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COMMISSION STAFF WORKING DOCUMENT

Subsidiarity Grid

Accompanying the document

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} - {SEC(2023) 390 final} - {SWD(2023) 192 final} - {SWD(2023) 193 final}

Subsidiarity Grid

- **As proposed by the Committee of the Regions with guidance in blue**
- **Obviously, the answers to the questions below, the explanatory memorandum and – if applicable – the impact assessment should be consistent. This may require some iterations.**
- **Please try to stay under 10 pages.**

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
The proposal is based on Articles 114(1) and 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU).
1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?
While the internal market and common safety concerns in public health matters fall within a shared competence of the EU and Member States, once the EU adopts harmonised legislation in such an area, Member States can no longer exercise their own competence. This is the case for the EU pharmaceutical legislation. The proposal respects Member States' exclusive competence in the provision of health services, including pricing and reimbursement policies and decisions as well as the prescription of medicines (cf. Article 168(7) of the TFEU).
2. Subsidiarity Principle: Why should the EU act?
2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[1]: - Has there been a wide consultation before proposing the act? - Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?
- To collect all relevant views and engage with stakeholders as much as possible, different consultation methods were combined. DG SANTE consulted with stakeholders via (i) the publication of inception impact assessments for feedback, (ii) two online consultations (one concerning general medicines, the other one targeted at medicines for children and rare diseases), (iii) targeted stakeholder surveys, (iv) interviews, (v) focus groups to discuss some of the main issue of the revision of the provisions relating to medicines for children and rare diseases, (vi) a validation workshop on the impact assessment findings. Summaries of all consultation activities and their outcomes are provided in Annex 2 – Synopsis report of the respective Impact Assessment SWDs. - The explanatory memorandum and the impact assessment SWD (chapter 3) contain a section on the principle of subsidiarity (see also question 2.2 below).

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

Common standards of quality, safety and efficacy for the authorisation of medicines constitute a cross-border issue for public health that affects all Member States and thus can effectively be regulated only at EU level. EU action relies also on the single market to achieve a stronger impact as regards access to safe, effective and affordable medicines, as well as the security of supply across the EU. Uncoordinated measures by Member States may result in distortions of competition and barriers to intra-Union trade for products that are relevant for the entire EU, and would also likely increase administrative burden for the pharmaceutical companies which often operate in more than one Member State.
At the same time, the proposed revisions of the pharmaceutical legislation respect Member States' exclusive competence in the provision of health services, including pricing and reimbursement policies and decisions.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

While the internal market and common safety concerns in public health matters fall within a shared competence of the EU and Member States, once the EU adopts harmonised legislation in such an area, Member States can no longer exercise their own competence.
As diseases do not know borders, common provisions for the authorisation of medicine are necessary. Uncoordinated measures by Member States could result in distortions of competition and barriers to intra-Union trade for products that are relevant for the entire EU, and would also likely increase administrative burden for the pharmaceutical companies which often operate in more than one Member State. Adapted frameworks with specific regulatory requirements tailored to the characteristics or methods inherent to certain, especially novel, medicines will ensure an agile and future proof common regulatory environment while keeping the high standards of quality, safety and efficacy. Furthermore, a specific objective of the revisions is to ensure timely patient access in all Member States, including in smaller Member States, which can partially be impacted by the EU pharmaceutical legislation.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

Diseases do not know borders. Common provisions for the authorisation of medicines constitute a cross-border issue for public health that affects all Member States and thus can effectively be regulated only at EU level, given that the authorisation of medicines is fully harmonised at EU level.
Data collected in the impact assessment SWD have shown that concerning access to medicines no major improvement over the last years have been observed. Indeed, there is a 90% variance between Northern and Western European countries and Southern and Eastern European countries in terms of patient access to new medicines, which also largely corresponds to the launch patterns according to market size and purchasing powers of these countries. The average delay between market authorisation and patient access can vary from as little as 4 months to 29 months.

(b) Would national action or the absence of the EU level action conflict with core objectives of

	the Treaty[2] or significantly damage the interests of other Member States?
	Uncoordinated measures by Member States could result in distortions of competition and barriers to intra-Union trade for products that are relevant for the entire EU, and would also likely increase administrative burden for the pharmaceutical companies which often operate in more than one Member State. Furthermore, the proposed revision of the EU pharmaceutical legislation should guarantee a high level of public health by ensuring the quality, safety and efficacy of medicines for EU patients. The proposal is based on Articles 114(1) and 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU).
(c)	To what extent do Member States have the ability or possibility to enact appropriate measures?
	While the internal market and common safety concerns in public health matters fall within a shared competence of the EU and Member States, once the EU adopts harmonised legislation in such an area, Member States can no longer exercise their own competence. This is the case for EU pharmaceutical legislation. However, the proposed revision of the pharmaceutical legislation respects Member States' exclusive competence in the provision of health services, including pricing and reimbursement policies and decisions.
(d)	How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?
	The problem and its causes are similar in all member States as most of the provisions in the pharmaceutical field are harmonised since long time.
(e)	Is the problem widespread across the EU or limited to a few Member States?
	The problem is affecting all Member States.
(f)	Are Member States overstretched in achieving the objectives of the planned measure?
	Some specific expertise might not be easily available in all Member States, therefore the necessity to bring simplification and efficiency in the current legislative.
(g)	How do the views/preferred courses of action of national, regional and local authorities differ across the EU?
	Pharmaceutical legislation is implemented at national level in the Member States. There is an overall consensus among competent authorities – as confirmed in the context of the various above-mentioned consultation activities - on the necessity to streamline and simplify and make the current legislative framework future-proof.
2.4	**Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?**
	Common standards of quality, safety and efficacy for the authorisation of medicines constitute a cross-border issue for public health that affects all Member States and thus can effectively be regulated only at EU level. Furthermore, provisions at European scale reduce burden amongst others for companies and preserve the single market. There will also be benefits for national authorities (streamlining of procedures and simplification will enhance

[2] https://europa.eu/european-union/about-eu/eu-in-brief_en

efficiencies at all levels, for instance).

(a) Are there clear benefits from EU level action?

Common standards of quality, safety and efficacy for the authorisation of medicines constitute a cross-border issue for public health that affects all Member States and thus can effectively be regulated only at EU level. EU action relies also on the single market to achieve a stronger impact as regards access to safe, effective and affordable medicines, as well as the security of supply across the EU. For example, a harmonised approach at EU level also provides greater potential for incentives to support innovation and for concerted action for development of medicines in areas of unmet needs.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

Having provisions at European level reduces the administrative burden and preserve the single market for pharmaceutical companies which often operate in more than one Member State ensuring a strongly positive environment for pharma industry to continue to develop its cutting-edge products within the EU. The revision will also aim at improving the affordability of medicinal products benefiting national health systems. A simplified and better integrated regulatory system will benefit national regulators.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

The sector is already completely harmonised since many years. The first legislation in the area of medicines was adopted in 1965.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

The proposal will not impact the existing national competencies with regard to Member States' exclusive competencies in the provision of health services, including pricing and reimbursement policies and decisions.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes, the proposed, revised legal framework will clarify definitions, introduce classification mechanisms as well as further streamlining and simplification. This will reduce administrative burden for companies and authorities and hence improve efficiency and attractiveness of the EU system.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The initiative does not go beyond what is necessary to achieve the objectives of the revision. It does so in a way that is conducive to national action, which would otherwise not be sufficient to achieve those objectives in a satisfactory way.

The principle of proportionality has been reflected in the comparison of different options evaluated in the impact assessment. For example, trade-offs are inherent between the objective of innovation (promoting the development of new medicines) and the objective of affordability (which is often achieved by generic/biosimilar competition). The revision maintains the incentives as a key element for innovation, but they are adapted to better encourage and reward product development in areas of unmet medical needs and to better address timely patient access to medicines in all Member States. The explanatory memorandum reflects the above considerations.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The initiative does not go beyond what is necessary to achieve the objectives of the revision and is appropriate to achieve them. The choice of the legal instrument is justified and as simple as possible and coherent. The proposal does not modify the current repartition of competences.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

The initiative does not go beyond what is necessary to achieve the objectives of the revision. It does so in a way that is conducive to national action, which would otherwise not be sufficient to achieve those objectives in a satisfactory way.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

The proposed Directive introduces a large number of amendments to Directive 2001/83/EC and incorporates part of the current provisions and amendments to Regulation (EC) No 1901/2006. The new Directive will introduce provisions aiming at promoting innovation and access to affordable medicines-creating a balanced pharmaceutical ecosystem modulating incentives related to regulatory data protection, increase competition thanks to earlier market entry of generic and biosimilar medicines, increase transparency of public financing, enhance the security of supply of medicines, reduce the environmental impact of the pharmaceutical product lifecycle, reduce the regulatory burden by providing a flexible regulatory framework to support innovation and competitiveness. A new directive (rather than an amending directive) is therefore considered the appropriate legal instrument. In addition, the Directive should both be maintained to avoid fragmentation of national legislation on medicinal products for human use, given that the legislation is based on a system of national and Union authorisations. National authorisations are granted and managed on the basis of national law implementing the EU law. The evaluation of the general pharmaceutical legislation has not shown that the choice of legal instrument has caused specific problems or created disharmonisation. In addition, a REFIT Platform opinion in 2019 showed that there is no support among the Member States to turn Directive 2001/83/EC into a Regulation.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)

The proposal does not modify the repartition of competencies between the Union and the

Member States compared to today.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

Budgetary implications are mainly related to additional tasks to be carried out by the European Medicines Agency in terms of providing scientific, administrative and IT support in the following main areas:

- Enhanced pre-authorisation scientific and regulatory support

- Decision-making on orphan designations and management of Union Register on designations of orphan medicines

- Active substance master file assessment and certification

- Inspection capacities in third countries and support to Member States

- Environmental Risk Assessment

- Shortage management and security of supply

Furthermore, for **health systems** the public health budgets would also benefit from the modulated incentive scheme since more EU citizens will have access to treatments, which results in savings due to more effective treatment and reduced hospitalisations. They will also benefit from stronger competition and transparency measures around public funding for clinical trials. There would be additional societal benefits for families and carers too, in terms of both quality of life / independence and earning potential. Overall, the new incentives will come with costs for healthcare budgets but the public health benefits should outweigh those.

For **regulators**, the effects of the proposed changes would be overall positive especially due to various horizontal measures, which will allow to better coordinate, simplify and accelerate regulatory processes to the benefit of industry and launch new digitalisation programmes to improve the integration and efficiency of the regulatory system overall (as well as its interfaces with other regulatory systems).

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

Cyprus, Ireland, Malta and Northern Ireland have historically relied on the supply of medicinal products from or through parts of the United Kingdom other than Northern Ireland. Following the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, to prevent shortages of medicinal products and ultimately to ensure a high level of public health protection, specific timely limited derogations are included for medicinal products supplied to Cyprus, Ireland, Malta and Northern Ireland from or through parts of the United Kingdom other than Northern Ireland.