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Paediatric Medicines Office

Boosting the development of medicines for children

Closing report of the European Medicines Agency and European Commission (DG Health and Food Safety) action plan on paediatrics

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Introduction

In 2017, the European Commission's (EC) 10-year report[1] on the implementation of the Paediatric Regulation[2] revealed specific challenges. Whereas the report showed an overall increase in medicines being developed for children, it also highlighted that paediatric development is lagging behind the adult one, causing a delay in availability of paediatric medicines at patients' bedsides. Another challenge is the development of medicines for which there is no adult indication and are targeted for diseases that exclusively affect children. In order to follow up on the report's conclusions and to boost the development of medicines for children in Europe, the EC and the European Medicines Agency (EMA) developed a detailed plan of short-term actions that could address the identified shortcomings under the current legal framework. The EMA-EC action plan was published on 2 October 2018 and took into account the suggestions made at a multi-stakeholder workshop[3] convened by the EC and EMA earlier that year.

The work on certain actions had to be temporarily paused due to the Agency's relocation from London to Amsterdam and the COVID-19 pandemic. Nevertheless, progress on all agreed actions has been made through collaboration of all stakeholders.

This report aims to highlight the main achievements of the action plan four years after its publication. For a comprehensive listing of all actions and initiatives completed as part of the action plan, please see the Appendix.

The actions were grouped according to the five topic areas highlighted by the Commission in the 10-year report on the implementation of the Regulation:

Topic areas
1. Identifying paediatric medical needs
2. Strengthening of cooperation of decision makers
3. Ensuring timely completion of paediatric investigation plans (PIPs)
4. Improving the handling of PIP applications
5. Increasing transparency around paediatric medicines

Selected achievements by topic area

1. Identifying paediatric medical needs

The EMA-EC paediatric action plan provided momentum for joint efforts of EMA and other stakeholders to raise awareness of paediatric therapeutic needs with a view to supporting strategic decision making. In 2019, EFPIA and EFGCP organised a multi-stakeholder workshop with EMA participation on defining paediatric unmet medical needs, which led to specific disease-focused workshops organised in collaboration with the IMI initiative conect4children (c4c) on paediatric inflammatory bowel disease (IBD) and atopic dermatitis (AD), respectively. Further, ACCELERATE, in collaboration with EMA, organised several multi-stakeholder platform meetings on topics related to therapies for children and adolescents with cancer.

These meetings provided an opportunity to assess disease burden, including the relevance of a given condition in the paediatric population, its seriousness, and the availability and suitability of treatments. Multi-stakeholder engagement in these discussions has been key and has enhanced communication

and understanding between academia, industry, patients and regulators. However, it also showed that a definition of "unmet needs" will have to take into account the perspective of different therapeutic areas.

The outcome of these interactions has been timely published in the scientific literature and has facilitated prioritisation of medicinal product development by considering each time the individual properties of a given substance. This includes assessment of its potential to fulfil an unmet therapeutic need in various age groups based on its mode of action and its unique pharmacological characteristics, regardless of the planned therapeutic indication in adults.

These learnings are being taken into account in the framework of product-specific discussions on PIPs and waivers.

More generally, the PDCO assessment of each product's potential to fulfil an unmet therapeutic need has been strengthened during the PIP evaluation process and better reflected in a new section on unmet needs. Moreover, on a monthly basis EMA discusses paediatric medicine development programmes in light of unmet therapeutic needs with the international regulatory bodies via the paediatric cluster.

2. Strengthening of cooperation of decision makers

Collaboration has been strengthened between the PDCO, who assesses paediatric investigation plans, and the Clinical Trials Coordination Group (CTCG, formerly Clinical Trials Facilitation Group (CTFG)), who authorise clinical trial applications. New ways of collaboration were established at a number of joint meetings in 2018-2021. This new approach has been put into practice in several product-related discussions proving specifically useful e.g. during the evaluation of PIPs for COVID-19 vaccines during the pandemic.

International compatibility of paediatric regulatory requirements to facilitate global development has been reinforced by enhanced integration of EMA/FDA paediatric cluster activities and in the EMA/PDCO PIP assessment process. For instance, a joint FDA/EMA Common Commentary on submitting an initial Pediatric Study Plan (iPSP) and Paediatric Investigation Plan (PIP) for the prevention and treatment of COVID-19 was published.

To further strengthen international collaboration of regulators and to improve the conduct of multi-regional paediatric clinical trials, the European network of paediatric research at EMA (Enpr-EMA) set up an international working group in 2018, including representatives from regulators and paediatric research networks from six different regions (Australia, Canada, EU, Japan, UK, USA). This group has been working on a white paper on requirements for paediatric clinical trial authorisation and ethics approval across different legislative regions as well as on recommendations regarding international standards for sustainable paediatric clinical trial sites.

With a view of improving the availability of authorised paediatric medicines at the bedside of paediatric patients, EMA has been working with Health Technology Assessment bodies in order to promote a mutual understanding of the strength of data supporting paediatric indications based on extrapolation of efficacy data from adults and its implications for the paediatric population.

3. Ensuring timely completion of paediatric investigation plans (PIPs)

Enpr-EMA published a framework about paediatric clinical trial preparedness in 2020 which provided the basis of a scientific publication the following year, outlining key factors expected to increase the likelihood of a smooth and timely course of a paediatric clinical trial.

Progress was made in regulatory discussions of trial designs and methodologies that may allow best use of data leading to inclusion of fewer paediatric patients in clinical trials. Notably, a reflection paper on the use of extrapolation in the development of medicines for paediatrics was adopted and published in 2018. In addition structured guidance for applicants/marketing authorisation holders on the use of extrapolation was also published, complementing its use and applicability.

In order to better enable young people/paediatric patients/parents to contribute to and represent their interests in the planning of clinical trials, a range of services and training resources for young people have been made available by the European Young People Advisory Group network (eYPAGnet), a member of Enpr-EMA, as well as of c4c (e.g. video about involvement of young people in EMA's activities related to medicine development).

4. Improving the handling of PIP applications

A focus group comprising representatives of the pharmaceutical industry, EMA, as well as members of the PDCO, has developed a framework for a "stepwise PIP" concept, i.e. a leaner regulatory-scientific approach in agreeing a PIP that allows for changes to be made to PIPs as more evidence becomes available over time. This will allow, in selected cases, to leave some elements of a PIP open to further refinement after first agreement, with a commitment to fill the gaps once certain milestones are reached, and necessary scientific evidence becomes available. Moreover, the key elements to be specified in PIP opinions have been revised in order to focus only on essential elements at an appropriate level of detail. The PIP summary report template has been revised along the same lines and is planned to be published in the near future. Exploring the feasibility of these new approaches and further finetuning is planned during a pilot phase to start in February 2023.

In addition, administrative submission requirements for PIP applications and procedural aspects of the PIP compliance check have been simplified.

5. Increasing transparency around paediatric medicines

An update to the Community Register of medicinal products with paediatric information (i.e. link to PIP information) and a public register for information on paediatric trials open for recruitment as well as for results of such trials in lay language are under development.

Conclusions

The EMA-EC paediatric action plan has provided a framework for improving the implementation of the Paediatric Regulation in a collaborative effort between all stakeholders. These actions have helped to focus development efforts on areas of high unmet medical need, spared paediatric resources and increased the possibility for earlier availability of new medicines through shorter developments. Administrative steps have been reduced, processes have been simplified and made adaptable to innovative new medicine developments to reduce bureaucracy. Moreover, cooperation among decision makers and stakeholders has been intensified and new lasting working relationships have been created and strengthened.

The action plan is herewith considered closed although acknowledging that certain action points require continuous improvement efforts and are taken forward in this way.

It is expected that the actions taken will increase the efficiency of paediatric regulatory processes under the current legal framework. Moreover, learnings from the action plan will be translated into the revision of the Paediatric Regulation which is expected to further support the availability of medicines for children.

References

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3. Multi-stakeholder workshop to further improve the implementation of the Paediatric Regulation (20/03/2018). Documents available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2018/01/event_detail_001570.jsp&mid=WC0b01ac058004d5c3 [Accessed 25 July, 2022].

Appendix

Comprehensive listing of actions by topic area

Progress since the 2020 interim report is marked "***new***".

1. Identifying paediatric medical needs

	Action	Objectives	Achievements by January 2023
1	Develop overview of selected therapeutic areas to identify paediatric medical needs. Actions include: • Conducting public survey on criteria proposed for determining paediatric medical needs and on perceived areas of needs • Selecting therapeutic areas based on various factors, including experience with PIPs and stakeholder feedback, for further analyses by multi-stakeholder focus groups • Conducting multi-stakeholder workshops in selected therapeutic areas • Publishing reports on the paediatric therapeutic landscape related to selected areas	To raise awareness for paediatric medical needs with a view to providing a basis for strategic decision making on paediatric medicine development.	• Strategies to address needs in children with malignancies were determined at multi-stakeholder forums organised by EMA together with the ACCELERATE platform: – ACCELERATE & EMA Paediatric Strategy Forum for medicinal product development of checkpoint inhibitors for use in combination therapy in paediatric patients (09/2018), related publication in Eur J Cancer (11/2019). – ACCELERATE & EMA Paediatric Strategy Forum for medicinal product development for acute myeloid leukaemia in children and adolescents (04/2019), related publication in Eur J Cancer (09/2020). – ACCELERATE & EMA Paediatric Strategy Forum for epigenetic modifiers in paediatric malignancies (01/2020), related publication in Eur J Cancer (11/2020). – ACCELERATE & EMA Paediatric Strategy Forum on CAR T-cell developments (5/2021), related publication in Eur J Cancer (11/2021). ***new*** – ACCELERATE & EMA 2nd Paediatric Strategy Forum on ALK inhibitors (06/2021), related publication in Eur J Cancer (11/2021). ***new***

Action	Objectives	Achievements by January 2023
		– ACCELERATE & EMA Paediatric Strategy Forum for medicinal product development of multi-targeted kinase inhibitors in bone sarcoma (12/2021), related publication in Eur J Cancer (09/2022). ***new*** – ACCELERATE & EMA Paediatric Strategy Forum for medicinal product development in MAPK pathway inhibitors (March 2022, related publication in Eur J Cancer (10/2022). ***new*** – ACCELERATE & EMA Paediatric Strategy Forum for medicinal product development of DNA Damage Repair Pathway Inhibitors (October 2022). ***new*** • Review of the value of Paediatric Strategy Forums for regulatory decision making was published in Clin Pharmacol Ther (06/2020). – Contribution to a multi-stakeholder workshop on paediatric unmet medical needs (12/2019), which identified the opportunity for disease-focused workshops during 2020/21 in collaboration with the IMI c4c project. – Contribution to a multi-stakeholder workshop on paediatric inflammatory bowel disease in collaboration with the IMI c4c project (04/2021). ***New*** – Contribution to a follow-up multi-stakeholder workshop on paediatric unmet needs (06/2021). ***New*** – Contribution to a multi-stakeholder meeting on priorities for antiretroviral drug optimisation in children (Paediatric Antiretroviral Drug Optimization [PADO] meeting) (09/2021). ***New*** – Contribution to a multi-stakeholder workshop on paediatric atopic dermatitis in collaboration with the IMI c4c project (03/2022). ***new***

	Action	Objectives	Achievements by January 2023
2	Develop framework to ascertain paediatric needs in the context of PIP discussions	To improve the systematic and structured assessment of medical need and the potential benefit of a medicine during PIP procedures	• The PDCO set up a dedicated working group to review the discussions around unmet needs, which resulted in the introduction of a new section in the minutes where the discussion on the potential to fulfil an unmet need is reflected since November 2018. • Based on this experience, an article on how to identify and address unmet needs in paediatric developments was published in Reg Rapp (07/2019).
3	Establish framework for collaboration of EMA/PDCO with the U.S. FDA's Oncology Center of Excellence Pediatric Oncology Program regarding the assessment of relevant molecular targets in paediatric cancers	To maximise synergies and share expertise in the assessment of relevant molecular targets and to address medical needs with a global perspective	• EMA discusses paediatric oncology programmes with the U.S. FDA on a monthly basis via the paediatric cluster. • Both EMA and FDA are represented in ACCELERATE steering committee since 2019 and engage in the organisation of shared paediatric strategy forums addressing needs in children with malignancies. • Article on accelerating the global development of paediatric cancer drugs: a call to coordinate the submissions of Paediatric Investigation Plans and Pediatric Study Plans to the European Medicines Agency and US Food and Drug Administration was published (09/2020). ***new***

2. Strengthening of cooperation of decision makers

	Action	Objectives	Achievements by January 2023
1	Establish framework for exchange of information between the EMA/PDCO and the Clinical Trials Facilitation Group (CTFG)* as well as ethics committees *[*Since the publication of the action pan the CTFG has been renamed as Clinical Trials Coordination Group (CTCG).]*	To improve dialogue between EMA/PDCO and clinical trial assessors and facilitate mutual understanding of the interplay between assessment of PIPs and of clinical trials	• Co-chair of CTFG attended PDCO plenary meetings in December 2018 and June 2019 to discuss how to further strengthen collaboration between the CTFG and the PDCO. Product-related discussions including CTFG/PDCO took place in January 2020 in the context of safety considerations for a specific class of products. A pathway for exchange and closer collaboration related to ongoing PIP discussions on an as needed basis has been established. • Discussion at PDCO's strategic review and learning meeting with co-chair of CTFG about reasons behind negative opinions in voluntary harmonisation procedures (VHP) 2009-2020 of multinational paediatric clinical trial applications (04/2021). ***new*** • Discussion with co-chair of CTFG at PDCO plenary meeting about collaboration aspects between CTFG and PDCO, including continuing the information exchange, e.g. on COVID-19 vaccine procedures (06/2021). ***new*** • Involvement of Enpr-EMA members in the ongoing EU Decentralised Clinical Trials (DCT) project as part of the Accelerating Clinical Trials in the EU (ACT EU) programme (2022). ***new***
2	Enhance integration of EMA/FDA paediatric cluster activities	To ensure knowledge and information exchange between PDCO and the paediatric regulatory cluster	• Establishment of regular reporting at the PDCO plenary meeting to provide timely feedback to members about paediatric cluster activities (11/2018). Paediatric cluster minutes are shared with PDCO members. – Invitation to paediatric cluster meetings has been extended to all PDCO members and, depending on the topic, also to Scientific Advice coordinators as well as CHMP members concerned (11/2018). – FDA/EMA Common Commentary on submitting an initial Pediatric Study Plan (iPSP) and Paediatric Investigation Plan (PIP) for the prevention and treatment of COVID-19 was published simultaneously by U.S. FDA and EMA (06/2020).

	Action	Objectives	Achievements by January 2023
			– FDA/EMA Common Commentary on common issues requested for discussion by the respective agency (EMA/PDCO and FDA) concerning paediatric oncology development plans (Paediatric Investigation Plans [PIPS]) and initial Pediatric Study Plans [iPSPs]) (04/2021). ***new***
3	Increase transparency with regard to EMA/FDA paediatric cluster discussions	To better inform sponsors about paediatric cluster discussions and to increase transparency for all relevant stakeholders regarding outcomes of non-product related interactions	• Outcomes of product related paediatric cluster discussions ("action points") are shared with the sponsor concerned.
4	Increase global interactions between EMA/PDCO and other stakeholders, including other regulators and paediatric clinical research networks such as the European Network of Paediatric Research at EMA (Enpr-EMA)	To promote a global and holistic approach for paediatric medicine development	• An Enpr-EMA WG on international collaboration was set up (12/2018), including representatives from international regulators, paediatric research networks and EMA/PDCO. Work on a white paper on requirements for paediatric clinical trial authorisation in different legislative regions is in progress. • Ongoing collaboration between EMA and Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard to promote global clinical research in children (10/2019). Series of webinars has been launched to present and discuss the deliverables of the project across a broader global audience. ***new*** • Ongoing collaboration between EMA and Health Technology Assessment bodies increasing mutual understanding of the extrapolation concept, including its application for the paediatric population, which is one of the priority areas of the joint work plan (2021-2023) between EMA and European HTA bodies facilitated through EUnetHTA21. ***new***

3. Ensuring timely completion of paediatric investigation plans (PIPs)

	Action	Objectives	Achievements by January 2023
1	Publish recommendations to support the conduct of paediatric clinical trials	To facilitate the conduct of paediatric clinical trials by focusing on identification and resolution of factors impeding the conduct of trials in children	• PDCO adopted a letter addressed to the department on HIV/AIDS of the World Health Organization (WHO) and to the Elizabeth Glaser Paediatric AIDS Foundation, supporting age inclusive research in paediatric HIV whenever scientifically justified (03/2019). • PDCO adopted a letter, addressed to Innovative Therapies for Children with Cancer (ITCC) and Accelerate, supporting age inclusive research in paediatric oncology whenever scientifically justified (04/2019). • Enpr-EMA facilitates connections between paediatric research nurse networks and groups in Europe. As a first step a list of contact details of European paediatric research nurse networks and groups was published (07/2018). • Enpr-EMA published a framework about paediatric clinical trial preparedness (08/2020), related publication in Arch Dis Child (04/2021). ***new*** • EMA co-authored an article in JCO on the critical role of academic clinical trials in paediatric cancer drug approvals, including considerations on fit for purpose data for regulatory decision making (11/2022). ***new*** • Enpr-EMA, together with the IMI c4c project, hosted a multi-stakeholder workshop on quality criteria of paediatric clinical trial sites to catalyse the discussion around this topic, which aims to support paediatric trial site selection by sponsors, and to enhance the development of high-quality paediatric trial sites (10/2022). ***new***
2	Make training material on paediatric medicine development publicly available	To raise awareness and understanding of regulatory and scientific aspects of paediatric medicine development among researchers and academia	• Training material on paediatric medicine development has been made available via the EU Network Training Centre (EU-NTC) to EU medicines agencies (12/1219) and is being prepared for making it accessible for public use.

	Action	Objectives	Achievements by January 2023
3	Develop training resources on clinical research for young people's advisory groups and patients/ parents organisations in collaboration with Enpr-EMA and increase opportunities for dialogue between young patients and EMA/ PDCO	To educate young people's advisory groups and patients/parents on clinical research in order to enable them to best contribute to and represent their interests in the planning of clinical trials	• Building on an Enpr-EMA working group the European Young People Advisory Group network (eYPAGnet) was established and became a member of Enpr-EMA in 2018. eYPAGnet provide a range of services and training resources to young people involved in clinical research. • EMA supported conect4children (c4c) in the development of a video about involvement of young people in EMA's activities related to medicine development (06/2020). • Discussing the need for feedback of patients' organisations has been included as an integral part of every PIP assessment by inclusion of a respective chapter in the PDCO meeting documents. Feedback from paediatric patients and their carers on their needs in the context of specific paediatric developments has since been sought in more than 10 cases. • Contribution to "train the trainers" workshop organised by c4c with the aim to build the capacity of patient organisations, which in turn will train patients/parents to become "expert patients" (09/2020). ***new***
4	Publish reflection paper on extrapolation methodologies in PIPs	To increase awareness regarding extrapolation methodologies among medicine developers and regulators	• Reflection paper on the use of extrapolation in the development of medicines for paediatrics was adopted and published (10/2018). • Structured guidance on the use of extrapolation was published (02/2022). ***new*** • Discussions with Health Technology Assessment (HTA) bodies are ongoing in order to increase mutual understanding of the extrapolation concept, including its application for the paediatric population (see Action 2.4). • ICH guideline E11A on pediatric extrapolation (draft - Step 2b) was released for public consultation (04/2022). ***new***

	Action	Objectives	Achievements by January 2023
5	Revise paediatric aspects of EMA scientific guidelines	To provide more guidance to support sponsors developing medicines for the paediatric population	• Concept paper on the need for revision of the guideline on the investigation of medicinal products in the term and preterm neonate was adopted and published (05/2019). • Paediatric Addendum (draft for consultation) to the guidelines on clinical investigation of medicinal products for the treatment and prophylaxis of venous thromboembolic disease was published (11/2018) and the final version was adopted by the PDCO (11/2022). ***new*** • Reflection paper on regulatory requirements for the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC, NASH) was published (11/2018). • Guideline on good pharmacovigilance practices (GVP), product- or population-specific considerations IV: Paediatric population was published (11/2018). • Guideline on the development of new medicinal products for the treatment of Crohn's Disease including guidance regarding the possibility for extrapolation from adults, or the need to generate separate data in children came into effect (01/2019). • Guideline on the development of new medicinal products for the treatment of Ulcerative Colitis Disease including guidance regarding the possibility for extrapolation from adults, or the need to generate separate data in children came into effect (01/2019). • Paediatric Addendum to the guideline on clinical investigation of medicinal products indicated for treatment of bacterial infections was published (05/2022). ***new*** • Revision of paediatric aspects of guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus is ongoing (2022). ***new***

4. Improving the handling of PIP applications

	Action	Objectives	Achievements by January 2023
1	Explore possibilities for a PIP model that allows, in certain cases, for changes to be made to PIPs as more evidence becomes available over time	To identify possibilities for and limitations of a PIP model that allows to develop along with the evolution of scientific knowledge	• Further to internal EMA/PDCO discussions, options regarding PIP models were exchanged between Industry and PDCO at the Industry stakeholder platform on research and development support (01/2019). • Focus group comprising representatives of pharmaceutical industry, EMA and PDCO was established in April 2021 and drew up a framework for an evolutionary/stepwise PIP (sPIP) concept, which will be piloted in 2023. A similar regulatory strategy has already been applied for supporting childhood cancer therapy developments (11/2022). ***new***
2	Explore opportunities for enhanced dialogue with sponsors in the context of PIP procedures	To foster informed discussions between EMA/PDCO and PIP applicants	• Business pipeline meetings focussing exclusively on paediatric developments have taken place (since 2020). • Focus group on "stepwise PIP" (see Action 4.1 above) drew up a framework for a stepwise PIP concept, including enhanced opportunities for dialogue between EMA/PDCO and PIP applicants (2022). Pilot phase of stepwise PIP concept planned to start in February 2023. ***new***
3	Improve processes for compliance checks	To minimise unnecessary administrative procedures	• Procedural aspects of the compliance check of an agreed paediatric investigation plan were simplified and endorsed by the PDCO, e.g. enabling EMA/PDCO conclusion without the need for PDCO plenary discussions in non-controversial cases (11/2019).
4	Revise PIP summary report template	To improve clarity of summary reports and focus on essential information	• A draft revision of the summary report template has been developed based on experience and is under discussion with the PDCO. Planned publication of revised summary report template in 2023. • A modified SR template was published in an FDA/EMA Common Commentary to facilitate efficient PIP submissions related to prevention and treatment of COVID-19 (06/2020, see Action 2.2).

	Action	Objectives	Achievements by January 2023
5	Review key elements (structure and granularity) of PIP opinions	To focus on essential key elements of the PIP opinion and the appropriate level of detail in order to optimise the need for modifications of an agreed PIP	• Focus group on "stepwise PIP" (see Action 4.1) reviewed key elements and agreed on new form, focussing on essential key elements only, i.e. on study concepts rather than protocol details. Planned publication of revised key elements form in 2023. ***new***
6	Improve procedural guidance related to paediatric medicine development	To enable stakeholders to easily find clear guidance on the Agency's website	• New structure and design of EMA website, including the paediatric medicine pages, was implemented (2018). • Guidance on paediatric submissions and Questions & Answers were updated (03/2020).
7	Simplify administrative submission requirements	To reduce unnecessary administrative burden	• Adoption of 11 submission deadlines for paediatric applications at regular intervals per year to avoid submission restrictions in the months May and June (04/2020). • Submission requirements for all paediatric procedures were revised and simplified. New simplified form for PIP modifications was published (10/2018). • Abolishment of the need to submit a letter of intent prior to submission of paediatric procedures (04/2020). • Product-specific waivers for diseases that do not occur in a paediatric age-group or where there is a lack of efficacy/safety in a paediatric age-group due to the product's mode of action are granted for "all pharmaceutical forms", avoiding administrative future applications to cover any newly developed pharmaceutical forms (01/2021). ***new*** • Streamlining of processes to permit more efficient PIP procedures (e.g. earlier adoption of PIP Opinion in certain cases) (2022). ***New***

	Action	Objectives	Achievements by January 2023
			• Improved handling of annual reports on deferrals, i.e. the process for creating the annual report has been reviewed to ensure a consistent approach for the evaluation of the correspondent parts of the PIP and the subsequent annual reporting to the EC. Specifically, revisions have been made to ensure timely communication either during the PIP procedure or the later stages of the PIP e.g. with respect to completion to avoid recurring loops at a later stage and thereby also reducing the need for revisions of the annual report (2022). ***new***

5. Increasing transparency around paediatric medicines

	Action	Objectives	Achievements by January 2023
1	Update Community Register of medicinal products with paediatric information (e.g. link to PIP information)	To facilitate the identification of medicinal products for which a PIP has been agreed and conducted	Development work to update the Community Register with paediatric information is ongoing. Planned launch in 2023. ***new***
2	Provide information on paediatric trials open for recruitment in a public register, as well as results of such trials in lay language (in accordance with the Clinical Trial Regulation)	To facilitate recruitment into paediatric trials and improve clarity of published trial data	Information on paediatric trials open for recruitment is now accessible via the public register of the European Clinical Trial Information System (CTIS) as provided by the clinical trial sponsors. Trial results in lay language will be made public once they are submitted by the sponsors (in accordance with the Clinical Trial Regulation). ***new***