced by fewer than five manufacturers certified to conform with European Pharmacopoeia monographs (CEP) ([3]). On top of this, the vast majority of the world's API producers depend on China for the supply of the intermediate materials needed to produce APIs ([4]). Several technologies required to produce raw materials are no longer available in the EU ([5]). The EU's remaining production includes a number of unique APIs (only one or two producers remain). The further phasing out of these manufacturing capacities will make reshoring extremely difficult, costly and time-consuming.

2.5. In Europe, most production facilities are located in the following countries ([6]):

— Italy (63 sites),

— Germany (54 sites),

— Spain (44 sites),

— France (43 sites).

Overall, there are around 440 API production sites in Europe, producing a total of 554 APIs ([7]).

2.6. Several policy documents (including some commissioned or drawn up by the European Parliament, the Council and the European Commission) and studies have looked into the production of APIs in Europe (often referred to as local production) as a potential solution to prevent or at least reduce medicine shortages. The documents acknowledged that reshoring API production would be difficult and involve high costs (particularly investment and wage costs) and regulatory changes. Nevertheless, it was viewed favourably, not only as a way of strengthening the supply chain and reducing disruptions, but also as a means of improving quality.

2.7. The pharmaceutical industry is already subject to the highest environmental protection standards. It is worth pointing out that imposing further requirements in this area should not constitute a development and competitive barrier.

([3]) Working Document on *Improving the security of medicines supply in Europe*.
([4]) Working Document on *Improving the security of medicines supply in Europe*.
([5]) COM(2020) 761 final.
([6]) *Potential measures to facilitate the productions of active pharmaceutical ingredients (APIs)*, Policy Department for Economic, Scientific and Quality of Life Policies, Directorate-General for Internal Policies. Authors: Stefan FISCHER, Verena KNOLL, Frank ALLEWELDT, Sabine VOGLER. PE 740.070 — March 2023.
([7]) *Potential measures to facilitate the productions of active pharmaceutical ingredients (APIs)*.

2.8. Pharmaceutical waste is an undesirable phenomenon from every perspective.

Taking into account the above and the phenomenon of drug shortages, actions should be taken to better manage the availability of pharmaceuticals. In this perspective, it is worth promoting the idea of pharmaceutical care and the pharmacy as a place of coordinated patient care.

3. **Key courses of action**

3.1. The pharmaceutical industries in the EU face a number of structural problems. Research and development (R & D) in these sectors have seen an alarming decline, especially in critical areas. Moreover, the security of vital research and development knowledge is at risk due to espionage concerns. In addition to these challenges, price regulation of pharmaceutical products in the EU poses another important problem, especially from the perspective of restoring and developing the existing industry producing active substances and essential medicines, i.e. generics, ensuring the drug safety of EU citizens.

3.2. To strengthen the European pharmaceutical industry, we need to reduce dependence on Asia and the USA, make investment more attractive, stimulate research and development efforts and review pricing policy, and create financial and institutional support in order to restore the production of active substances and essential medicines, i.e. generics, in the EU.

3.3. The current rules do not support pharmaceutical production in Europe. European producers are squeezed out of domestic and foreign markets due to increases in the costs of running a business, inflation and the need to comply with strict environmental standards, leading to a loss of price competitiveness and sales volumes. The lack of support for European manufacturers makes the production of APIs and finished medicines unprofitable for European producers when compared with their Chinese or Indian competitors.

3.4. To strengthen the European pharmaceutical sector, we need financial and institutional support for the production of active substances and essential medicines, i.e. generics, in the EU, more public-private partnerships, labour standards, subsidies, increased support for research and development (especially in the field of active substances and population medicines, i.e. generics), a sustainable legal framework, support for entrepreneurs, prices 'made in Europe', location clauses in public procurement, transparency, supply chain stress tests, strategic reserves created and replenished from EU production, limited bureaucracy and an attractive environment for researchers, labour and running businesses.

3.5. Innovation is not only about the most expensive medicinal products covered by patent protection. According to the OECD definition, innovation cannot be considered only as a technological benefit. The socioeconomic benefit is equally important, and introducing an equivalent (generic and biosimilar) medicinal product to the market changes its structure, making the therapy more affordable and building the country's economic growth. A narrow understanding of innovation deprives the European pharmaceutical industry of the opportunity to expand its competencies and build a competitive advantage, which translates into lost benefits both in the field of healthcare and the entire economy. Many innovations also involve changing production technologies to be less energy-intensive, more environmentally friendly or more cost-effective. New forms of medicinal product administration or combining several healing substances in one product are also innovations. This improves patients' quality of life and improves compliance with medical recommendations.

3.6. Specific investments are needed to bring the production of APIs and finished medicines back to Europe on the scale required to ensure the safety of medicines in the EU. The cost of producing a single active substance, depending on the required synthesis technology, is estimated at between EUR 50 and 180 million, with a timeframe of between three and six years.

3.7. A Critical Medicines Act, which should take the form of an EU regulation, would provide an overarching regulatory framework for the following:

1) a legislative framework setting out the process for choosing which APIs are to be reshored in Europe;

2) a financing mechanism to develop industrial infrastructure for producing APIs and finished medicines in Europe (R & D, investment in infrastructure and technology and operating costs during the financing period);

3) relevant EU guidelines on pricing in the European market for finished products, and on reimbursement so that APIs and finished medicines produced in Europe can be competitive.

3.8. The European Commission should also consider increasing independence for the medical use of personal protective equipment and medical devices.

3.9. In order to maintain patients' access to affordable therapies, the intellectual property (IP) framework should not hamper the development and market launch of generics/biosimilars and hence price competition.

3.10. The debate on fair pricing as well as transparency of R & D costs for medicines is therefore strongly supported by the EESC.

3.11. Action must be taken with the European Health Data Space in mind. The European Health Data Space will help the EU achieve a quantum leap forward in the way it delivers healthcare to citizens across Europe. It will enable citizens to control and use their health data in their home country or in other Member States.

4. **Financing mechanism to build industrial infrastructure for producing APIs and essential medicines**

4.1. The mechanism would be designed as a European fund for API and essential medicines, managed by a central EU authority (this power may be delegated to an existing institution/agency, e.g. the Health Emergency Preparedness and Response Authority (HERA)), with the support and financial commitment of Member States, the European Investment Bank, as well as private actors (banks, investment funds, etc.).

4.2. The fund would finance infrastructure development in individual Member States, for selected strategic APIs and essential medicines, by allocating resources according to specific rules (e.g. population, capacity, existing industrial technologies and infrastructure capacity).

4.3. The production of active substances and population medicines supported by European funds should be subject to geographical diversification and diversification in relation to external threats, such as armed conflicts near the EU borders. Moreover, these must be long-term investments that actually increase and ensure the EU's overall resilience.

5. **API and essential medicines trade finance mechanism in Europe**

5.1. Given the specific nature of the API market, in particular the price competitiveness of products offered by non-European operators, it makes sense to set up a European trade market financing mechanism for APIs and essential medicines manufactured in Europe.

5.2. This mechanism could be based on the following:

1) The basic instrument would be a decision to set a minimum price for a finished medicine on the basis of an API and essential medicines produced in Europe, the implementation of which would be the responsibility of the insurer/payer. The decision would be issued at the request of a European API and essential medicines manufacturer on the basis of clear and transparent criteria confirming the EU origin of the API and essential medicines. The minimum price would be granted for a certain period for a specific product and could not be subject to a non-EU supplier's competitive price discount policy.

2) An EU register of decisions on setting minimum prices for such medicines would be available online and have the status of a public register.

3) Given the specific nature of the market, it would not be advisable for the legislation to strictly define the concept of 'European API'; instead, it should set out the boundary conditions for such a classification, which could be adapted to the product category in the decisions by the granting authority. With this in mind, it can be assumed that the requirements for a product to qualify as a European API would be tightened as European API production develops and dependence on non-European intermediates decreases.

5.3. This key mechanism for ensuring the API and essential medicines trade in the EU, as described above, could be further enhanced with the following:

1) Preference in public procurement tenders (non-price criteria) for European APIs and essential medicines. Detailed procurement guidelines would be issued by the European Commission;

2) Intervention purchases — by the fund — of APIs and essential medicines from a given producer or producers, in the event of market situations as defined in EU legislation on medicine safety;

3) Preference for medicinal products to enter the reimbursement system more quickly;

4) An obligation on European medicine manufacturers to purchase European APIs and essential medicines (a certain percentage band) or to have a certain percentage of European APIs and essential medicines in stock, with the possibility of gradually tightening this obligation as the market develops;

5) Direct subsidies to API and essential medicines producers — production subsidies;

6) European joint purchases of medicines that come from production in the EU.

6. **Institutional solutions**

6.1. It is proposed that the remit of an existing decentralised agency or European Commission service (e.g. HERA or the European Medicines Agency (EMA)) be broadened to include the management of the fund. The argument in favour of this is that some of HERA's tasks may, in some respects, overlap with the fund's objectives, such as deciding on the location of API and essential medicines production in Europe taking into account current technologies and production capacities.

6.2. Another task would be to work together with the EMA to define critical medicines for the treatment of EU patients in the near future. This list would help identify the eligibility criteria for investment support, applicable to certain molecules in a specific location in Europe.

6.3. Europe should set an example of how it should prioritise attracting European-born researchers from the United States and other regions and invest in students who study abroad. Moreover, the Chips Act is an initiative worth replicating to bring competences and strategic industries back to the EU.

6.4. The European Commission must urgently take action to strengthen the health and safety of EU citizens. Unfortunately, it should be noted that actions that have not yet been taken are already overdue, which is why we call for the Commission's legislative workplan to be urgently supplemented with dedicated legislation and to urgently start the legislative process in this area.

Brussels, 13 December 2023.

The President
of the European Economic and Social Committee

Oliver RÖPKE