EU4Health 2023 work programme

Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients

Information session
Open calls for action grants
30 June 2023

Peter Bischoff-Everding
European Commission
Directorate-General Health and Food safety
DG SANTE D3 – Medical devices

Regulatory framework

- Regulation (EU) 2017/745 on medical devices – MDR
  - applicable since May 2021
- Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices – IVDR
  - applicable since May 2022
- No specific rules regarding „orphan devices“

“Orphan devices”

- No legal definition
- Call for proposals (EU4H-PJ-11)
  - *‘orphan devices’ are medical devices, including in vitro diagnostic medical devices, that benefit a relatively small group of patients in the treatment or diagnosis of a disease or condition*
- MDCG orphan device taskforce
  - Definition under development: *‘Orphan device’ means a medical device specifically intended to benefit patients in the treatment or diagnosis of a disease or condition that has an annual incidence* of not more than 1 in 37,000 per year in the EU.***

[to be calculated on the basis of an EU-population of 447 Mio; ~12.000 cases per year]*

*[** based on US/FDA definition of Humanitarian Use Device: “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year”]*

Motivation and purpose of the call

- Orphan devices
  - Low return on investment potential
  - High societal interest

- Financial support to activities fostering the development of ‚orphan devices‘, especially for **children**
  - from conceptualisation to marketing

Budget, timing and target applicants

- Overall available: 500,000 EUR
- Expected grants: 2
- Expected duration: 12-36 months
- Target applicants: Scientific societies, academia, research institutions, NGOs, SMEs

Thank you

European Commission