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Synopsis report

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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

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SYNOPSIS REPORT

1. INTRODUCTION

The report presents the outcome of the stakeholders' consultation conducted for the Pharmaceutical strategy for Europe. 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.

Stakeholders had the opportunity to provide their feedback on the Commission roadmap between 2 June and 7 July 2020. In addition, an online public consultation (OPC)[1] of all interested parties was conducted on the European Commission 'Public consultations' website from 16 June to 15 September 2020.

A stakeholder workshop took place, 14 – 15 July 2020.

Finally, ad hoc contributions were provided by stakeholders primarily through meetings.

2. METHODOLOGY

The analysis of the Commission roadmap was qualitative, drawing on machine learning and manual analysis to identify themes. Ten key themes were pre-identified A coding frame was created for each theme. In some instances, respondents submitted the same answers or the same position paper. A screening took place to redline duplicate or irrelevant responses.

For the OPC, analysis of cross-tabulations of closed answer questions and a qualitive analysis of additional textual feedback from respondents were carried out. No duplicate responses were identified, but there was some evidence of coordinated action where some respondents provided the same open reply. Responses were analysed according to the four main themes of the consultation survey.

3. CONSULTATION ACTIONS

a. FEEDBACK MECHANISM ON COMMISSION ROADMAP

There were 242 responses from stakeholders in 22 Member States and from outside the EU. After the screening, 232 responses 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 most commented theme was the *supply of medicines (*including dependency of supply, shortages and manufacturing capacity) followed by *accessability*. *Unmet needs* and *affordability* also scored highly. Themes with low traction were *simplification* and *incentives.*

In general, stakeholders were positive about the roadmap and the idea of a Pharmaceutical strategy for Europe. They also overall agreed with the main issues presented in the roadmap, though the emphasis on issues varied between interest groups. Some healthcare respondents

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines

called for a broader health strategy and some public authorities would like the Strategy to extend to medical devices and *in vitro* diagnostics.

Civil society organisations underlined the importance of improving affordability and accessibility of treatments to address unmet medicial need while industry focussed on ensuring supply and improving research and production infrastructure and EU. Public authorities stressed the need to increase production of active ingredients in Europe which was an issue taken on board across the stakeholders.

Several themes had support across all respondents: increased research funding, secure supply chains, shortages, addressing unmet medical need together with reduced dependency on third countries for production of active ingredients and essential medicines.

Access and affordability of medicines as well as adressing unmet medical need were a strong presence for civil society organisations, public authorities and healthcare respondents. These interest groups asked for further aligning incentives and research with public interest and unmet medical need, new pricing and procurement models, Member State collaboration on pricing, reimbursement and health technology assessment (HTA), and revision of the legislations on medicines for rare diseases and for children. Addressing environmental concerns and technologies to replace animal testing in medicines testing were mentioned by healthcare respondents and citizens.

The pharmaceutical industry and research and academia both supported improvement of the regulatory system. Research and academia expressed the need for enhanced cooperation with industry. In their view, greater cooperation in addition to maintenance of a strong intellectual property rights system, could generate economic benefits in terms of job creation and productivity in the EU.

Respondents from industry suggested further elaboration on, for example, promotion of innovative manufacturing; addressing root causes for supply shortages and supply chain risk and they supported use of real world data and evidence into clinical development and regulatory decision making, and building a European health data space.

The generics industry focussed on increased competition, revision of procurement criteria and intellectual property rights. The small and medium-sized enterprises (SMEs) expressed specific interest in improving access, in particular through actions concerning HTA and reimbursement.

b. STAKEHOLDER WORKSHOP

The purpose of the stakeholder workshop in July was to gather stakeholders' positions on specific issues to inform the Pharmaceutical strategy.

More than 460 participants, who – after an open call of interest – were invited to attend dedicated sessions to ensure a balanced representation. Patients, consumers, pharmaceutical industry, including SMEs, academia, healthcare professionals and Member States were represented. Participants attended from 22 Member States and also non-EU countries.

The workshop featured an initial roundtable on the roadmap followed by dedicated sessions on:

1) Access and incentives for patient centred innovation and umnet needs;

2) Ensuring availability of pharmaceuticals to patients; and

3) Ensuring affordablity of medicines for patients and health systems sustainability.

The main take aways were:

- General support for a holistic, patient centred, lifecycle approach in the Pharmaceutical strategy;
- Agreement that unmet medical need should be patient centred and support to develop a definition of *unmet medical need* and that incentives are important to ensure development of medicines, but non-industry stakeholders were in favour of balancing incentives with obligations to ensure access;
- Strong support for evidence-based actions to address shortages, call for specific actions to address availability issues like mapping of vulnerablities in the supply chains and diversification of suppliers;
- To address affordability a mix of approaches should be considered like stepping up information sharing efforts between Member States, for example on prices and procurement/payment models based on real world evidence.

A summary of the workshop was published[2].

c. ONLINE PUBLIC CONSULTATION

There were 473 responses received from stakeholders in 26 Member States and from outside the EU. The majority of 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 largest proportion of reponses from organisations came from those representing industry (141), including 49 SMEs, healthcare payer or provider (85) and academia, research, learned societies (62).

Overall, the respondents found the most urgent issues to be addressed by the Pharmaceutical strategy are innovation for unmet needs (53%) and improvement of access to medicines (44%).

International dependency and manufacturing

More than 40% of the respondents provided input on actions or initiatives to incentivise the production of active ingredients for essential medicines in the EU such as diversification of manufacturers, tax incentives to manufacturers and sustainable pricing of products. Actions suggested to enhance the quality of medicines covered strengthened regulatory oversight, encouraging international cooperation for high-quality standards in manufacturing and distribution, as well as more research.

Access to affordable medicines

Almost all respondents (87%) were concerned about shortages of medicines in the EU. Even though increased cooperation between national authorities featured highly among actions, stakeholder groups had different positions on actions to address shortages; while 76% of healthcare respondents and 70% of citizens agreed that companies with a centralised marketing authorisation should be required to market the medicine in all Member States only 14% of pharmaceutical industry respondents supported this action. Industry respondents called for actions like maintaining regulatory flexibility brought in for COVID-19 and harmonisation of marketing authorisations across the EU while healthcare respondents called

[2] https://ec.europa.eu/health/sites/health/files/human-use/docs/stakeholders_sum_workshop_en.pdf

for a framework for medicinal donation and reuse programmes and citizens supported financial penalties for manufactureres not providing the required amounts of medicines.

Also on prices of medicines divergent positions existed, with industry (72%) finding price levels justified which was in contrast to the civil society organisations (65%) and healthcare respondents (59%) who did not find prices justified.

Innovation in early development and authorisation

The actions considered most effective to support innovative research and development of medicines were to foster research collaboration between universities, research centres and industry (50%), make the legislative framework more adaptive to new technologies and advances in science (48%) and provide more public funding for research (35%). Stakeholder groups had different emphasis on actions, e.g. civil society organisations favoured making public funding transparent and conditional on access and affordability, researchers expressed support for public-private cooperation and public authorities supported alignment of research and development spending with public health needs identified at EU level.

For unmet medical need, there was support across stakeholders for more targeted research at EU level (61%) and agreement on a common understanding on what are the areas of unmet medical need in the EU (58%).

Digital technologies were considered to provide opportunities to promote development and use of medicines in different ways also in terms of aligning price and value. However, across stakeholder groups there was consensus that these technologies are associated with risks, e.g. non-compliance with data privacy and lack of transparency in artificial intelligence analysis.

Environmental sustainability of medicines and health challenges

The actions most supported across groups for limiting the environmental impact of medicines were stricter disposal rules for unused medicines (42%) and cleaner manufacturing processes (35%). Stakeholders also suggested other actions such as improvement of schemes for unused medicines, reutilisation of solvents and chemicals.

To fight antimicrobial resistence, over half of the respondents considered that more prudent use of antimicrobials would have the biggest impact and found support should be given for researching/discovering new antimicrobials or their alternatives.

d. AD HOC CONTRIBUTIONS

Pharmaceutical Committee

Input was sought from Member States through the advisory Pharmaceutical Committee[3]. In this forum, the Member States pointed to the need for a system allowing regulators to respond to challenges from scientific and technological developments in a coordinated manner. The system should make use of new digital technologies in development and monitoring of medicines while ensuring ethical handling and protection of patients' data. Member States suggested that the Pharmaceutical strategy covers medical devices and *in vitro* diagnostics in terms of access and regulatory convergence with medicines. Relevant expertise among regulators in new fields like data science needs to be ensured.

[3] https://ec.europa.eu/health/documents/pharmaceutical-committee/human-meeting_en

Member States identified shortages of medicines as a major problem. They suggested to establish a list of "essential medicines" and to ensure that the EU is not overly dependent on active ingredients from third countries. Addressing unmet medical need, including development of new antimicrobials, requires innovation and repurposing of medicines together with possibly a review of incentives. Actions on access should be combined with stronger enforcement of existing obligations on marketing authorisation holders. Equitable access to affordable medicines was identified as an important issue together with pharmaceuticals in the environment. Finally, as the COVID-19 pandemic developed, Member States put more emphasis on the need for a European approach, so that the EU is better prepared for future pandemic crises.

Ad hoc Group of the national authorities for pricing and reimbursement and public healthcare payers

In two ad hoc meetings of representatives of the national authorities for pricing and reimbursement and public healthcare payers, they voiced an interest for a standing EU level forum for exchange on issues of common interest and to allow concerns of these authorities and bodies to be heard at EU level.

In view of the upcoming Pharmaceutical strategy, the group flagged their broader concerns on the functioning of pharmaceutical markets, coordination challenges and issues of EU relevance. These include the impact from the early marketing authorisation schemes, incentives/creation of monopolies, significant price increases of "older" essential products. According to the group reducing uncertainty and asymmetry of the information payers have over the real-life effectiveness and costs of medicines (for instance medicines for rare diseases) is needed. Affordability could be increased through common guidelines on areas such as, pricing and procurement; having synergies with regulators, HTA bodies and payers; a better understanding of research and development costs of pharmaceutical companies; and cooperation for availability of generics. Future actions could build on the current tools and instruments from the EU health programme and on existing voluntary regional cooperation mechanisms.

Engagement with the European Parliament

On 11 September 2020, the European Parliament Committee on the Environment, Public Health and Food Safety held a technical briefing on the Pharmaceutical Strategy in which the background, objectives and main issues of the Strategy was presented by the Health and Food Safety Directorate-General. The Committee was particularly interested in how the Strategy would cover lessons learnt from COVID-19, preparedness for future pandemics and antimicrobial resistance actions as well as its linkage with the industrial strategy and funding for its implementation.

Meetings of Commissioner Kyriakides with key stakeholders

Commissioner Kyriakides has since June 2020 met with key stakeholders representing patients, consumers, healthcare professionals, pharmaceutical industry and payers. The stakeholders' positions were consistent with those expressed in other consultation activities.

Other outreach activities

On 12 November 2020, Commissioner Kyriakides met with EU social partners representing employers and workers to discuss the Pharmaceutical strategy. The social partners expressed positions that converged with those expressed in previous consultation activities, and skills featured more prominently in this meeting.

At Commission service level, Health and Food Safety Directorate-General has participated in conferences, like the European Health Forum Gastein 2020 and the The Organisation for Professionals in Regulatory Affairs (TOPRA) Symposium 2020, and meetings of stakeholder organisations. Stakeholders expressed positions identical to those gathered through other consultation activities.

4. HOW FEEDBACK WAS TAKEN INTO ACCOUNT

The Pharmaceutical strategy for Europe is wide-ranging and covers the issues identified by stakeholders as important to be included in the strategy. The strategy also sets out general actions for implementation.

By its nature, the Pharmaceutical strategy for Europe is a document that addresses the challenges and lays down policy objectives. It aims to give the general direction for each policy aspect and specifies specific, but high level actions. The Commission services have noted all the key messages mentioned in the consultations and summarised in this document. Most of the recommendations made in the consultation process relate to specific policy choices that are more relevant for the implementation phase of the strategy rather than the strategy document itself. Even so, these were very helpful to gauge the expectations and positions of consulted parties and have been fully taken into account in the drafting process.

In the implementation of the strategy, the options for the general actions will developed and at that stage, the recommendations from stakeholders will be further examined and further engagement with stakeholders will take place.