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From:	European Economic and Social Committee (EESC)
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To:	General Secretariat of the Council
Subject:	Opinion of the European Economic and Social Committee on files 2023/0132(COD) and 2023/0131(COD)

Delegations will find attached the Opinion of the European Economic and Social Committee on files 2023/0132(COD) and 2023/0131(COD).

Encl.: the Opinion of the European Economic and Social Committee on files 2023/0132(COD) and 2023/0131(COD).

European Economic and Social Committee

OPINION

European Economic and Social Committee

Pharmaceutical package

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a) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions –
Reform of the pharmaceutical legislation and measures addressing antimicrobial resistance
[COM(2023) 190 final]

b) Proposal for a Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach
[COM(2023) 191 final – 2023/0125 (NLE)]

c) Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing
Directive 2001/83/EC and Directive 2009/35/EC
[COM(2023) 192 final – 2023/0132 (COD)]

d) Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006
[COM(2023) 193 final – 2023/0131 (COD)]

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Rapporteur: **Martin SCHAFFENRATH**

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Referral	a) and b) European Commission, 02/06/2023 c) and d) European Parliament, 14/09/2023 Council, 21/09/2023
Legal basis	a), b), c) and d) Article 304 of the Treaty on the Functioning of the EU c) and d) Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union
Section responsible	Single Market, Production and Consumption
Adopted in section	03/10/2023
Adopted at plenary	25/10/2023
Plenary session No	582
Outcome of vote (for/against/abstentions)	219/0/1

1. Conclusions and recommendations

1.1 The European Economic and Social Committee (EESC) welcomes, first and foremost, the European Commission's long-awaited proposal for a revision of the European Pharmaceutical Framework which offers a unique chance to adjust the current provisions and to pave the way for a competitive, sustainable Europe. Improving the availability and accessibility of affordable medicines while at the same time boosting the competitiveness as well as attractiveness of its pharmaceutical industry should hence be the guiding principles and striking a balance will be crucial. In this respect, the EESC would like to recall its 2021 opinion on the Pharmaceutical Strategy[1].

1.2 Above all, the EESC supports improving affordability as one of the main goals of this revision. The functioning of a fair and efficient internal market, promoting and rewarding medical innovation with real added value on the one hand and strengthening competition for affordable access to medicines on the other hand, ultimately plays a central role. Increasing and strengthening the early and timely market entry of generics/biosimilars and consequently, competition from day one after patent expiry is crucial in this context.

1.3 Affordability and access continue to be key challenges, with a view to ensuring that all medicines and treatments are affordable for both Member States' health systems and patients. Different forms of European initiatives and models of joint purchasing of medicines between countries – such as Beneluxa or as seen during the COVID-19 pandemic regarding vaccines – have improved access to treatment. The debate on fair pricing as well as transparency of R&D costs for medicines is hence strongly supported by the EESC.

1.4 In the context of proactively and efficiently steering pharmaceutical R&D into areas with an unmet medical need (UMN), namely those areas where no adequate or effective therapy exists, and to break up clustering of pharmaceutical R&D in the same therapeutic areas, the EESC highly appreciates the proposal of the European Commission of a common, harmonised definition of UMN. This will serve as a basis for a variety of incentives for manufacturers but also for the different accelerated assessment and authorisation schemes for the benefit of rapid availability of innovative medicines. However, faster authorisations do not automatically guarantee a better supply of medicines. Hence, the EESC calls for caution when it comes to these fast-track procedures, which might be based on insufficient evidence as to the effectiveness of the medicinal products.

1.5 The EESC recalls in this respect the need for closer cooperation between the European Medicines Agency (EMA) and national authorities in the context of the scientific evaluation of medicines which cannot be exhausted at the simple phase of preliminary efficacy and safety tests for market approval.

1.6 The EESC supports the push for greater transparency across the complex authorisation process as a whole, but particularly with regard to R&D funding and post-launch evidence generation obligations. Particularly, it supports increasing the transparency of all public funding for R&D

[1] OJ C 286, 16.7.2021, p. 53.

in order to be able to take this into account during national P&R decision-making processes, to ensure a true public return on public investment. This will empower national authorities by reducing information asymmetry in pricing negotiations and enable an informed discussion on what constitutes a fair price for medicines.

1.7 In the EESC's view, it is especially positive that the growing threat of antimicrobial resistances (AMR) is explicitly highlighted in the pharmaceutical legislation. 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. It will be important in the future to decouple manufacturers' profits from sales volumes.

1.8 In the field of orphan medicinal products (OMPs), the EESC already positively stressed in prior opinions the fact that the current incentives have steadily increased the number of approved OMPs and hence significantly increased the number of therapies for patients. However, access is being undermined more and more by high price demands from manufacturers[2]. The EESC therefore stresses that OMP status should not be used for unreasonable price demands and therefore supports the revision and respective adjustment of these provisions. However, the EESC points out that this should go further than only reducing and staggering the market exclusivity periods. Consideration should be given to a regular re-evaluation of the criteria and a possible revision of the criteria, in particular prevalence (taking into account all authorised indications) and equally the criterion of profitability. The EESC especially regrets that the latter, namely the profitability criterion is no longer maintained for granting orphan status.

1.9 To ensure access to treatment for all patients suffering from rare diseases in Europe, and therefore genuine solidarity within the EU while taking into account economic disparities between Member States, the EESC calls upon the Member States to conduct a preliminary assessment on the possibility of setting up a special EU-level fund to which the Member States would contribute and from which they would benefit according to their financial capacities. Such a fund could be a useful add-on when statutory health insurances do not cover the entire costs of the treatment , i.e. travel costs etc, or where no reimbursement is possible at national level.

1.10 Especially in view of the rapidly increasing medicines shortages and their negative impact on healthcare and public health, the EESC agrees with the need to strengthen the current obligations for all supply chain actors in order to better monitor, manage and mitigate shortages as well as to improve the security of supply. The present framework could only ensure the safety of supply with medicines to a limited extent as it contains only a few general provisions. One of the key core demands of this revision must be to significantly increase transparency in this respect. However, the EESC regrets that the proposal does not introduce any real obligation for manufacturers to build up safety stocks or to establish EU-level stocks of active pharmaceutical ingredients (APIs) for critical medicines or even finished products via ad hoc decisions.

2 European Commission, Study to support the evaluation of the EU Orphan Regulation, Final report July 2019.

1.11 Additionally, the EESC highlights the importance of mitigating dependencies and at the same time strengthening the resilience as well as the strategic autonomy of the EU. It therefore recommends to introduce suitable legislative measures to enhance the existing production of pharmaceuticals, including APIs, in the Union 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 and/or measures to favour EU-based pharmaceutical manufacturers and encourage the relocation of production from third countries in order to strengthen our resilience in terms of access to medicines. The EESC firmly believes that the European Union will make every effort to develop a mechanism that will foster the growth of existing production and new investments in pharmaceutical manufacturing in the Union.

1.12 In line with the above required measures for supporting EU-based strategic pharmaceutical production and hence for a strengthened availability of quality medicinal products, the EESC stresses the crucial importance of a strong and resilient European infrastructure, namely R&D, high quality workplaces, good professional education and attractiveness for individual professional progress. In particular, the EESC sees a highly trained and qualified workforce as one of the key pillars for a strong and competitive European pharmaceutical industry. A strong social dialogue between employers and their trade unions as well as improved working conditions and collective bargaining are hence essential prerequisites in this context.

1.13 The EESC furthermore sees a need for the establishment of a pan-European R&D and innovation infrastructure to facilitate closer alignment with the long-term priorities of the public national health systems and to strengthen the strategic autonomy of the EU.

1.14 The EESC warmly welcomes the inclusion of environmental aspects when it comes to the production of pharmaceuticals. However, respect for decent working conditions and human rights in the supply chain need to be taken into account equally.

1.15 To be critically stressed is however the substantial number of aspects which should be clarified and defined by delegated as well as implementing acts and accompanying guidelines issued by the European Commission. Their impact cannot be assessed at this point in time. In any case and due to the immediate impact on stakeholders such as payers and patient organisations, their positions need to be taken duly into account and must be firmly anchored in the proposal. Particularly, the EESC cautions the co-legislators about postponing the concrete wording of too many aspects.

2. General comments

2.1 Above all, the EESC sees a need to adjust the current system of regulatory protection periods and hence warmly welcomes the proposal for a staggered approach. It also welcomes the reduction of the data protection period from eight to six years as baseline scenario together with the possibility to extend the regulatory protection periods to some extent, in order to provide for proportionate as well as tailored rewards for relevant innovations with a real UMN reaching all patients in Europe.

2.1.1 On a rather critical note, the EESC would like to raise the question of whether or not the staggered approach of protection periods all together would jeopardise competition even more, since it is foreseen that the maximal protection period could – under specific circumstances – be extended by one additional year, namely 12 years instead of 11 years. In international comparison, data and market protection periods are already longer than in other jurisdictions, e.g. the US and Canada. Therefore, the EESC calls for a robust assessment of how many products would really fulfil all conditionalities set out in the proposal and reach the twelve years of protection in order to realistically evaluate this tool.

2.1.2 Additionally, the EESC would like to once again emphasise that randomised controlled trials (RCT) with (ideally) relevant comparators and endpoints must continue to be considered the gold standard for market authorisation. Increased generation of comparable and robust data should be above all the main goal of the revised legislation. Exceptions should only be made in individual, well justified cases. The EESC is of the opinion that incentivising data generation through RCTs with six months of additional data protection as foreseen has the potential to hamper strict standards and rewarding this should be reconsidered carefully.

2.2 The EESC calls for caution when it comes to the different accelerated approval processes foreseen in the text. The increasing number of advanced medicinal products enter the market with limited information especially on effectiveness. It is important that the use of accelerated and conditional procedures is limited to a situation where no other medicinal alternative is available or when the quality of life is severely under pressure due to the condition, namely in areas with a proven UMN.

2.2.1 In this respect, the EESC has major concerns about reducing the assessment timelines from 210 to 180 days, as it could negatively affect the soundness of central authorisation procedures. Taking into account that experts within the Committee for Medicinal Products for Human Use (CHMP) will also have to eventually evaluate the environmental risk assessments and the ever increasing complexity of methods and technologies, this could seriously hamper the quality of rigorous authorisation procedures. In addition, the EESC would like to emphasise that the current, as well as the proposed regulatory framework, already foresees provisions for accelerated procedures within 150 days.

2.2.2 As COVID-19 made clear, timely access to efficient countermeasures is of utmost importance to tackle a public health emergency. The EESC consequently approves the need to introduce the possibility for a temporary compulsory licence suspending the respective data and market protection in order to ensure access. At the same time, the inclusion of the assessment and authorisation best practices adding more regulatory flexibility in emergency situations into the legal text, notably the rolling reviews and the temporary emergency marketing authorisation, are to be welcomed.

2.2.3 Ultimately, the EESC has major concerns about introducing regulatory sandboxes into pharmaceutical legislation, due to their high uncertainty with regard to the impact on the pharmaceutical system. Although the initial goal of these sandboxes, namely to provide the opportunity for advancing regulation through testing innovative technologies etc. in a secure environment, is to be welcomed, this would, in the EESC's view, open the door to massive

lobbying activities and hence undermine the high quality and independence of current as well as future European authorisation procedures. Ultimately, the EESC calls for a stricter regulatory framework for these sandboxes in order to limit them as far as possible.

2.3 With the goal of strengthening immediate competition, i.e. the market launch of generics/biosimilars, the EESC greatly welcomes the extension and harmonisation of the Bolar exemption by including additionally all activities related to applications for marketing authorisations, pricing and reimbursement, as well as HTA procedures. In its view, this is one of the key instruments for enabling day-one competition after patent expiry by generics/biosimilars, facilitating massive savings for healthcare systems and more equitable access to medicines, as well as strengthening the competitiveness of EU-based APIs and off-patent medicines manufacturers. However, the EESC sees an urgent need for further clarification of the legal wording of the Bolar exemption as it is foreseen in the proposal in order to ensure that the exemption covers all aspects related to the preparation of day-one generic/biosimilar market launch. In order to complement Bolar and to guarantee timely entry into the market for generics/biosimilars, the EESC welcomes the aim of the European Commission to efficiently prevent patent linkage in Recital 65 and urges the co-legislators to transpose this into respective provisions in the legal text. This would efficiently implement various claims of the European Parliament, notably the 2017 Resolution on Options for improving access to medicines[3] or the 2021 Report on the IP Action Plan[4], amongst others, for banning patent linkage practices for the sake of an equitable patient access to treatments and creating a level playing field for generics/biosimilars manufacturers in the Union. Eventually, the EESC calls for an inclusion also of pricing and reimbursement as well as tender decisions on national level into the legal wording in order to maximise savings for national healthcare budgets, improve affordability, accelerate patient access and prevent administrative burdens for generic/biosimilar manufacturers.

2.4 The revision of the pharmaceutical legislation aims to address unmet health needs and the accessibility and affordability of medicines. To achieve those goals, a shift is needed away from relying solely on de novo drug development and towards complementing that with encouraging innovation all throughout the lifecycle of a molecule, including in the off-patent space. Therefore, the EESC supports the recognition and inclusion of all types of repurposing of off-patent molecules into the legislative framework by rewarding it with four years of data protection, provided they bring a significant benefit to patients. Repurposing can serve as an accessible, affordable type of innovation to address unmet health needs, relieve burden on health systems and lead to better quality of life for patients. However, in order to ensure that the provisions in the legislation are not misused for so-called evergreening practices, the EESC suggests excluding products which have benefitted from market exclusivity in the context of the provisions for orphan medicinal products (OMP) and at the same time make the link to the concept of a global marketing authorisation.

2.5 The EESC warmly welcomes provisions and measures foreseen in the legislative texts, as well as the political push by the Council Recommendations on stepping up EU action and more

3 European Parliament, Resolution on Options for improving access to medicines, 2017.

4 European Parliament, Report on the IP Action Plan, 2021.

Member States action in combatting this silent pandemic. The EESC furthermore supports the call for appropriate as well as efficient incentives to guarantee financial returns for innovators and manufacturers with the caveat that those measures are fair, predictable and appropriate.

2.5.1 However, the EESC expresses its concerns about changing prescription status of antimicrobial products all together (in particular, antifungals and antivirals). It hence advocates for a restriction of prescription measures to only antibiotics and not antimicrobials all together. Putting all antimicrobials under prescription only status would lead to an inclusion of antiseptics also, as well as antifungals where no resistance data exists. This will in view of the EESC only have negative impact on the accessibility of self-care products and add an additional burden on national healthcare systems.

2.5.2 The EESC has major concerns about the introduction of transferable exclusivity vouchers (TEV) to foster antimicrobial R&D, especially in the area of the WHO priority pathogens list. While being fully committed to fighting AMR on a European level, the EESC expresses massive doubts that TEVs are the appropriate measure to bring new antimicrobials to the market. As Årdal et al. state, the voucher is a complex, untested, indirect incentive which will be unpredictably expensive with no guarantee of access for Member States[5]. The EESC thus agrees that legislating an untested costly voucher with these deficiencies, which moreover does not exist in this form in any other jurisdiction, into the new Regulation, is to be rejected. Ultimately, as mentioned above the EESC urges to restrict this measure to only antibiotics and not include antiseptics or antifungals in the scope of the TEVs.

2.5.3 As an adequate alternative, the EESC strongly supports the establishment of a reserve antibiotic fund as proposed in the draft Council Recommendations on AMR. This could enable rapid approval of novel as well as established antibiotics, and support an equitable supply of reserve molecules to all Member States, while also supporting SMEs that rely on those funds. Equally important would be a further strengthening of milestone prizes to support research done by SMEs in particular.

2.6 In the field of OMPs, the EESC welcomes the reduction of the market exclusivity period from ten to nine years for all OMPs in order to avoid misuse of market monopolies and extensive price demands. The share of costs for this specific area is constantly and rapidly increasing in view of the total pharmaceutical expenditure in the Member States jeopardising patients' access[6].

2.6.1 The EESC furthermore agrees with the possibility of extending this exclusivity period by one year when addressing a UMN as an efficient method to bring patient needs back into focus and steer R&D efforts to truly rare diseases where a UMN exists. A proper balance in the EU is needed between supporting R&D for new drugs addressing both rare and more common diseases threatening public health on the one hand, and financial sustainability of healthcare systems in the Member States on the other. Consequently, the EESC acknowledges the need to

5 C. Årdal et al., Transferable exclusivity voucher: a flawed incentive to stimulate antibiotic innovation, The Lancet, 2023.

6 European Commission, *Study to support the evaluation of the EU Orphan Regulation*, Final report 2019.

support and provide incentives accordingly to the R&D of OMPs tackling areas where additional measures are really needed.

2.6.2 However, the EESC notes with great concern the complete deletion of the profitability aspect from the criteria for orphan designation due to the fact that it has never been used since the entering into force of the Regulation (EC) No 141/2000. In this respect the EESC would like to recall Recital 1 of this Regulation stating that "some conditions occur so infrequently that the cost of developing and bringing to the market a medicinal product to diagnose, prevent or treat the condition would not be recovered by the expected sales of the medicinal product; the pharmaceutical industry would be unwilling to develop the medicinal product under normal market conditions; these medicinal products are known as 'orphan'". This was the core aim of the framework and should be maintained by all means.

2.6.3 The EESC therefore suggests reintroducing a certain kind of regular re-evaluation of orphan status after granting marketing authorisation and market exclusivity and consequently the possibility to reduce market exclusivity if it is established, in respect of the medicinal product concerned, that the criteria for orphan status are no longer met, i.e. the prevalence criterion, as well as introducing a threshold for the volume of sales for all authorised indications.

2.6.4 Furthermore, in order to focus incentives on the development of therapies for truly rare diseases, the EESC encourages a discussion on the possibility of further reducing the prevalence threshold of 5:10 000 patients in the EU, as already mentioned in its opinion on the pharmaceutical strategy adopted in 2021[7]. 5:10 000 patients equate 5 000 patients in a population of 10 million, i.e. about 220 000 patients in the entire Union affected by such a condition. With increasing prices for OMPs, this population size seems, in the EESC's view, sufficiently large to be an attractive target for a conventional marketing authorisation and could hence allow for an adequate return on investment by the manufacturer. By reducing the current prevalence criterion, the EESC is of the opinion that OMP incentives will be re-focused on truly rare or ultra-rare conditions – a criterion that just over 50% of all OMPs licensed between 2000-2017 would have fulfilled[8] – and reflect once more the initial aim of the Regulation as mentioned above.

2.7 As regards the increasing threat of medicines shortages, the EESC welcomes and supports the proposal for harmonised definitions of a shortage and a critical shortage, which will standardise shortage reporting and mitigation, while improving coordination across Europe. An extension of notification periods, not only for temporary disruptions but also for permanent withdrawals from the market, compared to the current period of two months, needs to be carefully designed to avoid putting an unnecessary burden on companies or manufacturers, and should remain flexible enough so that manufacturers can make notifications when they anticipate real shortage risks rather than simply averting the risks of penalties. The introduction of shortage prevention plans as the responsibility of the marketing authorisation holders on a risk-based approach, will efficiently improve and enforce the monitoring of global supply chains for the most critical

7 See footnote 1.

8 See footnote 2.

products and those that do not have alternatives. Overall, the EESC calls for all shortages to be made public as soon as they are notified.

2.7.1 In order to further strengthen an efficient monitoring and notification of shortages, the EESC encourages a debate on including also proportionate sanctions in case of deliberate non-compliance with and/or repeated violation of the provisions foreseen in the text, and could distinguish exceptional circumstances. Sanctions should be commensurate with the level of efforts made by the company.

2.7.2 Introducing an EU-wide list of critical medicinal products subject to even stricter monitoring mechanisms, a compulsory shortages prevention plan by manufacturers for those critical medicinal products and an automated notification mechanism are, in the EESC's view, adequate measures to allow targeted prevention and mitigation actions by manufacturers and authorities. In order to avoid any duplication of work and notifications as well as to prevent false reports, the EESC strongly advocates for clearly defining the EU list of critical medicinal products and superseding national lists and to move towards centralised reporting of shortages.

2.7.3 The EESC moreover believes that harnessing the potential resulting from the digitisation is key to ensuring medicine supply, guarantee enhanced predictability and enable pre-emptive measures against shortages overall. Especially important, and very much welcomed by the EESC, is thus the introduction of electronic product information (ePI) to support rapid and more equitable supply allocation across the EU when medicines shortages occur. While the full replacement of paper leaflets with the ePI in general will change the way patients access information, their right to receive a paper copy should be safeguarded to ensure that patients will not be left behind. In its view, the latter could indeed be replaced in hospital settings.

2.7.4 In this context, the provisions on the possibility to transfer the marketing authorisation to a third party in the case of a permanent market withdrawal is to be welcomed. The EESC however calls for further clarification of the definition of "reasonable terms" as it risks being ineffective in practice or in legal disputes.

2.7.5 A necessary addition to the above mentioned legislative proposals would be that the European Commission should take the necessary measures to strengthen existing manufacturing companies, encourage pharmaceutical production, including active pharmaceutical ingredients, along the entire supply chain in the EU Member States, and to support European production capacities. The Commission should also create appropriate administrative and financial incentives to favour already existing pharmaceutical manufacturers in the EU and encourage relocation of production from third countries, in order to strengthen our resilience in terms of access to medicines. We firmly believe that the European Union will make every effort to develop a mechanism that will foster the growth of existing production and new investments in pharmaceutical manufacturing in the European Union.

2.7.6 For a strategic sector such as the pharmaceutical industry, the professionality and specialisation of its workforce constitutes a fundamental value. From R&D to manufacturing and regulatory compliance, individuals with specialised expertise must maintain the industry's high standards. Safe and conducive working environments, fair wages, and opportunities for career growth

should be a priority. This includes promoting social dialogue and collective bargaining across all Member States to ensure fair labour practices. Given the dynamic nature of the pharmaceutical industry, ongoing training and lifelong learning opportunities must be readily available to pharmaceutical professionals. The EESC firmly believes that fostering a skilled, dedicated and quality-driven workforce is not only beneficial for industry but also serves as a cornerstone of the broader pharmaceutical framework for the purpose of meeting the ever-growing demand for innovative and affordable medicines while at the same time safeguarding public health across Europe.

Brussels, 25 October 2023

Oliver Röpke
The president of the European Economic and Social Committee