European Economic and Social Committee

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Pharmaceutical Strategy

OPINION

European Economic and Social Committee

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions
Pharmaceutical Strategy for Europe
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Section responsible	Single Market, Production and Consumption
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1. Conclusions and recommendations

1.1 The European Economic and Social Committee (EESC) welcomes, first and foremost, the European Commission's intention to ensure the supply of safe, high quality and affordable medicines and the financial sustainability of Member States' health systems through the new Pharmaceutical Strategy for Europe, alongside promoting the competitiveness of the pharmaceutical industry. New common European approaches play a key role in the following areas in particular:

- access to and availability of medicines;
- affordability and financial sustainability of national health systems;
- promotion of research and innovation in order to strengthen the competitiveness of the European pharmaceutical industry;
- strengthening of resilient and transparent supply and production chains;
- efficient implementation of the objectives of the Green Deal[1] by a climate-neutral pharmaceutical industry.

1.2 The current COVID-19 pandemic is highlighting the importance of a coordinated European approach. The EESC would therefore draw attention to the importance of common strategies for pharmaceutical research and development and pricing, particularly where high-risk products are concerned and where the return on investment for manufacturers is not guaranteed.

1.3 The EESC stresses that any policy measures at EU level must ensure respect for Member States' competences and the subsidiarity principle in accordance with Article 168(7) TFEU, in order to take account of the fact that national health systems are not organised in a uniform way and so as not to destabilise them financially. This is particularly important when it comes to matters of pricing and reimbursement, which are solely the responsibility of Member States. It is nonetheless important to ensure that information, knowledge and best practices are continuously shared at EU level in order to avoid any fragmentation or inequalities.

1.4 The EESC notes that, under the current framework conditions, the European pharmaceutical sector has in recent years evolved in a direction that has led in part to misuse of the various incentive schemes, that lacks transparency in many respects and that has resulted in a concentration on business areas with high profit margins and in some cases excessive price demands. The EESC therefore feels that there is an urgent need to revise and adapt the current regulatory framework for medicines and to link it more closely to conditionalities relating to affordability and availability.

1.5 The EESC stresses in particular the central role of a functioning, fair and efficient internal market, which, on the one hand, promotes and rewards genuine medical innovation with real added value for healthcare and, on the other, strengthens competition for fair and affordable access to medicines.

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1 https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en.

1.6 With a view to promoting innovative research and development (R&D) as a basis for the global competitiveness of the European pharmaceutical industry, the EESC particularly supports the idea of harmonising the legal framework for the protection of intellectual property and its consistent application in the Member States.

1.7 As regards boosting the resilience of supply and production chains as a way of strengthening Europe's strategic autonomy and avoiding supply shortages, the EESC advocates a balanced approach between increasing the diversification of production sites and a progressive/gradual, partial, but – at the same time – sustainable, reshoring of production to Europe. Possible financial and tax incentives at Member State level and the efficiency thereof should be discussed and analysed jointly at EU level.

1.8 The EESC also welcomes the planned revision of the European incentive system for pharmaceutical R&D in Europe, particularly the legal framework for paediatric medicines and medicines for rare diseases. In particular, the considerable unmet need for suitable therapies for paediatric cancer must be a priority in future strategies.

1.9 The EESC believes that the revision of the regulatory framework for medicines and any future initiatives at EU level must be based primarily on the principle of transparency in order to generate real added value for the public good. This concerns not only costs for manufacturers, but also public funding for R&D, take-up of incentives, etc.

1.10 The EESC welcomes and supports initiatives by the Member States, supported by the European Commission, to jointly procure innovative and high-priced medicines in order to ensure the financial sustainability of national health systems.

1.11 The EESC recognises the positive role of generics and biosimilars in terms of access to affordable medicines, their importance for the sustainable financing of health systems and their contribution to a resilient, strategically independent European pharmaceutical market. The EESC supports measures, for example in the context of public procurement, through the application of MEAT (most economically advantageous tender) criteria and multi-winner tenders, taking environmental and social protection aspects into account, that lead to a sustainable market for generics and biosimilar medicines.

1.12 The EESC appeals for caution when it comes to accelerated authorisations based on insufficient evidence and increased use of real world data, except in the case of a cross-border health crisis. It is essential to prevent a shifting of risk, to the detriment of patients, from the pre- to the post-market authorisation phases. Data and study results should therefore be consistently published in order to ensure effective post-market authorisation monitoring.

2. General comments

2.1 According to the *Health at a Glance: Europe* report[2] published on 18 November 2020, health expenditure in all 27 EU Member States grew by an average of 3% per year between 2013 and 2019, reaching 8.3% of GDP in 2019. Although this share has evolved in line with economic growth in the Member States, a sharp increase can be expected in the context of the current COVID-19 pandemic.

2.2 As already stressed in the 2016 Council Conclusions[3] and the European Parliament's own-initiative report on options to improve access to medicines[4], the rising prices of medicines are putting increasing pressure on national health systems. The balance in the complex pharmaceutical system between authorisation and measures to promote innovation must therefore be restored in the EU in order to ensure equal access to medicines in all Member States.

2.3 In particular, rising prices for newly authorised therapies threaten the stability of the pharmaceutical budget and thus patients' access to medicines[5]. Here the EESC is particularly critical of strong clustering (e.g. in the field of cancer) around areas that are already well researched and which largely coincide with manufacturers' existing portfolios. In future, it will therefore be necessary to find effective ways to break up this clustering; therapies should be affordable and as a result equally accessible to all patients. To this end, R&D needs to be channelled towards areas with real unmet medical needs, such as rare diseases or paediatric cancers.

2.4 The European Intellectual Property Action Plan Roadmap[6] already stresses that the Union has a strong legal framework for protecting intellectual property. Any change to this system should therefore be accompanied by a robust impact assessment in order to make only necessary changes.

2.4.1 Patents, supplementary protection certificates (SPCs) and data exclusivity aim to incentivise research in new areas. The development of the Pharmaceutical Strategy must be guided by its added value for society. The key focus should be on access to and availability of effective, safe and affordable medicines for the benefit of all patients, in keeping with the right to adequate healthcare, as set out in the European Pillar of Social Rights[7]. This relates not only to the supply of innovative new patented medicines, but equally to access to generics and biosimilars. A functioning and fair internal market therefore plays a central role.

2.4.2 The EESC also supports the harmonisation of the legal framework on SPCs in order to make the granting procedure more coherent and eliminate fragmented application in the Member States.

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2 https://ec.europa.eu/health/state/glance_en.

3 OJ C 269, 23.7.2016, p. 31.

4 https://www.europarl.europa.eu/doceo/document/A-8-2017-0040_EN.pdf.

5 https://www.oecd.org/health/health-systems/Addressing-Challenges-in-Access-to-Oncology-Medicines-Analytical-Report.pdf.

6 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12510-Intellectual-Property-Action-Plan.

7 https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet_en.pdf.

Given the social impact of SPCs, it is important to ensure that the central authority to be set up in this connection comes under the authority of EU institutions.

2.4.3 The EESC is very concerned about a possible extension of exclusive rights and a further strengthening of intellectual property rights with regard to the pharmaceutical market. In order to maintain patients' access to affordable therapies, the development and market launch of generics and biosimilars should not make price competition more difficult. It is therefore important to avoid multiple protection of a product in the different Member States or through several patents (patent slicing), especially since there is no evidence that strong intellectual property protection promotes innovation and productivity[8].

2.4.4 Particularly in the context of the current political debate on the reshoring of production sites to Europe in order to secure supply, a detailed analysis of a change to the legal framework on intellectual property needs to be carried out. According to the impact assessment of what is called the Falsified Medicines Directive (2011/62/EU)[9], the vast majority of active pharmaceutical ingredients (API) for generics are sourced in India and China, whereas the API of new patented medicines are mostly produced in Europe. Accordingly, incentives and mechanisms other than further strengthening intellectual property rights would have to be put in place to reshore production of generics in particular. Alternative measures could be, for example, licensing agreements, advance purchase agreements or what are known as patent pools for medicines[10]. At the same time as reshoring, ways should also be found to further diversify production both inside and outside Europe in order to strengthen and secure supply chains.

2.5 In the field of orphan medicinal products (OMPs), the EESC welcomes the fact that the incentives set out in Regulation (EC) 141/2000[11] have steadily increased the number of approved OMPs, which has significantly improved equal access for patients and is therefore to be welcomed. However, access is increasingly being undermined by high price demands from manufacturers[12]. The EESC therefore stresses that OMP status should not be used for unreasonable price demands and profits and therefore supports the revision of this legal framework launched by the impact assessment[13] published in November 2020. Consideration should be given to a regular automatic re-evaluation of the criteria and an adjustment of the duration of market exclusivity under certain conditions still to be defined. The EESC also supports a possible revision of the criteria, in particular prevalence (taking into account all authorised indications), as regards designation as an OMP.

2.6 The EESC particularly supports the European Commission's call, as well as that of many MEPs, for greater transparency across the pharmaceutical sector as a whole, particularly with regard to

8 https://pubs.aeaweb.org/doi/pdf/10.1257/jep.27.1.3.

9 https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0074:0087:EN:PDF.

10 https://www.who.int/bulletin/volumes/97/8/18-229179/en/.

11 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02000R0141-20190726&qid=1598193643269&from=EN.

12 https://ec.europa.eu/health/sites/health/files/files/paediatrics/docs/orphan-regulation_study_final-report_en.pdf.

13 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12767-Revision-of-the-EU-legislation-on-medicines-for-children-and-rare-diseases.

R&D costs. In the absence in most cases of basic rules on cost transparency in the development of medicines, the competent pricing and reimbursement authorities are unable to verify whether the pricing of new medicines, and thus the reasonableness of the prices charged, is justified by high research costs.

2.6.1 According to the EESC, the Transparency Directive 89/105/EEC[14] could be an important instrument in this context. Article 6 of that directive provides that Member States which have a positive list must publish a complete list of products covered by their health insurance system and the prices set by their competent authorities and communicate them to the Commission. However, the actual prices paid are protected by confidential purchasing agreements, which makes exchanges between national authorities considerably more difficult. The EURIPID database[15] could serve as a starting point in this context, provided that all Member States are required to register their price information.

2.6.2 The EESC also considers it essential to significantly increase transparency in respect of global pharmaceutical supply and production chains in order to address possible supply shortages and strengthen the resilience of health systems. In addition to putting in place a coordinated reporting system, as already provided for under the European Health Union, with the mandatory participation of all relevant stakeholders, it is also vital here to introduce strategic stockpiling of medicines designated as essential by the WHO.

2.6.3 In the context of the current COVID-19 pandemic, the EESC backs the call of many MEPs and relevant stakeholders for more transparency on the advance purchase agreements with pharmaceutical manufacturers for COVID-19 vaccines. Transparency is key to trust and acceptance by EU citizens in immunisation against the virus. This should not only apply to the current vaccine contracts, but should also serve as a new transparency framework for any future joint procurement measures.

2.7 As regards measures to jointly procure newly authorised high-priced medicines, these should be explicitly strengthened and promoted at European level. In addition to increased security of supply in Europe, this can also strengthen the negotiating position vis-à-vis pharmaceutical manufacturers and achieve clear cost reductions through larger volumes of purchases.

2.8 With regard to the promotion of pharmaceutical R&D, the EESC agrees with the criticism levelled by many actors and stakeholders regarding the lack of transparency, the lack of involvement of public stakeholders and the lack of public access to research results.

2.8.1 The EESC therefore calls for all public funding for research and R&D costs to be made public in future in order to be able to take this into account when it comes to national pricing issues and to ensure a true public return on public investment. Consideration should be given here to regular evaluation of research funding and a report to the European Parliament. Especially in sensitive

14 OJ L 40, 12.2.1989, p. 8.

15 EURIPID is a voluntary database for national authorities responsible for pricing and reimbursement issues. It contains data – in line with the Transparency Directive 89/105/EEC – on official prices of mainly out-patient medicinal products. See https://www.euripid.eu/aboutus.

areas of healthcare, the mere alignment of research funding with industrial interests is detrimental. All relevant stakeholders must therefore be closely involved in the European Commission's research agendas in future in order to ensure they are aligned with actual medical and social needs.

2.8.2 In this context, it is essential to set a common EU-wide definition of unmet medical need (UMN) in order to efficiently channel pharmaceutical R&D activities to those areas where no adequate or effective therapy exists. These criteria should be based on patients' needs and on public health.

2.9 At the same time, in the context of medical R&D and clinical studies, the EESC calls for action at EU level to take more account of gender differences and the different effects of medicinal products in everyday medicine, based on corresponding relevant indicators. It also calls for more transparency and thus for greater stakeholder awareness in this connection.

2.10 In the EESC's view, it is especially positive that the growing threat of antimicrobial resistance (AMR) is explicitly highlighted in the Pharmaceutical Strategy. In addition to effective measures to reduce the use of antibiotics, the focus must in particular be on alternative incentive models throughout the R&D cycle, as well as on new pricing models. Proven incentives, such as early dialogue with the European Medicines Agency (EMA) and the fee waiver, can also be used here. It will be important in the future to decouple manufacturers' profits from sales volumes. However, in parallel with the promotion of new antibiotics, other measures, such as advance purchase agreements, could also be taken to provide manufacturers with more predictability.

2.11 With regard to authorisation and market entry issues, the EESC generally welcomes the rapid availability of innovative medicines, especially in areas with a high UMN. However, faster authorisations do not automatically guarantee a better supply of medicines. The primary objective of European pharmaceutical policy must therefore be equal access to safe, affordable and high-quality medicines for all patients.

2.11.1 The EESC agrees with the European Commission that randomised controlled studies with (ideally) relevant comparators and endpoints must continue to be considered the gold standard for market authorisation, given the rapidly evolving technological possibilities and the accompanying call for flexible study designs. Exceptions should only be made in individual cases, giving the reasons for doing so. If data generation is transferred to the post-market authorisation phase, steps must be taken to ensure that the associated costs are not shifted from pharmaceutical companies to the public sector, and that patients' safety is not jeopardised by premature authorisations. The fact that there is insufficient data, and that further data is therefore needed, should be taken into account in pricing.

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