



## Questionnaire for the PDCO Members on involvement of children, adolescents, their parents, carers or legal representatives and members representing patients' organisations in the activities of the PDCO

Name of the PDCO member:

Country:

**1) Do you see a benefit to involve children and/or adolescents in the activities of the PDCO?**

Yes

No. Please comment:

*If you have answered "Yes" to this question, please respond to all following questions.*

*If you have answered "No" to this question, please jump to questions 11, 12 and 13.*

**2) For which specific situation(s), would you see a benefit to involve children and/or adolescents in the activities of the PDCO (e.g. during plenary meeting discussions, or EMA workshops on specific conditions, or preparation of EMA guidelines). Please specify each case where you see a need.**

**3) What should be the targeted paediatric population? Please specify.**

Onwards age:

Healthy children:  Yes  No

Healthy adolescents:  Yes  No

Children with (or experience of) specific conditions:  Yes  No

Adolescents with (or experience of) specific conditions:  Yes  No

Prioritised therapeutic areas; please specify:



Prioritised conditions; please specify:

**4) How often would you like to involve children and/or adolescents?**

**5) Do you see a need to involve, along with children and/or adolescents, parents, carers, or legal representatives in the activities of the PDCO?**

No. Please comment:

Yes. Please comment:

**6) What would be the most appropriate way to involve children and/or adolescents (and parents, carers or legal representatives)?**

Direct participation in the PDCO plenary meetings:

In person

Via teleconference/videoconference

Written comments on specific topics between PDCO plenary meetings

Other; please specify:

**7) How could the access to children and/or adolescents (and parents, carers, or legal representatives) be facilitated in each Member State?**

By the Enpr-EMA networks; please specify:

By established Young Patients Advisory Groups; please specify:

Through EU Patient's Organisations; please specify:

Other: please specify:

**8) Do you/your organisation have access to children and/or adolescents (and parents, carers or legal representatives) potentially keen and suitable to be involved in the PDCO activities?**

No. Please comment:

Yes. Please comment:

**9) How could keen children and/or adolescents (and parents, carers or legal representatives) be best trained/informed so as to be prepared for their involvement in the PDCO activities? Please list any ideas you may have:**

**10) Do you think it may be beneficial to set up a small PDCO Working Group whose primary role would be to further define the scope and specific objectives of the involvement of children and/or adolescents (and parents, carers or legal representatives) in the activities of the PDCO?**

No

Yes

*If you have responded Yes, would you like to be a member of this Working Group:*

No

Yes

**11) In order to strengthen the input from members representing patients' organisations in the PDCO activities, when do you think a systematic feedback from them would be required, i.e. their opinion to be systematically expressed?**

On selected topics discussed at PDCO; please specify which ones:

For each new PIP procedure (i.e. PDCO Day 30 discussion)

For ongoing PIP procedures (after PDCO Day 30 discussion); please specify when:

As additional Peer Reviewers of PIP procedures; please specify:

At the time of debriefing/conclusion following an Oral Explanation Meeting

Other: please specify:

**12) What would be the issues the members representing patients' organisations attending the PDCO could provide systematic input on?**

Therapeutic need in the paediatric population

PIP targeted population

Study feasibility

Study design

Acceptability and suitability of proposed or requested study endpoints

Acceptability and suitability of proposed or requested formulation(s) in the PIP

Other; please specify:

**13) Do you have any comments or suggestions you wish to add for our consideration?**

**Many thanks for completing the questionnaire !**