



Analysis of consultation activities directed towards the adoption of a Pharmaceutical Strategy for Europe

Factual Summary Report - Replies to the Roadmap

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Pharmaceutical Strategy for Europe

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1 Introduction

The European Commission published a Roadmap on the Pharmaceutical Strategy - Timely Patient Access to Affordable Medicines, which was available for stakeholders to comment on and share their views from 2 June 2020 to 7 July 2020.

This factual summary report presents a neutral analysis of all the replies received. The analysis was qualitative, drawing on machine learning and manual qualitative analysis to identify themes. Views and opinions as well as recommendations for the forthcoming EU Pharmaceutical Strategy are presented for all stakeholder groups as well as by key stakeholder group. Views and positions expressed by stakeholders may not necessarily be shared by the Commission but will be taken into consideration.

2 Overview of contributions

The Pharmaceutical Strategy Roadmap received 242 responses. After screening the responses and eliminating duplicates, 238 responses were considered for the analysis. Of these 238, 6 were found not relevant. Therefore 232 responses were used for the analysis. Of these 232, 101 respondents included an attachment to their response.

Some evidence of redlining was present. Where two respondents were found to have submitted the same response or the same attachments, only the first response was considered. On two occasions it was identified that the same file had been repeatedly attached: in the first instance, four respondents attached the same position paper. In the second, two respondents attached the same position paper.

Table 1 presents an overview of the responses by key stakeholder group. These groups include civil society organisations (CSOs), representing patients and consumers, public health, alternative treatments or organisations from different therapeutic areas, particularly cancer organisations. CSOs also includes two environmental organisations. The Industry stakeholder group is formed of the pharmaceutical industry and trade organisations and other industries (including parallel traders, distributors, medical technology and the chemical industry). There were three respondents from the pharmaceutical industry that were classified as small or medium-sized enterprises (SMEs). The healthcare professionals / healthcare provider group is composed of healthcare professionals', insurers' and hospitals' associations among others.

Table 1. Number of contributions by stakeholder group

Stakeholder group:	Number:	Stakeholder group:	Number:
CSOs including environmental organisations	52	Industry: Business associations	33
Healthcare professionals / healthcare providers associations	23	Industry: Other ¹	7
EU citizens	20	EU ² and national public authorities	14
Industry: pharmaceutical	43	Researchers, academia and learned societies	19
		Other ³	21

¹ This group includes parallel traders, distributors, MedTech and representatives from the chemicals industry.

² This includes the EMA and the EU Parliament.

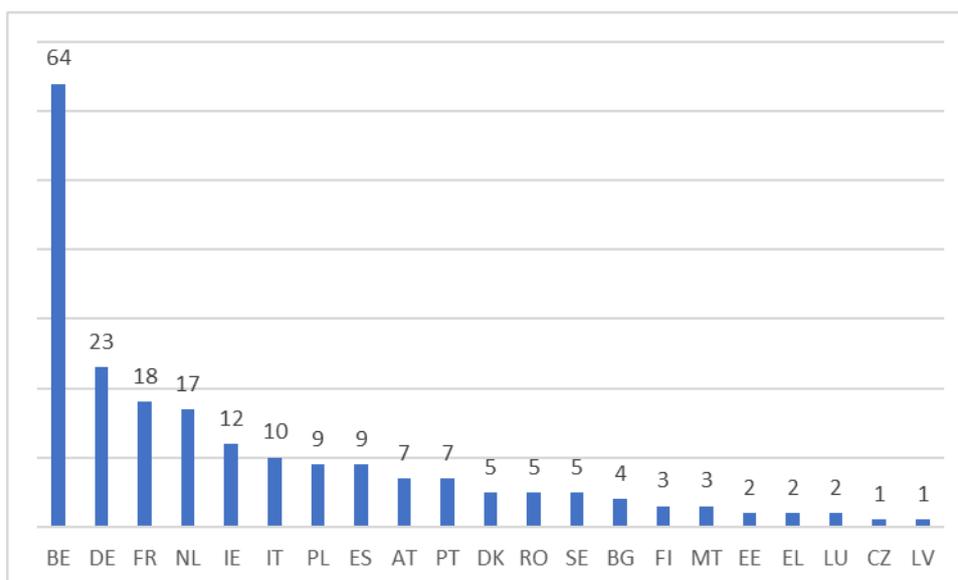
³ This group includes think tanks, consultancy firms, water providers, and employers' associations.

Stakeholder group:	Number:	Stakeholder group:	Number:
Total:	232		

Note: ICF analysis of contributions to the Roadmap.

Figure 1 presents an overview of the contributions by country. Contributions were received from all Member States except Croatia, Cyprus, Estonia, Slovakia, Slovenia. A contribution from Lithuania was excluded as it provided the same information as another contribution. The highest number of replies were received from Belgium (64), Germany (23), France (18) and the Netherlands (17). 29 replies were also received from third countries – the most common were the United States (11) and the United Kingdom (11).

Figure 1. Overview of contributions from EU Member States



Note: ICF analysis of contributions to the Roadmap.

Ten themes were pre-identified as key areas covered in the roadmap and in order to understand which replies covered these themes, a coding frame was created for each of the themes. Coding frame keywords and phrases were identified following a literature review of key relevant documents including the Mission Letter for the Commissioner for Health and Food Safety⁴, the Roadmap⁵ and the European Parliament resolution⁶.

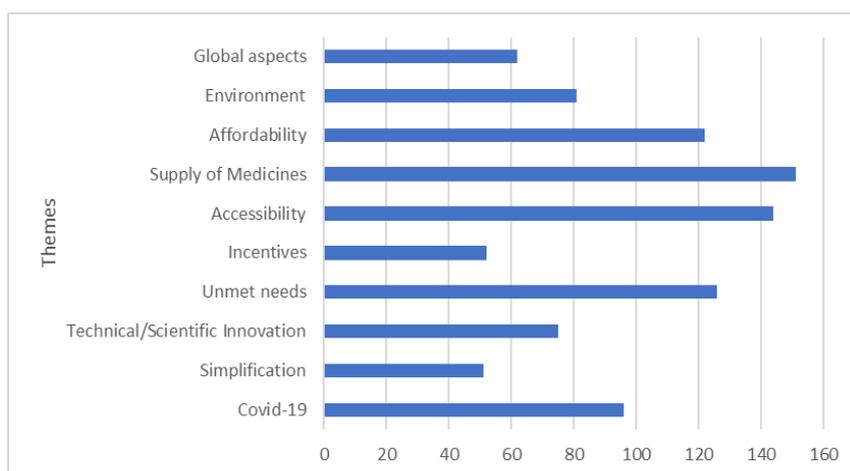
Figure 2 shows each of the themes and in how many of the replies this theme was discussed. The most discussed theme is **Supply of medicines (which includes dependency of supply, shortages and manufacturing capacity)** followed by **Accessibility**, **Unmet Needs** and **Affordability** also score highly appearing in over half of all responses. **Covid-19** is a mid-level theme, appearing in just under half of the responses. Themes with low traction are **Simplification** and **Incentives**.

⁴ European Commission (2019) [Mission Letter to Stella Kyriades, Commissioner for Health and Food Safety](#).

⁵ European Commission (2020) [Pharmaceuticals – safe and affordable medicines \(new EU strategy\). Roadmap](#).

⁶ European Parliament resolution of 2 March 2017 on [EU options for improving access to medicines \(2016/2057\(INI\)\)](#) OJ C 263, 25.7.2018, p. 4–18.

Figure 2. Frequency of themes identified in the replies



Note: ICF analysis of contributions to the Roadmap

3 Key issues and recommendations by stakeholder group

3.1 Industry stakeholders

Industry stakeholders welcome the European Commission's plans to introduce a Strategy as laid out in the Roadmap. They suggest several areas where further development and additions would be welcome in relation to improving the **EU research and production infrastructure** and **ensuring supply**⁷:

- Increasing the funding available for research and development (R&D) in particular for early stage medicine development;
- Promoting European upskilling;
- Promoting innovative manufacturing and the development of the research ecosystem (e.g. biobanks, databanks);
- Reducing the dependence on non-EU production: shifting production of active pharmaceutical ingredients (APIS) and other essential processes towards Europe;
- Ensuring the efficient and equitable distribution of medicines within the Member States through a stronger industry-EU and industry-government cooperation efforts, especially in health crises.
- Strengthening strategic value chains and framework conditions for European production;
- Maintaining the absence of export restrictions to facilitate free trade and the smooth functioning of the internal market; and
- Addressing the root causes of supply shortages and supply chain risks.

Concerning **improving the pharmaceutical regulatory environment**, industry stakeholders underlined the need for more clarity, adaptability and speed, that could be promoted by the following:

- A robust intellectual property framework that safeguards patents;
- Incentives to stimulate and speed up research and harmonise supplementary protection certificates (SPC);
- Introducing Real World Data (RWD) and Real World Evidence (RWE) into clinical development and regulatory decision making;
- Developing pan-European clinical trial networks; and
- Building a European Health Data Space.

⁷ These were the three priority areas identified through the machine learning analysis.

The **off patent sector** whose stance is slightly differentiated from other respondents in the industry stakeholder group focused on enhancing competition, revising procurement criteria, and IP rights.

While raised to a lesser degree, environmental concerns⁸ were also received positively by this stakeholder group. While the number of contributions from SMEs was low, there was an indication of greater support for improving access and availability of treatments in particular addressing challenges relating to Health Technology Assessment (HTA) and reimbursement (novel payment models) to enable early and broad patient access was highlighted by these stakeholders.

3.2 Civil society organisations (CSOs) stakeholders

CSO stakeholders responded positively to the Roadmap and stressed the importance of improving **affordability** and the **accessibility of treatments** to address **unmet medical needs**⁹. There is a notable degree of overlap in their views with those from industry with some important distinctions however, notably as regards their position on the current system of incentives. While industry stakeholders tend to favour a stable incentives system and favour the status quo, CSOs believe that it should be revised to favour access to therapies especially as regards medicines for unmet needs. CSOs consider that certain areas could be developed further including:

- Revising the current system of incentives (including the R&D funding) to exclusively align research priorities with the public interest and unmet medical needs rather than economic gains for industry;
- Promoting the meaningful involvement of patient and other civil society groups in setting research priorities;
- Exploring new pricing and procurement models to promote the development of new medicines and vaccines that address unmet needs especially for rare forms of cancer – for example, the Orphan Medicinal Products Regulation should be reviewed to stimulate research for rare diseases such as paediatric cancers;
- Reducing dependence on other countries to ensure provision of essential medicines including derived medicines;
- Enhancing Member State coordination with the pharmaceutical sector;
- Harmonising the clinical trial approval process across Member States to accelerate access to innovative treatments (e.g. fast-track condition approval) and strengthen the competitive edge of European pharmaceutical companies;
- Promoting data sharing initiatives between academia and industry; and investing and promoting non-animal technologies to replace animal testing for medicine safety and efficacy testing.

3.3 Healthcare stakeholders

Healthcare professionals and providers also expressed a strong support for the EU Pharmaceutical Strategy. Their main concern is the **availability of medicines while innovation** was also a notable concern particularly in relation to **meeting unmet needs**¹⁰. This concern was more pronounced in relation to anti-cancer and paediatric medicines.

Some respondents highlighted the need for more concrete actions and associated timetables under each objective. Two contributions felt that the strategy should rather

⁸ No concerns on the current system of Environmental Risk assessment were reported. Two respondents highlighted their support for an extended environmental risk assessment. Another stakeholder proposed that the EC develops criteria for accelerated assessment, green procurement and reviews policies that hinder the adoption of circular approaches.

⁹ The machine analysis identified 'need' and 'access' to have a high independent frequency as well as joint frequency among CSO contributions.

¹⁰ These priority areas were identified through the machine learning analysis.

focus on health more broadly rather than pharmaceuticals. One contribution suggested that the Roadmap completely overlooked some key issues¹¹. More broadly, the key issues that carried more attention from this stakeholder group's perspective include:

- Promoting coordination and collaboration between Member States in terms of monitoring physical stocks of supplies¹², redistribution of supplies according to need, pricing and reimbursement policies, and HTA evaluations (facilitated by European-wide mechanisms);
- Ensuring that medicines and APIs are produced and distributed in Europe;
- Introducing stricter due diligence at procurement and post-authorisation e.g. on ability to supply;
- Revising the orphan and paediatric medical products regulations and approving draft HTA regulation legislation; and
- Incentivising and supporting European-based research to develop new or repurposed medicinal products and therapies that address unmet needs.

Healthcare stakeholders generally agreed on the importance of **digital tools** (e.g. electronic product information, smart prescriptions and medical records). The inclusion of **environmental concerns** is also welcomed by this stakeholder group. Several contributions make specific suggestions in relation to the avoidance of medicinal product wastage including stability testing of older medicines to enable prolonged usage.

3.4 Public authorities

Public authorities stressed the need to increase the production of APIs in Europe to alleviate **shortages** and **promote access and affordability** of medicines and to facilitate the repurposing of medicines. This stakeholder group was also concerned with the alignment of the Strategy with other EU policies (e.g. water, chemicals and antibiotic resistance) as well as linkages (e.g. new Industry Strategy for Europe, Horizon Europe, the EU recovery plan, the EU4Health programme). Public authorities also would like the Strategy to address medical devices including in vitro devices.

3.5 Researchers, academia and learned societies

Researchers and academia stakeholders stressed the need for greater emphasis on enhancing cooperation with industry in terms of increasing knowledge and information exchange, modernising pharmaceutical and medical education and training of staff and students, revising the regulatory environment to promote pharmaceutical **innovation** in Europe, and enhancing the commercialisation of academic knowledge. Greater cooperation in addition to maintenance of a strong intellectual property rights system, could generate economic benefits in terms of job creation in the life sciences sector and productivity in the EU. In their view, the Roadmap also lacks a strong evidence base¹³ and should more strongly emphasise patients and **unmet needs** at the centre of medicinal product development¹⁴. Lastly, a contribution from this stakeholder group

¹¹ A small association highlighted the need to expand the issue of patient safety to include issues of correct and quality prescription and dispensing; measures for ensuring compliance with existing legislation, guidance and regulatory efforts; and the concept of waste beyond the environmental impact of disposal. The necessary 'synergies' across Member States should be more specific.

¹² One specific suggestion is to introduce an EU-level framework for monitoring supplies of and access to essential medicines. The role of the European Medicines Agency could be expanded to support this and lead on information exchange. Some caution against using the European Medicines Verification System. Other suggestions include the development of a cross-EU list of essential medicines, strengthening of the Directive 2001/83/EC to enforce equitable market launch obligations, and enabling the off-label use of medicinal products particularly for rare and very rare cancers.

¹³ Key reports that could be cited for example include: the DRIVE-AB report (financed by the EU's Innovative Medicines Initiative, the World Health Organization's Antibiotic Shortages report, and the ongoing outputs of the EU Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI).

¹⁴ In line with the [EORCO manifesto](#).

suggests that the Strategy could highlight the need for a joint venture between DG SANTE, DG CNECT to address global health, security and bio-defence matters¹⁵.

3.6 EU citizens and other stakeholder groups

The views of other stakeholders including EU citizens were generally reflected amongst those identified among the key stakeholder groups presented above. Their main concerns focused on the **availability and affordability** of innovative medicines and the need for standardisation in production and availability across the EU to alleviate **shortages** and promote competitiveness of EU industry at a global level. Support for addressing **environmental concerns** in the Strategy was also voiced, but to a lesser degree.

¹⁵ This is referred to as a Foresight Directorate for Health Security and Defence.