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SCIENCE MEDICINES HEALTH

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Human Medicines Division

Procedural advice on paediatric applications

Guidance for applicants²

¹ Rev. 13: Revised sections 6.1, 6.2 and 9 with updates relating to key elements and PDCO request for supplementary information and modification of proposed PIP (RSI) – formerly known as RfM.

Rev. 14: In section 6.2 information clarifies that new studies are not needed in a separate KEF form.

In section 9 information clarifies that using key element form is not mandatory if it was already submitted in IRIS.

Rev 15: In section 9 reminder on technicalities for submitting RSI responses in IRIS and update in section 14.1 regarding amending contact for public enquires for published decisions.

² To be consulted together with the [IRIS guide for applicants](#).



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1. Legislative background, requirements

[Regulation \(EC\) No 1901/2006](#) of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use.

[Regulation \(EC\) No 1902/2006](#), an amending regulation in which changes to the original text were introduced relating to decision procedures for the European Commission.

Regulation (EC) No 1901/2006 (the 'Paediatric Regulation') lays down obligations, rewards and incentives for the development and placing on the market of medicines for use in children. The Paediatric Regulation places some obligations for the applicant when developing a new medicinal product, in order to ensure that medicines to treat children are subject to ethical research of high quality and are appropriately authorised for use in children, and to improve collection of information on the use of medicines in the various subsets of the paediatric population. The paediatric population is defined as the population between birth and the age of 18 years (meaning up to but not including 18 years).

As set out in Article 7 of the Paediatric Regulation, applications concerning a medicinal product "not authorised in the Union" on 26 July 2008 must include one of the following documents/data in order to be considered 'valid':

- The results of all studies performed and details of all information collected in compliance with an agreed paediatric investigation plan (PIP).

This means that the application will have to include the PIP decision but also the results in accordance with the agreed PIP.

- A decision of the EMA on a PIP including the granting of a deferral.

This means that the application will have to include the PIP decision including the deferral granted and if applicable, any completed studies

- A decision of the EMA granting a product-specific waiver
- A decision of the EMA granting a class waiver (together with the EMA confirmation letter of applicability if requested by the MAH.)

Where results of paediatric studies are submitted, applicants should include in the clinical overview a rationale supporting the proposed changes to the Product Information. In particular, if the PIP is completed and the results of all studies are available, the applicant should explicitly discuss why the generated data support or do not support the intended paediatric indication(s) stated in the PIP.

Inclusion of the results of all studies performed in compliance with an agreed paediatric investigation plan requirement in the Product Information is a prerequisite for benefiting from the paediatric reward (Article 36(1) of Regulation (EC) No 1901/2006).

The Global Marketing Authorisation (GMA) concept together with the notion of "same marketing authorisation holder" should be used to determine whether an application concerns a "medicinal product for human use which is authorised or not in the Union". Further information can be found in the [Procedural Advice document on "applications for PIPs, Waivers and Modifications](#).

However, the following types of application are exempted from the application of the above requirements:

- Generic medicinal products (Art 10(1) of Directive 2001/83/EC)
- Hybrid medicinal products (Art 10(3) of Directive 2001/83/EC)
- Similar biological medicinal products (Art 10(4) of Directive 2001/83/EC)
- Medicinal products containing active substance(s) of well-established medicinal use (Art 10a of Directive 2001/83/EC)

Furthermore, when planning submission of their marketing authorisation application, the applicant must also take into account the need for a “PIP compliance check” to be done.

2. Objectives

The Paediatric Regulation came into force in the European Union (EU) on 26 January 2007. Its objective is to improve the health of children in Europe by facilitating the development and availability of medicines for children between birth and the age of 18 years.

The Regulation aims to: ensure that medicines for use in children are of high quality, ethically researched and authorised appropriately; and improve the availability of information on the use of medicines for children. It aims to achieve this without subjecting children to unnecessary trials or delaying the authorisation of medicines for use in adults.

The Regulation dramatically changed the regulatory environment for paediatric medicines in Europe. Its main impact was the establishment of the Paediatric Committee (PDCO), which is responsible for coordinating the Agency's work on medicines for children. The Committee's main role is to determine the studies that companies must carry out on children as part of [paediatric investigation plans](#) (PIPs). The PDCO replaced the Agency's previous Paediatric Working Group.

3. Fees payable for paediatric procedures

According to [Regulation \(EU\) 2024/568](#) of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, which repeals Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95, and amends Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council, fees shall apply to paediatric applications in accordance with [Regulation \(EC\) No 1901/2006](#).

Applicants submitting a paediatric procedure do not need to pay as such fees shall be waived in full, however, an administrative charge may apply.

*Please note a **valid Customer Account Number is required** before submitting any paediatric-related applications. For more details, please visit: [How to pay | European Medicines Agency \(EMA\)](#)*

Administrative charge

An administrative charge as laid out in [Fees payable to the European Medicines Agency](#) shall apply for applications in any of the following situations:

Application withdrawal

- If your request/application is withdrawn after 24 hours from its submission and prior to the completion of the administrative validation, an administrative charge will apply.
- For registered micro, small or medium sized enterprises, the administrative charge is waived.

Note: *Withdrawals of valid applications after start of procedure will not be subject to administrative charges.*

Negative validation

- If your application is rejected following the conclusion of the administrative validation, the Agency will issue an invoice for an administrative charge as laid down in section 6.1, Annex IV, of the Fee Regulation.
- For registered micro, small or medium sized enterprises, the administrative charge is waived.

For a more comprehensive understanding please consult the [Regulation \(EU\) 2024/568](#) and [Fee Regulation working arrangements](#). Continuous updates about fees and charges payable to the European Medicines Agency are published on the EMA Website under [Fees payable to the European Medicines Agency](#).

4. General principles

[Regulatory & Scientific Information Management Platform \(IRIS portal\)](#) is a secure online portal for submitting applications for:

- Initial paediatric investigation plan (PIP) including the response to PDCO RSI (if applicable)
- Modification of paediatric investigation plan (modification of an agreed PIP)
- Product-specific waiver
- Compliance check
- Annual report on paediatric deferred measures
- Confirmation requests:
 - Confirmation of applicability of a class waiver, or
 - Confirmation of inclusion of an indication within a condition
- Discontinuation of paediatric development.

The [IRIS portal](#) contains guidance and support to applicants, including registration, substances and research product identifiers (RPIs), and how to create, submit and manage applications.

For pre-submission interactions: [Send a question to the European Medicines Agency](#)

4.1. Glossary related to PIP or waiver applications

See also: [Glossary of regulatory terms](#)

Active substance: The substance responsible for the activity of a medicine.

The public name (preferred term) of the active substance(s) included in the research product identifier (RPI) should be suitable for a PIP as per the [EC guidance](#) (below) but also [SMS guidance](#).

"The active substance should be stated by its recommended International Non-proprietary Name (INN), accompanied by its salt or hydrate form if relevant.

If no INN exists, the European Pharmacopoeia name should be used or if the substance is not in the European Pharmacopoeia, the usual common name should be used.

In the absence of a common name, the exact scientific designation should be given. Substances not having an exact scientific designation should be described by a statement of how and from

what they were prepared, supplemented where appropriate by any relevant details. **A company or laboratory code cannot be used as the sole identifier of the active substance.** Considering the timing for submission of applications, only preliminary names of the active substance might be provided. In this situation and in the event that the application is resubmitted (e.g. for modification of a paediatric investigation plan) it is suggested to record all successive name changes in the document.”

Invented name: The trade name of a medicine. Invented names of medicinal products being assessed by the Agency need to be approved by the Agency’s [\(Invented\) Name Review Group](#).

For authorised products, the PIP application should cover all the existing and the new [indications](#), [pharmaceutical forms](#) and routes of administration (where relevant), in keeping with the [Global Marketing Authorisation concept](#).

Proposed pharmaceutical form(s): Proposed way a medicine is presented, e.g. tablet, capsule, solution for injection, cream, etc.

For authorised products, all existing pharmaceutical forms and new pharmaceutical forms under development for the proposed PIP or waiver should be listed. You should specify whether the pharmaceutical form is under development or is already authorised.

In case of authorised or off-patent products intended for a future paediatric-use marketing authorisation (PUMA) application, only the pharmaceutical forms discussed in the PIP should be mentioned. You should also specify whether each pharmaceutical form is under development or is authorised.

Proposed route of administration: Proposed way in which a medicine is given, e.g. orally (by mouth), intravenously (into a vein), subcutaneously (under the skin), etc.

Authorised product: centrally authorised or authorised in at least one EU Member State.

Product information: Documents providing officially approved information for healthcare professionals and patients about a medicine. The product information includes the summary of product characteristics, package leaflet and labelling.

Details of the medicinal product: The proposed pharmaceutical form should be associated with the corresponding route(s) of administration. If an additional formulation is under development (an adult formulation for example), it should be mentioned. Please use the list of standard terms from the [European Pharmacopoeia](#).

Date of completion of human pharmacokinetic studies in adults/planned submission of application: If an exact date cannot be specified, you should select the last month of the proposed interval and select the last day of that month by default (e.g. 31/07/2024 for the interval from January to July 2024). These dates are not obligatory or binding but are important for the discussion on deferrals.

Deferral: The possibility to defer a measure in a paediatric investigation plan until after studies in adults (or other populations such as adolescents) have been conducted. This ensures that research in children is done only when it is safe and ethical to do so. Deferrals are adopted by the Paediatric Committee (PDCO).

Scientific document: Document to be used for PIP/waiver applications using ‘[Template Scientific document](#)’ which includes specific guidance.

Response to Paediatric Committee request for supplementary information and modification of proposed PIP (RSI) : Document to be used for answering issues identified

before clock-stop, using *Template Answers to RSI* published on page [Paediatric investigation plans: Templates and forms | European Medicines Agency \(EMA\)](#).

Additional information: Document to be used to clarify issues only and **if asked** by the PDCO following any discussion but not before clock-stop; using *Template Additional information* published on page [Paediatric investigation plans: Templates and forms | European Medicines Agency \(EMA\)](#).

Key element form: Document to be used for the detailed plan using *Template Key element form* published on page [Paediatric investigation plans: Templates and forms | European Medicines Agency \(EMA\)](#).

Waiver:

Product-specific waiver (full and partial): An exemption from the obligation to acquire data, through a paediatric investigation plan, in some (partial waiver) or all (full waiver) subsets of the paediatric population for a given condition, route of administration and pharmaceutical form of a specified medicine. Product-specific waivers are adopted by the Paediatric Committee (PDCO). More information can be found under '[Class waivers](#)'.

The appropriate age group or other paediatric subset where the waiver applies must be specified. It is possible to define specific groups that differ from the [International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use \(ICH\)](#) classification, if this is more appropriate.

Class waiver: For products belonging to a class of medicinal products included in the [Agency's list of class waivers](#), see under "Request for confirmation of the applicability of the Agency decision on class waivers"

Related information: [Guideline on the format and content of applications for agreement or modification of a paediatric investigation plan and requests for waivers or deferrals and concerning the operation of the compliance check and on criteria for assessing significant studies](#)

5. Prior to application submission (or re-submission)

5.1. Timelines and planning

[Submission deadlines for paediatric applications 2026-2028](#)

Applicants are advised to consult the above timetable and plan ahead of time so as not to delay their regulatory submission. It is also important to consider that PIP compliance checks must be carried out prior to marketing authorisation/variation/extension of marketing authorisation.

Important note:

In IRIS each submission for a paediatric investigation plan or a product-specific waiver must specify a single condition. For example, if a PIP is required for two different conditions (not indications in the same condition), then two separate submissions are required, one for each condition, and separate Regulatory Entitlements will be generated by IRIS after a positive PIP decision has been granted.

Note: Submission timelines are set according to [Paediatric Committee \(PDCO\) meetings](#).

Well in advance of the targeted submission deadline, applicants must ensure that they have:

- registered and have access to EMA's [IRIS portal](#)

- requested and been granted a research product identifier (RPI) number for their product: [IRIS guide to Registration, Substances and RPIs](#)
- familiarised themselves with the [IRIS guide for applicants \(creating submissions\)](#)
- downloaded the latest versions of the necessary [paediatric templates](#).
- *have a valid Customer Account Number (See in section 3)*

5.2. Interactions prior to submission or re-submission (during clock-stop)

5.2.1. General questions

If the EMA Scientific Officer is not known, general questions should be sent via [Send a question to the European Medicines Agency](#).

Please note that the paediatrics[@]ema.europa.eu inbox is no longer in use.

5.2.2. Pre-submission interactions

The Paediatric Medicines Office offers scientific and regulatory pre-submission PIP guidance where required.

1. **Requests** should be submitted via [Send a question to the European Medicines Agency](#), preferably two months prior to the intended submission date, and **include a summary of the intended questions**.
2. An EMA Scientific Officer will then be in contact with the applicant to request a **more detailed list of questions** to be addressed, together with proposed justifications, if needed.
3. EMA will review the questions and determine the appropriate channel for addressing them, on a case-by-case basis. The applicant will be informed whether the questions will be resolved in writing or with a virtual meeting.
4. In case of a virtual meeting, the timeslot will be confirmed, and the applicant will be requested to provide the following within a specific deadline:
 - Agenda with agreed questions and justifications
 - Invitation to all participants either with a toll-free number or link to virtual meeting (Webex, Teams)
 - Draft scientific document.

Applicants should submit a post-meeting summary within two weeks of the meeting (EMA participants may comment where necessary).

5.2.3. Clarification dialogues before re-submission (during clock-stop)

1. Applicants should request a clarification meeting with a proposed date by **replying to the latest communication** sent by the [IRIS portal](#) (e.g. E-mail "Request for RSI for case xx") **without changing the subject to ensure correct routing**,
AND
2. **Upload the requested documents into "Documents from applicant" in the [IRIS portal](#).**

IMPORTANT note: Do not amend the application's submission form at this stage but use "Documents from Applicant" to upload the requested documents. Despite the instructions stating, "After uploading new documents, or editing the existing ones, please make sure to resubmit the application by using the buttons in the main page", in this instance, **DO NOT PRESS** the "Submit Application" button, to avoid triggering re-submission and restarting of the case/procedure.

Requested documents:

- **Detailed list of questions** to be addressed together with proposed justifications (mandatory document).
 - Draft scientific document, updated with proposals.
3. **It is also possible that issues can be resolved in writing and no virtual meeting will take place.**
4. In case of a virtual meeting, the timeslot will be confirmed and the applicant will be requested to upload the following documents within a specific deadline (please refer to important note under point 2):
- Agenda with agreed questions and justification
 - Applicant's list of participants
 - Invitation to all participants either with a toll-free number or link to virtual meeting (Webex, Teams).

6. Applications and documentation to be supplied

All types of paediatric applications must be submitted using the [IRIS portal](#).

Follow the [IRIS guide for applicants](#), step-by-step, under Paediatric medicines development, and also refer to the following chapters in this guide for information on the content and format of documents for submitting and receiving.

6.1. Initial paediatric investigation plan (PIP)

According to Article 16 of the Paediatric Regulation (Regulation (EC) No 1901/2006), in the case of the applications for marketing authorisation referred to in Articles 7 and 8, or the applications for waiver referred to in Articles 11 and 12, the paediatric investigation plan or the application for waiver shall be submitted with a request for agreement, except in duly justified cases, not later than upon completion of the human pharmaco-kinetic studies in adults specified in Section 5.2.3 of Part I of Annex I to Directive 2001/83/EC, so as to ensure that an opinion on use in the paediatric population of the medicinal product concerned can be given at the time of the assessment of the marketing authorisation or other application concerned.

In general, paediatric investigation plans should be submitted early during product development, in time for studies to be conducted in the paediatric population, where appropriate, before marketing authorisation applications are submitted. It is appropriate to set a deadline for the submission of a PIP in order to ensure early dialogue between the applicant and the Paediatric Committee.

Specifically, the timing of submission should not be later than the end of healthy subject or patient PK, which can coincide with the initial tolerability studies, or the initiation of the adult phase-II studies (proof-of-concept studies); it cannot be after initiation of pivotal trials or confirmatory (phase-III) trials. Applicants are welcome to submit their PIP applications during or even before

initial PK studies in adults. Submitting a PIP application for a new active substance during confirmatory or phase-III trials in adults, or after starting clinical trials in children, is likely to be considered unjustified.

Also refer to section 4.1 above regarding timelines and planning.

- Initial PIP applications containing procedural and scientific information (along with other sections) must be submitted in the [IRIS portal](#)
- **Key elements** are part of the scientific information and no longer have to be detailed in the [IRIS portal](#), however it is essential to enter high level information as per the guidance in [Template Key element form](#). This template must be completed and submitted first with the initial PIP application, then a revised version after clock-stop.

The following documents should be uploaded in IRIS under “Documents from applicant”:

- Scientific document in Word format, using [Template scientific document](#)
- Key elements in Word format, using [Template Key element form](#)
- Pre-submission meeting minutes (if applicable)
- Literature references in a ZIP file
- Supporting information, if applicable (list not exhaustive):
 - Copy of any Advice/Opinion/Decision given by other competent authorities
 - Copy of FDA written request; PPSR or iPSP
 - Risk Management Plan
 - Investigator's Brochure
 - Summary of product characteristics (SmPC).

Upload only stand-alone documents except for “Literature references” which should be together in a ZIP file.

6.2. Modification of an agreed paediatric investigation plan (PIP)

According to Article 22 of the [Paediatric Regulation](#) (Regulation (EC) No 1901/2006), if, following the decision agreeing the paediatric investigation plan, the applicant encounters such difficulties with its implementation as to render the plan unworkable or no longer appropriate, the applicant may propose changes or request a deferral or a waiver, based on detailed grounds, to the Paediatric Committee.

Note: It is not possible change or add a new [active substance](#) via the modification of an agreed PIP procedure (apart from very exceptional cases) - this requires submission of a separate PIP application. Naming of the active substance(s) should be in line with the preceding EMA decision, unless an INN has meanwhile been approved. Changes to, or the addition of, a [route of administration](#) or [pharmaceutical form](#) are permitted.

- PIP modification applications connected to the corresponding Paediatric Regulatory Entitlement must be submitted in the [IRIS portal](#).
- **Key elements** no longer have to be detailed in the [IRIS portal](#), however due to mandatory fields in the system some high level information is needed. Please see details on page 2 in [Template Key element form](#).

- [Template Key element form](#) in Word format is not needed for modifications, all changes including deleting or adding new studies must be included in [Request for modification of an agreed paediatric investigation plan template](#).

The following documents should be uploaded in IRIS under “Documents from applicant”:

- Modification request document in Word format using [Request for modification of an agreed paediatric investigation plan template](#), listing **all** requested changes and adding new studies if applicable.

Do not submit an updated scientific document. All proposed modifications of the agreed PIP and rationale/justification should be listed in the 'Request for modification of an agreed paediatric investigation plan' template.

- Literature references used in the request in a ZIP file
- Supporting documents used in this request
- “EMA Decision with annexes” issued in the preceding procedure that is now being modified.

Note: Procedures not finalised in IRIS: “Decision with annexes” refers to the pdf document containing EMA decision, PDCO Opinion and Summary report

Procedures (cases) finalised in IRIS: “Decision with annexes” refers to 3 stand-alone WORD documents, EMA decision, PDCO Opinion and Summary report and should be submitted together, preferably merged into one file (using Adobe Acrobat or print/scanned document).

Upload only stand-alone documents except for “Literature references” which should be in a ZIP file.

6.3. Waivers

6.3.1. Product-specific waiver

According to Article 13 of the [Paediatric Regulation \(Regulation \(EC\) No 1901/2006\)](#), the applicant may, on the grounds set out in Article 11 (1), apply to the Agency for a product-specific waiver.

- Product-specific waiver applications connected to the corresponding Paediatric Regulatory Entitlement must be submitted in the [IRIS portal](#).

There are no key elements for product-specific waiver applications.

The following documents should be uploaded in IRIS under “Documents from applicant”:

- Scientific document in Word format, using [Template Scientific document](#)
- Literature references in a ZIP file
- Supporting information if applicable, *for example, list not exhaustive:*
 - Copy of any Advice/Opinion/Decision given by other competent authorities
 - Copy of FDA written request; PPSR or iPSP
 - Risk Management Plan
 - Investigator's Brochure
 - Summary of product characteristics (SmPC).

Upload only stand-alone documents except for “Literature references” which should be together in a ZIP file.

The product-specific waiver is applied to products exempt from conducting paediatric studies in a given condition, therefore proposed studies and key elements are not applicable.

It is often referred to as full waiver as it relates to the age range covering all paediatric subsets.

6.3.2. Request for confirmation of the applicability of the Agency decision on class waivers

According to Article 14 of the Paediatric Regulation (Regulation (EC) No 1901/2006), the Agency shall maintain a list of all waivers.

Please refer to: [Class waivers | European Medicines Agency \(europa.eu\)](#)

Confirmation of applicability of a class waiver applications containing scientific information (along with other sections) must be submitted in the [IRIS portal](#):

- **The following information should be added in Scientific Information in Applicant's position text field:**
 - Class (condition) waiver referred to as per [EMA decision CW/001/2015](#)
 - Indication(s) in adults: Please indicate if proposed or authorised
 - Proposed non-confidential name: mandatory if the applicant considers the name of active substance as confidential
 - Mechanism of action: Please provide a brief summary on the mechanism of action
 - Applicability of the published class waiver(s) to the indication(s): Please provide a short justification. This could include references to literature and/or disease classifications if available.
 - Potential use of the product in areas other than the proposed condition: If available, please provide a short summary on any potential or experimental use of your product in other therapeutic areas (paediatric or not) you are aware of or are planning to investigate.
- **The following documents should be uploaded into “Documents from applicant”:**
 - Annexes: Please upload any documents that may be relevant to your request, such as investigator brochure, etc.

Review and outcome

Your request will be reviewed by EMA and maybe referred to the [PDCO](#) where the outcome will be adopted at a plenary, and published in the PDCO minutes.

Then you will be informed of the outcome via IRIS within approximately two months.

In case it is considered that the [class waiver](#) is applicable to your product, the confirmation is to be included in any subsequent relevant application for [marketing authorisation](#), extension or [variation](#), to facilitate the validation.

In case it is considered that the [class waiver](#) is not applicable to your product, you will need to submit a request for a [product-specific waiver](#) or a [paediatric investigation plan](#).

Information on an ongoing request and an outcome communication (if already available) should always be attached to all relevant paediatric submissions.

You will be also informed in case an area of high interest for paediatric development is identified and hence a PIP is recommended.

6.4. Compliance check request

According to Article 23 of the Paediatric Regulation (Regulation (EC) No 1901/2006), the competent authority responsible for granting marketing authorisation shall verify whether an application for marketing authorisation or variation complies with the requirements laid down in Articles 7 and 8 and whether an application submitted pursuant to Article 30 complies with the agreed paediatric investigation plan.

Furthermore, the PDCO may be requested to give its opinion on whether studies conducted by the applicant are in compliance with the agreed [paediatric investigation plan](#).

It is strongly recommended that the request for compliance check is submitted to the Paediatric Medicines Office **well in advance** of the planned marketing authorisation (MA) submission to minimise the risk of potential delays to the MA submission validation. A partial/interim compliance check may be requested.

See also: [Paediatric requirements for marketing-authorisation applications](#)

- Compliance check applications connected to the corresponding Paediatric Regulatory Entitlement must be submitted in the [IRIS portal](#).

The following documents should be uploaded in IRIS under “Documents from applicant”:

- Stand-alone document listing all agreed key elements as per the PDCO opinion annexed to the latest agreed decision, adding justification and citing the location in the study report(s) using [Template Compliance check request](#) in Word format.

- “EMA decision with annexes” issued in the procedure that is being checked for compliance.

Note: Procedures not finalised in IRIS: “Decision with annexes” refers to the pdf document containing EMA decision, PDCO Opinion and Summary report

Procedures (cases) finalised in IRIS: “Decision with annexes” refers to 3 stand-alone WORD documents, EMA decision, PDCO Opinion and Summary report and should be submitted together, preferably merged into one file (using Adobe Acrobat or print/scanned document).

- Study report(s)

Note: Full (complete) study reports should be submitted for the compliance check. If not yet issued, the latest available report or a similar document may be submitted, which must contain sufficient information to allow the check of compliance against the agreed key elements in the decision. In such cases, discussion of the suitability of the available report with the EMA Scientific Officer is recommended prior to submission of the compliance check. Individual patient data listings are not required.

- Supporting information if applicable, *for example, list not exhaustive*:

- Summary of product characteristics (SmPC)

- Evidence of study initiation

Note: When initiation of a clinical study is not deferred, the applicant should submit a signed and dated declaration from the principal investigator certifying that at least one participant has been included in the study/trial (i.e. specifying the date of signature of the informed consent).

- Quality measures (e.g. age-appropriate formulation).

7. Validation of application and start of procedure

Following receipt of the paediatric application, the EMA Scientific Officer will review and validate the submission package.

In case of validation issues the applicant will be contacted via the [IRIS portal](#) with instructions on how to respond.

- Validation responses (if required) shall be submitted in the [IRIS portal](#), linked to the related initial submission, by the indicated deadline. (Do not upload documents that have not been modified.)

PDCO rapporteur and peer reviewer will be nominated before the start of procedure.

In line with the submission date, on the start of procedure date, applicants will receive confirmation via the [IRIS portal](#), which will include the names of the appointed EMA Scientific Officer, PDCO rapporteur and peer reviewer.

The EMA Scientific Officer will prepare a summary report for the assessment.

8. Assessment

The summary report will be made available to the PDCO rapporteur and peer reviewer for their comments and will be shared with the PDCO for discussion and/or conclusion. Additional experts, working groups, working parties and other committees may be consulted during the assessment.

After the first PDCO meeting at which the application is discussed, the applicant may receive the draft summary report either for information, or requesting additional information, via the [IRIS portal](#), with instructions on how to respond (if needed):

- Additional information, if requested, must be submitted in the [IRIS portal](#), linked to the related initial submission, by the indicated deadline using template "Additional information" published on page [Paediatric investigation plans: Templates and forms | European Medicines Agency \(EMA\)](#).

During the second PDCO discussion, either an RSI or PDCO opinion is adopted:

- Adoption of RSI: Summary report containing the RSI is transmitted via the [IRIS portal](#) with instructions on how to respond, approximately 10 days after the last day of the PDCO meeting.
- Adoption of PDCO opinion: Opinion is transmitted together with summary report as 2 stand-alone WORD documents via the [IRIS portal](#) within 10 days of the last day of the PDCO plenary meeting.

9. Response to PDCO request for supplementary information and modification of proposed PIP (RSI) - re-submission following clock-stop

According to Article 17(2) of the Paediatric Regulation (Regulation (EC) No 1901/2006), within the 60-day period referred to in paragraph 1, the Paediatric Committee may request the applicant to propose modifications to the plan, in which case the time-limit referred to in paragraph 1 for the adoption of the final opinion shall be extended for a maximum of 60 days... The time-limit shall be suspended until such time as the supplementary information requested has been provided.

It is expected that the response to a PDCO RSI will be submitted within three months of the PDCO's request. It is acknowledged that in some cases the applicant may need more time to propose modifications to the application.

Response to the RSI must be submitted in the [IRIS portal](#), linked to the related initial submission, and according to submission deadlines.

[Submission deadlines for paediatric applications 2024-2026 \(europa.eu\)](#)

Please do not use old templates, always download the latest version from our website.

The initial PIP application must be amended directly in the [IRIS portal](#) and key elements should be revised using the latest published template [Key elements form](#).

Where key elements have only been submitted in IRIS before, if possible, please submit a Word document including the changes, using the latest published template [Key elements form](#). Alternatively, please indicate the changes to the relevant sections in the response document.

The following documents should be uploaded in IRIS under "Documents from applicant":

- Responses using the published template "Response to RSI" on page [Paediatric investigation plans: Templates and forms | European Medicines Agency \(EMA\)](#), including list of references, in Word format.
- Key elements form including the changes

*Note: An updated scientific document is **not** required and therefore should not be submitted. All responses, including rationale, must be provided in template "Response to RSI".*

- Clarification meeting minutes - if applicable
- Literature references used in the RSI (only if not previously sent) t
- Supporting documents (only if not previously sent).

Upload only stand-alone documents except for "Literature references" which should be together in a ZIP file.

Reminder: Uploading the documents in IRIS alone does not trigger a submission, it will not be received until all steps are completed. Applicants must **complete** the submission process as described in the IRIS guide for applicants, section 13.1.1. Failure to do so will delay the re-start of the procedure.

Following receipt of this submission, the procedure will re-start and a PDCO opinion will be adopted within 60 days.

The applicant will be kept informed via the [IRIS portal](#).

10. PDCO opinion³

10.1. Prior to adoption of opinion

The summary report will be updated with the response to RSI and made available to the PDCO rapporteur and peer reviewer for re-assessment comments, and will be shared with PDCO for discussion and/or conclusion. Additional experts, working groups, working parties and other committees may be consulted during the assessment.

During the third PDCO meeting, RSI responses are discussed, and the applicant may receive the draft summary report either for information, or asking for additional information, via the [IRIS portal](#), with instructions on how to respond (if needed), within approximately 10 days of the last day of the plenary meeting.

The draft opinion with instructions on how to respond may be sent to the applicant for review via the [IRIS portal](#).

- Additional information or comments on the draft opinion (if required) must be submitted in the [IRIS portal](#), linked to the related procedure, by the deadline indicated.

³ In general PDCO Opinions are adopted either during 2nd or 4th PDCO meeting or following re-examination, however they may be adopted earlier or via written procedure if justified as necessary.

10.2. Oral explanation meeting

An applicant or the PDCO may request an oral explanation meeting, if agreed by both, and will take place during the plenary meeting when the adoption of the opinion is scheduled.

- Applicants should notify their intention to request an oral explanation meeting, replying to the latest communication in the [IRIS portal](#) **without changing the subject, to ensure correct routing**, before submitting any documents.

Details on organisational matters and which documents should be submitted, with deadline, will be communicated to the applicant via the [IRIS portal](#).

10.3. Opinion

According to Article 25(1) of the Paediatric Regulation (EC) No 1901/2006, within ten days of its receipt, the Agency shall transmit the opinion of the Paediatric Committee to the applicant.

During the fourth PDCO meeting, a PDCO opinion is adopted, then transmitted together with the summary report as two stand-alone Word documents via the [IRIS portal](#), within 10 days of the last day of the plenary meeting.

The 30-day period entitling an applicant to request re-examination of the opinion starts the day after the applicant receives the opinion.

If, within the 30-day period, the applicant does not request re-examination, the PDCO opinion shall become definitive.

11. Re-examination of PDCO opinion

According to Article 25(2) of the Paediatric Regulation (EC) No 1901/2006, within 30 days following receipt of the PDCO opinion, the applicant may submit to the Agency a written request, citing detailed grounds, for the re-examination of the opinion.

Applicants should notify their intention to request a re-examination by replying to the latest communication in the [IRIS portal](#) (e.g. PDCO Opinion notification) **without changing the subject to ensure correct routing**, before submitting detailed grounds for re-examination of the PDCO Opinion.

Once a notification is received, timelines will be discussed and agreed with the applicant, and the [IRIS portal](#) will be made available for submitting documents.

The following documents should be uploaded in IRIS under "Documents from applicant":

- Detailed grounds for re-examination in a Word document
- Supporting documents if applicable.

See also: [Re-examination procedure of paediatric investigation plan and / or waiver opinions by the PDCO](#).

The final PDCO opinion with summary report becomes definitive upon adoption, and transmitted together with the summary report as two stand-alone Word documents to the applicant via [IRIS](#).

If the applicant would like to contact us related to this subject but without requesting the re-examination procedure, they may reply to the latest communication in the IRIS portal, and then submitting of further information will be enabled.

12. EMA decision

According to Article 25(5) of the Paediatric Regulation (EC) No 1901/2006, the Agency issues its decision within 10 days of the Paediatric Committee's definitive opinion.

The EMA decision is issued within 10 days of the definitive PDCO opinion, and is transmitted to the applicant via [IRIS](#).

EMA decisions on PDCO opinions, including the applicant's contact point for public enquiries, are published on the EMA website in due course:

[Opinions and decisions on paediatric investigation plans](#)

"EMA decision with annexes" is the document required for any regulatory submission e.g. Marketing authorisation application.

Note: Procedures not finalised in IRIS: "Decision with annexes" refers to the pdf document containing EMA decision, PDCO Opinion and Summary report

Procedures (cases) finalised in IRIS: "Decision with annexes" refers to 3 stand-alone WORD documents, EMA decision, PDCO Opinion and Summary report and should be submitted together, preferably merged into one file (using Adobe Acrobat or print/scanned document).

13. Other paediatric procedures

13.1. Request for confirmation of the applicability of the Agency decision on class waivers

See point 5.3.2 in this document.

13.2. Request for confirmation of condition versus indication

Applicants can request confirmation of whether an indication is part of a condition (in an agreed PIP or waiver decision) via IRIS. See point 13.6.1. in the [IRIS guide for applicants](#).

Upon review by the Paediatric Committee, the outcome will be communicated to the applicant.

For more information, see [European Medicines Agency policy on changes in scope of paediatric-investigation-plan decisions](#).

13.3. Discontinuation of paediatric development

Before submitting a discontinuation notification, please note that if the PIP has been submitted as part of a marketing authorisation application in order to comply with the requirements of Article 7 of the Paediatric Regulation (as a condition of the validation of the respective application), and a marketing authorisation was granted based on this application, then there is a legal obligation to complete that PIP. The same applies if there has been a successful post-authorisation application, where the PIP was included in order to comply with the requirements of Article 8 of the Paediatric Regulation.

The following documents should be uploaded into "Documents from applicant" in addition to the IRIS application for Discontinuation of paediatric development:

- Notification form using template [Notification of discontinuation of an agreed PIP](#)

If the discontinuation of the paediatric development is agreed, the form will be published on the Agency's website. For this reason, please ensure that the submitted form does not contain any commercially confidential information and that the contact details for public enquiries are accurate.

If an agreed PIP is intended to be suspended or put on long-term hold, please contact the respective EMA Scientific Officer directly or via [Send a question to the European Medicines Agency](#). A notification form is not needed in this case.

13.4. Annual reports on deferrals

According to Article 34(4) of the Paediatric Regulation (Regulation (EC) No 1901/2006), in the case of a deferral, the marketing authorisation holder shall submit an annual report to the Agency providing an update on progress with paediatric studies in accordance with the decision of the Agency agreeing the paediatric investigation plan and granting a deferral.

Annual reports must be submitted via [IRIS](#), creating a new submission "Annual report on paediatric deferred measures".

See also: [Annual report on deferrals | European Medicines Agency \(europa.eu\)](#)

13.5. Placing paediatric medicines on the market

According to Article 33 of the Paediatric Regulation (Regulation (EC) No 1901/2006), where medicinal products are authorised for a paediatric indication following completion of an agreed paediatric investigation plan and those products have already been marketed with other indications, the marketing authorisation holder shall, within two years of the date on which the paediatric indication is authorised, place the product on the market taking into account the paediatric indication. A register, coordinated by the Agency, and made publicly available, shall mention these deadlines.

Updating EMA about placing a product on the market in the relevant Member State(s) after completion of an agreed PIP can be done via [IRIS](#), creating a new submission "Annual report on paediatric deferred measures", adding the information in Submission notes field.

See also: [Deadlines for placing paediatric medicines on the market](#)

14. Changing contacts or transferring a PIP

Any changes to an applicant's particulars for paediatric procedures should be notified to the Agency without delay via IRIS including changes related to an applicant's contact point for public enquiries from interested parties.

Although the **Error! Hyperlink reference not valid.** does not establish a specific procedure for the transfer of rights and obligations between legal entities in relation to a **Error! Hyperlink reference not valid.** (PIP) or waiver, it is necessary for technical and administrative purposes.

The Agency is aware that the applicant or addressee may change based on a contractual agreement, it is therefore acknowledged that the applicant for a **Error! Hyperlink reference not valid.** may be different from the PIP/waiver addressee, therefore amendment of the EMA decision is not necessary in this respect.

14.1. Changing contacts

- To change the submission contact for ongoing procedures in IRIS, please see sections 2.4 and 2.5 in the [IRIS guide for applicants](#).

- To change the contact person and/or the contact for public enquiries of a PIP/waiver for which a decision has been issued, please update the regulatory entitlement, please see sections 13.6.6 in the [IRIS guide for applicants](#).
- If the PIP/waiver decision has already been published on the EMA website, two actions are required:
 - update the contact for public enquiries in the relevant regulatory entitlement record in IRIS, and
 - raise an EMA Service Desk ticket to update the contact details on the published web page.

14.2. Transferring a PIP to another company

While the Paediatric Regulation does not establish a specific procedure for transfer of rights and obligations between legal entities in relation to a paediatric investigation plan (PIP) or waiver, this step can be necessary in IRIS for technical and administrative purposes, before submitting procedures based on the PIP or Waiver granted (the "Regulatory Entitlement" or RE).

For example, to submit a request for Modification of an Agreed PIP, a Compliance check or an Annual Report on Deferred Measures, the applicant must be the holder of the relevant PIP Regulatory Entitlement, and a transfer may thus be necessary beforehand, if the applicant is not the same organisation as the holder of the PIP RE.

In addition, the holder of the PIP or waiver RE can update the data on the RE contact person, or the email and phone for public enquiries, directly in the [IRIS portal](#).

Please refer to [IRIS guide for applicants](#) (13.6.3.) for details on how to transfer the agreed PIP to another company.