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Guidance

International Recognition Procedure

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Contents

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Overview

From 1 January 2024, the EC Decision Reliance Procedure (ECDRP) will be replaced by the new International Recognition procedure (IRP). The Mutual Recognition/Decentralised Reliance Procedure (MRDCRP) will be incorporated under the umbrella of IRP.

ECDRP and MRDCRP submissions received before 1 January 2024 will be processed under the existing practices. For ECDRP applications, the Committee for Medicinal Products for Human Use (CHMP) positive opinion (but not necessarily the European Commission Decision) should be received before 31 December 2023.

IRP will be open to applicants that have already received an authorisation for the same product from one of MHRA's specified Reference Regulators (RRs). A CHMP positive opinion or an MRDC positive end of procedure outcome is an RR authorisation for the purposes of IRP.

The same product is defined as having the same qualitative and quantitative composition (active substance(s) and excipients), and the same pharmaceutical form, from Applicants belonging to the same company or group of companies or which are 'licensees'.

IRP will allow the MHRA to take into account the expertise and decision-making of trusted regulatory partners for the benefit of UK patients. The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust.

IRP can be used for the following types of marketing authorisation applications (MAAs) according to the Human Medicines Regulations 2012 (HMRs):

- Regulation 50: chemical and biological new active substances and known active substances.
- Regulation 51, 51A and 51B: generic applications
- Regulation 52, 52A and 52B: hybrid applications
- Regulation 53, 53A and 53B: biosimilar applications
- Regulation 55: new fixed combination product applications

Traditional Herbal Registrations, Homoeopathic Registrations (Simplified Registration Scheme) and Homeopathic National Rules Authorisations (National Rules Scheme) are excluded from IRP. Bibliographic applications (Regulation 54 of the Human Medicines Regulations) are also not eligible.

IRP can also be used for post-authorisation procedures including line extensions, variations and renewals (see Product lifecycle).

The RR assessment must have undergone a full and standalone review. RR assessments based on reliance or recognition cannot be used to support an IRP application.

Conditional and exceptional circumstances MAAs (or international equivalent such as provisional or accelerated approval) can support an IRP application. Emergency approvals are not eligible.

Until the Windsor Framework is implemented in Northern Ireland on 1 January 2025, products falling within the scope of the EU Centralised Procedure can only be authorised in Great Britain.

Reference Regulators (RRs)

Acceptable RRs are shown in the table below.

Country or Jurisdiction	Regulatory Authority
Australia	Therapeutic Goods Administration (TGA)
Canada	Health Canada
Switzerland	SwissMedic
Singapore	Health Science Authority Singapore (HSA)
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)
United States	Food and Drug Administration (FDA)
European Union	European Medicines Agency (EMA) and Member State Competent Authorities (This includes approvals through the centralised, MRP/DCP and individual member state national routes)

Access Consortium approvals that did not include MHRA as part of the work-sharing procedure can be used for IRP. The Applicant may choose **one** of the trusted regulators within the Access Consortium as the RR and submit the relevant documents as approved by that specific regulator (see How to apply).

Recognition A and B

There are two recognition timetables for **initial MAAs**:

- Recognition A: 60-day timetable
- Recognition B: 110-day timetable

The timetables are calendar days and start once the IRP submission has been validated by MHRA.

Suitability for Recognition A or B is determined by means of an eligibility form to be completed by the Applicant 6 weeks before the planned date of MAA submission (see under section ‘How to apply’).

Applications that are determined not eligible for Recognition A or B can be submitted as full national applications if MHRA requirements are met.

Key features of Recognition A:

To be eligible for Recognition A, the RR approval must have been granted within the previous 2 years. A CHMP positive opinion or an MRDC positive end of procedure outcome is an RR approval for the purposes of IRP.

The manufacturing process must be the same as that approved by the RR, with evidence of compliance with Good Manufacturing Practice (GMP) at the time of IRP submission.

The Recognition A route will be open to applications that meet the criteria for IRP and do not meet **any** of the Recognition B criteria (see below).

Recognition A procedures will run to a 60-day timetable from validation, with no clock stop. However, if Major Objections are identified which cannot be resolved within 60 days, the timetable may revert to Recognition B.

Key features of Recognition B:

To be eligible for Recognition B, the RR approval should have been granted within the previous 10 years. A CHMP positive opinion or an MRDC positive end of procedure outcome is an RR approval for the purposes of IRP.

IRP applications will follow Recognition B if **any one** of the following criteria applies:

- RR has granted a conditional or exceptional circumstances MA (or international equivalent).
- A conditional or exceptional circumstances MA is sought in UK/GB.
- Additional manufacturing sites are cited that have not been assessed by the RR (except for secondary packaging, labelling and QP release sites).
- There are substantial changes in the manufacturing process or analytical methods compared to what was assessed by the RR.
- At least one manufacturing site is not yet GMP certified.
- The Environmental Risk Assessment (ERA) has not been assessed by the RR.
- The Risk Management Plan (RMP) has not been assessed by the RR.
- There are UK-specific risk management activities (e.g., which may be reflected as additional pharmacovigilance or additional risk minimisation activities).
- The RR has mandated one or more post-authorisation safety studies (PASS).
- The product contains a first-in-class new active substance.
- The product incorporates novel or cutting-edge technologies.

- Clinical efficacy or safety data are available for a later cutoff than those assessed by the RR.
- The pivotal clinical data are from single arm studies.
- The pivotal clinical data include real world data.
- Advanced therapy medicinal product (ATMP) as classified by the HMRs 2012.
- Fractionated plasma product.
- Application for orphan drug designation.
- Comparator product used in bioequivalence or therapeutic equivalence study was sourced outside the UK/EU/EEA (generic/hybrid applications).
- Product is not subject to medical prescription.
- Co-packaged medical device components are not CE or UKCA marked.
- Where an IVD is required for correct use, the IVD is not CE or UKCA marked.
- An approved body or notified body report is not available for integral medical device components.
- The RR assessment cites guideline(s) that are not adopted by the MHRA.
- Proposed container closure system, shelf-life or storage conditions differ compared to those accepted by the RR and/or additional stability studies have been provided to MHRA.

Recognition B procedures will run to a 110-day timetable from validation to allow for consultation with the Commission on Human Medicines (CHM). Submission dates for Recognition B to align with CHM dates for New Active Substances (NAS) will be published in due course.

Recognition B includes one clock stop at day 70, allowing the Applicant up to 60 days to respond to any issues identified. If there are outstanding Major Objections at Day 110, formal advice on approvability will be sought from CHM, and the timetable will revert to the national 210-day timetable.

Product lifecycle

IRP can be used for line extensions, variations (Type 1B, Type II) and renewal applications (including annual renewal of conditional MAs and annual reassessment of exceptional circumstance MAs).

IRP can be used during the lifecycle of products that have been initially authorised or subsequently varied via standalone national, MRDCRP or ECDRP routes. Conversely, where a product has been authorised via IRP, it is acceptable to submit standalone national post-authorisation procedures including variations.

Generally, it is recommended that the same RR is used for IRP applications throughout an individual product lifecycle. Marketing Authorisation Holders (MAHs) may use more than one RR during an individual product lifecycle, if this can be justified, for example, on patient benefit grounds. Changes of RR during the product lifecycle should be highlighted in the post-authorisation procedure cover letter.

The relevant published MHRA timetables for national post-authorisation procedures will apply to IRP. The classification of Recognition routes A and B is only applicable for initial MAAs; thus, the eligibility form is not relevant for post-authorisation procedures.

Variations submitted via IRP should be classified according to MHRA Guidance (https://www.gov.uk/guidance/variations-to-marketing-authorisations-mas) on Variations to MAs.

The MHRA retains the authority to reject a variation application if the evidence provided is considered insufficiently robust. Variations which impact on patient safety will be assessed in the context of the UK clinical situation and the MHRA may require assessment through a national route where there are specific UK considerations.

Applicants are reminded of the obligation to notify MHRA as soon as reasonably practicable, of any information that might influence the evaluation of the benefits and risks of an authorised product. IRP is not a substitute for MAH's obligations to submit pharmacovigilance data and information to the MHRA and to keep the MA up to date with current scientific knowledge. Where there is new information, that might impact evaluation of the benefits and risks of a product, likely to impact clinical management of patients, and/or require proactive communications, there should be no delay in submitting this information to the MHRA. UK requirements (https://www.gov.uk/government/publications/guidance-on-pharmacovigilance-procedures) for the submission of pharmacovigilance data will apply to the MA including the submission of Periodic Safety Update Reports (PSURs). It may be possible to align the PSUR submission cycle with that of the RR.

How to apply

The Applicant

The Applicant/MAH must be established in the UK (Great Britain or Northern Ireland) or in the EU/EEA. It is anticipated that the Applicant for an IRP application is the same company or belongs to the same (legal) group of companies as the MAH of the RR procedure. This is to ensure that the Applicant/MAH can fulfil the submission requirements as well as all their legal obligations as holder of an MA, such as the obligations stated in Regulations 74 and 75 of the Human Medicines Regulations 2012 (HMRs).

Provided an Applicant can demonstrate and provide written assurance that all the legal obligations can be met at submission, during the assessment process and throughout the life of the MA, it may be possible to accept applications from third parties.

Eligibility form (initial MAAs only)

Suitability for Recognition A or B is determined by means of an online eligibility form to be completed by the Applicant 6 weeks before the planned date of MAA submission. A link to the online form will be provided in due course. The eligibility form should be emailed to Recognition@mhra.gov.uk at least 6 weeks before the intended date of IRP submission where applicable (see table below).

A product licence (PL) number is required before completion of the eligibility form. If you do not have a 5-digit company number, to allow registration on the MHRA Submissions Portal, this should be requested from Reference.Data@mhra.gov.uk. A PL number can then be obtained through MHRA Submissions or by emailing PLNumberAllocation@mhra.gov.uk.

The following table indicates when and how to submit the eligibility form:

The completed form indicates you are suitable for Recognition A or B	Submit the form along with your MAA application.
The completed form indicates that it requires triage by the MHRA	Submit the form directly to Recognition@mhra.gov.uk at least 6 weeks before the intended date of MAA submission. On receipt of the eligibility form by email, the MHRA will conduct a triage and inform you of the outcome or request further information.
Your product is a New Active Substance and the completed form indicates it is Recognition A or B	You are required to notify the MHRA of your intention to submit a NAS. To do this, submit the form directly to Recognition@mhra.gov.uk at least 6 weeks before the intended date of MAA submission. You should not expect to be contacted by the MHRA prior to submission. Submit the form along with your MAA application.
Your product is a New Active Substance, and the completed form indicates that it requires triage by the MHRA	Submit the form directly to Recognition@mhra.gov.uk at least 6 weeks before the intended date MAA submission. On receipt of the eligibility form by email, the MHRA will conduct a triage and inform you of the outcome or request further information.

The form should be included in module 1.2 of the eCTD and the cover letter should indicate which recognition route (A or B) and RR you are using.

If you are notified that your application is not suitable for IRP, you can submit an MAA via the national route if MHRA requirements are met. For a national route application, you should request a pre-submission meeting 3 months prior to planned submission if your product contains a new active substance.

IR Submission

You should submit your application through the Human Medicines Portal. No other submission route is acceptable for IRP. You will be asked when submitting to indicate if your application is Recognition Route A or Route B or if you are submitting a Recognition variation. As per the current functionality, you will need to indicate if your submission is one of the following:

- Original submission
- Validation Correction Request (VCR)
- Response

An IRP application should be submitted to the MHRA as one electronic Common Technical Document (eCTD) sequence through the MHRA Submissions portal. The eCTD should be in EU format with a UK-specific module 1. You must include certain information in the cover letter (see below). Further guidance on the eCTD module 1 requirements for IRP will be provided in due course.

The eCTD submission should be aligned with the consolidated dossier as reviewed by the RR, including the full responses of the Applicant to RR questions. Approved post-authorisation changes including variations should be included with the MHRA MAA submission once approved by the RR. For initial MAAs, the IRP submission should include:

- documentation of the RR’s approval decision.
- all iterations of the RR’s unredacted assessment reports for the initial authorisation and any major post-authorisation procedures (e.g., significant variations, renewals).
- the final product information (or international equivalent) approved by the RR.

For post-authorisation IRP applications (including variations), the submission should include:

- documentation of the RR’s approval decision.
- all iterations of the RR’s unredacted assessment reports for the relevant post-authorisation procedure.
- the final product information (or international equivalent) approved by the RR if applicable.

Where EMA is the RR, a CHMP positive opinion letter is sufficient documentation of approval. Applicants should not submit their IRP applications until they have received the CHMP positive opinion and agreed final Product Information. For MR-DC recognition, a positive End of Procedure (EoP) letter is sufficient documentation of approval.

All RR documents submitted in support of an IRP application to MHRA must be in English. A certified translation (verified translation may be acceptable) should be provided for any original documents that are not in English. If a translation is submitted, the Applicant must confirm in writing that it is correct.

It is your responsibility to provide the requested documentation. It is not the responsibility of the RR to provide any documentation to the MHRA.

Further information on the location of the RR documents within module 1 of the eCTD will be provided in due course.

A pre-submission meeting (PSM) is not required for IRP applications. However, you may request a pre-submission meeting to discuss the IRP dossier and requirements, and procedural or regulatory issues. For scientific or technical questions, a scientific advice meeting should be requested.

Cover letter

For IRP applications to be validated, you must include certain information in the cover letter. The required information is listed below:

- State that the route is International Recognition, who the RR is, and whether it is Recognition A or Recognition B (as determined by the eligibility form which should be included in Module 1.2 with the Electronic Application form (eAF)).
- If you are submitting a recognition variation, state that the route is International Recognition and who the RR is.
- Provide a declaration that all iterations of the RR assessment reports have been submitted (see Reference regulator documents). Assessment reports should be listed.
- For initial MAAs, state the type of RR approval, such as full approval or conditional/provisional/accelerated approval (or international equivalent).
- State any conditions associated with the RR approval, including where the RR has approved a conditional or exceptional use MA (or international equivalent). Details of RR decisions on the fulfilment of any conditions should also be provided.
- State any proposed conditions for UK/GB approval.
- For initial MAAs and extension of indication applications, state if there are differences in the wording of the proposed therapeutic indications for UK/GB and the therapeutic indications approved by the RR. A justification for these changes should be provided.
- Provide a justification for the adverse drug reactions (preferred terms and frequencies) listed in section 4.8 of the SmPC, or indicate where in the eCTD module 2 this information is provided.
- If the procedure includes an active substance master file (ASMF), include a declaration that the ASMF Holder has submitted the Applicant’s and Restricted Parts of the ASMF, including approved variations and all iterations of the assessment reports on the Applicant’s and Restricted Parts.

- State whether or not there are any differences in the proposed UK RMP compared to the RMP that was approved by the RR (where relevant) and describe any differences.
- Provide a summary of the global regulatory history of the medicinal product.
- State whether an application for the same product has been approved, withdrawn, refused, or rejected by another RR. Provide reasons for any withdrawal, refusal or rejection.
- State whether a marketing authorisation for the same product has been withdrawn, revoked, suspended or not renewed by another RR. Provide reasons for any withdrawal, revocation, suspension or non-renewal.

As indicated previously, guidance on eCTD requirements will follow in due course.

National requirements

The medicinal product must be classified as a medicinal product under the UK Human Medicines Regulations and the standard MHRA requirements for a UK marketing authorisation will apply. Further relevant information about national requirements is provided in the following subsections.

Orphan drug designation

IRPs that include GB orphan drug designation applications will not be eligible for Route A. See further information on orphan drug designation application (https://www.gov.uk/guidance/orphan-medicinal-products-in-great-britain).

Paediatric requirements

For submissions that will trigger paediatric requirements, applicants should ensure the latest UK Paediatric Investigation Plan (PIP) / waiver opinion / decision or class waiver decision, and the compliance check outcome documents, are included in the IRP application dossier.

If paediatric requirements are triggered in any other jurisdiction, the latest PIP/Paediatric Study Plan (PSP)/waiver opinion/decision or class waiver decision should be submitted to the MHRA Paediatrics Team as part of the UK-PIP submission.

Further information can be found here (https://www.gov.uk/guidance/procedures-for-uk-paediatric-investigation-plan-pips).

Risk Management Plan (RMP)

The RMP must meet MHRA requirements and follow the EU RMP template. Where appropriate, the format of GB/UK-specific RMP annex + approved EU RMP is also acceptable. Please see the following guidance for further information on the required format of the RMP:

Guidance on pharmacovigilance procedures (https://www.gov.uk/government/publications/guidance-on-pharmacovigilance-procedures/guidance-on-pharmacovigilance-procedures#risk-management-plans-rmps)

If the RR has not assessed the RMP, the product will be eligible for Recognition B only.

In the case that the RR has assessed an RMP, but the RMP proposed for UK/GB is not the same or not in the same format as the RMP approved by the RR, the product will be eligible for Recognition B only.

Advanced therapy medicinal products (ATMPs)

ATMPs are eligible for Recognition B only. See a definition of ATMPs (https://www.gov.uk/guidance/advanced-therapy-medicinal-products-regulation-and-licensing)

Environmental risk assessment (ERA)

The ERA needs to have been assessed by the reference regulator for the product to be eligible for Recognition A. If the ERA has not yet been assessed by an RR, the product will be eligible for Recognition B only.

Good manufacturing practice (GMP)

The Applicant will need to confirm that all manufacturing sites have a current GMP certificate that meets MHRA requirements.

If a new site is added specifically for the MHRA, the application is eligible for Recognition B only.

If the site in question has no relevant inspection history, the timelines for the Recognition process may be extended until an inspection has been successfully completed.

Where available, inspection information from Mutual Recognition Agreement (MRA) partners and Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) participating authorities should be submitted to support verification of the GMP status of manufacturing sites based in third countries. This information will be utilised in accordance with the principles of Inspection Reliance: https://picscheme.org/docview/2475 (https://picscheme.org/docview/2475)

Nitrosamine risk assessment

Before the Recognition procedure for a new product can be approved, the Applicant must provide a nitrosamine risk assessment in line with MHRA guidance. Please see the following link for more information: Medicines: Marketing

Authorisation Holders' submission of Nitrosamine risk evaluation, risk assessment and confirmatory testing - GOV.UK (www.gov.uk) (https://www.gov.uk/guidance/medicines-marketing-authorisation-holders-submission-of-nitrosamine-risk-evaluation#overview)

Generic and biosimilar applications

The proposed indications and posology must be in line with the UK Reference Product.

Applicants should ensure that there is no infringement of data and market exclusivity (DME).

In the case of generic or hybrid medicines, if the comparator product used in the bioequivalence or therapeutic equivalence study was not sourced from the UK/EU/EEA market, reference should be made to the MHRA guidance on comparator products in bioequivalence and therapeutic equivalence studies:

https://www.gov.uk/guidance/comparator-products-in-bioequivalencetherapeutic-equivalence-studies (https://www.gov.uk/guidance/comparator-products-in-bioequivalencetherapeutic-equivalence-studies)

Until the Windsor Framework is implemented on 1 January 2025, if the comparator product is not sourced from the UK/EU/EEA market, the generic or hybrid medicine can only be authorised in Great Britain.

See MHRA's guidance for biosimilars (http://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products/guidance-on-the-licensing-of-biosimilar-products).

Plasma Products

Fractionated plasma products are eligible for Recognition B only.

Plasma products must meet all relevant European requirements in particular with regard to viral safety and donor eligibility and they must comply with relevant European Pharmacopoeia (Ph Eur) monographs.

Compendial requirements

References to compendia in Module 3 will need to be to either the British Pharmacopoeia (BP) or Ph Eur, unless otherwise justified.

Active Substance Master Files (ASMFs)

If Module 3 does not include full information on the active substance, then an ASMF should be submitted. See RR assessment documents section below.

Fees

Fees for submission for international recognition applications will be included on MHRA fees - GOV.UK (www.gov.uk) (https://www.gov.uk/government/publications/mhra-fees) in due course.

Reference regulator documents

The lists below show the documents that comprise a complete assessment for each RR.

The full set of documents must be submitted in your application.

Reference regulator: European Medicines Agency (EMA)

Documentation

- Centralised procedure assessment reports (where applicable):
- Day 80 (Co)-Rapporteur Quality, Non-Clinical, Clinical, and Overview Assessment Reports
- Day 94 PRAC Assessment Report
- Day 120 CHMP List of Questions
- Day 150 Joint Quality, Non-Clinical, Clinical, and Overview Assessment Reports, updated PRAC Assessment Report
- Day 180 CHMP List of Outstanding Issues
- Final CHMP Assessment Report
- Final product information
- Summaries of meetings with the EMA and/or Rapporteurs (including scientific or pre-submission advice, where relevant)
- Any other questions from the regulator to the Applicant/MAH (and responses)
- CHMP Summary of Opinion
- Post marketing review(s)

Reference regulator: EU Member States MR/DC requirements

Documentation

- All assessment reports including quality, non-clinical, clinical and risk management plan
- Questions from the regulator to the Applicant/ MAH (and responses)

- Summaries of meetings with Reference member state (RMS) and concerned member states (CMS) including scientific or pre-submission advice, where relevant
- RMS positive End of Procedure letter
- Final assessment report
- Final common product information
- Post marketing reviews

Reference regulator: EU Member states National requirements

Documentation

- All assessment reports including quality, non-clinical, clinical and risk management plan
- Questions from the regulator to the Applicant/MAH (and responses)
- Summaries of meetings with the Member State competent authorities (including scientific or pre-submission advice, where relevant)
- Final product information
- Approval letter
- Post marketing reviews

Reference regulator: Pharmaceutical and Medical Devices Agency (PMDA), Japan

Documentation

- Discussion documents, questions from PMDA and answers provided, and Finalised Minutes from Scientific Consultation Meetings (if applicable)
- Outcome of Orphan designation, priority or SAKIGAKE determination (if relevant)
- Copies of questions and answers exchanged between Sponsor and PMDA
- Un-redacted English Translated Review Report consisting of:
- Review Report 1
- Review Report 2
- Review Result
- Report on the Deliberation Results
- Final product information
- Approval Letter
- Post-marketing review(s)

Reference regulator: Health Canada

Documentation

- Screening: Screening Report
- Clinical Review: Pharmaceutical Safety and Efficacy Assessment Report (PSEAR)
- Quality: Quality Evaluation Summary (QES) and Manager's Memo
- Non-clinical report
- Bioequivalence: Comprehensive Summary – Bioequivalence (CS-BE) and Manager's Memo
- Biostatistics: Biostatistics Consult Report (if applicable)
- Questions from the regulator to the Applicant/MAH (and responses)
- Summaries of meetings with Health Canada (including scientific or pre-submission advice, where relevant)
- Final product information
- Approval letter
- Final Manager's Memo, and Executive Summary

Reference regulator: Health Sciences Authority (HSA), Singapore

Documentation

- Questions from the regulator to the Applicant/MAH (and answers)
- HSA assessment of responses to questions
- Final Quality, Non-clinical and Clinical reports and summaries, where applicable
- (Risk management plan assessment where applicable)
- Summaries of meetings with HSA (including scientific or pre-submission advice, where relevant)
- Approval letter
- Final product information
- Post marketing reviews

Reference regulator: Therapeutic Goods Administration (TGA), Australia

Documentation

- All assessment reports including quality, non-clinical, clinical and risk management plan.

- Questions from the regulator to the Applicant/MAH (and responses)
- Summaries of other meetings with the TGA (including scientific or pre-submission advice, where relevant)
- Approval letter
- Final product information
- Post marketing review(s)

Reference regulator: SwissMedic, Switzerland

Documentation

- All assessment reports including quality, non-clinical, clinical and risk management plan.
- Questions from the regulator to the Applicant/MAH (and answers)
- Summaries of meetings with SwissMedic (including scientific and pre-submission advice, where relevant)
- Approval letter
- Final product information
- Post marketing reviews

Reference regulator: United States Food and Drug Administration (US FDA)

Documentation

- Medical review(s)
- Chemistry review(s)
- Pharmacology review(s)
- Statistical review(s)
- Non-clinical review(s)
- Clinical pharmacology biopharmaceutics review(s)
- Risk assessment and risk mitigation review(s)
- Administrative document(s) and correspondence
- Cross discipline team leader review
- Office Director memo, where relevant
- Summaries of meetings with the US FDA (including scientific or pre-submission advice, where relevant)
- Summary review
- Final FDA label
- Approval letter
- Post marketing reviews

Active Substance Master File (ASMF)

If an ASMF has been submitted to the reference authority for the application in question, the ASMF holder must submit an identical copy of the complete ASMF (Applicant's and Restricted Parts) to MHRA. Modules 2.3 and 3 must be submitted in consolidated form together with relevant sections of Module 1 according to MHRA requirements that includes the Letter of Access, the Assessment Report from the Restricted Part, the List of Questions and the response of the ASMF holder to the Restricted Part. If the ASMF has been subsequently modified (i.e. after first authorisation abroad and before submission to MHRA), the approved variations, with the corresponding assessment reports, must be submitted separately in parallel and noted in the cover letter together with a comparison showing the changes (old / new).

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