

EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION AND DOCUMENTS

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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

Submitted by Department of Health and Social Care on 16/12/2020

SUBJECT MATTER

1. The Commission is proposing a new pharmaceutical strategy which is patient-centred aiming to ensure quality and safety of medicines, while also boosting the pharmaceutical sector's global competitiveness. This has been developed as part of the Commission's vision for a stronger European Health Union, which President von der Leyen set out on 25 October 2020.
2. The new pharmaceutical strategy will build on the existing strong foundations the EU already benefits from, such as its comprehensive pharmaceuticals system, from the development and authorisation of medicines to their post-authorisation monitoring, and the contribution the pharmaceutical sector makes to the economy; for research and investment this was said to be one of the highest contributions in 2019 with over £33 billion, providing 800 000 direct jobs and a £98.6 billion trade surplus.
3. The strategy will also focus on the areas relating to data availability, the supply of medicines or the availability of manufacturing capacities to adapt and support the production of medicines. This could enable the sector to have well-functioning international supply chains and a well-performing single market for pharmaceutical products throughout their lifecycle. In addition, this strategy will complement the work of the Commission, the European Medicines Agency (EMA), the medicines regulatory authorities in the Member States and the European Economic Area as part of the European medicines regulatory network so as to ensure that patients have access to high-quality, effective and safe medicines.
4. The Pharmaceutical Strategy for Europe has the following four objectives:
 - to foster patient access to innovative and affordable medicines that address unmet needs such as medicines for paediatric and rare cancers, and vaccinations for infectious diseases.

- to support the competitiveness and innovative capacity of the EU's pharmaceutical industry;
 - to develop the EU open strategic autonomy and ensure robust supply chains so that Europe can be self-sufficient in providing for its needs, especially in times of public health crisis.
 - ensuring a strong EU voice on the global stage through facilitating trade in medicinal products with national competent authorities through bilateral and multilateral cooperation; and supporting international collaborations such as with the International Pharmaceutical Regulators Programme (IPRP), International Coalition of Medicines Regulatory Authorities (ICMRA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and World Health Organization (WHO).
5. The Strategy's four workstreams flow from the above objectives and each of these have considered different approaches, including proposals recommending legislative changes and non-legislative measures in order to achieve them.
6. The 4 workstreams are outlined below:
- The first workstream aims to fulfil unmet medical needs for EU patients and ensure accessibility and affordability of medicines.
 - The second workstream aims to support the European pharmaceutical industry to be competitive and innovative. To achieve this, the strategy is proposing the following;
 - The third workstream aims to enhance resilience of the sector through ensuring a diversified and secured supply chains; high quality, safe and environmentally sustainable pharmaceuticals; and enhance Europe's crisis preparedness and response mechanisms.
 - The fourth workstream is about ensuring a strong EU voice globally through international cooperation.
7. The Commission will pursue the objectives of the strategy and implement specific actions in partnership with the Member States, through enhanced dialogue, close interaction and a proactive exchange of information between the Member States and the Commission.

SCRUTINY HISTORY

8. N/A. This is a new proposal that has been developed in response to the COVID-19 Pandemic.

MINISTERIAL RESPONSIBILITY

9. The Secretary of State for Health and Social Care has lead responsibility. The Office for Life Sciences at Department for Business, Energy and Industrial Strategy (BEIS), has an interest with regard to the implementation of this strategy. The Secretary of State for the Environment, Food and Rural Affairs also has an interest with regard to the contributions this strategy will make to realising environmental commitments set out in the European Green Deal, the Zero Pollution ambition for a toxic-free environment, and in reducing greenhouse emissions along the value chain.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

10. Medicines regulation is reserved in relation to Scotland and Wales but devolved to Northern Ireland. Officials in the devolved administrations have been kept informed of developments in relation to this Pharmaceutical strategy and have received a copy of this EM.

LEGAL AND PROCEDURAL ISSUES

11. There are no legal or procedural issues as this document is a communication, not a legislative proposal. European Commission guidelines are not legally binding on the UK during the transition period, under the terms of the Withdrawal Agreement.

POLICY IMPLICATIONS

12. On 31 January 2020 the United Kingdom left the European Union and the UK is currently in the Transition Period, which is due to end on 31 December 2020.
13. During the Transition Period, this strategy will have no impact on Great Britain as none of the proposals apply during this period. The implementation of this strategy, including those actions recommending legislative proposals, is dependent on the Commission deciding jointly with the Member States which areas of the medicines regulatory framework of the Directive 2001/83/EC and Regulation (EC) No 726/2004 will be reviewed.
14. After the transition period this strategy will not have any direct impact in Great Britain, given that the UK will no longer be a Member State and any implementation of any of the specific actions will not be applicable. In the event this strategy leads to a change in legislation at EU level none of it will be applicable in Great Britain.
15. It is not clear how this strategy would be applied in Northern Ireland at the end of transition period under the Northern Ireland Protocol to the Withdrawal Agreement. However, any new legislative changes made by the Commission on medicinal products will likely be subject to the Northern Ireland Protocol (NIP), and products that would automatically be authorised in Northern Ireland will need

to comply with the regulatory requirements of the EU legislation for the duration the Protocol will be in force.

16. It is anticipated that this strategy will support international collaborations with the European Medicines Agency, national competent authorities within the EU, and bilateral cooperation with other countries as well as advance international harmonisations standards for medicine regulation.
17. However, it is unclear how this would be of benefit to the UK's relationship with the EU given that this strategy aims to promote EU interests in both multilateral and bilateral relations with other countries especially in enhancing regulatory convergence of medicines globally where possible.
18. This goes against the Government's negotiating position on the Future Relationship with the EU, which states that any agreement must respect the autonomy of both parties and it cannot therefore include any regulatory alignment, any jurisdiction for the Court of Justice of the European Union (CJEU) over the UK's laws, or any supranational control in any area, including the UK's borders and immigration policy.

CONSULTATION

19. This strategy has been informed by findings from stakeholders who responded to the online public consultation (OPC) conducted for the Pharmaceutical strategy for Europe. This can be accessed at <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines> . The consultation received a total number of 473 responses received from stakeholders in 26 Member states and also from outside the EU. Majority of the responses were from organisations and 47 from citizens. The largest number of responses came from Belgium (81), Germany (68) and France (56) and 47 from non-EU countries. The consultation covered aspects relating to access, availability and affordability of medicines, in the context of promoting sustainable innovation and support of EU industry to remain an innovator and world leader. Overall, the respondents indicated that innovation for unmet needs (53%) and improvement of access to medicines (44%) to be the most urgent issues the strategy should address.
20. This strategy also took into account feedback on the Commission roadmap which ran between 2 June and 7 July 2020, and its online public consultation (OPC) held from 16 June to September 2020. There were 242 responses received from stakeholders in 22 Member States and also from outside the EU. Out of the responses received 232 were considered. There were 20 responses from citizens and the rest from organisations. The largest number of responses came from Belgium (64), Germany (23) and France (18). From organisations, the largest

proportion of responses came from organisations representing civil society (52), pharmaceutical industry (43) and business associations (33). The area that received the highest number of responses was on the supply of medicines (including dependency of supply, shortages and manufacturing capacity) followed by accessibility. Unmet needs and affordability also scored highly. Themes with low traction were simplification and incentives.

21. A stakeholder workshop was held between 14th -15th July 2020 to gather positions on specific issues to inform the strategy where more than 460 participants were invited with representation from patients, consumers, pharmaceutical industry, including SMEs, academia, healthcare professionals and Member States were represented. Participants who attended were from 22 Member States and also non-EU countries. The session covered were on; access and incentives for patient centred innovation and unmet needs; ensuring availability of pharmaceuticals to patients; and ensuring affordability of medicines for patients and health systems sustainability. The summary of the workshop can be accessed at https://ec.europa.eu/health/sites/health/files/human-use/docs/stakeholders_sum_workshop_en.pdf

22. Further additional contributions were provided through meetings such as the advisory Pharmaceutical Committee, the Ad hoc Group of the national authorities for pricing and reimbursement and public healthcare payers, Engagement with the European Parliament, Meetings of Commissioner Kyriakides with key stakeholders representing patients, consumers, healthcare professionals, pharmaceutical industry and payers and with EU social partners representing employers and workers other outreach activities held in 2020 such as the European Health Forum Gastein 2020 and the Organisation for Professionals in Regulatory Affairs (TOPRA) Symposium 2020 .

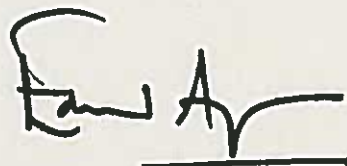
FINANCIAL IMPLICATIONS

There are no financial implications for the UK, or the EU, as a result of this guidance. The guidance does not commit the UK or the EU to any financial contribution.

MINISTERIAL NAME AND SIGNATURE

Edouard Arcene MP

Minister of State for Health



[1] [Section 13A of the EU \(Withdrawal\) Act 2018](#), as inserted by [section 29 of the European Union \(Withdrawal Agreement\) Act 2020](#).

