



Updates on the Pharmaceutical Strategy

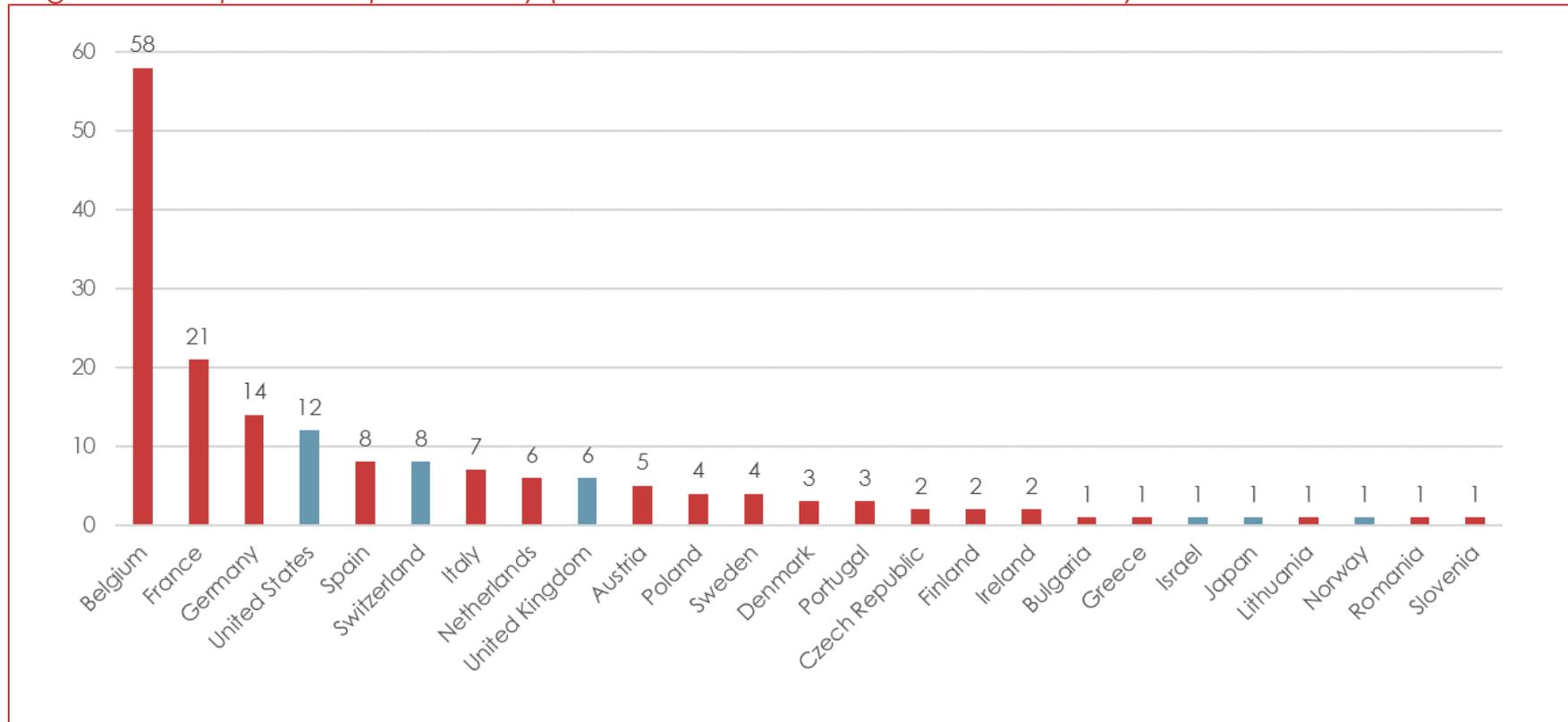
Extraordinary Pharmaceutical Committee meeting 17
September

Topics

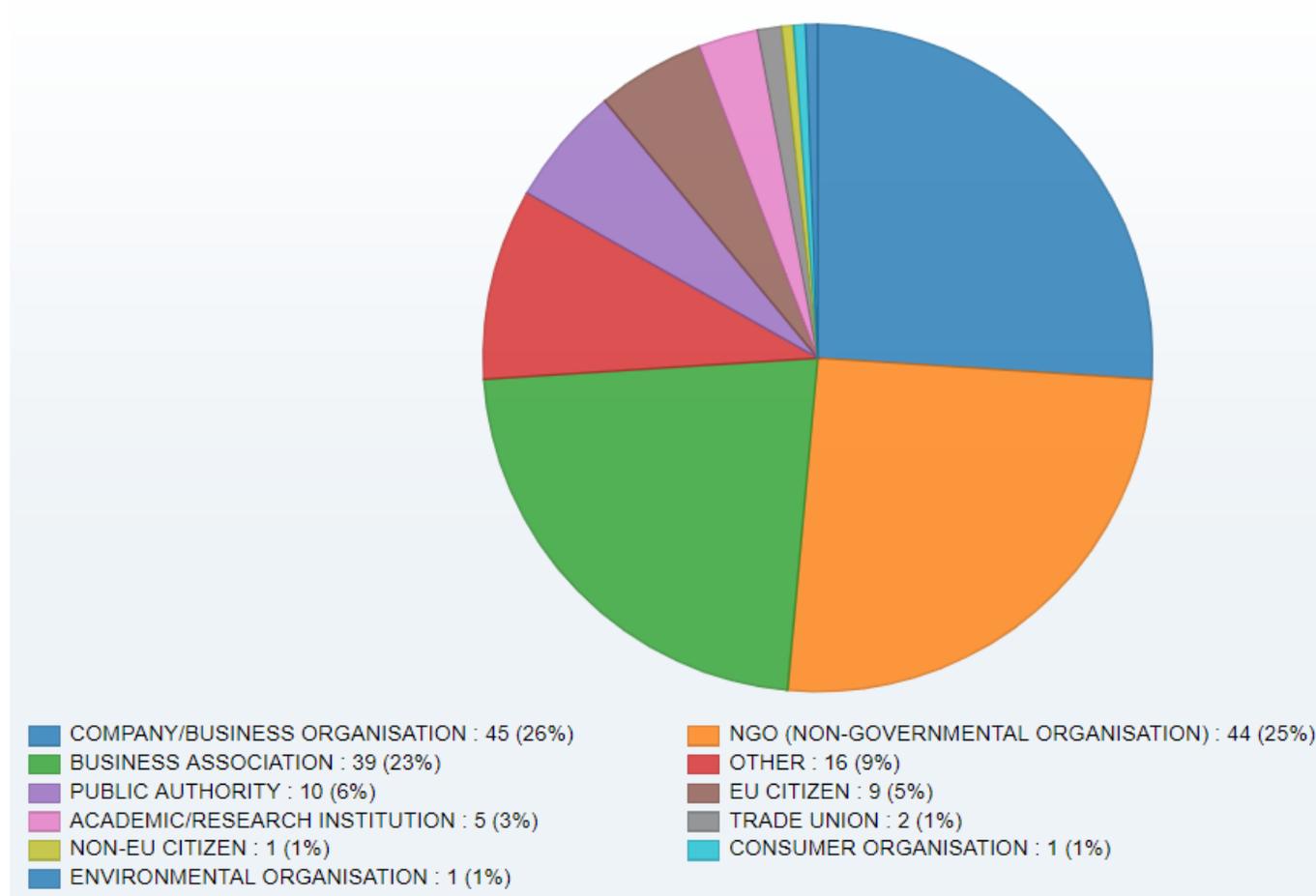
- Feedback to the Commission Roadmap on the Revision on the basic pharmaceutical legislation
- Open public consultation/targeted consultation
- Concept papers
- Forward planning

Feedback to the roadmap

Figure 1 Respondents per country (*non-EU countries are coloured in blue)



Feedback to the roadmap II



Feedback to the roadmap

- Evident and strongly positive **support for the revision** of the legislation and a general agreement on the need to make the legislative framework more patient-centred, future-proof and crisis-resistant
- Around 80% of all the stakeholders representing a business association or a company were **concerned about the fitness of the current legislative framework** in terms of its ability to respond to innovations and new developments
- All stakeholder groups emphasised a point raised in the Roadmap about the need to better **conceptualise ‘unmet medical need’** (UNM).
- With regards to areas where there is a high unmet need and (perceived) market failure, Antimicrobial Resistance (**AMR**) was mentioned by academic stakeholders, NGOs as well as industry stakeholders.
- **Patient involvement** is stressed by almost all (80%) NGOs as essential at different stages of the revision of the legislation itself, as well as integral component of the new or revised procedures

Consultation activities

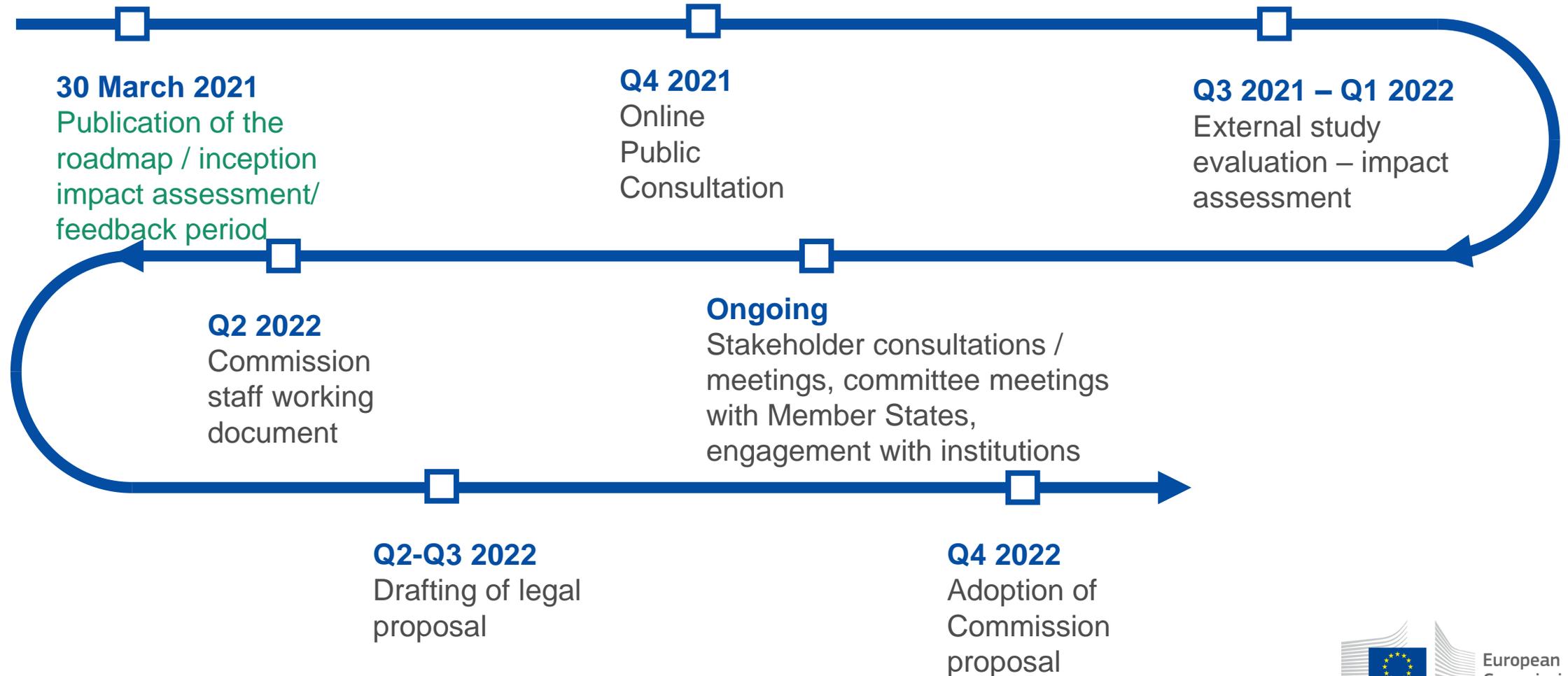
- Open public consultation will be launched end of September
 - Evaluation question and forward looking questions
- Targeted consultations will be initiated in parallel with different stakeholder groups

Pharmaceutical Strategy – Concept papers

- **Purpose:** Support the review and future-proofing of the pharma legislation with regard to “technical” aspects
- **Task:** Solution-oriented papers reflecting on adaptation of concepts, streamlining of procedures, necessary business processes (legislative aspects)
- To be developed (depending on the topic) by **EMA/HMA/Cmdh** and other committees within the next 4-8 months
- **13 topics** identified together with EMA and HMA management group – inspired by the workshops hosted by the Commission earlier this year
- **Output** will inform the review of the legislation and drafting of legal proposal – specificity if important

“Let’s learn from the experience of the network”

Pharmaceutical Strategy – Forward planning



Pharmaceutical Strategy – Forward planning

- Pharmaceutical Committee actively involved in all steps of the process
- Next dedicated Pharmaceutical Committee meeting on strategy organised in October/November
- 2 planned workshops organised by contractor and EC (December and January)