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European Commission

SGPP Focus Group on Orphanet Sustainability

Conclusions

Outline of the tabled document

- One pager from the EC
- Final deliverable of the SGPP Focus Group on Orphanet Sustainability
    - Executive summary report & proposals of the Focus Group
    - Summary document on Orphanet sustainability roadmap & annexes
    - Orphanet within the Rare disease European ecosystem: Orphanet as a key component for the implementation of the EU Cross border directive and support for European Reference Networks' action
    - Minutes of the Focus Group meetings
    - Concept paper on the possible future of Orphanet/ Advancing cooperation on rare diseases in Europe (October 2018)

What is Orphanet

- The Orphanet network, developed thanks to sustained European and Member States efforts, constitutes the worlds' largest and most comprehensive resource of information and the international reference source for codification in the field of rare diseases.

- In particular, Orphanet network is instrumental for the achievement of several of the objectives described in the Article 12 of the Directive 2011/24/EU on the application of patients' rights in cross--border healthcare.

- ERNs and Orphanet constitutes a unique European ecosystem dedicated to rare diseases with complementary roles: ERNs have the clinical and scientific expertise on RDs and Orphanet has the expertise on databasing and standardization. Orphanet Network's national anchorage contributes to national integration of ERNs.

Report of the Focus Group

The purpose for establishing the Focus Group was to propose to "***the Steering Group no later than spring 2020, a shared solution between MSs for sustained support (either financially or in kind) to Orphanet's activities***".

The focus group has met 4 times : 10 October 2019, 25 November 2019, 14 January 2020, 5 June 2020 - 12 Member States represented (Austria, Belgium, Czech Republic, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Spain, Sweden) and Norway

1st conclusion : ***the Amendment to the Orphanet Network is not currently an actionable solution for the transnational distribution of core Orphanet functions***

Advice of the Focus Group on sustainability options

- To take into account a longer term vision in line with EU rare disease prospective, and secure EU wide umbrella, to make sure that no EU country is left out

- To share MS contribution to core/transnational activities (currently supported by INSERM) through membership-based common pot that would open access to a package of core services to all MS. Fees could be collected through a nonprofit international association established under Belgium Law or through another Legal form established for that purpose

Orphanet sustainability roadmap / operational priorities

- To structure the partnership through setting up Orphanet into International non--profit association under the Belgian law (AISBL) or European Economic Interest Grouping (EEIG) or any other legal form of EU relevance
  - With a shared Governance across members/ « common-pot » in cash and/or in kind.
  - Annual workplan agreed by members to decide priorities and funding allocation
- To develop new services in response to market demand (*link ORPHA codes with patient data and other relevant data*)
- To seek appropriate funding
- To enhance the ecosystem attractiveness (formalize alliances with communities (ERNs, NGOs, Learned societies, etc.); develop specialized communities (geographical and/or thematic); link with the private sector (licencing and collaborative projects).

European Commission

Thank you

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Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases

Focus Group on sustainability of Orphanet:

The SGPP is invited to take note of the Focus Group report and its proposed stepwise approach, especially as regards the relevance of such an approach for rare diseases efforts at national level.

25 November 2020, 14:00 – 16:30 CET