

## **WHO PAEDIATRIC REGULATORY NETWORK VIRTUAL MEETING**

**12 and 13 May 2022**

### **TERMS OF REFERENCE**

---

#### **BACKGROUND**

The Paediatric Regulatory Network was re-activated at the Initiation Task Force Meeting held on 5-6 December 2019 in Geneva with strong engagement from National Regulatory Authorities from 13 countries, development partners and other stakeholders.

The Paediatric medicines Regulatory Network (PmRN) was initially created in February 2010 in response to a recommendation from the 2008 International Conference on Drug Regulatory Authorities and as part of the Bill and Melinda Gates Foundation “Better Medicines for Children” Project as a global paediatric working group to offer a platform for discussion on paediatric regulatory considerations for National Regulatory Agencies (NRAs).

The PRN is a global paediatric working network supporting the availability of quality medical products for children through facilitation of communication, collaboration, training, and regulatory harmonization across the development, registration and pharmacovigilance of paediatric medical products.

The PRN activities efficiently contribute to the implementation of the actions laid out in the World Health Assembly resolutions WHA60.20 on ‘Better medicines for children’ (23 May 2007), WHA69.20 on ‘Promoting innovation and access to quality, safe, efficacious and affordable medicines for children’ (28 May 2016), WHA67.20 on ‘Regulatory system strengthening for medical products’ (24 May 2014) and WHA67.22 on ‘Access to essential medicines’ (24 May 2014).

The previous PRN meeting took place on 14-15 April 2021 virtually and involved 22 NRAs (44 NRA representative) with 67 participants in total.

## **OBJECTIVES**

The aim of the meeting is to share updates, experience and good practices between the Paediatric Regulatory Network members:

- give a platform to members to share paediatric regulatory information, updates and achievements;
- discuss the need for prioritization of paediatric medicines;
- present the WHO Essential Medicines List for Children process;
- present recent developments in terms of paediatric extrapolation;
- share best practices in terms of quality, non-clinical and clinical evaluation of paediatric medicines and good product information for children.

## **EXPECTED OUTCOMES**

- share updates and best practices between countries and regions to promote global development of paediatric medicines and overcome common challenges;
- promote prioritization activities for paediatric medicines and the WHO Essential Medicines List for Children;
- discuss and promote the use of paediatric extrapolation;
- share best practices in terms of quality, non-clinical and clinical evaluation of paediatric medicines and good product information for children.

## **DATE AND VENUE**

- To be held virtually on 12 and 13 May 2022.

## **BUDGET AND COSTS**

- Interpretation will be available in English and French, Spanish and Russian throughout the meeting.

## **PARTICIPANTS**

Representatives of National Regulatory Authorities (NRAs), development partners, donors, and ethic representatives.