Pharmaceutical Strategy for Europe

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Timeline

242 feedbacks – all published online

470 responses received

Publication of the roadmap — June 2020

Online Public Consultation — June 2020

Stakeholder workshop — July 2020

Pharmaceutical Committee meetings — May-Sept

Online Public Consultation closed — Sept 2020

Adoption by College — Q4 2020

Implementation Phase — 2021-24

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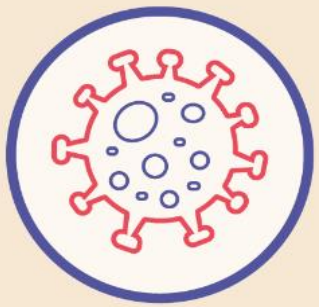
PHARMACEUTICAL STRATEGY FOR EUROPE



Learning from COVID-19, towards a crisis-resistant system

Ensuring accessibility and affordability of medicines

Supporting sustainable innovation, emerging science and digitalisation

Reducing medicines shortages and securing strategic autonomy

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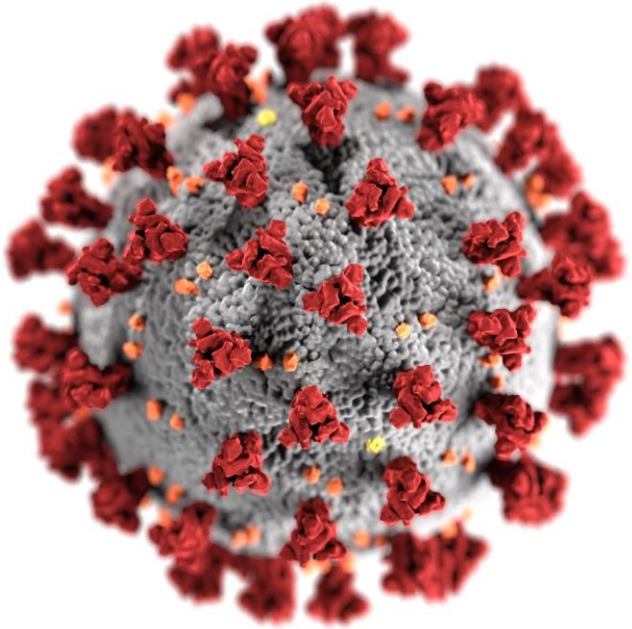
Aspects highlighted by COVID-19

Crisis management and preparedness

Importance of secure supply chains & dependency on APIs



International aspects

Innovation

Shortages

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A holistic approach covering the full lifecycle of medicines

- Research & Development
- Innovation
- Clinical Trials
- Digital & data
- Advanced therapies
- IP/incentives
- Pharma legislation
- Health technology assessment
- …

- Market function
- Procurement
- Manufacturing
- Generics, biosimilars, APIs
- Supply chains
- Environment
- Competition policy
- Trade
- …

Public consultation

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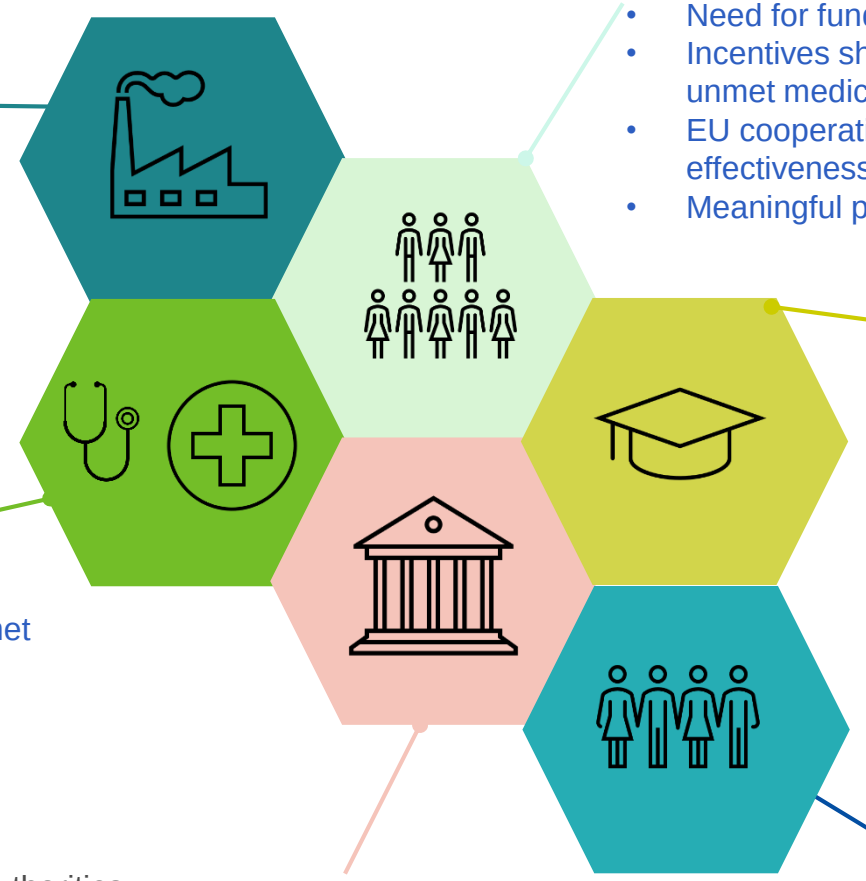
Feedback to the ROADMAP: Key points



Industry

- Need for funding for R&D in early stages of drug development
- Stable regulatory environment, flexibility where needed
- Use of RWD and RWE in clinical development and regulation
- Role of a European Health Data Space and pan-European clinical trial networks
- Off-patent sector: emphasis on competition, procurement criteria, IP

Healthcare stakeholders

- Increase availability of medicines especially for unmet needs
- Promote the use of digital tools (e.g. ePI, smart prescriptions, digital medical records)
- Measures to monitor/prevent shortages
- An EU approach to repurposing of medicines
- Environmental concerns

Civil Society Organisations

- Need for funding and R&D
- Incentives should improve availability of treatments to address unmet medical need
- EU cooperation on affordability, assessment of value, cost effectiveness, P&R, procurement
- Meaningful patient involvement in setting research priorities

Researchers, academia and learned societies

- Cooperation with industry at early stages of R&D
- Promote upskilling & education
- Emphasize patients needs at the centre of drug development

Public authorities

- Measures to monitor/prevent shortages and diversify supply
- Measures to support affordability, access to medicines and financial sustainability of health systems
- Address medical devices incl. in vitro

EU citizens & others

- Measures needed on availability of medicines and tackle high prices
- Measures to monitor/prevent shortages and diversify supply
- Competitiveness and environmental concerns

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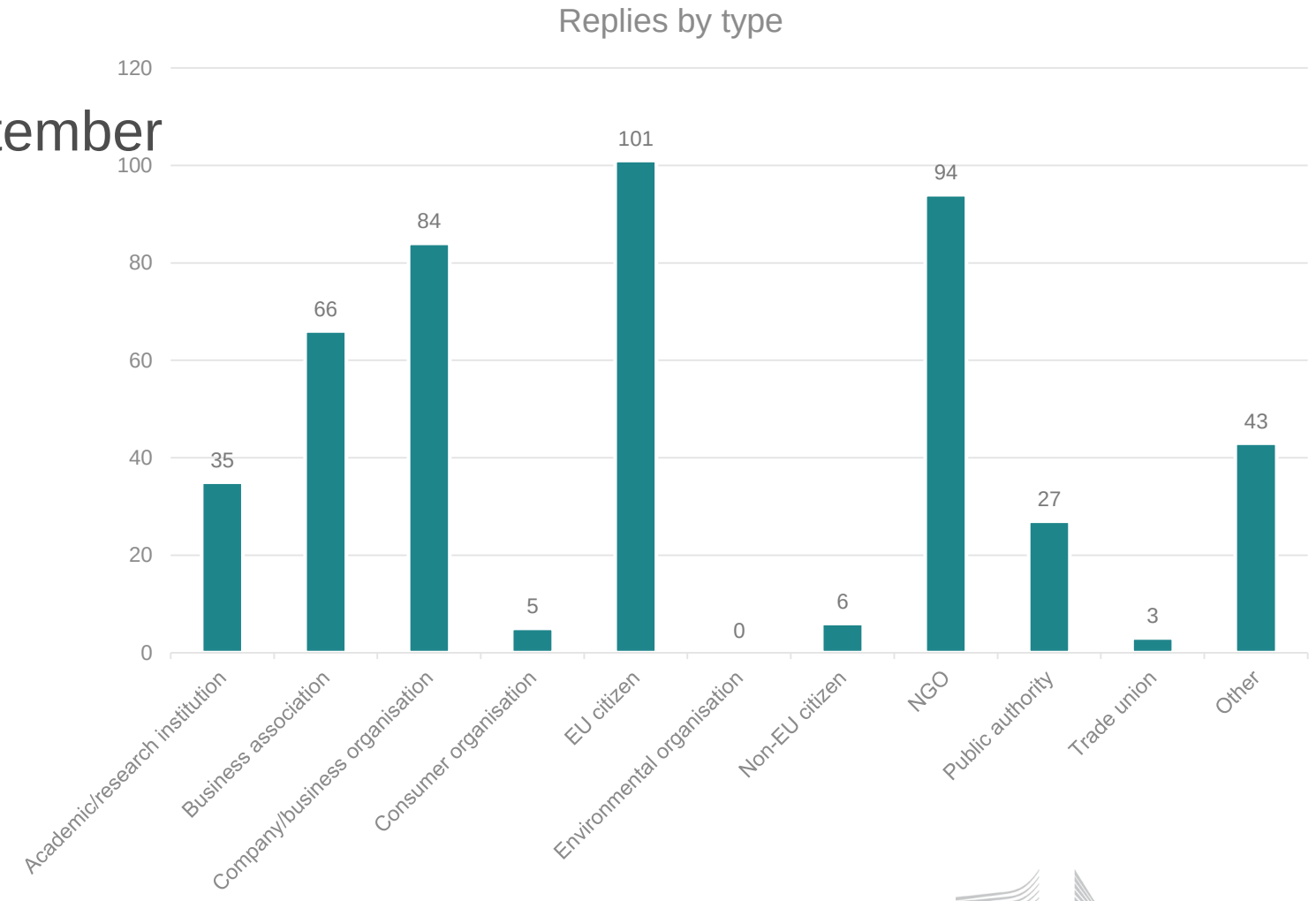
July workshop

Key points

- General support for the roadmap
- Different views as regards what is “unmet need”, reasons for non-availability of medicines, the role of incentives
- Call for regulatory flexibility, adaptation of legislation to digital
- Call for measures on EU dependency on 3rd countries, shortages
- Call for exchange of best practices on procurement /P&R

Online Public Consultation (basic data)

- Deadline closed on 15 September
- 473 replies
- 21% SMEs
- Analysis by early October



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HTA key messages

- Innovation: Support for alignment of R&D spending with public health needs identified at EU level through a list of essential medicines based on HTA.

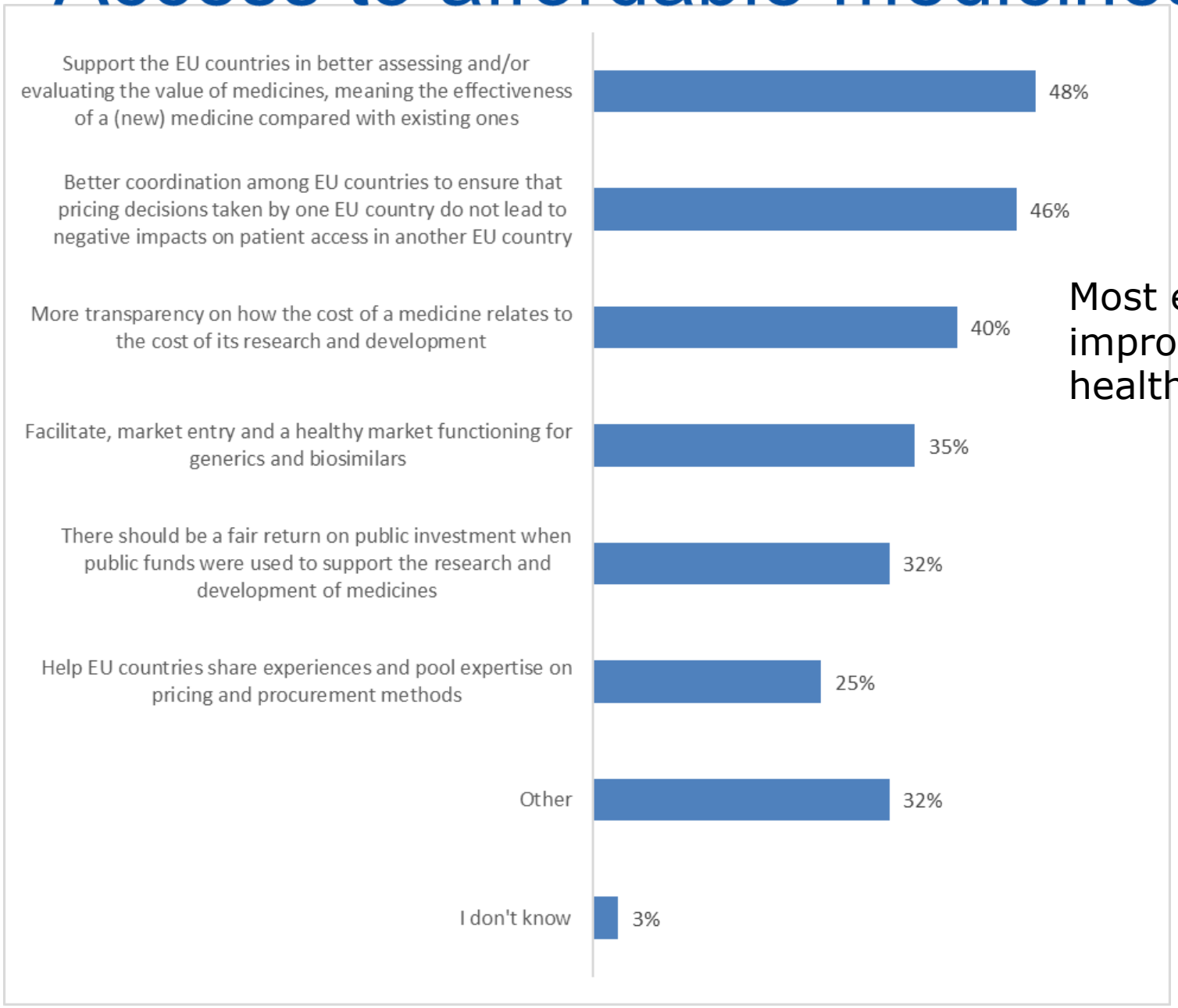
- Strong support by industry for an EU-wide HTA assessment process and for patient centred design of clinical trials (incl. in global clinical trial networks) with early endorsement by HTA / payer authorities.

- A harmonised EU HTA process would help with market launch and quicker access to medicines and increase affordability.

- Regulatory simplification: Reducing regulatory fragmentation and duplications of assessment would lead to faster assessments and reduce costs

- Conducting high quality HTA and sharing information about prices and pricing and reimbursement strategies will enhance Member States' ability to prioritise medicines with higher clinical value, review and adjust prices based on new evidence, effectively negotiate prices and get a clear understanding of their added value in real-life settings.

Access to affordable medicines



Most effective ways the EU can help improve affordability of medicines for health systems

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Delivering for patients – the role of HTA

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- Prioritize unmet medical needs:
  - **Alignment of research to needs of patients and health systems – ‘break the silos’ approach**
  - Revision of legislation on medicines for children and rare diseases
  - tailored incentives
  - Special actions for AMR

- Access
  - Market launch
  - Uptake of generics / biosimilars
  - **Adoption of the HTA proposal**

- Affordability of medicines for patients / sustainability of health systems
  - Support cooperation among MS
  - Guidelines / principles on costing and public procurement
  - Transparency R&D costs
  - Competition

Thank you

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Public Health information:
http://ec.europa.eu/health/index_en.htm
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https://ec.europa.eu/health/human-use/strategy_en

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Feedback mechanism: source: ICF Analysis of contributions to the Roadmap

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