



Results of the online public consultation

DG SANTE
B4 – Medical products:
safety, quality, innovation

Public consultation

- Launched: 21/10/2016
- Deadline: 13/01/2017
- Extended: 30/01 (requests from MS)

Total number of replies = 249

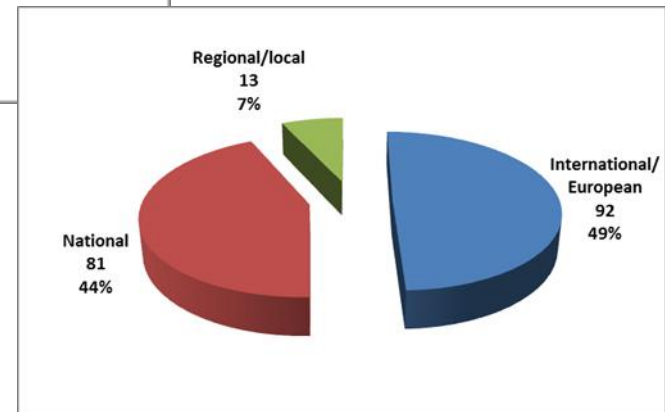
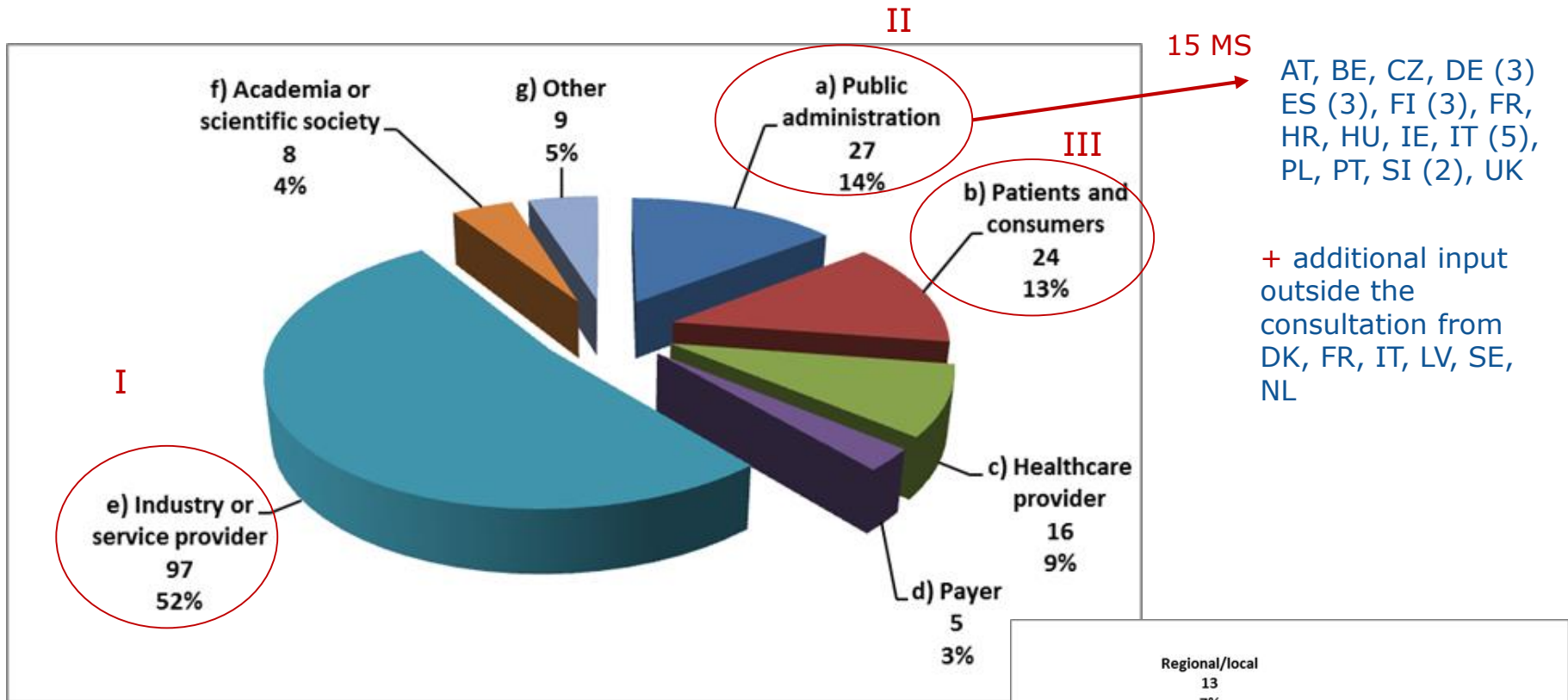
- **Questionnaire for citizens:** 63 (from 21 MS)

Profile: Tertiary education; with background/working in HTA sector, healthcare sector or industry

- **Questionnaire for administrations, organisations, associations:** 150
- **Questionnaire for SMEs** (DG GROW – SME Network): 36 replies

- **98% consider HTA useful**
- **83% consider very important or important** to assess whether a new health technology works better, equally well or worse than health technologies already available
- **Most important factors to be considered when carrying out HTA** (very high or high importance):
 - Transparency of the HTA process (98 %) -> involving stakeholders
 - Expertise of the assessor (96%) -> high-quality reports
 - Independence of the assessor (94%) -> no conflict of interest
 - Timely delivery of the assessment report (92%) -> useful for decision making
- **HTA information should be accessible to doctors and patients/patients' representatives**
- **57% consider that clinical assessment should not be performed in parallel by HTA bodies in the MS**

186 contributions

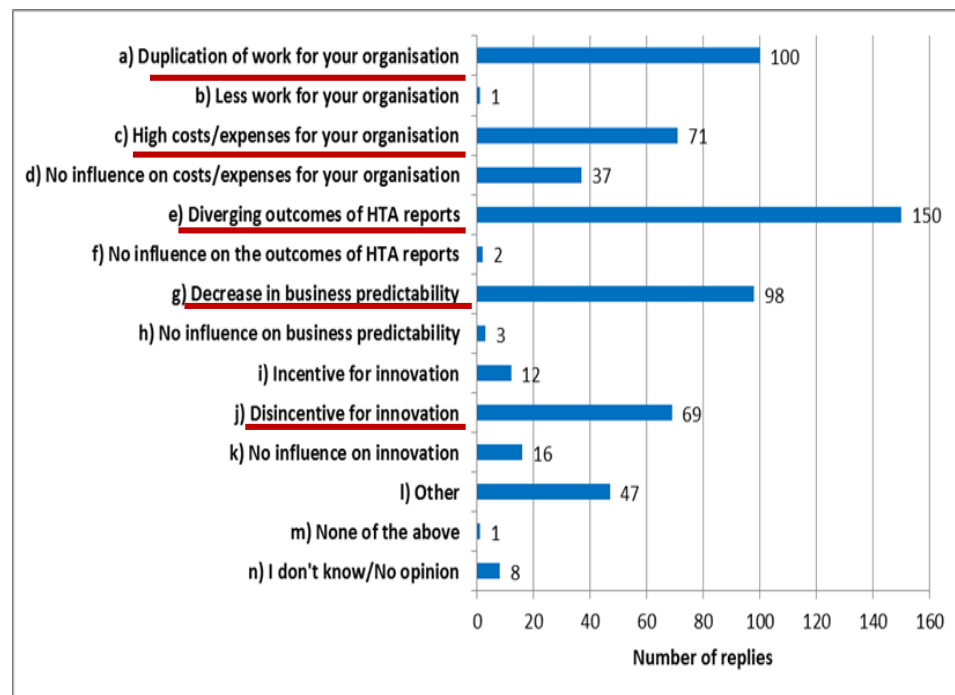


Differences between MS acknowledged by most respondents (agreement + strong agreement), including public administrations

- HTA processes 91%/96%
- HTA clinical methodology 80%/89%
- HTA economic methodology 85%/93%

Most important consequences of the different HTA procedures and/or methodologies across EU

- Diverging outcomes of HTA reports
- Duplication of work
- Decrease in business predictability
- High costs for organisations
- Disincentive for innovation



Current EU cooperation (overall/public administration)

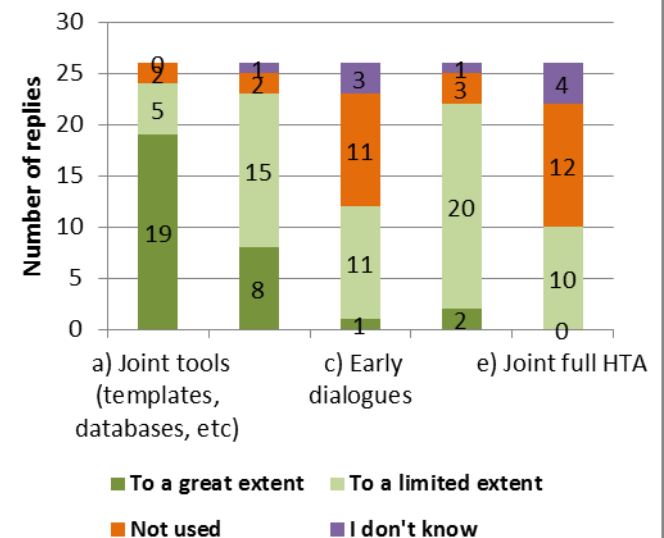
- **Participation** to EU-funded actions: 32%/70%
- **Awareness** of EU funding actions: 47%/26%
- EU cooperation **useful/to some extent useful**: 69%/96%

Uptake of joint work remained low.

E.g. Used to a *great/limited extent*:

- Joint tools – 9/33%
- Guidelines – 9/32%
- Early dialogues – 11/23%
- Joint clinical assessments (REA) – 3/51%
- Joint full HTA (clinical + non-clinical/economic) – 1/21%

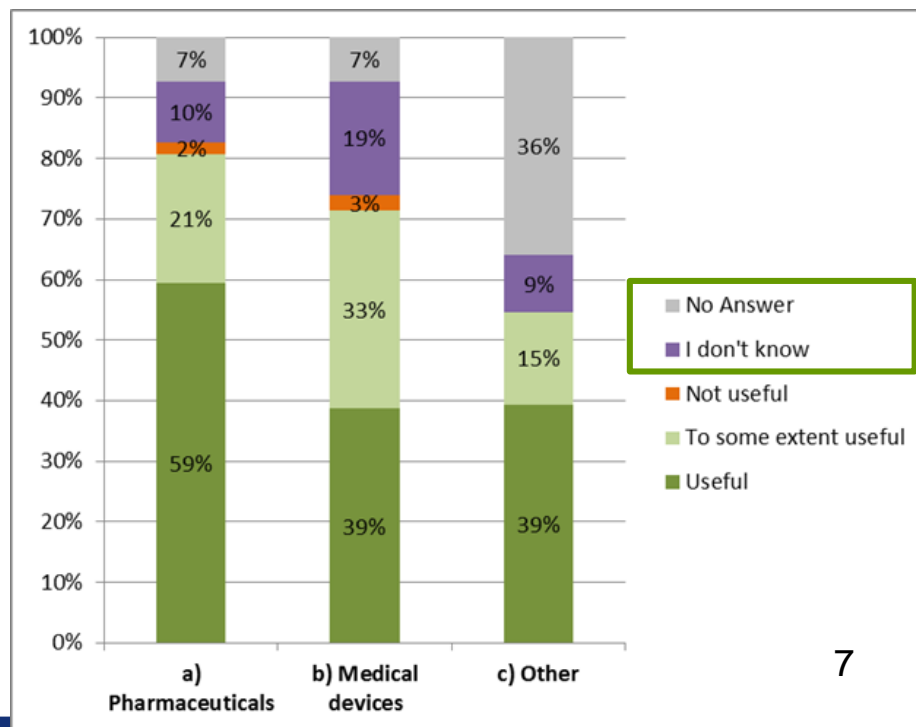
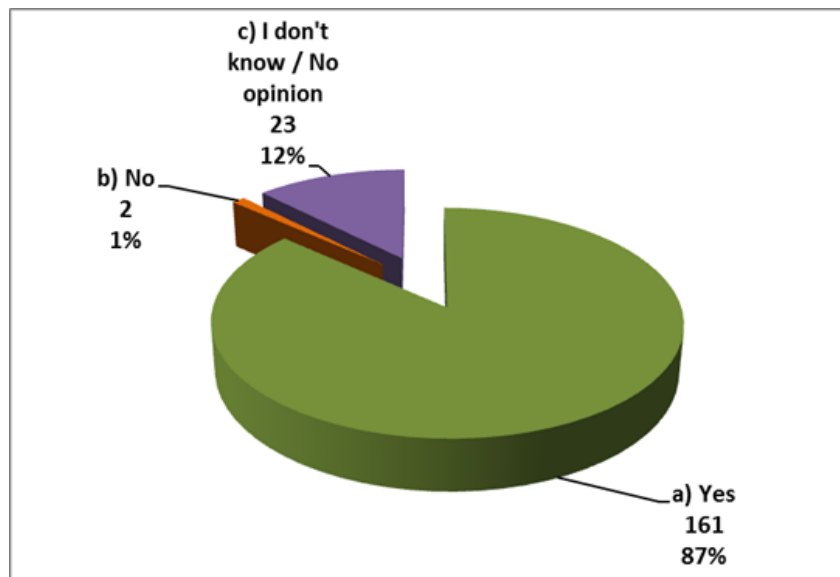
Uptake of joint work - replies from public administrations



EU cooperation beyond 2020: supported by 87%

- **Scope of EU cooperation** (useful and to some extent useful) - Overall/ public administrations replies:

- Pharmaceuticals 80%/100%
- Medical technologies 72%/89%
- Other technologies 54%/67%



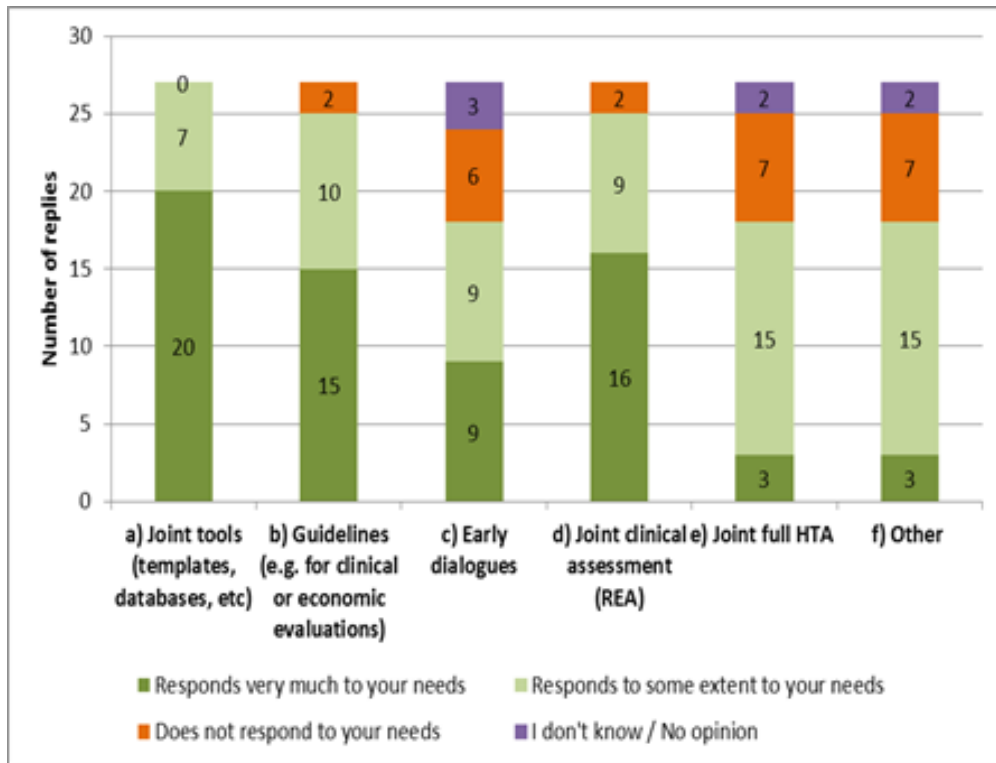


EU cooperation beyond 2020

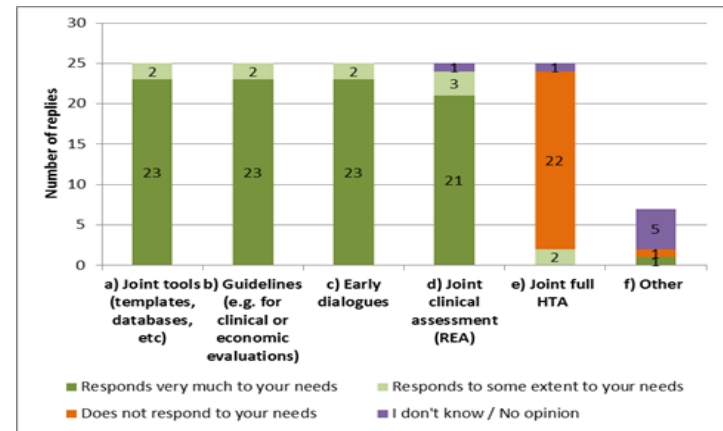
Different needs for EU joint activities

-> may require a step wise approach

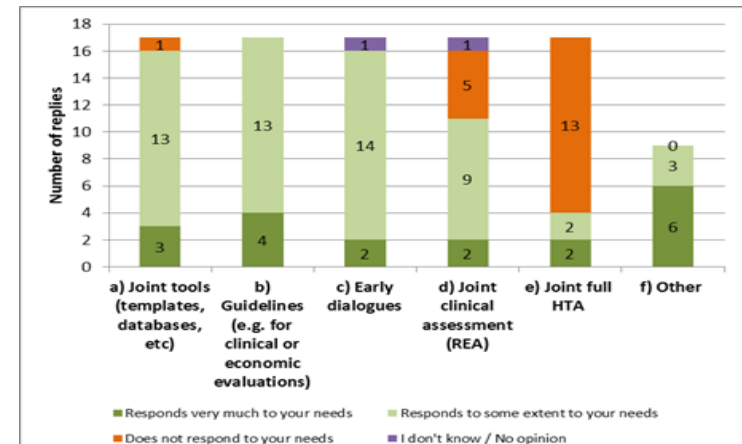
Public administrations



Pharmaceutical industry



Medical technologies industry

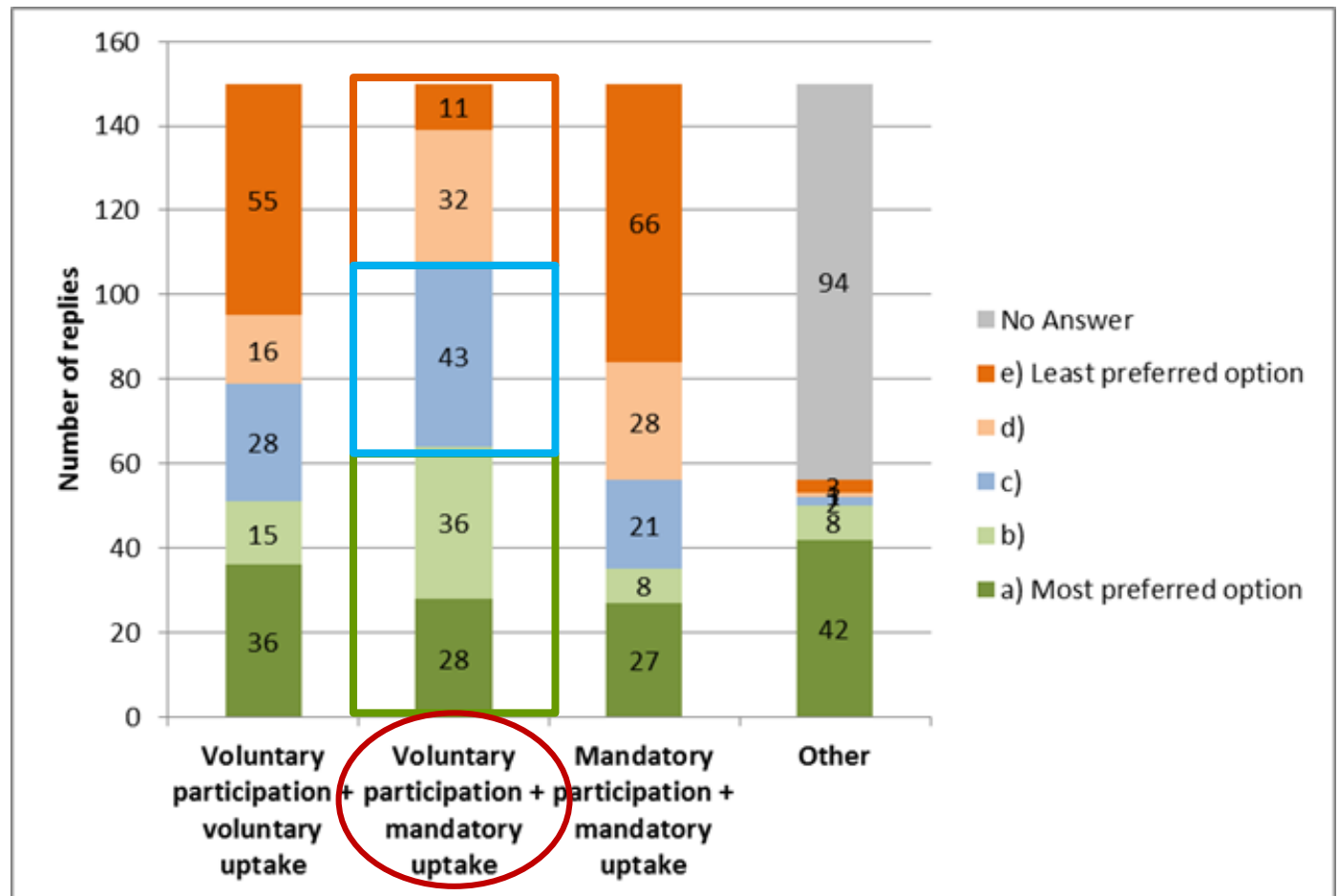


EU cooperation beyond 2020 – Policy options

Lowest opposition

Highest % of
neutral responses

Most preferred



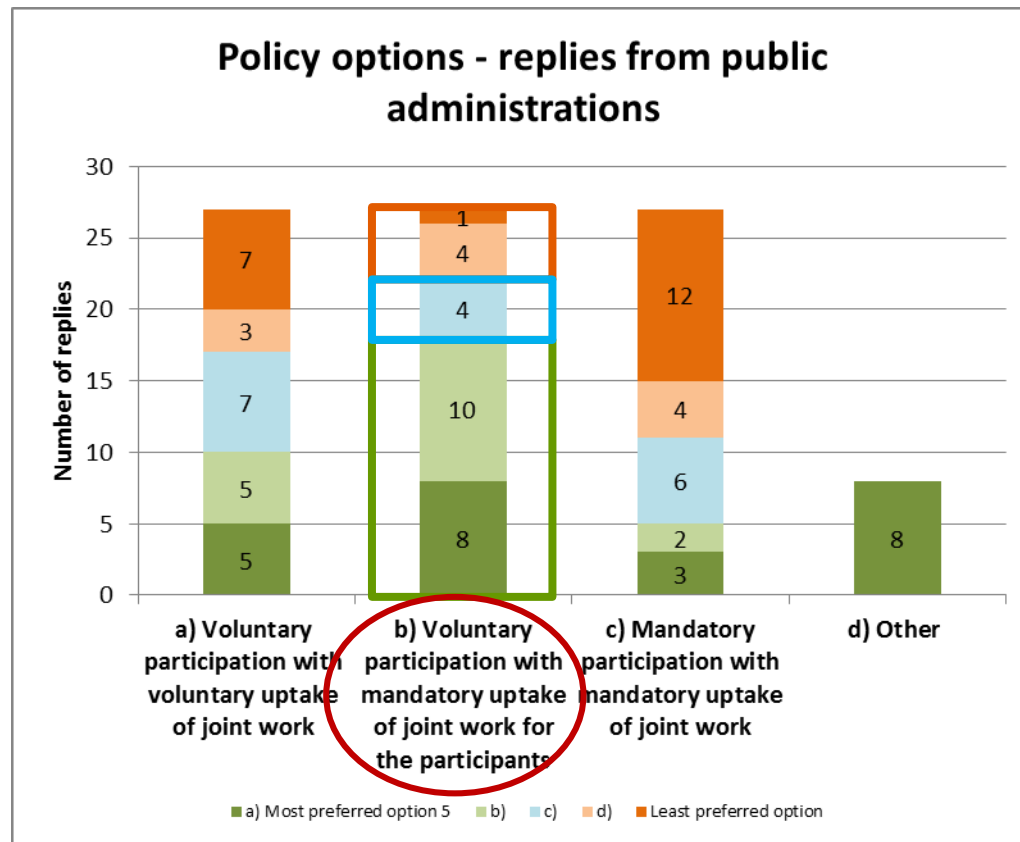
EU cooperation beyond 2020 – Policy options

Public administrations' replies

Lowest opposition

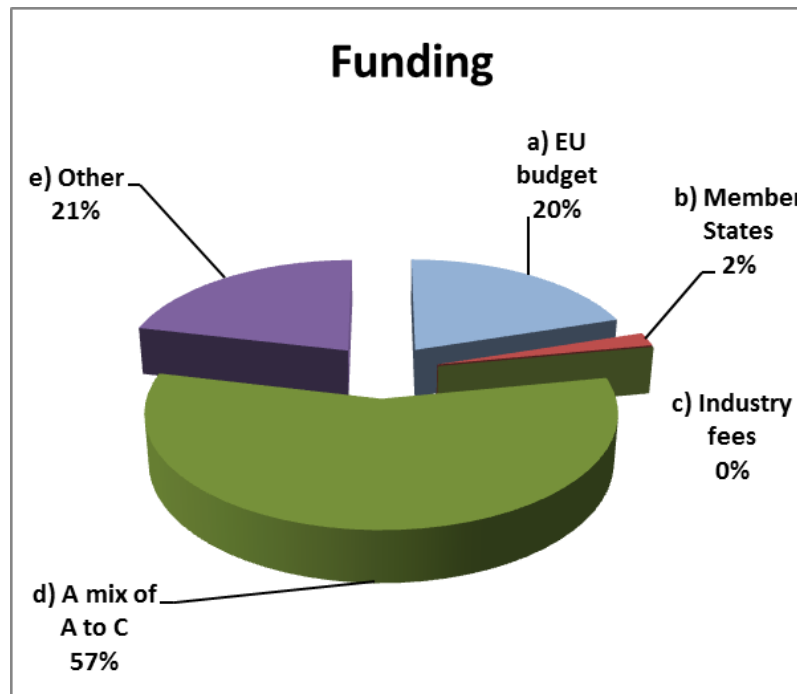
Low % of neutral responses

Most preferred



EU cooperation beyond 2020 – Policy options

- **Governance:** Existing/new EU agency, EC
- **Funding:** EU budget + MS contributions + industry fees
(66% of public administrations responding to the consultations)





- Publication of the public consultation report – Q2
- Conclusion of studies supporting the impact assessment – Q1 and Q2
- Consultation meetings (MS MoH, HTA Network, EUnetHTA, stakeholders) – on a continuous basis
- Impact assessment - Q2 + RSB – Q3
- Proposal – Q4



Thank you