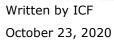


## Pharmaceutical Strategy for Europe

Final Report - Replies to the public consultation





### **EUROPEAN COMMISSION**

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#### **EUROPEAN COMMISSION**

## Pharmaceutical Strategy for Europe

Final Report - Replies to the public consultation

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#### List of abbreviations and acronyms

API - Active Pharmaceutical Ingredient/s

AMR - antimicrobial resistance

ATMPs - Advanced therapy medicinal products

EMA - European Medicines Agency

EMVS - European Medicines Verification System

EPSCO - Employment, Social Policy, Health and Consumer Affairs Council

ERN - European Reference Networks

CSO - Civil Society Organisation

FDA - Food and Drug Administration

FDFs - full dosage forms

FPP - Finished Pharmaceutical Product

FTA - Free Trade Agreements

GMP - Good Manufacturing Practice

GP - General Practitioner

HE - Hospital Exception

HTA - Health Technology Assessment

ICH - International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

MAH - Marketing Authorisation Holder

MEAT - Most Economically Advantageous Tender

PACs - Post-Approval Changes

PDMPs - prescription drug monitoring programmes

PDP - Product Development Partnership

PIC/S - Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme

PNEC - predicted no-effect concentrations

PROMs - Patient Reported Outcomes

QoL - Quality of Life

RWE - Real World Evidence

R&D - Research and Development

SME - Small and Medium-sized Enterprises

WTO - World Trade Organization

### **Executive Summary**

The European Commission published a public consultation on the Pharmaceutical Strategy - Timely Patient Access to Affordable Medicines, which was available for stakeholders to comment on and share their views from 16 June 2020 to 15 September 2020. The public consultation questionnaire was structured by four strands or themes.

The public consultation received 473 contributions of which 108 included a position paper in attachment to their response. These contributions were received from a range of stakeholders across the EU Member States¹ including public authorities; industry; civil society organisations including patient organisations; healthcare professionals, providers and payers; and citizens. An overview of the overall findings by strand/theme is presented below.

### International dependency and manufacturing

Stakeholders believe that EU actions that strengthen global value chains through trade agreements and reforms can help incentivise the production of active pharmaceutical ingredients for essential medicines. Other effective actions for the EU include the generation of financial support to local companies that produce active pharmaceutical ingredients and universities to build their expertise. Stakeholders consider that the quality of medicines can be enhanced through greater standardisation and control at a global level in terms of standards and audits.

#### Access to affordable medicines

Most respondents (87%) are concerned about access to affordable medicines. This concern appears to be exacerbated by the COVID-19 pandemic. Many noted that the dependency on non-EU countries for manufacturing ingredients is a driver of shortages. Public authorities, CSOs and the research community also noted the limited cooperation between Member States that can lead to shortages (e.g. wholesalers keeping limited stocks) and an uneven distribution of supplies across the EU.

#### Innovation in early development and authorisation

Stakeholders believe that research collaborations between universities, research centres and industry and adaptive legislative frameworks are key to promoting innovative research and development of medicines. With regards to research and development for medicines addressing unmet needs, stakeholders believe that the European Commission can do more to fund targeted research and to identify the main areas of unmet need in the EU. Patient experiences could also be sought in the earlier phases of medicine design. While optimistic about digital technologies, particularly in relation to testing the safety profile and benefits of medicinal products, stakeholders are also aware of their risks and the need for regulation.

#### Environmental sustainability of medicines and health challenges

Stakeholders believe that the strict disposal of unused medicines and clearer manufacturing processes are important measures to limit the negative environmental impact of medicines. Many also believe that strengthening regulations on the non-human use of antibiotics especially in the farming industry could have a sizeable impact on fighting antimicrobial resistance. Stakeholders would welcome new research and investment models to promote the development of new antimicrobials as well as national and EU action plans that outline funding incentives, public-private partnerships and innovative research.

Replies were received from all EU Member States except for Slovakia.

#### 1 Introduction

The European Commission published a public consultation on the Pharmaceutical Strategy - Timely Patient Access to Affordable Medicines, which was available for stakeholders to comment on and share their views from 16 June 2020 to 15 September 2020.

This report presents a neutral, over-arching review of the replies received. Section 2 presents the methodology including an overview of the contributions. Section 3 presents an analysis of replies to the survey questions while Section 4 presents a synthesis of position papers received with a focus on additional views and recommendations not already expressed in reply to the survey.

The core of the report lies in Section 3 where the analysis is reported by survey question. An overall analysis is followed by an analysis by relevant stakeholder group with attention to divergent views and opinions as well as recommendations for the forthcoming EU Pharmaceutical Strategy. The quantitative analysis was broken down by stakeholder groups for which there was sufficient sample size. In order to have a complete picture, the findings from this analysis should be read in combination with the relevant figures and charts in the Annex. Additional qualitative analysis delved further into smaller, more specific stakeholder groups considered to be relevant for the survey question. Views and positions expressed by stakeholders may not necessarily be shared by the Commission but will be taken into consideration in the development of the EU Pharmaceutical Strategy.

### 2 Methodology

#### 2.1 Overview of contributions

The public consultation received 473 contributions of which 108 included a position paper in attachment to their response. While no duplicates were identified, there is some evidence of redlining where different respondents provided the same open reply. Table 1 presents an overview of the contributions to the public consultation questionnaire by key stakeholder group as self-identified by the respondent. Of the 142 replies from industry, 65 were from active pharmaceutical ingredients (API) producers or importers and 49 were SMEs. Nineteen respondents were both API producers or importers and an SME. Table 2 presents a breakdown of the position papers by stakeholder group.

Table 1. Number of contributions by stakeholder group

Stakeholder Type	Frequency	Stakeholder Type	Frequency
Academia/research	62	Healthcare professional, payer or provider	85
Academic researcher	27	Healthcare professional	49
Scientific organisation	20	Healthcare provider organisation (incl. hospitals, pharmacies)	,
Learned society	7	Healthcare pricing & reimbursement body and/or final payer	6
European research infrastructure	4	Healthcare technology assessment body	4
Research funder	4	Industry*	142
Citizens	47	Industry: API producer/importer	65
Patients	6	Industry: SME	49
Other members of the public	41	Industry: Pharmaceuticals	117
Civic Society Organisations (CSO)	59	Industry: Pharmaceuticals traders/wholesalers	14
Patient or consumer organisation	58	Industry: Medical devices	6
Environmental Organisation	1	Industry: Chemicals industry	5
Public authorities	25	Other**	53
National public authorities	24	Grand Total	473
EU regulatory partner / EU institution	1		

*Note:* ICF analysis of replies to the public consultation. \*The breakdown of this group included overlaps, for example, between SMEs and pharmaceuticals. \*\*This group included business associations, water and water resources organisations, alternative medicine associations, and medical publications.

Figure 1 presents an overview of the replies by country. Contributions were received from all Member States except Slovakia. The highest number of replies were received from Belgium (81), Germany (68), France (56)<sup>2</sup>. In addition, 47 replies were received from non-EU countries – the most common were the United States (16), the United Kingdom (13) and Switzerland (13).

<sup>&</sup>lt;sup>2</sup> This distributional pattern was also evident in the analysis of the replies to the Roadmap.

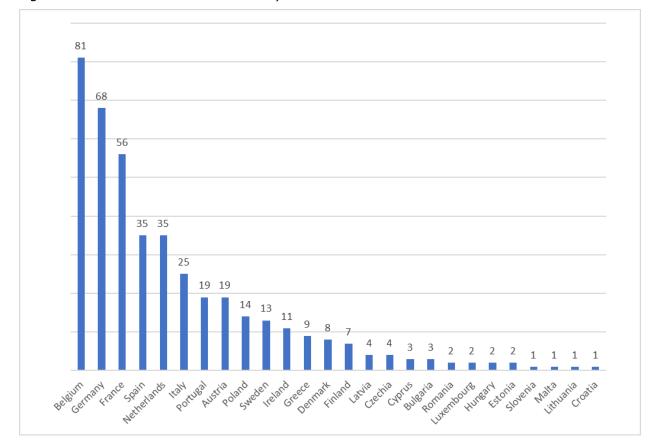


Figure 1. Overview of contributions by EU Member State

*Note:* ICF analysis of replies to the public consultation. Replies were also received from non-EU countries: United States (16), United Kingdom (13), Switzerland (13), Israel (2) and one each from Bosnia and Herzegovina, Serbia and India.

Table 2. Composition of position papers received by stakeholder group

Stakeholder Type	Frequency	Stakeholder Type	Frequency
Academia/research	15	Industry	33
Civic Society Organisations (CSOs)	14	Industry: API producers and importers	13
Healthcare professional, payer or provider	22	Industry: SME	10
Public authorities <sup>3</sup>	6	Industry: Pharmaceutical traders/wholesalers	5
		Other <sup>4</sup>	18

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<sup>&</sup>lt;sup>3</sup> EU and National Public Authorities

<sup>&</sup>lt;sup>4</sup> Other: Business Associations, Water and water resources organisations, alternative medicine associations, medical publication

#### 2.2 Analytic approach

The analysis includes cross-tabulations of closed answer questions and a qualitative analysis of additional textual feedback provided by respondents in open answer questions and through position papers. The qualitative analysis drew on both text analytics techniques and manual qualitative analysis to provide insight into the themes being discussed.

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 Safety<sup>5</sup>, the Roadmap<sup>6</sup>, the European Parliament resolution of 4 March 2017<sup>7</sup>, the Council conclusions of 17 June 2016<sup>8</sup> and the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) Conclusions of 9 December 2019<sup>9</sup>.

No duplicates among the replies were identified, however, instances of campaigns and redlining were evident among the open replies to some questions. For example, several respondents among Civil Society Organisations (CSOs) stressed the importance for the strategy to promote the development of paediatric medicines and treatments for cancers. These instances are highlighted in the analyses by question in Section 3. The analytic approach sought to highlight these views while also identifying others.

### 3 Findings

#### 3.1 International dependency and manufacturing

# 3.1.1 Q1. What type of EU action or initiative do you consider helpful to incentivise the production of active pharmaceutical ingredients for essential medicines (e.g. antibiotics, oncology medicines) in the EU?

A wide range of stakeholder groups responded to this question – see **Error! Reference source not found.**. No overarching consensus was identified across respondents. Views put forward by different stakeholder groups are summarised below.

Views from the **chemical industry** focussed on supply and standards. Stakeholders believe that European companies should be used for strategically important substances, and as a minimum, "second suppliers" should also be used and serve at least 40% of the market. Because of COVID-19, and in an effort to avoid future shortages, stakeholders in this group think that global value chains should be strengthened through trade agreements and the abolishment of unilateral public incentives. With respect to standards, these stakeholders support harmonised global standards to ensure that the EU is a competitive region for manufacturing.

With respect to **pharmaceutical traders and wholesalers**, views included a demand for more financial support from the EU to local companies that produce active pharmaceutical ingredients, and the need for universities to have more experts on the subject area. Diversification of production is also a theme that arose among the

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<sup>&</sup>lt;sup>5</sup> European Commission (2019) Mission Letter to Stella Kyriakides, Commissioner for Health and Food Safety.

<sup>&</sup>lt;sup>6</sup> European Commission (2020) Pharmaceuticals – safe and affordable medicines (new EU strategy). Roadmap.

<sup>&</sup>lt;sup>7</sup> 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.

<sup>&</sup>lt;sup>8</sup> Council conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the EU and its Member States.

<sup>&</sup>lt;sup>9</sup> Council of the European Union (2019). Preparation of the Employment, Social Policy, Health and Consumer Affairs Council session on 9 December 2019. European pharmaceutical policy – strengthened cooperation and coordination with the aim to improve access to medicines.

responses, noting that having only one or a few production sites for a given API, excipient, or finished pharmaceutical product (FPP) makes supply more fragile to disruptions. Respondents also seek to reduce the pressure on pharmaceutical prices and produce more medicines within the EU. They believe the absence of pressure for the lowest possible price of medicines will also lead to a reduction in parallel trade. Relatedly, support for innovation and investments to enhance greener production and manufacturing sites is also expressed among pharmaceutical traders and wholesalers.

Views from the **pharmaceutical industry** can be classified by the following themes: regulatory environment requirements and guidance, incentives and supply. With regards to regulatory guidance, API producers and importers suggest that active pharmaceutical ingredients' developers and manufacturers would benefit from more regulatory support and education from competent authorities when it comes to implementing legal requirements that are high quality(such as good manufacturing practices). They also see the need for greater regulatory guidance, as well as specific guidance for some categories of innovative products or complex diseases (e.g. microbiome-based products). Also, for faecal material-based products or transplantation there is no regulatory framework. Respondents also highlighted the need for incentives to create a prosperous business environment that attracts manufacturers who have moved their production sites outside the EU/EEA or decided to source active ingredients from non-EU producers. To achieve this goal the EU/EEA would have to focus on an attractive regulatory framework, educational and employment opportunities, and financial incentives. Other respondent suggestions include considering incentives for global supply chain investment in Europe, incentivizing academic-industry collaboration and translation of research, and developing a robust incentive model within Europe to help in realizing the full potential that gene therapies and other advanced therapy medicinal products can deliver to patients and national healthcare systems. In addition, API producers and importers feel the global regulatory complexity for managing Post-Approval Changes hinders and disincentivises continuous improvement and technical innovation. It is also an aggravating factor for medicine shortages.

Supply was the most used word amongst the pharmaceutical industry with the consensus being that there is support for measures that support robust, global, diversified supply chains which can respond to external stressors in a consistent way and ensures security of supply within Europe. Suggestions of how this could be achieved include through Free Trade Agreements (FTAs) and World Trade Organization reform and making security of supply one of the Most Economically Advantageous Tender criteria within medicine procurement.

## 3.1.2 Q2. What action do you consider most effective in enhancing the high quality of medicines in the EU?

As shown in Figure 3, a quarter of respondents believed that increased controls would be the most effective, whilst a fifth chose stronger enforcement. Almost half (47%) proposed another action than what was presented as a response option. Differences in views were evident by stakeholder group (see Figure 4).

The main areas of discussion by **API producers and importers** relates to good manufacturing practice and regulatory oversight. For non-EU countries, stakeholders express wanting to create a level playing field with respect to good manufacturing practice enforcement, as well as Falsified Medicine's Directive implementation in the EU distribution chain. In addition to levelling the playing field, stakeholders believe non-EU pharmaceutical companies should meet the same standard of good manufacturing practice (GMP) and environmental standards that their EU-based counterparts must. Stakeholders also opine on regulatory oversight for both EU and non-EU countries. For non-EU countries, this group encourages strengthening regulatory oversight in emerging market countries. They also suggest streamlining the regulatory process, noting that things like recognition of harmonised International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use standards and

Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme inspection practices will make it more efficient and effective. This group also believes that the EU must play a leading role in promoting regulatory convergence, with an aim towards the adoption of worldwide, high-quality standards. Finally, stakeholders said that regulatory audits of non-EU pharmaceutical manufacturers should be increased.

Views from the **chemicals industry** focussed on the themes of inspection and international cooperation. Respondents express a need to reinforce inspections of non-EU production sites of APIs and their intermediaries so that they adhere to EU criteria on specific elements. These include quality, environmental, sustainability, and social standards. Like the API producers and importers group, they also advocate for regular audits, like those that occur with the Food and Drug Administration and German authorities, to guarantee standards compliance. This group also wants to promote international cooperation that supports consistent rules in global manufacturing and distribution chains. As well, they believe that continued international cooperation with partner countries is essential for the efficiency and security of pharmaceutical supply.

Almost all the replies from **pharmaceuticals traders and wholesalers** were duplicates, suggesting a campaign. This group expressed the need to distribute medicines via a more consistent process, such as full-service healthcare distributors, due to high standards requirements based on careful monitoring of temperature during storage and transport, detailed documentation and self-inspection, and utilisation of end-to-end verification of medicines to ensure patient safety.

Furthermore, there is a suggestion of stronger enforcement of marketing authorisation holder obligations and increased controls in manufacturing and distribution. This is a view mentioned and supported by other stakeholder groups as well.

Several replies from **CSOs** focussed on the issue of funding or paediatric cancer research and the need to exploit the research potential of European Reference Networks (ERNs). These replies appeared to be part of a campaign.

#### 3.2 Access to affordable medicines

#### 3.2.1 Q3. Are you concerned about medicines shortages in the EU?

Nearly nine out of ten (87%) of all respondents stated that they are concerned about medicines shortages in the EU – see Figure 4. Only a small proportion are not concerned (6%) or had no opinion on the matter (7%). Similar levels of concern are evident across different stakeholder groups (see Figure 5), although the qualitative analysis identified divergent underlying views. Views by stakeholder group are presented below.

Members of the public highlighted personal experience of shortages; an awareness of the dependency on non-EU countries for manufacturing ingredients and certain medicines; concerns about pharmaceutical practices and monopolies; and wider concerns about ensuring the rights of EU citizens' to access to medicines. The pharmaceutical industry noted that the lack of manufacturing of APIs in the EU and the dependency on a global, complex supply chain are driving factors of medicine shortages in the EU. They also identified other factors that include a fragmented EU market, with complex supply chains and different pricing and reimbursement policies across Member States. They also pointed towards a lack of consistent definitions of shortage and consequently, the poor reporting and monitoring of them. The majority of **API producers/importers** echo the wider pharmaceutical industry group in identifying multiple factors for shortages and calling for multi-stakeholder responses. One respondent is particularly keen that the Strategy should not solely focus on the importance of innovation and continual improvement for new products but also support the 'crucial' innovation and improvement of medicines already on the market to ensure availability and maintain a state of control. Only three raise explicit concerns about API

production being located in Asia (China and India), with an additional respondent less explicit but querying whether it is time to reassess the EU's capability to produce full dosage forms (FDFs) within its borders. All respondents from the **chemicals industry** indicated concern about shortages and some echoed other stakeholder groups in linking these concerns specifically to the lack of production of generic medicines and APIs within the EU.

**Public authorities** expressed concern with the dependency on complex global supply chains and insufficient EU-based manufacturing. They point towards a lack of collaboration between Member States and unfair distribution of supplies across the EU, which has been exacerbated by the pandemic. Member States with small markets felt that they are potentially particularly vulnerable to issues with access. The **research community** also highlighted the limited cooperation between Member States and block manufacturing (e.g. one respondent suggested that the current production of generics in Eastern Europe could potentially compromise the safety of western Member States). In addition, they noted that shortages were more pressing for antibiotics, generics and innovative therapies for children. **CSOs** were also for the most part concerned about shortages and referred to concerns about patient outcomes (particularly for children with cancer) individual practices within Member States that lead to shortages (wholesalers keeping limited stock); the potential use of legal obligations at the marketing authorisation stage and that, echoing the public authority respondents, COVID-19 worsened an already difficult problem.

The main concerns of **healthcare professionals, providers and payers** relate to the impact of shortages on patients and professionals, and the shortages of not just particular medicines but also medical equipment such as dialysis machines. All six of the respondents from the **healthcare pricing and reimbursement bodies** expressed concern about shortages, viewing it as a global and an increasingly common phenomenon. There are two calls for an EU assessment of the reasons for, and prevalence of shortages.

Those indicating they are **not concerned** come from a wide range of stakeholder groups. Their reasons for not being concerned include confidence in EU mechanisms to enforce equal access to medicines and the limited relevance of shortages to particular professions (e.g. homeopathy) or medicines (e.g. shortages in generic medicines rather than innovative products in biotech).

## 3.2.2 Q4. Which actions do you think would have the biggest impact on reducing shortages in the EU?

The most favoured action was an increased cooperation among public authorities/national governments on shortages with nearly half (52%) choosing this option – as shown in Figure 6. The distribution of responses across individual stakeholder groups is shown in Figure 6Figure 7.

Among **pharmaceuticals industry** respondents, many of their 'other' responses appear to have been intended to provide more nuance to the predetermined options highlighted rather than offer additional actions – e.g. incentivising the production of APIs and raw materials, not just medicines (particularly plasma); going further than either increased cooperation or transparent information exchange between countries with the introduction of a pan-European standardised response to shortage reporting (including a shared shortage definition) and pan-European database or portal of stock levels and alert system, to avoid national stockpiling; using images or QR codes on labels to save space as an alternative to multiple languages. A campaign response identified in this group (not seen among the smaller subgroup of API producers) calls for: an early warning system for anticipated and existing shortages, involving and informing all supply chain stakeholders.

Some additional or alternative actions from this stakeholder group include: an EU-wide procurement and pricing strategy and/or approach for some medicines - particularly low

cost generics (to support Member States where volumes required are too low to meet economic viability for manufacturers); permanence of regulation flexibility brought in as result of COVID-19 in relation to marketing authorisations and good manufacturing practice (GMP); limiting and/or regulation of parallel trading; accelerated approval timelines for manufacturing and production transfers (i.e. from EMA); exemption of prescription drug monitoring programmes (PDMPs) from taxes and other pricing policies; mechanisms which promote competition (e.g. use of criteria other than price in procurement); and better planning between the industry and public authorities in planning vaccine stock levels ready for winter. Obligations on manufacturers supported by individual respondents or a small group include – a requirement to register multiple/ alternative API production sites (based in the EU) in the market authorisation holder (MAH) application and the requirement on manufacturers (subject to financial penalties) to supply sufficient stocks and/or plan for shortages.

A respondent representing the **generics industry** provided a campaign response (also submitted by seven other API producer respondents) calling for: Predictable pricing/reimbursement policies for off-patent medicines and sustainable markets that guarantee economic viability; targeted EU guidelines on medicines procurement; incentives for multisource manufacturing and supply reliability investment; pan-EU reporting/notification system and single definitions; two-way dialogue regulators-stakeholders and regulatory optimisation and digitalisation (e.g. variations legislation, telematics tools) and flexibility (e.g. e-leaflet; fast-track procedures). Other responses relating to generics include that EU should improve its communication strategy on appropriate therapeutic or generic medicines substitution.

Among **APIs producers and importers**, only two did not select any of the predetermined options and only one expanded on their answer – indicating that they would like to see the EU explore the full potential of complementary medicines alongside traditional products. Subsequently they would also like to see a balanced system of incentives for EU production which includes homeopathic and anthroposophic medicines. Among those who also selected 'Other' as an option, recommended alternative actions tended to echo those of the wider industry group. One particular additional recommendation was the extension of a centralised EU-wide marketing authorisation holder (MAH) process to all medicines but reduced in cost to support smaller producers (the reduction suggested was from EUR 200 000 to EUR 10 000). Other actions suggested included contractual minimum volume commitments on public authorities to purchase certain amounts of medicines from qualified manufacturers; and bonuses for producers based on their past ability to deliver uninterrupted supplies.

Of the five respondents from the **chemicals industry** to this question, only one had an additional suggestion that as opposed to multi-lingual packaging, labelling should be simplified and the paper leaflet in medicines phased out. They would like to see the use of mandatory coding for prescription medicines to enable authorisation conditions to be captured electronically in real time without the need to consult package information.

Among respondents from the **research** community who selected 'Other', one provided a campaign response similar to those seen among other groups further supporting transparent information exchange but pointing specifically towards using the WHO List of Essential Medicines and evidence from the European paediatric cancer community. Of those who did suggest alternative actions, these include: a general revision of the regulatory framework for innovative radiopharmaceuticals; annual roundtables with stakeholders involved in the restock of medicines (public authorities, governments and industries) to prevent the shortage and study plans to manage it (and the creation on an online platform for patients about substitutions); and calls for cooperation between Member States but specifically the revision of legislation 'to remove requirements which primarily function to undermine effective competition'.

**Healthcare providers and professional respondents** who selected 'Other' also sought to add more detail to the options given; for example, indicating support for

transparent information exchange through specifically (as with the pharmaceutical industry) a standardised and harmonised reporting of stock levels across the EU, into which manufacturers and public authorities are bound by legislation to provide data inputs. Some particular alternative actions put forward by health providers and professionals include: labelling medicines with active ingredient name and class, or particular biological molecules, rather than brands to more accurately reflect stock levels; creation of storage facilities for medicines; review of regulations to enable medicinal donation and reuse programmes (involving surplus unused unexpired medicines) or return of medicines to producers for them to redistribute; diversification of procurement practices (multiple awards, based on more than price criteria).

The main concerns among **CSOs** who selected 'Other' were the availability of palliative care, and treatment options for children and adolescents with cancer. These concerns were highlighted by separate campaign responses. Other actions recommended (by individual respondents) include: enabling the autonomous public production of medicines (or in cooperation with industry); increase the capacity of the EU to collect plasma in particular (to avoid reliance on the US); joint procurement or joint licensing of medicines for small patient populations; an agreed list of essential medicines developed in collaboration with stakeholders; mutual recognition or harmonised approach to marketing authorisations across the EU; and increased use of anthroposophic medicines.

Among **citizens**, some alternative actions suggested by 9 respondents who selected 'other' include financial penalties for manufacturers who consistently do not deliver the required amounts of medicines or can be identified as the root cause of particular shortages; introducing QR codes to facilitate shared electronic package information; and widening access across the EU to raw materials either by bringing production to the EU or through better monitoring of non-EU producers.

Public authorities also suggested other options which included: an obligation on manufacturers to register alternative API production sites in the EU in order to obtain marketing authorisation; imposing European sourcing research during the Drug Master File registration phase or European production quotas as a back-up for non-EU production; an obligation of shortage management plans (PGP) at the EU level for any MAH for an essential product; transparent reporting and quality auditing by manufactures of their logistic supply chains; banning of parallel trading between Member States; wider use of the European Medicines Verification System (EMVS) to monitor supply levels, switching from monitoring end-to-end security in the supply chain to a track-and-trace system; informing health professionals about substitutes for medicines that are at risk of shortage; imposition of minimum stock levels ( 6 months supply) of medicines and APIs (important for older medicines); a general increase in the availability of stocks in the pharmaceutical supply chain; the reallocation of stocks of vaccines and biomedicines to other Member States more in need, and the marketing of innovative medicines across all Member States given there is a centralised EU marketing authorisation process for this type of medicine.

# 3.2.3 Q5. Do you think that companies that apply for and receive an EU-wide marketing authorisation should be required to make that product available in all EU countries?

The majority of respondents (57%) agreed that that this requirement should be placed on companies whilst a quarter (24%) did not (as shown in Figure 8). Among individual stakeholder groups this level of agreement varied widely from 18% among industry to

<sup>&</sup>lt;sup>10</sup> There was a particular duplicate or campaign response (n=4) which calls on the commission to make reference to WHO List of Essential Medicines for children (EMLc) and evidence created by the European paediatric cancer community (doctors and those who are in charge of therapeutic protocols).

81% among healthcare professionals, payers or providers and 86% among CSOs (Figure 8 provides more information on individual stakeholder groups).

Only 18% of **pharmaceutical industry** respondents agreed with the statement although there was common argument made that this is for the EU to facilitate and support, not individual companies, through harmonised pricing structures and approval processes. Some indicated that EU-wide marketing authorisation would benefit SMEs as multiple individual approval processes in national member states are costly. Among those who disagreed, the most common reason given was the heterogeneity of regulations and pricing and reimbursement policies and evaluation processes in Member States. Other issues highlighted include different approaches to patent validity, low patient numbers to facilitate distribution of more rare medicines; and lack of local capacity to market medicines in 27 countries. A representative from the generics industry disagreed noting that some off-patent medicines (e.g. biosimilars) are already approved via a central procedure and cannot always launch in all Member States due to secondary patents. They suggest that courts in individual Member States may take different views on patent validity or on whether an injunction is appropriate; that launch plans can depend on other market dynamics, or limited operations of SMEs and that patent linkage can also delay generic/biosimilar market launch. Chemical industry respondents also indicated a lack of capacity to launch in all 27 Member States and also noted that market launch is affected by a range of factors 'mostly unrelated to the MAH'. They hold this suggestion to be contrary to the Single Market principle.

More than half of public authorities (64%) agreed with the statement with several calling for a review of the so-called "sunset clause" which one respondent considers insufficient to incentivise marketing authorisation holders to put their products on the market in economically less attractive smaller Member States. Among those who did not agree with the statement, one respondent indicated this was because of the difficulty of imposing this approach; a concern that it would lead to a reduction in MAH applications; and the need for further investigation before such an approach is adopted. One alternative suggested was to require a MAH to supply a certain number of EU Member States (or certain population).

**Academic and research** respondents largely agreed (70%) with the statement. Several think the industry should also be obliged to make medicines available at affordable prices in all Member States regardless of individual profit margins relating to pricing and reimbursement policies. One respondent calls for an EU wide pricing 'platform' to set EU wide prices, another for a mandatory clinical evaluation by a European Health Technology Assessment (HTA) following marketing authorisation. Those who disagreed felt that this would not be the right strategy to resolve issues with access and one highlights that it may not be possible to set up centres with the appropriate and requisite expertise to administer advanced therapy medicinal products (ATMPs) for rare and ultra-rare diseases in every Member State. Among **CSOs** there was a campaign response (different wording, but similar sentiments) about the inequalities in access, treatment and outcome that the circulation of different medicines and different approval timetables leads to across the EU.

The majority of **healthcare provider organisations and professionals** (81%) agreed with this proposal, with a strong emphasis on its potential to combat health inequalities. There was not necessarily agreement that medicines must, as a consequence, be marketed across all Member States simultaneously – several respondents indicated support for staggered plans with timelines for distribution approved by a regulatory body (e.g. EMA). Those who disagreed had concerns about the disadvantages for SMEs; the possibility that certain medicines are not needed in every Member State and the suggestion that if considered essential the EU should instead remove patent restrictions and enable public laboratories to produce additional stocks. Similar views were held by **healthcare reimbursement and payer organisations**. The majority of **citizens** (72%) support the proposal noting that it would be discriminatory not to do so and is vital for guaranteeing equal access to

medicines across the EU, mirroring the free movement of people. Additional suggestions from citizens related to this include the harmonisation of packaging and labelling; the creation of an EU-wide health index (indicating date of marketing of molecule, appraisal of side effects and prevalence of use among patients); and a centralised EU evaluation of new medicines to avoid different acceptance and approval timelines within Member States.

### 3.2.4 Q6. Do you have an opinion on the reasons for these market withdrawals?

Three-quarters of all respondent (76%) reported that they had an opinion on the reasons for market withdrawals (as shown in Figure 10). This share varied between 61% among academia and research respondents to 86% among healthcare professionals, payers or providers. A further stakeholder breakdown is provided in Figure 10).

Respondents from the **pharmaceutical industry** acknowledged the financial drivers for market withdrawals, but emphasised that there are many reasons which currently affect the market viability of different medicines from an industry perspective. These include price and reimbursement regulations; tender specifications and procurement approaches; Member States' medicines policies and the complexity of implementing both the Falsified Medicines Directive and Brexit. All of these factors are perceived to hinder competition and do not give the marketing authorisation holder a return on investment. Low sales of medicines and high and increasing competition between branded and generic medicines are also economic and market reasons cited by multiple respondents, but not the one respondent representing the generics industry.<sup>11</sup> Two respondents emphasise that decisions to withdraw medicines are only taken following consultation with relevant authorities<sup>12</sup>, with the intention of minimising negative impacts on patients. This was echoed by one of two respondents from the **chemicals industry** that indicated an opinion<sup>13</sup>.

Similar to other groups, **academia and researchers** predominantly cite economic and/or commercial reasons for withdrawals including hostile pricing discussions with payers who vary too much in their pricing and reimbursement policies – only one respondent cites side effects as more important than profitability in explaining withdrawals.

**Healthcare professionals, payers and providers** who indicated an opinion noted the issue of company profitability. The achievement of new patents for newer medicines or those with one characteristic changed is identified by many as a key mechanism and reason for market withdrawal of older medicines, regardless of whether they continue to be useful and suitable for treatment, as a lever for higher prices and increased profitability. Among four **healthcare pricing and reimbursement body and/or payer organisations** respondents (all with opinions), other aspects or concerns raised include the replacement of older effective medicines with newer, potentially less effective but more expensive medicines and the shortage of APIs.

**Citizens** also underscored the economic costs to the manufacturer. Some suggested other reasons relating to risk of liability for side effects from obsolete medicines; lack of testing at market launch and subsequent identification of problems after a market launch. The responses from 79% of **CSOs** with opinions echo the views of healthcare professionals and individual citizens, particularly the reflections on the withdrawal of adult products, which could continue to be developed for children and adolescents.

<sup>&</sup>lt;sup>11</sup> Rather than focusing on generics, Medicines for Europe who represent generics industry, in their response focus on the previous issues which are undermining competition e.g. pricing, procurement practices, individual Member State policies and therefore do not differ from other pharmaceutical industry respondents.

<sup>&</sup>lt;sup>12</sup> For one respondent this is health authorities, another only mentions 'all relevant authorities'.

<sup>&</sup>lt;sup>13</sup> The other provided no further explanation for their answer. Two other chemical industry respondents did not have an opinion.

Almost all **public authorities** had an opinion and cited the lack of profitability as a key reason for the withdrawal of medicines.

## 3.2.5 Q7. Are you aware of patients not receiving the medicine they need because of its price?

Three-quarters of respondents (74%) reported that they are aware of patients not receiving the medicine they need because of its price, as shown in Figure 12. This share is higher among CSOs (95%) and healthcare professionals and providers (79%). A more detailed breakdown of stakeholder responses is provided in Figure 12.

Among those expanding on this to provide more detail there was frequent reference to this as an issue for cancer treatments in particular and medicines for rare diseases, particularly due to the long approval and evaluation process and the time it takes for them to come to market. A lack of reimbursement and higher proportion of out-of-pocket expenses for patients in certain Member States was highlighted. There was no personal experience cited by individual citizens, but several respondents from the healthcare professions or provider organisations describe professional experience of patients not proceeding with certain treatments (including cancer treatments) for unaffordability reasons.

# 3.2.6 Q8. Do you think that medicine prices are justified, taking into consideration the costs associated to their development and manufacturing?

Less than half of respondents (38%) felt that prices were justified – see Figure 14. Among different stakeholder groups there were some strong contrasting views, as shown in Figure 14, ranging from 75% of industry stakeholders who think the prices are justified to only 5% of public authorities who agree.

**Pharmaceutical industry** stakeholders, for the large part, believe that prices should and already do take into account the social and personal value to patients as well as costs; the existing controls the EU has to negotiate prices; the low prices and profit margins of certain medicines such as novel antibiotics and over the counter medicines. A representative from the **generics industry** agreed that prices are justified on the basis that most EU markets are highly regulated with dedicated pricing and reimbursement for off-patent medicines focused on setting a lower list-price in comparison to the originator. They also highlight that companies frequently bid in tender processes designed to deliver the lowest price possible, which can lead to market consolidation and shortage risks.

Conversely, a majority of **public authorities** do not think that prices are justified. The majority call for more transparency on the correlation between price and research and development costs. One respondent points out that for certain gene therapy products the price is estimated in comparison to the cost of the previous treatments needed along a patient's life, without taking into account the real cost linked to their development and manufacturing. One respondent calls for more information to be made available relating to the several factors that affect cost and consequently price: e.g. orphan disease vs. non-orphan disease; new molecule vs. new indication of an already authorised active substance; breakthrough new therapy vs. authorisation of an already used active substance without marketing authorisation. A lack of transparency is also a key concern among academic and research stakeholders. They feel that development costs should remain the driving factor in calculating the price of medicines rather than value-based pricing, which they see as artificial. A majority of CSOs (68%) and healthcare professionals, payer and provider organisations (65%) do not feel that prices are justified, citing their perception that the industry benefits from excessive profit margins; they also call for more transparency. One respondent from the latter group calculated that development costs represent only 10-15% of medicine prices on average. This group also has concerns about some prices being too high and others too low, with suggestions that a safeguarding clause should be introduced to protect price levels at

time of crises (i.e. currently, as a result of COVID-19). Among **citizens**, views are split between the belief that profit margins are too high for the pharmaceutical industry and the view that prices should be high enough to support innovation.

## 3.2.7 Q9. What are the most effective ways the EU can help improve affordability of medicines for health systems?

Among respondents overall, the two most popular actions were to support the EU countries in better assessing and/or evaluating the value of medicines (48%) and better coordination among EU countries to ensure that pricing decisions taken by one EU country do not lead to negative impacts on patient access in another EU country (46%) – see Figure 16.

Among different stakeholder groups (see Figure 16), supporting Member States to better assess the value of medicines was the most popular action among respondents from the industry stakeholder group (55%) and healthcare professionals, providers and payer organisations (48%). For public authorities, the most popular option was to enhance transparency about the costs of research and development (65%) – this was also the most popular action among academic and research respondents (52%) and CSOs (56%). For citizens, promoting better coordination among EU countries on pricing was the most popular (57%).

Three in ten respondents (32%) overall selected the 'other' option as opposed to the main selections. These were not always alternative suggestions but as with other questions often provided more nuance or detail to the selected options. <sup>14</sup> For example one citizen respondent highlighted that transparency is needed not just in relation to research and development budgets, but also in relation to amortization of the investment. There were multiple comments across the different stakeholder groups that pricing should be fair and based on actual value (with transparency on the costs to companies and public payers) and several support the removal of all barriers entirely for the market entry of generics and biosimilars. <sup>15</sup>

However, there was a wide variety of alternative actions recommended by different stakeholder groups. For **industry** respondents this included the bundling of orders together by wholesalers to avoid waste and the adoption of net price confidentiality during negotiations relating to affordable access agreements. <sup>16</sup> The adoption of different pricing and payment models were also recommended including outcome-based pricing, conditional reimbursement, pay-for-performance, and annuity-based payments (particularly recommended for ATMPs). There was strong support for the adoption of an EU-wide health technology assessment process, and procurement and tendering processes which enable multiple awards and apply Most Economically Advantageous Tender (MEAT) criteria correctly.

For **academic and research respondents**, some important alternative or additional actions include support for equitable licensing; data sharing initiatives and the deprioritisation of animal tests perceived as expensive and inefficient. Respondents also called for joint, EU-wide pricing and reimbursement policies to avoid fragmentation. In contrast, respondents from the **public authorities** stakeholder group called for pricing to remain a national competence – one respondent did though support a joint approach for greater transparency on research and development costs between the EU and Member States.

<sup>&</sup>lt;sup>14</sup> Other respondents who selected 'Other' expanded on this by reemphasising their other choices, indicating that all of them are important or indicating that they did not have an opinion.

 $<sup>^{15}</sup>$  The removal of barriers to market entry for generics was recommended by a campaign response among the industry stakeholder group (n=6).

<sup>&</sup>lt;sup>16</sup> Both of these appear to have been suggested by campaign responses or responses with very similar wording: bundling of orders was referenced by four respondents and net price confidentiality by three others.

Several respondents from the **CSO** stakeholder group suggested that all of the options in the question were important elements of a multi-faceted approach. Alternative or additional suggestions included the EU-led development of a transparent methodology for calculating prices. The group echoed other stakeholders in calling for either joint pricing negotiations or joint procurement exercises between Member States. Several respondents called for appropriate pricing strategies for either paediatric medicines, orphan medicines or those for rare diseases to be prioritised. Finally, one respondent highlighted the importance of strengthening meaningful patient involvement (especially in HTA and horizon scanning), both nationally and at EU level, ensuring that any actions taken mitigate against any negative impacts on patients.

One citizen<sup>17</sup> recommended that the EU should stimulate the re-purposing of older medicines, which chimed with a recommendation from within the healthcare professionals, provider and payer organisation stakeholder group, that the EU should promote the redistribution of donated unused, unexpired medicines to patients in need. Other alternative or additional recommendations for action from this group included a call for a review of patent coverage rules, monopolies and dispensation conditions. One respondent called for the removal of monopolies entirely, to be replaced by direct funding of research and development. Several respondents called for centralised EU-level approval, authorisation, pricing and surveillance processes. Like CSOs, this group were particularly concerned about the impact of pricing policy fragmentation across the EU on paediatric patients. 18 Two similar, but slightly variant responses on this theme called for an EU framework for reference pricing or a central pricing negotiation process resulting in different price ranges and timelines for distribution in individual Member States. The cost-effectiveness of introducing more traditional or complimentary medicines, including homeopathic remedies was discussed by three respondents. Within this group, respondents from smaller subgroups did not make recommendations for alternative actions but instead chose from the main options. For healthcare reimbursement and payment organisation respondents the most popular option was ensuring increased transparency in relation to research and development costs Among staff working in hospital procurement the joint most popular options were to support the EU countries in better assessing and/or evaluating the value of medicines and to facilitate, market entry and a healthy market functioning for generics and biosimilars.

#### 3.3 Innovation in early development and authorisation

## 3.3.1 Q10. What actions at EU level do you consider most effective in supporting innovative research and development of medicines?

The most commonly identified actions across stakeholder groups were to foster research collaboration between universities, research centres and industry (52% of replies) and making the legislative framework more adaptive to new technologies and advances in science (51% of replies) - see Figure 18.

Differences were evident across stakeholder groups (see Figure 18). Among **industry stakeholders** the most popular option among was to make the legislative framework more adaptive to new technologies and advances in science, followed by providing research and development incentives in the form of intellectual property or market exclusivity rights for pharmaceutical companies investing in research; and foster research collaboration between universities, research centres and industry. Additional suggestions included to dedicate EU funding for research on green pharmaceutical

<sup>&</sup>lt;sup>17</sup> Only two citizens expanded on their choices – the other highlighted the need to introduce greater transparency in both research and development budgets and amortisation.

<sup>&</sup>lt;sup>18</sup> A campaign response among this group, about the impact of fragmentation on paediatric patients, was provided by four respondents, among a group of 20 who provided free text responses.

manufacturing technologies and promote the use of real world data/real world evidence. The generics industry suggests boosting value added R&D on off-patent molecules/tailor development program/allow global development.

Fostering research collaboration between universities, research centres and industry was the most popular option for researchers, public authorities and CSOs. **Researchers** support public-private cooperation, particularly in paediatrics innovation but also focused on addressing global health threats; improved legislative framework to meet the unmet medical need; pull incentives; and a public investment fund at European level for the development of innovative medical technologies. **Public authorities** (including pricing and health technology assessment bodies) support the alignment of R&D spending with public health needs identified at the EU level; an essential medicine list based on health technology assessment (HTA); and access to real world data for assessments of effectiveness.

# 3.3.2 Q11. What do you consider are the most effective actions related to research and development of medicines in areas where there are limited or no therapeutic options (unmet needs)?

Stakeholders considered that funding more targeted research at EU level (66%) and agreeing on a common understanding on what are the areas of unmet need in the EU (62%) are the most effective actions to take to address the issue of unmet needs – see Figure 20 and Figure 20 for a breakdown by stakeholder group. About a quarter of respondents provided other suggestions, which were typically an elaboration of an option presented in the survey. The alternative actions recommended by different stakeholder groups is presented below.

**Industry stakeholders** recommended an efficient enforcement of data protection; the acceptance of real world evidence; the creation of a legal framework that particularly supports R&D to meet unmet needs; to provide accelerated and simplified R&D path for areas where there are limited/no therapeutic options. **Researchers** (including academic researchers, research funder, European research infrastructure, other scientific organisations, learned society) suggested to: facilitate collaboration between industry and academia/philanthropy to address unmet needs; encourage the repurposing of existing medicines; provide incentives/tax reductions for R&D studies, including nonclinical and clinical studies; specific pull incentives for diseases with unmet needs and little market opportunity; and support for novel reimbursement measures. Public authorities (including pricing and Health technology assessment bodies) highlighted that economic incentives should be decoupled from the sales volume; the revision of the Orphan Medicinal Product Regulation and implementing instruments to penalize its misuse; a shared definition of 'high unmet medical needs'; and public funded orphan medicines that are only available at fixed prices. **CSOs** support to leverage European Reference Networks (ERN) research potential and revisit EU regulatory areas such as the Regulation on orphan medicinal products and the Regulation on medicinal products for paediatric use; define unmet needs with patients and to co-produce R&D with patients.

# 3.3.3 Q12. Which opportunities do you see in digital technologies (such as artificial intelligence and use of real world data) for the development and use of medicines?

Stakeholders consider that digital technologies (such as artificial intelligence and use of real-world data) may promote the development and use of medicines by helping to better understand the safety profile, and the benefits of products. Digital technologies could also be used to help identify eligible patient groups and improving diagnostics to personalise treatment approaches. Ultimately, the use of digital technologies could help enhance patient outcomes, access to treatment and align price with value. Divergent views were not evident across stakeholder groups. Other specific opportunities identified by stakeholders include support to clinical decision making, improved patient

engagement; predictive pharmacovigilance, and better assessment of treatment outcomes and real-life effectiveness of a given treatment.

# 3.3.4 Q13. Which risks do you see in digital technologies (such as artificial intelligence and use of real world data) for the development and use of medicines?

The replies to this question follow from Question 12. A general consensus emerged among stakeholder groups on the risks associated with digital technologies. These risks include: non- compliance with data privacy; moving from human accountability to decisions based on digital solutions; a lack of technical standardisation in the description of how large datasets are constructed and their associated biases, and possible discrimination of certain groups. These risks are especially concerning in relation to artificial intelligence, which is highly dependent on the quality of the underlying data set.

### 3.3.5 Q14. Are you aware of any obstacles in the EU in taking advantage of technological progress in the manufacturing of medicines?

Less than half of respondents (41%) reported obstacles to leverage technological process in the manufacturing of medicines. Around two in 10 (22%) reported no obstacles while the remainder (37%) did not respond to this question or did not knowsee Figure 22 and Figure 22 for the breakdown by stakeholder group.

Of those that report being aware of obstacles, industry stakeholders have the higher representation, followed by researchers, patients, pricing and reimbursement bodies and public providers–see Figure 23. Similar obstacles were raised across stakeholder groups – the main obstacles were (1) limitations in infrastructure that hinder the technological progress and (2) regulations that are not aligned with the requirements of the latest technological developments and complex authorization procedures. Public authorities noted that Good Manufacturing Practices (GMP) validation can be complex and especially when clear directions are not provided.

## 3.3.6 Q15. How could clinical trials in the EU be driven more by patients' needs while keeping them robust, relevant and safe for participants?

More than half of respondents noted that patients' experiences could be involved in the early phases of medicine design (64%) while half (50%) suggest that non-commercial organisations conduct clinical trials in fields where financial interest is weaker. In addition, a better coordination for larger trials comparing different treatment strategies, and the design of more trials that collect information on medicine tolerability or the impact of a treatment on the quality of life were also supported by barely half of the respondents – see Figure 24Figure 23. The distribution of responses across individual stakeholder groups is shown in Figure 25. The alternative actions suggested by different stakeholder groups is presented below.

**CSOs** support international academic research linked to the inclusion and training of patients; requiring quality of life data and Patient Reported Outcomes (PROMs) to obtain marketing authorisation; limiting the bias of clinical studies (patient profile); systematising the measurement of quality of life (QoL) and better use of health data/digital data. **Researchers** suggested that the application of selected options by clinical trial sponsors should be mandatory; to include women and older people in clinical trials; to increase treatment efficacy and patient safety; and to ensure that clinical trial results and relevant data are duly reported and made available. **Industry stakeholders** propose to enforce patient-centric concept and patient-measured outcomes; new harmonised and consistent implementation of guidelines (e.g. ICH E19

and ICH Q8<sup>19</sup>); promote international regulatory alignment, technology and rules for off-patent medicines; global clinical trial networks; increasing support/monitoring of trials from the regulation bodies; harmonisation for study designs, regulatory acceptability; and regulatory initiatives which support patient involvement for rare diseases and HTA and payer endorsement. **Healthcare payer and providers** advocate for an inclusion of patient-reported outcomes in clinical trials and evaluation of health technologies and to improve the collaboration with specific clinical research networks, with links to experts and patients. No additional suggestions were provided by public authorities.

## 3.3.7 Q16. Is the current legal framework suitable to support the development of cell-based advanced therapy medicines in hospitals?

Overall, half of respondents did not know if the current legal framework is suitable to support the development of cell-based advanced therapy medicines in hospitals. Nearly four out of ten stated that they agreed (32% "partially agreed" and 6% "strongly agreed"). In total 12 % of the respondents disagreed with this statement<sup>20</sup> – see Figure 26. Public authorities had the higher representation among those that strongly agreed with this statement, whereas Academia and Researchers were the stakeholder group most represented across those that disagreed. A more detailed breakdown of stakeholder responses is provided in Figure 26.

Industry stakeholders expressed concerns that the administration of products that have not been evaluated according to the same standards as products with a marketing authorisation may put patients at risk and highlighted the need to consistently regulate the hospital exemption ("HE") and to avoid different interpretation across MS. It was also noted that regulatory fragmentation and duplications of assessment (clinical trials, HTA, drug-device combinations) hinders the development of the field and calls were made to avoiding duplications and faster assessments. In addition, several developers of microbiome products asked for clarification regarding the legal framework applicable to these products. Researchers, in general, expressed same concerns as industry in relation to HE. Other changes refer to incentivise hospitals to become marketing authorisation holders (MAH) and stimulate the centralised authorisation to deal with non-commercial parties and organize training programs. The development of a specific framework for manufacturing of CAR-T cells in an academic setting was also suggested.

Healthcare providers advocate for the establishment of collaborative networks involving patients, academic hospitals, medical societies, European health authorities and industry. They also suggest optimising and harmonise the hospital exemption and to increase transparency (public EU-wide registry). Finally, they support investments in academic research in close partnership with the local hospitals. Public authorities consider that the current framework for cell based ATMP is fragmented, and therefore, it is hard for developers to gain an understanding of all requirements from many different authorities. One respondent suggests that a "down-sized (national) procedure is needed for evaluation of such products in a more time and work-saving approach, especially on the formal and administrative level. In contrast, other respondents considered that it would be useful to have a common approach to the hospital exemption and to promote clinical trials when the indication is not well established.

<sup>&</sup>lt;sup>19</sup> ICH guideline E19 on optimisation of safety data collection and the pharmaceutical development section of a regulatory submission.

<sup>&</sup>lt;sup>20</sup> The response options for this question was biased with two agree options (strongly agree or partially agree) and only one disagree option. This will likely have skewed results.

#### 3.4 Environmental sustainability of medicines and health challenges

### 3.4.1 Q17. What actions at EU level do you consider most effective in limiting the negative environmental impact of medicines?

Stakeholders consider that the most effective action at the EU level to limit the negative environmental impact of medicines is strict disposal rules for unused medicines (47%). A high share of stakeholders also considered actions to promote cleaner manufacturing processes (39%) to be effective as well – see **Error! Reference source not found.** Figure 28 for the overall responses, and Figure 28 for the responses by stakeholder group.

Other actions were suggested by respondents. Industry stakeholders suggested to: recognise and incentivise PNEC (predicted no-effect concentrations) initiatives from the industry; to provide incentives for environmentally safe and compliant products; to raise patients' awareness and educate them on the correct disposal of unused medicines; to make a more prudent use of antimicrobial and antibiotics and favour medicines that do not pose environmental issues; to carry out research to identify the sources of contamination; to improve schemes for unused medicines, reutilisation of solvents and chemicals; and to encourage the replacement of paper leaflets by e-leaflets. Public authorities suggested to make sure that the medicines are produced in Europe, where the environmental standards are controlled. Also, transparency should be ensured on environmental risks for patients and health care professionals, and for the water sector. Healthcare payers or providers recommended funding of deprescribing, adherence and personalised therapeutic services in pharmacies; promotion of medicinal products with low environmental impact; supporting initiatives to redistribute unused medicine. CSOs made similar recommendations. Their suggestions included to not import APIs or medicines from countries with lower quality environmental protection laws; encourage the disposal of medicines, by making it easier for citizens; conduct public education campaigns on environmental risks of medicines; favour formulations suitable for children, given that the adaptation of forms for adults leads to waste.

## 3.4.2 Q18. Which actions do you think would have the biggest impact on fighting AMR concerning the use of medicines for patients?

Over half (59%) consider that more prudent use of antimicrobials would have the biggest impact – see Figure 30 for the overall responses and Figure 30 for the answers by stakeholder group.

Other actions were suggested by respondents. Industry stakeholders provided a number of additional suggestions for action, mainly to harmonise the use of antibiotics, target pack sizes; to encourage the use and development of alternatives such as microbiome-based medicinal products; to increase public awareness and health literacy at global level; to improve wastewater treatment, to limit pathogens & resistant microorganisms discharge to environment; and to reduce the use of antibiotics use in farming. Public authorities provided similar responses when giving additional views. They suggested to: decrease use of antibiotics in breeding animals; developing new antimicrobials and in particular antibiotics; focus on prevention and carry out controls in hospitals; increase the use of digital tools, such as infection control software, which could help control AMR. Healthcare payers (and providers) proposed to better involve community pharmacists in national plans to curtail antibiotic resistance; put stronger restrictions on the use of antibiotics in animal hunsbandry; run AMR rapid diagnostic tests. CSOs main suggestion was to invest in research, in particular on the impact of AMR on childhood cancer patients. They also proposed to: reduce antimicrobials usage in farming, as suggested by other stakeholder groups; market entry rewards to delink incentives from prices and utilisation; promote healthy habits; and improve diagnostic, in order to avoid overuse of medicines. Similarly, citizens suggested to promote organic and natural treatments, and to limit the use of antibiotics in farming. Researchers and academia made similar suggestions: strengthening the

regulation of non-human use of antibiotics (meat industry, fishery); consolidate research on the impact of AMR on childhood cancer patients.

### 3.4.3 Q19. Where, in your view, should the EU focus its support for the creation of new antimicrobials or their alternatives?

More than half of respondents (59%) noted that support should be given to academia for researching/discovering new antimicrobials or their alternatives - see Figure 32.

Other actions were suggested by respondents with the greatest divergence noted among industry. **Industry stakeholders** mainly suggested to: promote and support research and development; provide economic incentives to industry (antibiotic developers) and to academia; to put in place market reforms to attract and sustain private R&D investment; to support prevention through the use of vaccines. Similarly, public authorities recommended to incentivise the use of antibiotics, to focus on infection prevention and control measures; to fund public research. Healthcare payers (and providers) suggested to focus on non-antibiotic strategies; to investigate alternative incentives e.g. delink prices from volume; to separate medicine prices from the manufacturer's profit / turnover; to support tailored collaborative support across stakeholders with stewardship conditions and access provisions. CSOs and research and academia mainly recommended to put in place national and EU action plans on AMR with innovative research, to create new antimicrobial medicines, and to ensure medicines' availability and affordability; supporting public-private partnerships, or other co-funding schemes for product development; or more in general develop new kinds of incentives that can ensure affordability and universal access of medicines. Citizens similarly suggested to support research in preventive lifestyle and alternative medicines, as well as new research and investment models as well as to create national and EU action plans on AMR.

### 3.4.4 Q20. How has the coronavirus (COVID-19) pandemic affected you in relation to access to medicines and treatments?

A large number of replies was provided to this question. A summary of the views by stakeholder group below.

Public authorities pointed out that shortages on medicines and medical equipment experienced during the pandemic, have made them realise the importance of: transparency of supply, lists of critical medicines, central stockpiling, collaboration with industry and international cooperation. CSOs highlighted that many treatments and non-emergency medical services were not available or were severely limited during the pandemic; in particular, paediatric cancer diagnosis and treatment was reduced, and clinical trials were postponed or stopped. Healthcare professionals pointed out that hospitals and pharmacies faced shortages in basic and generic medicines, and of medicines used for the treatment of COVID-19 (e.g. sedatives, painkillers, muscle relaxants, antibiotics, antivirals and antimalarials), as well as protective equipment, ventilators, medications to facilitate intubation, etc. Some respondents highlighted that the pandemic exposed more widely the already existing problems associated with medicines shortages in Europe, and the need to: 'strengthen notification requirements, ensure robust shortage management plans, improve early warning systems for medicines shortages at national and European level, and a permanent system for monitoring of medicine shortages in the EU'. Citizens also experienced difficulties in accessing medicines, vaccines, protective equipment, delays in clinical trials; they had to limit access to hospitals and changing their behaviours in healthcare facilities; difficulties in accessing GPs.

**Industry stakeholders** highlighted that they experienced: supply chain disruptions; insufficient deployment of digital infrastructure to support continuity of care; delayed and insufficient access to care for chronically ill patients, including cancer and cardiology patients, and other procedures, affecting preventive care, appropriate treatment and quality of life, leading to backlogs in hospitals and negatively impacting the wellbeing of

patients. The COVID-19 measures have also endangered the economic viability of healthcare organisations and businesses. Industry also experienced export bans and border closures, lack of personal protective equipment, uncoordinated and competitive governmental purchasing plans.

Similarly, **healthcare payers and providers** pointed out that there were: disruptions in the supply of medicines; higher prices of certain medicines; difficulties in providing treatment to chronic patients; reduction of paediatric cancer appointments, diagnosis and treatments procedures, due to the fear of infections; delays in new treatments and performance of clinical trials; shortages of personal protective equipment.

# 3.4.5 Q21. In your opinion and based on your experience, what can the EU do to prepare for and manage such a situation better in the future in relation to pharmaceuticals?

A similarly high level of replies was received for this question. A summary of the views by stakeholder group below.

**Research organisations and academia** suggest a number of actions, in particular: timely provision of guidelines and recommendations to ensure some degree of uniformity of national approaches; better and faster provision of information: among Member States (e.g. coordination of activities of different national authorities); management and coordination of (trans-)national preparedness stocks; cooperation with pharmaceutical companies; encouraging the production of essential active pharmaceutical ingredients within the EU, and granting access to raw materials, to minimise supply chain disruptions.

**Public authorities** recommend better information provision and increase public awareness as the pandemic appears; ensure better coordination of research on treatments to make better use of resources and facilitate the achievement of results; improve coordination and transparency between Member States and increase responsiveness to the measures to be taken; enhance European level stockpiling of the most critical medicinal products; focus on common schemes for development of vaccines and treatments during pandemics to secure availability for all Member States; identify new trading partners and decrease dependency regarding pharmaceuticals on single suppliers; improve the EU manufacturing capacity to ensure the supply medicinal products considered as critical for national health services in Europe; foresee the creation of a permanent platform for the collection and sharing of data on stocks and shortages with clear responsibilities for doing so, shared between Member States, the European Commission, the European Medicines Agency (EMA), the European Medicines Verification Organisation, pharmaceutical companies, distributors, pharmacists and physicians.

**Industry** stakeholders suggested to set minimum stock quantities of medicines in each country, reduce trade barriers to ensure diversity in supply sources, applying regulatory flexibility to ensure the distribution of medicines in the EU, and building a research infrastructure that can be activated in the instance of a pandemic. **Healthcare payers and providers** highlighted that the EU should: coordinate an EU-level stockpiling system for essential medicines; a centralised system for the detection and reporting of shortages and a framework for joint procurement should also be developed: foresee the creation of a permanent platform for the collection and sharing of data on shortages with clear responsibilities; empower EMA to monitor and coordinate medicines' availability and supply at EU level; strengthen the resilience of supply chains, increase diversification of supply sources and reduce reliance on third country manufacturing.

**CSOs** suggestions were similar to that mentioned above: implement a European system for management, information and reporting of shortage at EMA level; EU legislation providing a specific statute for essential old medicines, including incentive to be kept on market; build collaborative mechanisms to develop new diagnostics, vaccines, medical technologies and treatments swiftly and ensure equitable access and affordability;

secure medicine supply chain and invest in more and better treatments for young cancer patients. **Citizens** pointed out that the EU should: ensure production, distribution and stockpiling of vital medicines within the EU; establish a system of common or shared contingency stocks of medical equipment and medicines to be used in emergencies; support the digitalisation for prescriptions and non-essential consultations.

### 3.5 Summary questions

# 3.5.1 Q22. While the Commission is working on improving the EU pharmaceuticals framework, which areas of work do you find most urgent?

The most popular choice was to support innovation for unmet needs with just over half (54%) choosing this option – see Figure 34 for the overall results and Figure 35 for the breakdown by stakeholder group. **Academia** and **CSOs** (69% and 63% respectively) are most likely to hold this view. The views of **healthcare providers and payers** varied across the options. **Citizens** were most likely to be concerned about the dependency on APIs and medicines produced outside the EU (60%).

## 3.5.2 Q23. If you were asked before the coronavirus (COVID-19) pandemic, would you have responded differently to any of the previous questions?

A fifth (18%) of respondents stated that if they had been asked the survey questions prior to COVID-19, they would have responded differently – see Figure 36. **Public authorities** and the **pharmaceuticals industry** were more likely to provide this option. A campaign response was evident among the **pharmaceuticals industry** highlight their ability to urgently coordinate with the Commission and the EMA to respond to the increased demand for medicines and the logistical challenges.

### 3.5.3 Q24. Is there anything else you would like to add that has not been covered in this consultation?

More than half of respondents (63%) from different stakeholder groups provided a reply. Most sought to emphasise views provided earlier in the survey. Issues concerning the production, regulation and access to medicines was high. Some stakeholders highlighted the importance of addressing certain health conditions including cardiovascular disease and paediatric cancer – concerns pertaining to the latter appear to be driven by a campaign. Some new issues were raised. For example, a **healthcare payer or provider** highlighted the role that social media has in influencing the attitudes of patients and therefore its relevance when considering access and affordability of medicines. A representative from the **pharmaceutical industry** highlighted the need to review the patent system and the definition of medicines and services as the distinction is not always clear and may imply different regulatory frameworks. A **CSO** noted the need to promote the resilience of the healthcare system and highlighted the shift to community care taking place in many countries. A **public authority** noted that ensuring equal access to affordable medicines also requires reviewing and better enforcing the obligations of manufacturing authorisation holders.

#### 4. Position papers

As noted in Table 2, most position papers were received by industry followed by healthcare professionals, payers or providers. A summary of views by stakeholder group that were not already discussed in relation to the survey question is presented below.

#### Pharmaceutical industry

Many note that moving the production of APIs back to the EU would not be sufficient to promote supply and to guarantee a more diversified supply chain. The EU should look into other tools at its disposal (e.g. public procurement tenders). Parallel imports offer two unique opportunities for policymakers; 1) by introducing price competition, help lower the prices of especially patented medicines, creating significant savings for

healthcare systems and 2) alleviating national and/or regional shortages in the EU. Both are to the benefit of healthcare systems and more importantly patients.

Pharmaceutical industry stakeholders who submitted position papers strive for adaptable yet clearer and faster regulatory pathways to harness the potential of new technologies; Reducing administrative burdens and overregulation; and promoting harmonisation of Intellectual Property (IP) and technology transfer policy. One notes that the Commission should consider deeper collaborations with the US FDA and other Health Authorities towards models comparing to Project Orbis, and within Europe by enabling simplified, rolling reviews comparable to the US Real Time Oncology Review (RTOR) process.

Affordable Medicines Europe suggests that MAHs be required to pay the price difference (if positive) between emergency or parallel imports and the normal reimbursement price for products in shortage in a given Member State, which is understood as the 'PSO-responsible-pay' principle. One respondent speaking in favour of parallel trade requested that the Commission should review how shortages are influenced by anti-competitive behaviour and abuse of dominant position in relation to the imposition of supply quotas, territorial supply restrictions, and other exclusive distribution models (such as direct-to-pharmacy) and propose measures to tackle such practices.

One respondent suggested that the level of sanctions for manufacturers responsible for a shortage could be inspired by the French model, where financial sanctions can go up to 30% of the average daily benefit made in the given market, but should not exceed 10% of the annual turnover or 1 million euro.

Lastly, one respondent recommended the inclusion of tracking of shortages of APIs in national medicines' databases to improve transparency of unavailability of medicines at EU level. This would allow for solving, or at least mitigating, medicines shortages by importing from other Member States.

#### Pharmaceutical industry - API producers/importers

API producers/importers call for ensuring innovation through market and commercial incentives, strengthening of intellectual property protection, financing and building biotechnology hubs while implementing tax incentives and supporting R&D. To increase strategic autonomy in medicines production, the EU should adopt an industrial strategy to strengthen the resilience and competitiveness of the manufacturing chain in Europe. The strategy should introduce resilience criteria in procurement, reimbursement and state aid policies and better integrate API in the regulation of medicines. An EU Recovery Fund should provide investment in key value chains crucial for our future resilience, such as the medicines sector. In this context, the EU Green Deal and Digital Transformation can help to boost resilience.

#### Healthcare professionals, payers and providers

The Commission should seek to achieve a more holistic approach to the reward of innovation in health and cancer care that is orientated more towards concepts of outcome and value. The current pharmaceutical regulations principally focus on the development of new medicines, not new indications for existing medicines, and there is a clear lack of EU and national pathways to facilitate repurposing.

Concerned with shortages, healthcare professionals and providers call for the adoption of preventive measures across the EU, such as the implementation of prudent tendering mechanism; facilitating the European-wide uptake of prospective risk assessments; developing a comprehensive European-wide communication strategy on medicines shortages which foresees a stronger role for the European Medicines Agency and helps improve information exchange, including best practice sharing, between authorities, pharmaceutical industry, supply chain actors and healthcare professional.

A common European strategy should address the problem of shortages. The strategy should consider a combination of various measures and initiatives. The obligations for

manufacturers need to be strengthened (e.g. alternative production units, shortage mitigation plans). Efforts to secure a level playing field globally with the aim to decrease the dependence on the manufacturing capacity of single suppliers. For example, procurement procedures for medicines should be amended to apply other criteria than price in tendering processes and award contracts to a number of successful tenderers instead of only to one.

#### **Civil Society Organisations (CSOs)**

Regulators and policy makers need to ensure that the EU maintains a world-class approval system of medicines by ensuring clear and short timelines for the development of medicines and increasing the time they are subject to patents on the market. Prices should be reviewed and adjusted for those who need them most. The Commission should increase education on innovative technologies including for example: digital medicine, bioengineering and genome screening.

The Commission should exercise strong stewardship to ensure that the public interest is at the core of joint partnerships with the industry and support the pooling of resources and international cooperation between EU Member States in order to prepare health systems for the arrival of new medicines and technologies. For example: the recently intensified collaboration between the EMA and US Food and Drug Administration (FDA) is a good step in the direction of mutual recognition of approval authorities for medicinal products on both sides of the Atlantic. Similarly, it is also important to ensure clinical research with the UK after Brexit. Conducting high quality health technology assessment (HTA) and sharing information about prices and pricing and reimbursement strategies, in order to enhance Member States' ability to prioritise medicines with higher clinical value, review and adjust prices based on new evidence, and effectively negotiate the prices of medicines and also get a clear understanding of their added value in real-life settings. For example, non-pharmaceutical treatment options should not be left aside in favour of pharmaceutical products.

CSOs highlight the importance of improving transparency and inclusion of patients and their opinion in different discussions. Better transparency is needed given the current pandemic. For example: the Commission should require all medicines marketed in more than one EU Member State to have accompanying European shortage management and prevention plans.

#### **Public authorities**

Public authorities consider that cooperation between Member States and actors of the pharmaceutical sector could be strengthened in terms of sharing and promoting the availability of research data and information e.g. disease registers, e-health records and electronic prescription records. Regulatory frameworks and incentives should be revised, to recognise, for example, the different forms of public funding - direct funding, trainings, clinical trial support. For treatments that have received funding, prices should be capped and the sunset clause for centrally authorised products should be enforced.

Environmental issues were discussed by some public authorities particularly with respect to prescription and disposal rules. Medicines that pose an environmental risk should only be available by prescription to promote their prudent use, e.g.: only the necessary number of pills are prescribed. In addition, risk assessments and market authorisations should consider environmental risk evaluation and comparison with other lower risk alternatives and extended producer responsibility (EPR). In particular, there is a need to apply the "polluter pays" principle. In the current context where this principle does not hold, the production of APIs in the EU is hindered by the high cost related to environmental protection in the EU.

This stakeholder group also expressed support for initiatives to promote the local production of APIs through incentives. A public commitment to buy a certain number of specific products could incentivise the increase in production facilities in the EU and ensure a stable market for producers. The European Commission could also incentivise

the development and production of select and critical active ingredients, raw materials and medicines in the EU including support for innovation and more efficient production technologies.

#### Research and academia

Academia and research stakeholders provided position papers that followed the same line of reasoning of their responses to the survey. Some believe that simplification and unification of the regulatory landscape in Europe would make it feasible to carry out clinical trials across countries. This option is desirable when patient numbers are small or when the disease is rare. The research policy framework should also be flexible enough to accommodate and promote innovative approaches.

Position papers from this stakeholder group also underscored the importance of promoting artificial intelligence which could benefit not only to drug discovery and development, but also outcomes research the efficiency of pharmaceutical research and development. It is important that the policy and regulatory environment can adapt to advances in data and technology.

Lastly, this stakeholder group highlighted the importance of partnerships including private-public partnerships to ensure the possible collaboration and interchanges between the public healthcare, research, training and academic sector and the industries. The EU should support alternative funding models, like not-for-profit product development partnerships (PDP).

### **Annex - Charts and figures**

Figure 2. Q1: What type of EU action or initiative do you consider helpful to incentivise the production of active pharmaceutical ingredients for essential medicines (e.g. antibiotics, oncology medicines) in the EU? – reply by stakeholder group

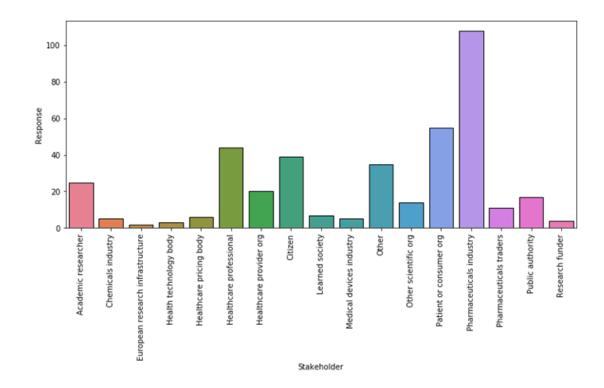
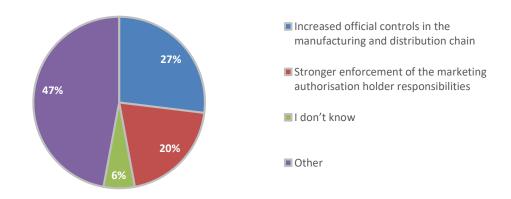


Figure 3. Q2: What action do you consider most effective in enhancing the high quality of medicines in the EU?- Overall response



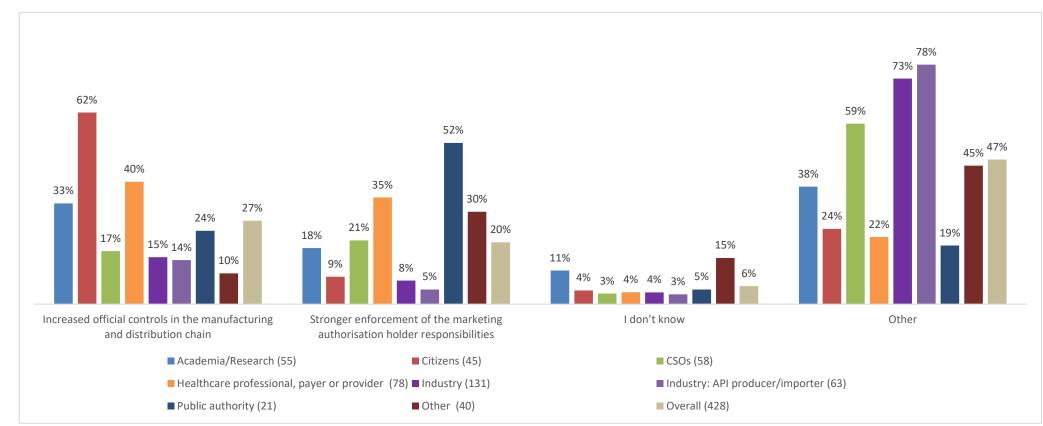
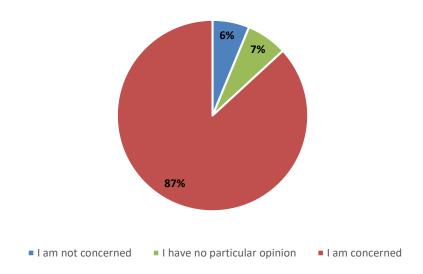
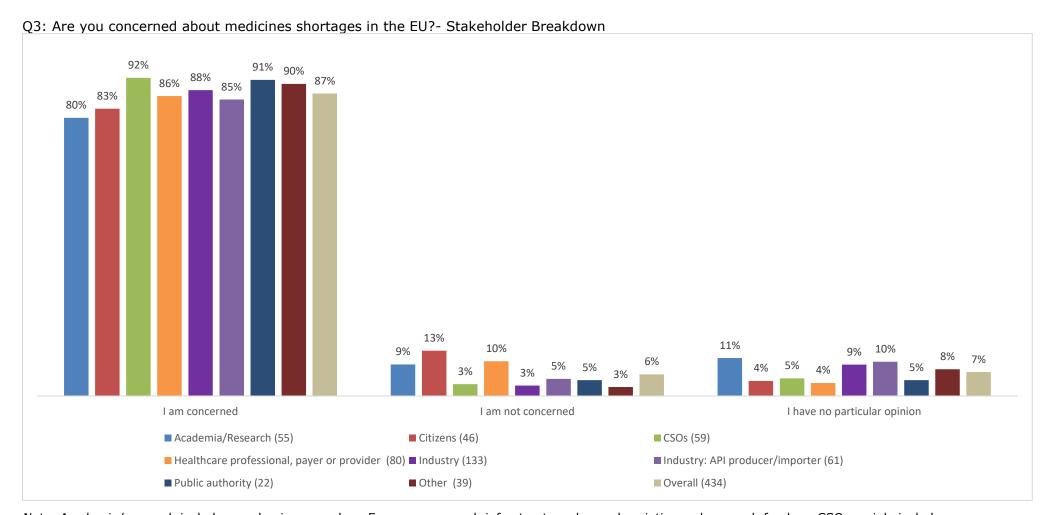


Figure 4. Q2: What action do you consider most effective in enhancing the high quality of medicines in the EU?- Stakeholder Breakdown

Note: Academia/research includes academic researchers, European research infrastructure, learned societies and research funders. CSOs mainly include patient or consumer organisations. Public authorities mainly include national authorities. Healthcare professionals, payers and providers include pricing and reimbursement bodies, hospitals, pharmacies and health technology assessment bodies. Industry includes API producers/importers, pharmaceutical traders/wholesalers, as well as representatives from the chemicals industry and medical device companies.

Figure 5. Q3: Are you concerned about medicines shortages in the EU?-Overall response





Note: Academia/research includes academic researches, European research infrastructure, learned societies and research funders. CSOs mainly include patient or consumer organisations. Public authorities mainly include national authorities. Healthcare professionals, payers and providers include pricing and reimbursement bodies, hospitals, pharmacies and health technology assessment bodies. Industry includes API producers/importers, pharmaceutical traders/wholesalers, as well as representatives from the chemicals industry and medical device companies.

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Figure 6. Q4: Which actions do you think would have the biggest impact on reducing shortages in the EU? (Maximum 3 choices)- Overall response

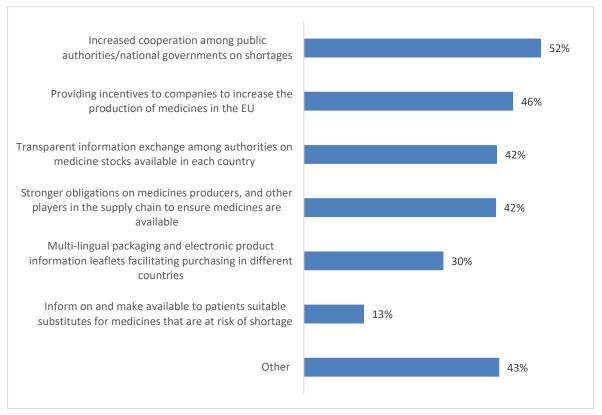
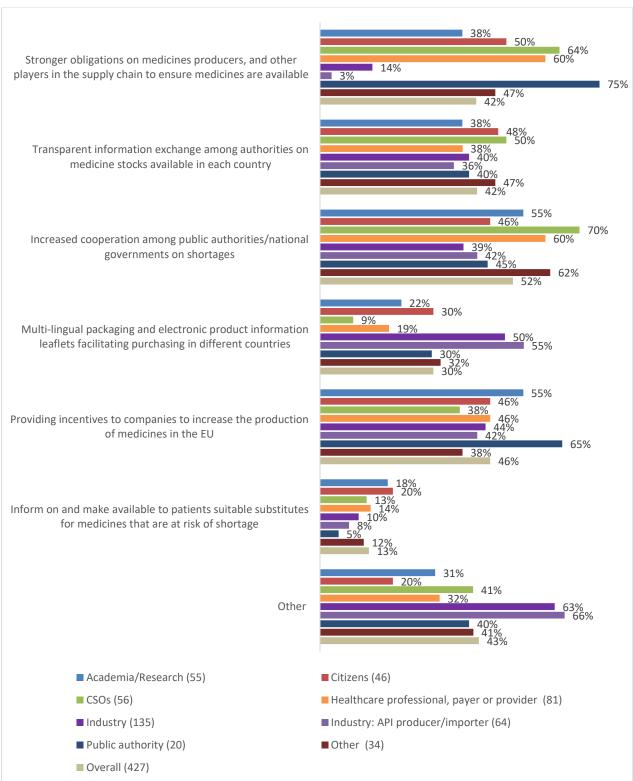


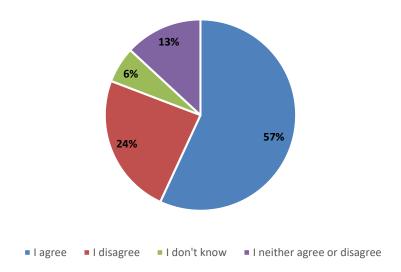
Figure 7. Q4: Which actions do you think would have the biggest impact on reducing shortages in the EU? (Maximum 3 choices)- Stakeholder Breakdown



Note: Academia/research includes academic researches, European research infrastructure, learned societies and research funders. CSOs mainly include patient or consumer organisations. Public authorities mainly include national authorities. Healthcare professionals, payers and providers include pricing and reimbursement bodies, hospitals, pharmacies and health

technology assessment bodies. Industry includes API producers/importers, pharmaceutical traders/wholesalers, as well as representatives from the chemicals industry and medical device companies.

Figure 8. Q5: Do you think that companies that apply for and receive an EU-wide marketing authorisation should be required to make that product available in all EU countries?- Overall response



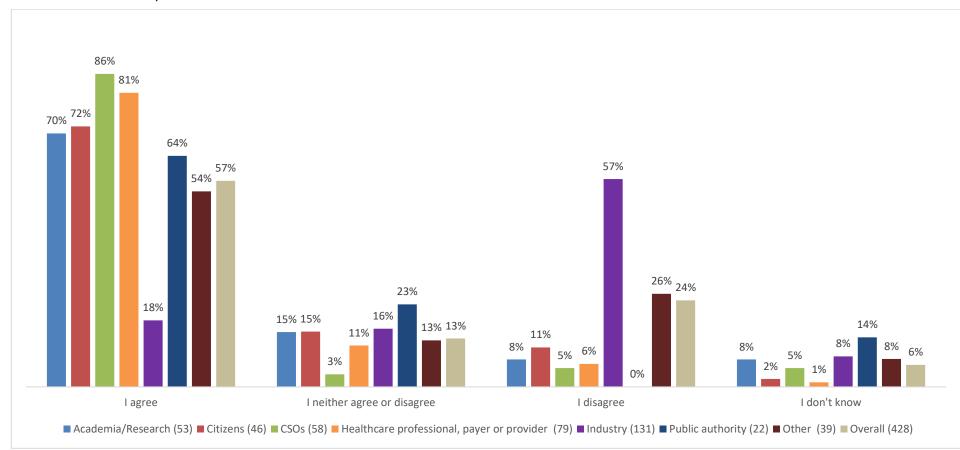
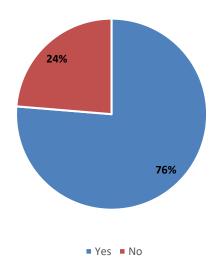


Figure 9. Q5: Do you think that companies that apply for and receive an EU-wide marketing authorisation should be required to make that product available in all EU countries?- Stakeholder Breakdown

Figure 10. Q6: Do you have an opinion on the reasons for these market withdrawals?-Overall response



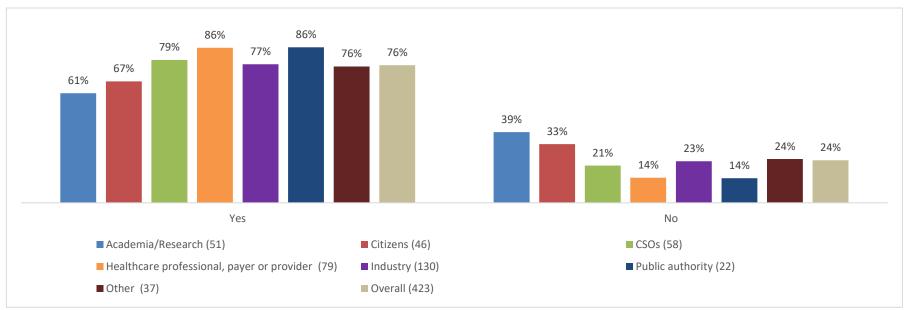
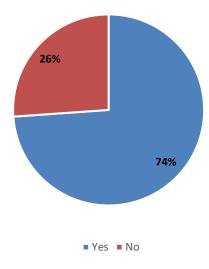


Figure 11. Q6: Do you have an opinion on the reasons for these market withdrawals?- Stakeholder Breakdown

Figure 12. Q7: Are you aware of patients not receiving the medicine they need because of its price?- Overall response



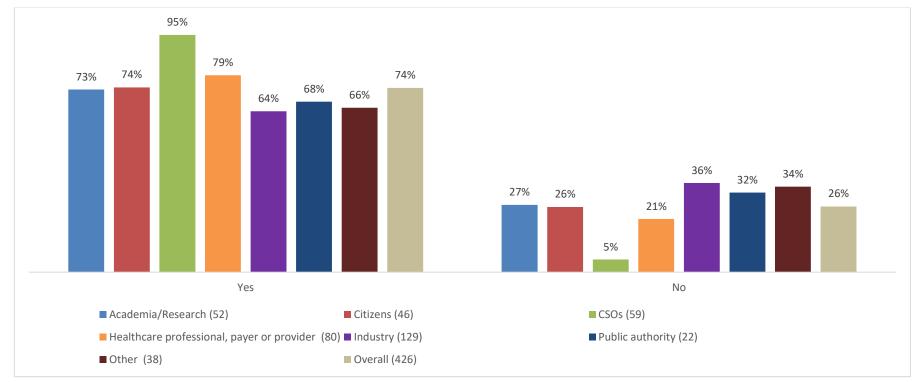
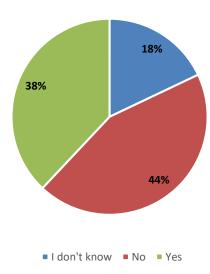


Figure 13. Q7: Are you aware of patients not receiving the medicine they need because of its price?- Stakeholder Breakdown

Figure 14. Q8: Do you think that medicine prices are justified, taking into consideration the costs associated to their development and manufacturing?- Overall response



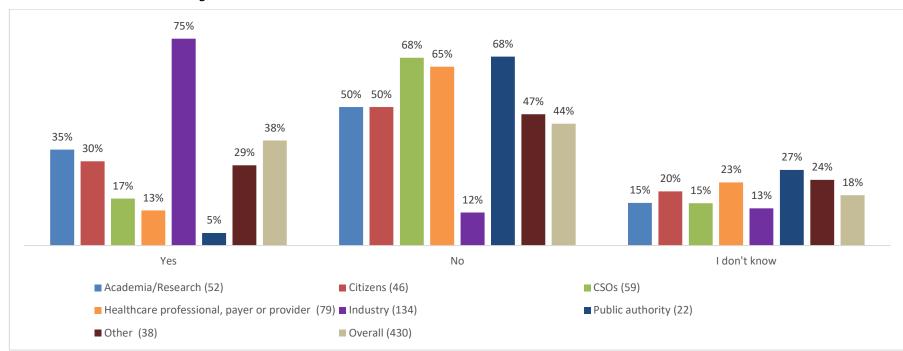


Figure 15. Q8: Do you think that medicine prices are justified, taking into consideration the costs associated to their development and manufacturing?- Stakeholder Breakdown

Figure 16. Q9: What are the most effective ways the EU can help improve affordability of medicines for health systems? (Maximum 3 choices)-Overall response

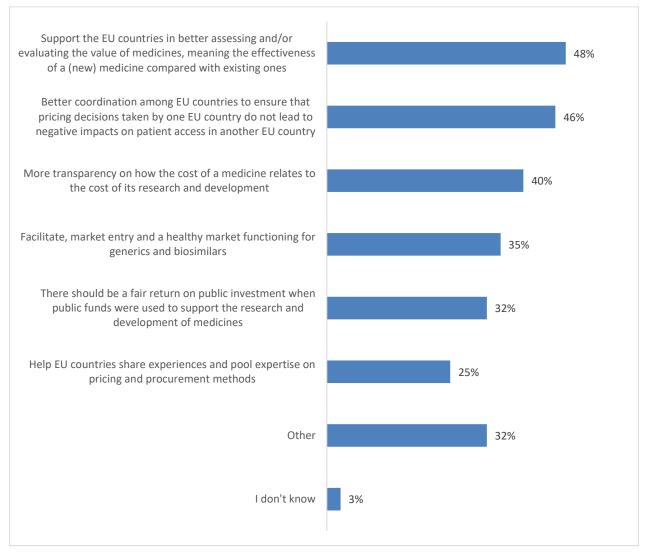
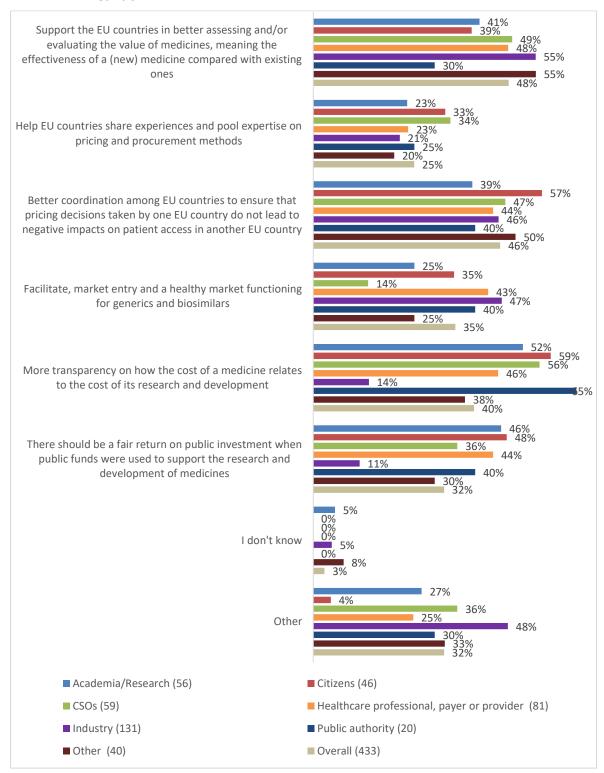


Figure 17. Q9: What are the most effective ways the EU can help improve affordability of medicines for health systems? (Maximum 3 choices)- Stakeholder Breakdown



*Note:* Academia/research includes academic researches, European research infrastructure, learned societies and research funders. CSOs mainly include patient or consumer organisations. Public authorities mainly include national authorities. Healthcare professionals, payers and providers include pricing and reimbursement bodies, hospitals, pharmacies and health

technology assessment bodies. Industry includes API producers/importers, pharmaceutical traders/wholesalers, as well as representatives from the chemicals industry and medical device companies.

Figure 18. Q10: What actions at EU level do you consider most effective in supporting innovative research and development of medicines? (Maximum 3 choices)-Overall response

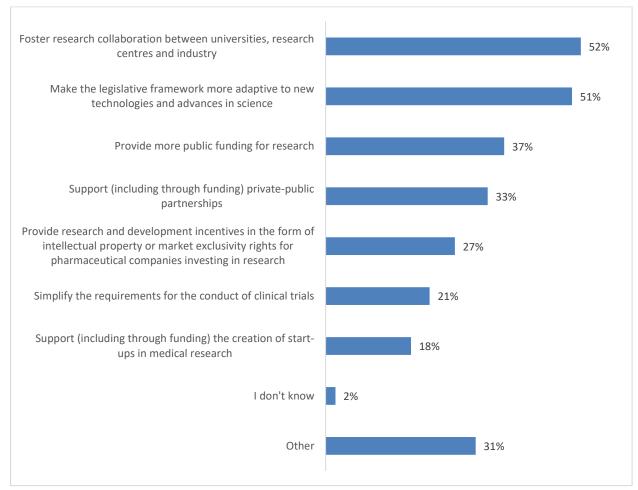


Figure 19. Q10: What actions at EU level do you consider most effective in supporting innovative research and development of medicines? (Maximum 3 choices)-Stakeholder Breakdown

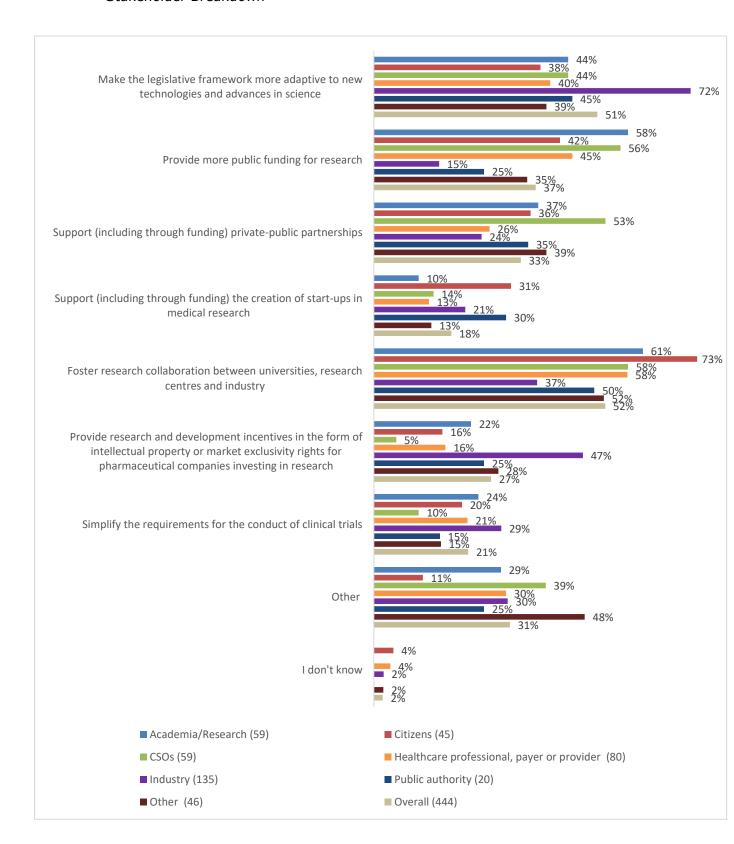


Figure 20. Q11: What do you consider are the most effective actions related to research and development of medicines in areas where there are limited or no therapeutic options (unmet needs)? (Maximum 3 choices)-Overall response

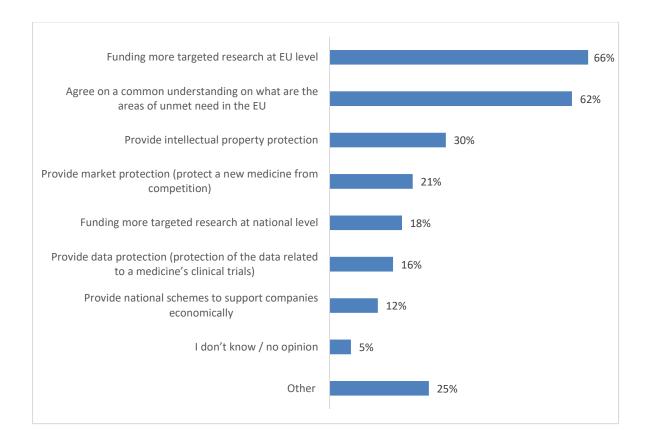
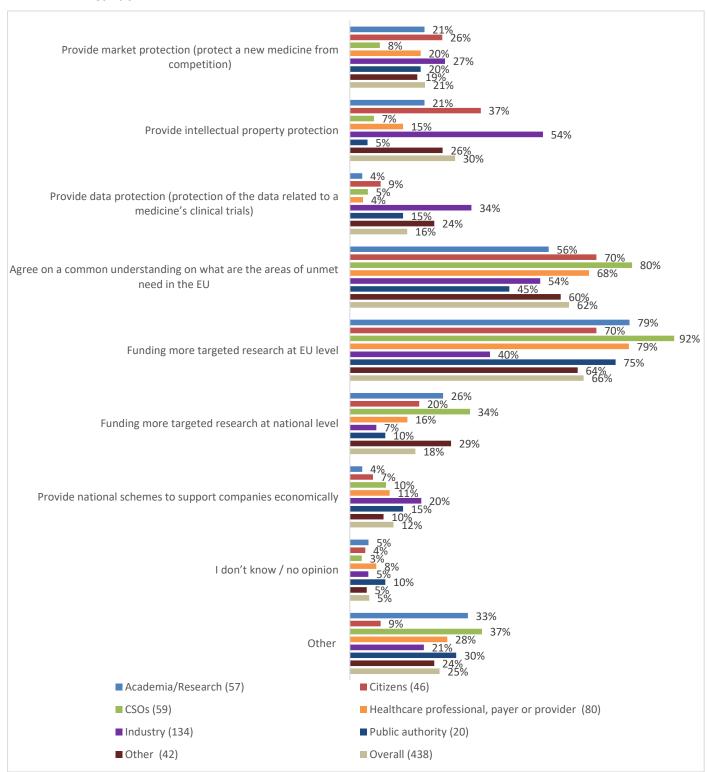


Figure 21. Q11: What do you consider are the most effective actions related to research and development of medicines in areas where there are limited or no therapeutic options (unmet needs)? (Maximum 3 choices)-Stakeholder Breakdown



*Note:* Academia/research includes academic researches, European research infrastructure, learned societies and research funders. CSOs mainly include patient or consumer organisations. Public authorities mainly include national authorities. Healthcare professionals, payers and

providers include pricing and reimbursement bodies, hospitals, pharmacies and health technology assessment bodies. Industry includes API producers/importers, pharmaceutical traders/wholesalers, as well as representatives from the chemicals industry and medical device companies.

Figure 22. Q14: Are you aware of any obstacles in the EU in taking advantage of technological progress in the manufacturing of medicines?-Overall response

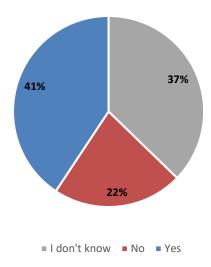


Figure 23. Q14: Are you aware of any obstacles in the EU in taking advantage of technological progress in the manufacturing of medicines?-Stakeholder Breakdown

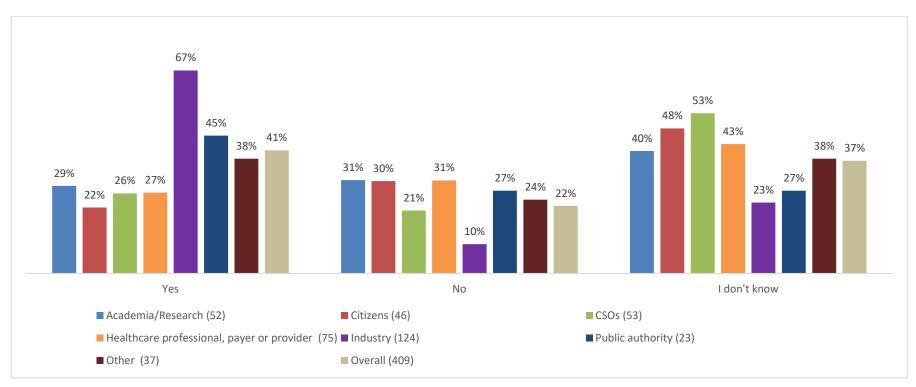


Figure 24. Q15: How could clinical trials in the EU be driven more by patients' needs while keeping them robust, relevant and safe for participants? (Maximum 3 choices)-Overall response

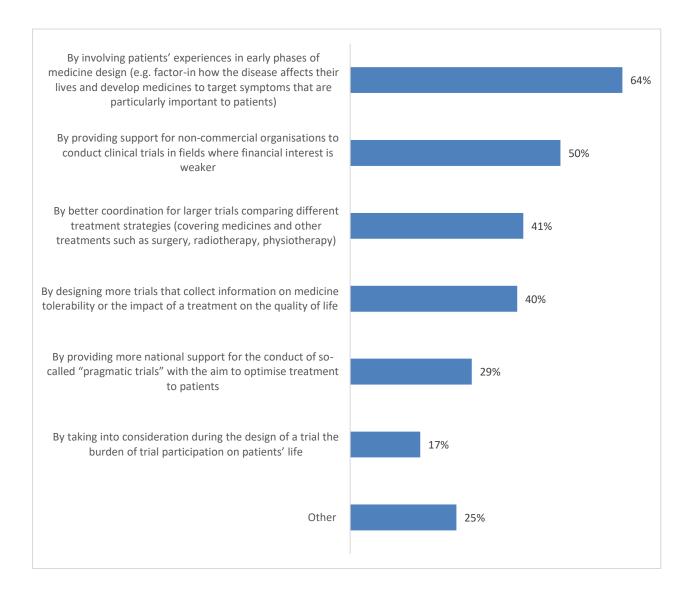


Figure 25. Q15: How could clinical trials in the EU be driven more by patients' needs while keeping them robust, relevant and safe for participants? (Maximum 3 choices)-Stakeholder Breakdown

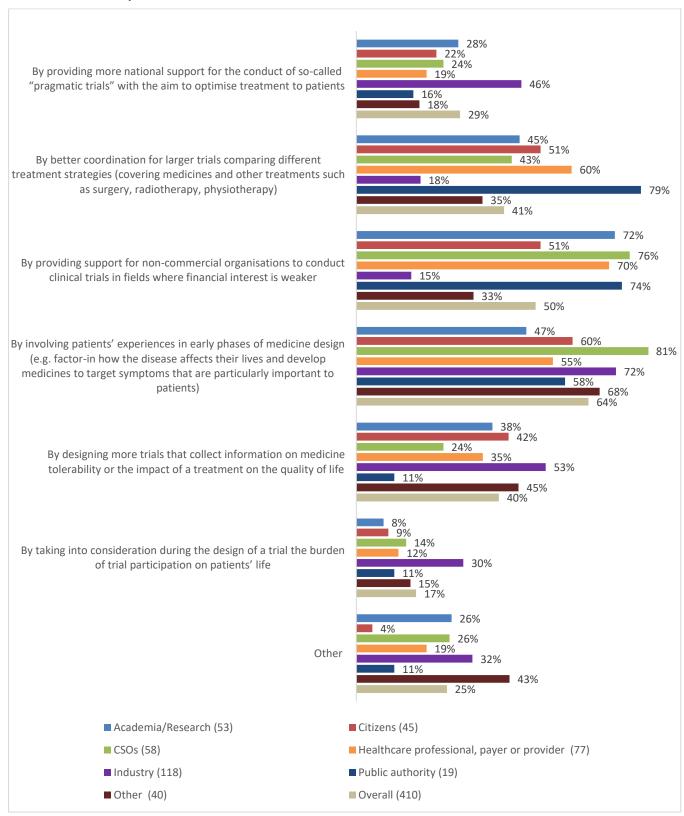
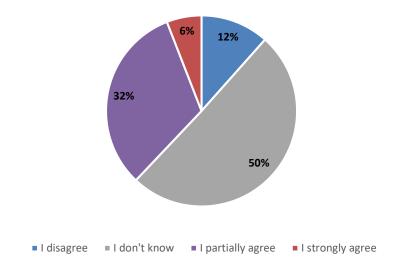


Figure 26. Q16: Is the current legal framework suitable to support the development of cell-based advanced therapy medicines in hospitals?-Overall response



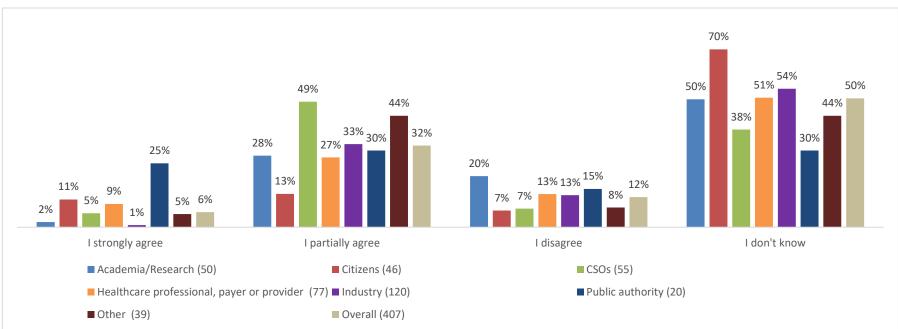


Figure 27. Q16: Is the current legal framework suitable to support the development of cell-based advanced therapy medicines in hospitals?-Stakeholder Breakdown

Figure 28. Q17: What actions at EU level do you consider most effective in limiting the negative environmental impact of medicines? (Maximum 3 choices)-Overall response

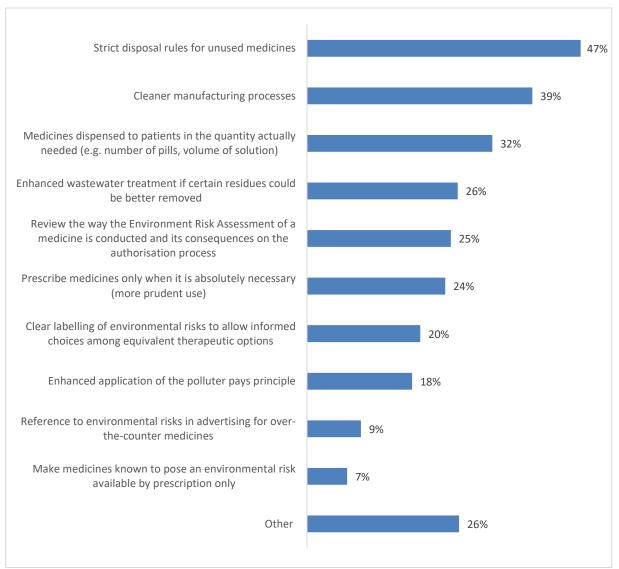


Figure 29. Q17: What actions at EU level do you consider most effective in limiting the negative environmental impact of medicines? (Maximum 3 choices)Stakeholder Breakdown

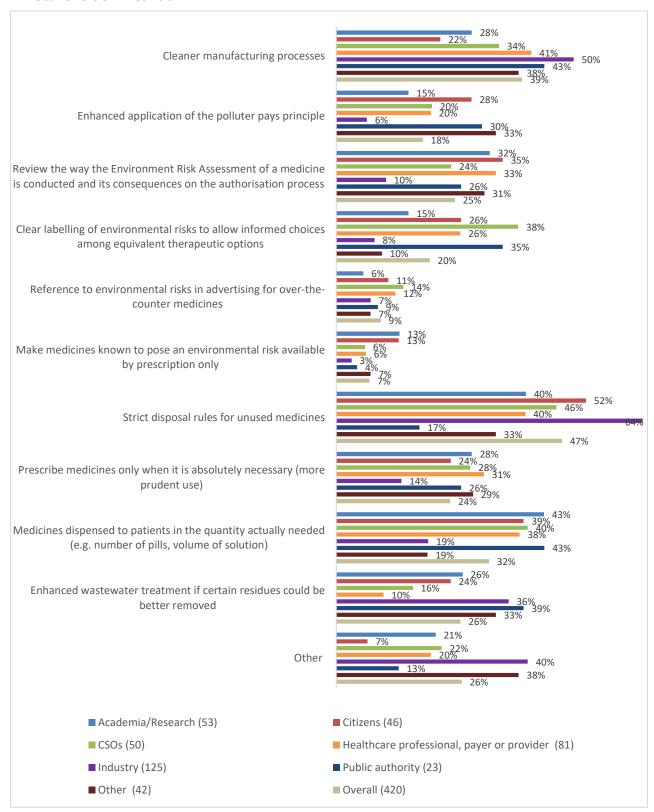


Figure 30. Q18: Which actions do you think would have the biggest impact on fighting AMR concerning the use of medicines for patients? (Maximum 3 choices)-Overall response

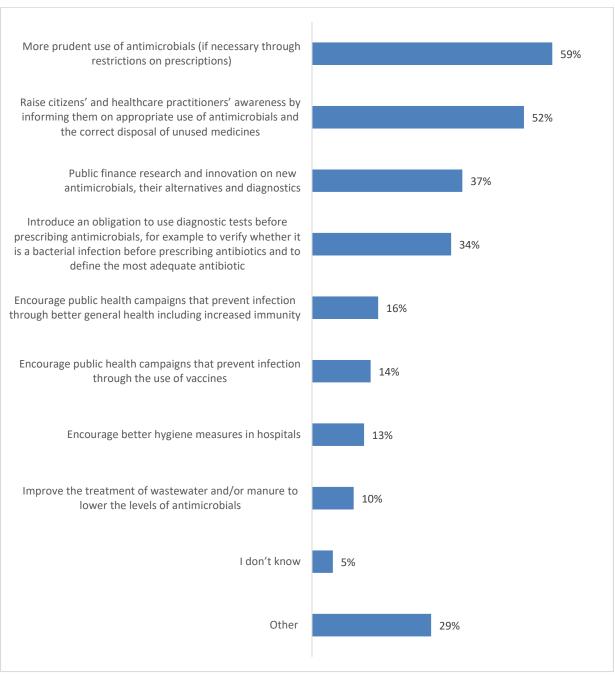
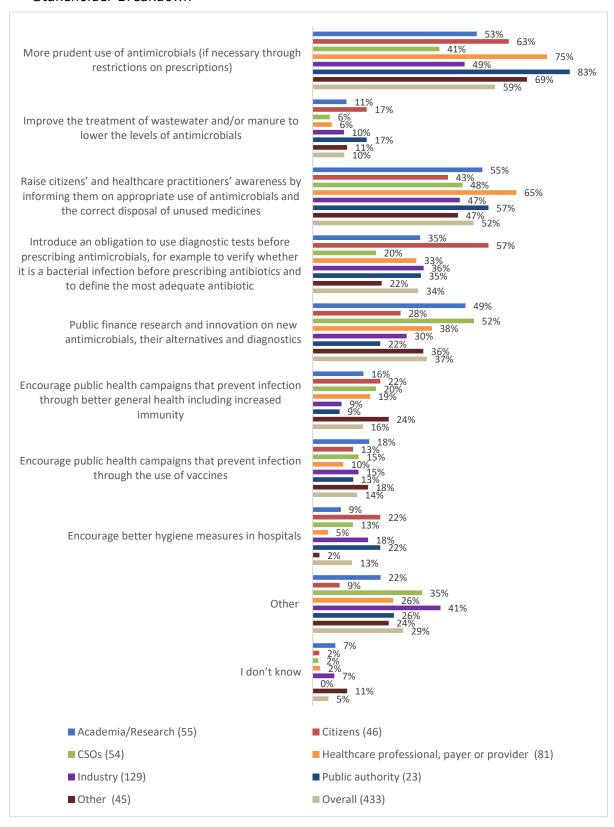


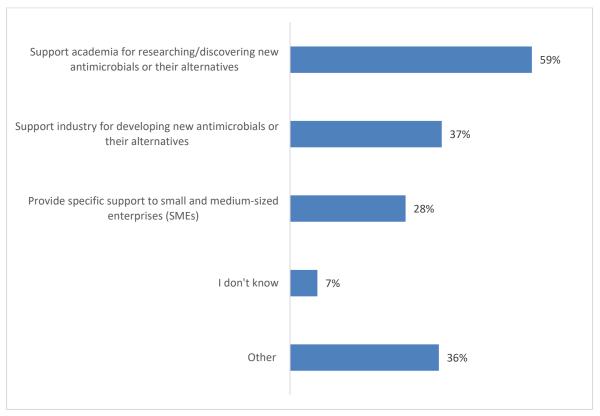
Figure 31. Q18: Which actions do you think would have the biggest impact on fighting AMR concerning the use of medicines for patients? (Maximum 3 choices)-Stakeholder Breakdown



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

*Note:* Academia/research includes academic researches, European research infrastructure, learned societies and research funders. CSOs mainly include patient or consumer organisations. Public authorities mainly include national authorities. Healthcare professionals, payers and providers include pricing and reimbursement bodies, hospitals, pharmacies and health technology assessment bodies. Industry includes API producers/importers, pharmaceutical traders/wholesalers, as well as representatives from the chemicals industry and medical device companies.

Figure 32. Q19: Where, in your view, should the EU focus its support for the creation of new antimicrobials or their alternatives? (Maximum 2 choices)-Overall response



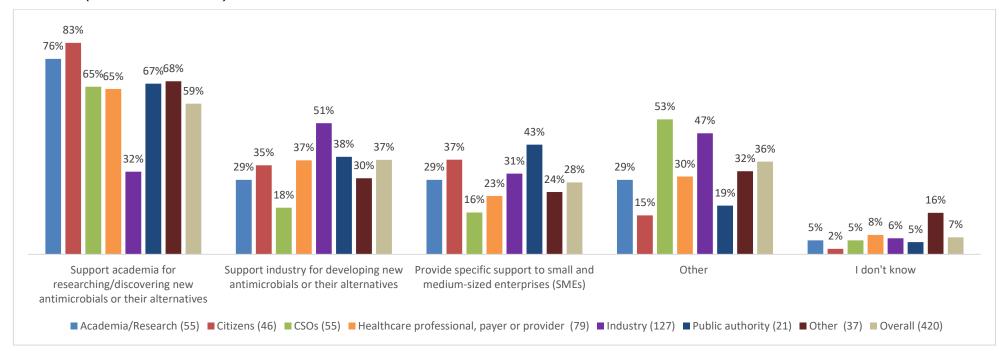


Figure 33. Q19: Where, in your view, should the EU focus its support for the creation of new antimicrobials or their alternatives? (Maximum 2 choices)-Stakeholder Breakdown

Figure 34. Q22: While the Commission is working on improving the EU pharmaceuticals framework, which areas of work do you find most urgent? (Maximum 3 choices)-Overall response

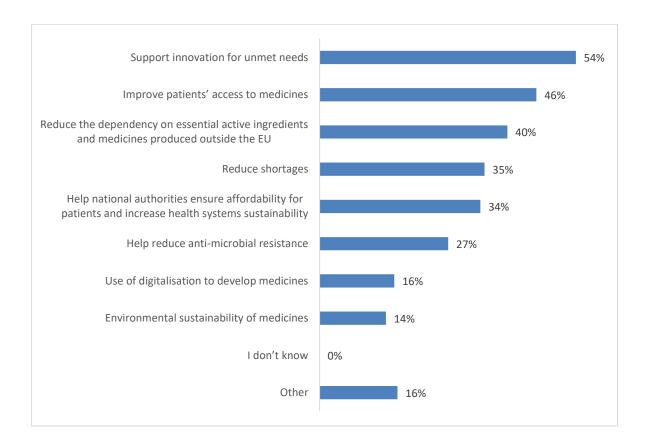
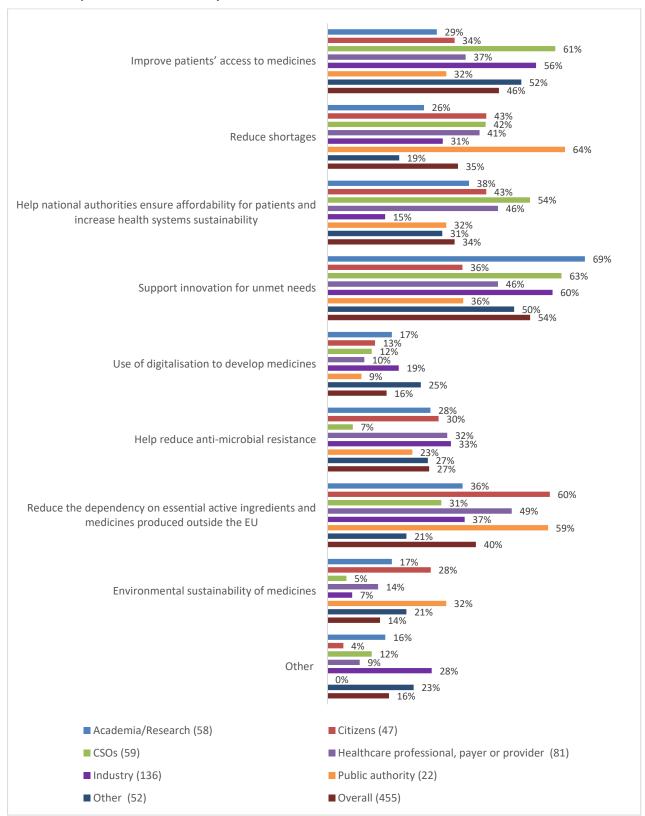


Figure 35. Q22: While the Commission is working on improving the EU pharmaceuticals framework, which areas of work do you find most urgent? (Maximum 3 choices)-Stakeholder Breakdown



Q23: If you were asked before the coronavirus (COVID-19) pandemic, would you have responded differently to any of the previous questions?-Overall response

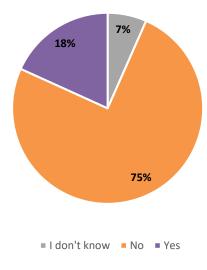
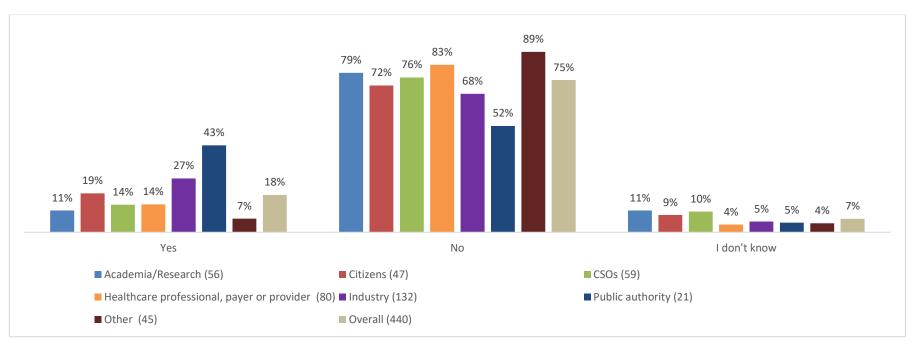


Figure 36. Q23: If you were asked before the coronavirus (COVID-19) pandemic, would you have responded differently to any of the previous questions?-Stakeholder Breakdown



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