Commission on Human Medicines

GUIDANCE NOTE FOR APPLICANTS[1] ON WRITTEN AND ORAL REPRESENTATIONS UNDER SCHEDULE 11 TO THE HUMAN MEDICINES REGULATIONS 2012 (AS AMENDED) and SCHEDULE 5 TO THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004

THE MARKET AUTHORISATION PROCESS

Any queries that are not answered by this guidance should be directed to the Committee Services Team Secretariat (Secretariat)
Email: CHMrepresentations@mhra.gov.uk

1. How to use this guidance

1.1. This guidance is intended to help any Applicant who wishes to represent their case for market authorisation before the Commission on Human Medicines (the CHM). Representations are provided for in Schedule 11 to The Human Medicines Regulations 2012 (as amended) (the Regulations) and Schedule 5 to The Medicines for Human Use (Clinical Trials) Regulations 2004 (Clinical Trials Regulations).

1.2. This guidance addresses the legal foundation and pathways for representation and explains the CHM process which leads to a provisional opinion, and then final advice, for the Licensing Authority[2] (LA) to consider. It is important to remember that the CHM is an advisory body, and not a decision-making body. The LA will make the final decision about an application, taking into consideration the CHM's advice.

1.3. This guidance also highlights specific points for the Applicant to consider which should help them navigate this process. As mentioned above, please do not hesitate to contact the Secretariat should any queries arise after reading this document.

1.4. This document covers -

- 1.4.1. Part 1 of Schedule 11 to the Regulations
- 1.4.2. Part 1A of Schedule 11 to the Regulations – Paediatric Decisions (Paediatric Investigation Plans, or PIPs)
- 1.4.3. A note on Type 1B Variation applications under Schedule 11 to the Regulations
- 1.4.4. Part 2 of Schedule 11 to the Regulations - Type II Variation applications, complex variation applications and new excipient variation applications
- 1.4.5. Schedule 5 to the Clinical Trials Regulations – Clinical trials
- 1.4.6. CHM Procedure - Written Representations
- 1.4.7. CHM Procedure - Oral Representations
- 1.4.8. General Points

[1] Under The Medicines for Human Use (Clinical Trials) Regulations 2004 Applicants are referred to as Sponsor or Investigator. For the purposes of this document all those who submit applications for authorisation will be referred to as Applicant.

[2] Also referred to as the Medicines and Healthcare products Regulatory Agency (MHRA).

2. Where does this guidance sit in the market authorisation process?

2.1. The opportunity to make representations to the CHM may arise under the following circumstances:

2.1.1. In respect of the LA deciding, or proposing, to refuse, revoke, or vary, on grounds relating to safety, quality and efficacy, an application for the grant or renewal of a marketing authorisation, or a proposed revocation, variation or suspension of such an authorisation.

2.1.2. Representations may also apply to PIPs where the LA is proposing to refuse a PIP; make a modification to a PIP; impose, revoke, or refuse to grant a waiver of obligation; or revoke a waiver which was previously agreed.

2.1.3. Regarding clinical trials[3], representations to the CHM may also apply where the LA has chosen not to accept, or chooses to amend, or impose conditions, relating to clinical trial authorisations, or the termination of clinical trials.

2.2. Although this guidance note gives a general description of the provisions of the law in this regard and the way in which the procedures operate in practice, it is not, and must not be regarded as a complete or authoritative statement of the law, nor as binding on the bodies concerned as to the way in which they conduct a particular oral hearing[4] or written representation.

3. The LA Market Authorisation Process and how it links to the Commission on Human Medicines

3.1. **The following sections apply to all applications <u>that must be submitted to the LA for assessment and decision</u>.** Any application that is automatically referred to the CHM, or for which the CHM is asked to advise on, will be discussed during one of the monthly scheduled meetings.

Part 1 of Schedule 11 to the Regulations

3.2. For applications which fall under Part 1[5] of Schedule 11 to the Regulations, the LA is required to consult the appropriate committee (which in most cases is the CHM and so CHM will be used going forward) before it proposes a decision to refuse to grant, renew, revoke, suspend, or vary, a marketing authorisation on the grounds of safety, quality, or efficacy.

3.3. Should the CHM agree with the LA's intention to refuse, renew, revoke, suspend, or vary, an application based upon concerns for the product's safety, quality, or efficacy, this is communicated to the Applicant who is also given the opportunity (a legal right)

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[3] Please refer to regulation 26 and 31 of, and Schedule 5 to, The Medicines for Human Use (Clinical Trials) Regulations 2004.

[4] The oral representation pathway involves a hearing which takes place during a scheduled meeting of the Commission on Human Medicines (CHM).

[5] These applications will typically be classed as new, renewal of license, abridged (established medicines), or orphan designation.

to present a case in their favour to the CHM. The case may be presented by written representation or by oral representation[6].

3.4. Whether an application is new, a renewal, a variation, a PIP, or for a clinical trial, the Applicant has a legal right, when the mechanism is activated, to make a representation before the CHM gives its final advice to the LA.[7]

3.5. The legal requirement for the LA to consult the CHM does not apply to cases of a proposed suspension where the LA assesses it is necessary to suspend the marketing authorisation with immediate effect in the interest of safety, for a period of up to three months, nor where the Applicant has failed to provide the LA with information it has specifically asked for.

Part 1A of Schedule 11 to the Regulations - Paediatric decisions (Paediatric Investigation Plans or PIPs)

3.6. Part 1A applications follow a slightly different route. The LA may propose a decision to refuse to agree a PIP or modification to a PIP; or impose, revoke or refuse to grant a waiver or obligation; or revoke a waiver previously agreed, without consulting the CHM. The LA communication, if other than to grant authorisation, will include an offer to the Applicant to make written or oral representations to the CHM.

3.7. Under regulation 10 of the Regulations, the LA may consult the CHM on any matter relating to the application should it choose to do so, in addition to the above. Should the LA choose to consult with the CHM this will also result in the opportunity for the Applicant to make a representation if the CHM agrees with the LA that the application should be refused, modified, or revoked, in any manner provided for in the Regulations.

A note on Type 1B Variation applications under Schedule 11 to the Regulations

3.8. Type IB Variations are provided for under Schedule 10A of the Regulations, and they are not covered by Schedule 11. The LA may refuse Type 1B Variation applications without consulting with the CHM. It is uncommon for the LA to consult the CHM regarding Type 1B Variations, but as with all market authorisation applications the LA may consult the CHM on any matter.

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[6] Please note that following the February 2026 CHM meeting, and a formal request from the Licensing Authority (LA), the CHM has agreed not to further review applications for established medicines where the LA is of the view that major objections have been addressed and a product is able to progress to approval. This means that in practice the Applicant will not need to proceed to written or oral representations to the CHM as per requirements in Schedule 11 to The Human Medicines Regulations 2012 (as amended), and consent will be sought from the Applicant not to do so. This is intended to be an ongoing arrangement. The LA will ensure the Applicant is fully aware of the amended process for established medicines and obtain written consent from the Applicant. All queries should be directed to the application contact within the LA. However, the LA reserves the right to return to the CHM for further discussion on any established medicines application if it is considered necessary.

[7] The process followed is a little different depending on what type of application is being made. Please refer to Schedule 11 to The Human Medicines Regulations 2012 (as amended), and regulation 26 and 31 of, and Schedule 5 to, The Medicines for Human Use (Clinical Trials) Regulations 2004.

3.9. Should the LA choose to consult with the CHM regarding the application, and the CHM agrees to advise against authorising the application, please note that there **is no legal right** to a representation provided for an Applicant under the Regulations.

3.10. It is important to note that, under the Regulations, the Review Panel is not available for Type 1B Variations.

3.11. If you have any questions about this procedure, please contact the Committee Services Team Secretariat on CHMrepresentations@mhra.gov.uk .

Part 2 of Schedule 11 to the Regulations - Type II Variation applications, complex variation applications and new excipient variation applications

3.12. Following assessment of an application the LA may refuse, or grant authorisation otherwise than in accordance with the application, on grounds relating to safety, quality, or efficacy, under Part 2 of Schedule 11 without consulting the CHM. The LA communication, if other than to grant authorisation, will include an offer to the Applicant to make written or oral representations to the CHM.

3.13. Under regulation 10 of the Regulations the LA may consult the CHM on any matter relating to the application should it choose to do so, in addition to the above. Should the LA choose to consult with the CHM this will also result in the opportunity for the Applicant to make a representation if the CHM agrees with the LA that the application should be refused or revoked in any manner provided for in the Regulations.

Schedule 5 to the Clinical Trials Regulations

3.14. The LA may refuse to accept, amend, or impose conditions to a clinical trial, under regulation 26, or suspend or terminate a clinical trial under regulation 31, of the Clinical Trials Regulations, without consulting the CHM. The LA communication, if other than to grant authorisation, will include an offer to the Applicant to make written or oral representations to the CHM.

3.15. Under regulation 10 of the Regulations, the LA may consult the CHM on any matter relating to an application should it choose to do so. Should the LA choose to consult with the CHM this will also result in the opportunity for the Applicant to make a representation if the CHM agrees with the LA that the application should be refused, amended, or conditions should be imposed, in any manner provided for in the Regulations.

4. CHM Procedures[8]

Summary table at Annex 1

Communicating with the Applicant after the CHM meeting

4.1. Once the CHM gives provisional advice against granting authorisation the following things may happen:
  4.1.1. The Applicant may choose to agree with the provisional advice.
  4.1.2. The Applicant may choose to progress with a written or oral representation, as communicated in writing following the relevant CHM meeting. The Applicant will be notified of their right to representations in the following ways:
    4.1.2.1. **The Secretariat to the CHM will notify the Applicant** if the application is submitted under Part 1 of Schedule 11 to the Regulations.
    4.1.2.2. **The LA will notify the Applicant** if the application is submitted to the CHM under Part 1A or Part 2 of Schedule 11 to the Regulations.
    4.1.2.3. **The LA will notify the Applicant** if the application is submitted to the CHM under Schedule 5 to the Clinical Trials Regulations.
  4.1.3. The notifications will explain the outcome, detail the provisional advice from the CHM, and explain next steps for the Applicant. The Applicant will have 28 calendar days to respond, unless another date is provided by the LA or Secretariat.

4.2. It is important that the Applicant carefully considers all points presented in the letter it receives. <u>All points must be fully understood, as they must all be addressed comprehensively for authorisation to be considered.</u> Failure to do so may result in delays, and a rejection of documents submitted for the representation process. If there is any confusion the Applicant should seek advice from the appropriate Assessor as listed in the written communication.

4.3. It is important to understand that the Applicant must decide for themselves whether to pursue written or oral representations, and this request must be submitted within the relevant time limit of 28 calendar days, unless otherwise stated.

Written Representations

4.4. If the Applicant chooses written representation, they will need to notify the CHM, via the Secretariat, or the LA depending on the type of application (see above), **within 28 calendar days** dated from receipt of the notification letter. Details of whom to contact will be specified in the letter.

4.5. Following the 28 calendar days, the Applicant must proceed according to the following:
  4.5.1. **Under Part 1 and Part 2 of Schedule 11 to the Regulations** the Applicant will have **six months** (or other shorter deadline as specified) by which to submit written representation and any other supporting documents.

[8] Please refer to paragraph 5, 13 (b), and paragraph 18, of Schedule 11 to The Human Medicines Regulations 2012 (as amended), and regulations 26 and 31 of, and Schedule 5 to, The Medicines for Human Use (Clinical Trials) Regulations 2004.

4.5.2. **Under Part 1A of Schedule 11 to the Regulations** the Applicant will have **28 calendar days** (or other shorter deadline as specified) by which to submit written representation and any other supporting documents.

4.5.3. **Under Schedule 5 to the Clinical Trials Regulations** the Applicant will have **six months** (or other shorter deadline as specified) by which to submit written representation and any other supporting documents.

4.6. All pertinent data must be submitted, whether published or unpublished, and whether or not favourable to the Applicant's desired positive outcome.

4.7. The CHM will only wish to see and assess data pertinent to the issues listed in the letter sent. However, new adverse drug reaction data, or adverse data relating to a PIP or clinical trial, must be flagged to the relevant Assessors or the CHM, via the Secretariat, as soon as possible, regardless of source, and regardless of when in the representation timeline it is. Additional non-related data is not necessary at any time and will only delay the process.

4.8. Please note that if an Applicant submits data that substantially alters the initial application it may not be accepted, and the Applicant may be asked to resubmit as a new application if they wish to proceed seeking authorisation. The data provided to support an Applicant's case must be directly related to the initial application's purpose and scope.

4.9. All data will be submitted to the CHM by the relevant MHRA Assessment Team, once it has been assessed.

4.10. The Applicant may pursue the following options if considering a deadline extension:

4.10.1. **Under Part 1, and Part 2 of Schedule 11 to the Regulations** request a deadline extension to the six months, **up to no more than 12 months altogether**, and only if permission is granted by the CHM, who will consult with the LA. An extension will only be granted under exceptional circumstances. Details for how to request an extension will be included in the letter to the Applicant.

4.10.2. **Under Part 1A of Schedule 11 to the Regulations** request a deadline extension to the 28 calendar days, **up to no more than 56 calendar days altogether**, and only if permission is granted by the CHM, who will consult with the LA. An extension will only be granted under exceptional circumstances. Details for how to request an extension will be included in the letter to the Applicant.

4.10.3. **Under Schedule 5 to the Clinical Trials Regulations** request a deadline extension to the six months, **up to no more than 12 months altogether**, and only if permission is granted by the CHM, who will consult with the LA. An extension will only be granted under exceptional circumstances. Details for how to request an extension will be included in the letter to the Applicant.

4.11. An Applicant may also submit additional documents after the agreed deadline but only if permission is obtained from the CHM. The CHM will consult with the LA regarding any requests to submit additional data. Permission to submit additional documents after the deadline has passed will only be granted under exceptional circumstances.

4.12. At any time before the written representation is assessed by the CHM during a scheduled meeting, the LA may issue a request for information (RFI) on the application.

4.13. The CHM will assess the written representation during a scheduled meeting and submit final advice to the LA. The LA must consider the final advice, and all documentation submitted by the Applicant, when making its decision on the application.

4.13.1. This final advice may also include advice to proceed with a grant of authorisation, subject to certain conditions being met.

4.14. The Applicant will receive a comprehensive letter from the LA explaining the outcome, which will include the advice from the CHM.

Oral Representations

4.15. If the Applicant chooses oral representation, they will need to notify the CHM, via the Secretariat, or the LA, depending on type of application, **within 28 calendar days** dated from receipt of the letter. Details of whom to contact will be specified in the letter.

4.16. Following the 28 calendar days the Applicant must proceed according to the following:

4.16.1. **Under Part 1 and Part 2 of Schedule 11 to the Regulations** the Applicant will have **six months** (or other shorter deadline as specified) by which to submit a written summary of their representation, and any other supporting documents. At this time the Secretariat will schedule an oral hearing.

4.16.2. **Under Part 1A of Schedule 11 to the Regulations** the Applicant will have **28 calendar days** (or other shorter deadline as specified) by which to submit a written summary and any other supporting documents.

4.16.3. **Under Schedule 5 to the Clinical Trials Regulations** the Applicant will have **six months** (or other shorter deadline as specified) by which to submit a written summary and any other supporting documents.

4.17. All pertinent data must be submitted, whether published or unpublished, and whether or not favourable to the Applicant's desired positive outcome.

4.18. The CHM will only wish to see and assess data pertinent to the issues listed in the letter sent. However, new adverse drug reaction data, or adverse data relating to a PIP or clinical trial, must be flagged to the relevant Assessors or the CHM, via the Secretariat, as soon as possible, regardless of source, and regardless of when in the representation timeline it is. Additional non-related data is not necessary at any time and will only delay the process.

4.19. Please note that data submitted that substantially alters the initial application may not be accepted and the Applicant may be asked to resubmit as a new application if they wish to proceed seeking authorisation. The data provided to support an Applicant's case must be directly related to the initial application's purpose and scope.

4.20. All data will be submitted to the CHM once it has been assessed, by the relevant MHRA Assessment Team. The written summary and supporting data submitted should be considered the full package for consideration. Additional data should not be submitted to the CHM on the day of the oral hearing without permission from the CHM, or without a formal RFI.

4.21. The Applicant may pursue the following options if considering a deadline extension:

4.21.1. **Under Part 1, and Part 2 of Schedule 11 to the Regulations** request a deadline extension to the six months, **up to no more than 12 months altogether,** and only if permission is granted by the CHM, who will consult with the LA. An extension will only be granted under exceptional circumstances. Details for how to request an extension will be included in the letter to the Applicant.

4.21.2. **Under Part 1A of Schedule 11 to the Regulations** request a deadline extension to the 28 calendar days, **up to no more than 56 calendar days altogether**, and only if permission is granted by the CHM, who will consult with the LA. An extension will only be granted under exceptional circumstances. Details for how to request an extension will be included in the letter to the Applicant.

4.21.3. **Under Schedule 5 to the Clinical Trials Regulations** request a deadline extension to the six months, **up to no more than 12 months altogether**, and only if permission is granted by the CHM, who will consult with the LA. An extension will only be granted under exceptional circumstances. Details for how to request an extension will be included in the letter to the Applicant.

4.22. The Applicant may also submit additional documents after the agreed deadline but only if permission is obtained from the CHM. Permission to submit additional documents after the deadline has passed will only be granted under exceptional circumstances.

4.23. At any time before the scheduled oral hearing takes place during a scheduled CHM meeting, a RFI may be issued on the application.

4.24. The CHM will carry out, with the LA, a pre-hearing discussion and assessment of the written summary of the oral representation and any additional documents submitted during a scheduled meeting, prior to the oral hearing. This might take place before the Applicant presents their case during the same day, or it might take place during an earlier meeting. This is subject to availability on the CHM agenda and subject to urgent business having to take priority.

4.25. Please note the following regarding the oral hearing pathway:

4.25.1. The Applicant may decide to cancel a scheduled oral hearing at any stage in the process, but it is important they fully understand what it means for their application.

4.25.2. Where the application receives an indicative positive response during a CHM pre-hearing discussion in relation to identified major objections, an Applicant still retains the legal right to an oral hearing should they wish to proceed. It is important to understand that all outstanding matters communicated to the Applicant must be resolved, ideally between the Applicant and the LA, for a positive outcome to be reached regarding the application.

4.25.2.1. It is very unusual for an Applicant to receive notification of an indicative positive response following a pre-hearing discussion and still wish to proceed with an oral hearing. The Applicant should provide the CHM with clear reasons as to why they wish to proceed so that necessary arrangements can be made.

4.25.2.2. If the pre-hearing discussion takes place during a different meeting on a different day to the hearing itself, the indicative outcome will be communicated to the Applicant. If the pre-hearing discussion takes place ahead of an oral hearing scheduled during the same meeting on the same day the indicative outcome will still be communicated to the Applicant, and the oral hearing may still be cancelled by the Applicant.

4.25.3. If the outcome of the pre-hearing discussion is negative, or not wholly positive, regarding major objections the scheduled oral hearing will proceed as planned, unless the Applicant wishes to withdraw their application from proceeding further.

4.26. During an oral hearing the CHM will consider the representation as presented by the Applicant before submitting its final advice to the LA. The LA must consider the final advice, along with all documentation submitted by the Applicant, when making its decision on the application.

4.26.1. This final advice may include an outcome of authorisation being granted subject to certain conditions being met.

4.27. The Applicant will receive a comprehensive letter from the LA explaining the outcome, which will include the advice from the CHM.

Oral Representations
Who will be present at an oral hearing and what can be expected?

4.28. The hearing will be attended by the CHM Chair, CHM Members, the Secretariat, and various officials across MHRA Departments who are connected to CHM business. A complete list of the CHM Membership can be found here.

4.29. When the CHM and other attendees are ready, the Applicant will be invited to join the call, which will be via Microsoft Teams. Please check internet connections are working, and stable. To ensure an effective and efficient hearing, a maximum of four representatives for the Applicant is recommended. Please notify the Secretariat if more than four representatives are required.

4.30. Introductions will be made, usually directed by the Chair. It helps to have one lead presenter for the application who can introduce themselves and colleagues who may also be presenting or fielding questions from the attendees.

4.31. The application data already submitted for the hearing will have been studied in detail by the CHM Membership, and by the relevant Assessors. Please do not repeat data or conclusions during the presentation and only focus on the issues which are of main concern or yet to be satisfactorily resolved.

4.32. The Chair will ask the Applicant to confirm they have brought to the CHM's attention all pertinent data, published or unpublished, whether or not favourable to the

Applicant's position. The Chair will then reiterate any points which the CHM is satisfied with and which it is not necessary for the Applicant to address in the presentation for the oral hearing. The Chair will also point out, however, that this will not prevent CHM Members, or professional staff from the LA (including the Assessors), from asking questions on those points, arising out of anything mentioned in response to the outstanding issues, or raising questions of clarification.

4.33. The CHM is only interested in scientific evidence, clearly and comprehensively presented. Marketing or commercial elements to the application cannot and will not be taken into consideration and should be omitted from a presentation.

4.34. A visual presentation can be helpful when presenting application data and this is always encouraged.

4.35. **Presenting a case to the CHM should not take more than 15 minutes, not including time for Q&A from the attendees**. Please keep this in mind as time is limited. If the presentation is overrunning the Chair may also prompt a time check.

4.36. After the presentation, there will be a Q&A session. All those representing the application must have appropriate authority and knowledge to address questions on behalf of the application from the source company. All attendees must be fluent in English. Please contact the Secretariat if there are any accessibility requirements, or anything the CHM needs to be aware of prior to the oral hearing.

4.37. Once the session is completed all those attending on behalf of the source company/Applicant will be asked to leave the meeting. The CHM will reconsider the provisional opinion, considering the quality and accuracy of all data presented during the presentation. It will then submit final advice to the LA. The LA will consider all the data and advice and communicate its decision to the Applicant. The LA will also explain the final advice given by the CHM.

5. The MHRA Review Panel

5.1. For Part 1, 1A, and Part 2 of Schedule 11 to the Regulations, if the LA's final decision is negative and provided the representation pathway was followed comprehensively and within all time limits, the Applicant will be offered the opportunity to make a review upon oral representations to a Review Panel.

5.1.1. This will be an oral review as provided for by Schedule 5 to the Regulations. The Review Panel will be appointed by the LA.

5.2. For Schedule 5 to the Clinical Trials Regulations, if the outcome is negative and provided the representation pathway was followed comprehensively and within all time limits, the Applicant will be offered two options[9]:

5.2.1. To notify the LA that they wish to appear before or be heard by a person appointed by the LA (application decision to be reviewed); or

5.2.2. To make written representations to the LA with respect to the decision.

5.3. All Applicants are encouraged to seek appropriate counsel to make a considered decision.

[9] Please refer to Schedule 5 to The Medicines for Human Use (Clinical Trials) Regulations 2004.

5.4. Please refer to the Review Panel Guidance Note by contacting the Review Panel Secretariat via reviewpanel.secretariat@mhra.gov.uk .

6. General points

6.1. Correspondence will be carried out by electronic mail, with consent from the Applicant[10]. Should the Applicant wish to receive hard copies they should inform the Secretariat.

6.2. All additional data for applications being submitted for attention of the CHM must be submitted via the MHRA Submission Portal. Applicants must register with the portal before use. Further details can be found here.

6.2.1. An Applicant's additional data for Northern Ireland Concerned Member State applications can be submitted via the Common European Submission Platform (CESP). To register, and for further details on how to use CESP, please click on the following link: http://cesp.hma.eu/Home

6.3. The representation should be as concise as possible and relate directly to the grounds referred to in the letter received from the CHM or where applicable, the LA. PowerPoint presentations are welcome if concise and easy to follow. Representations should also be submitted in Word format, whenever possible.

6.3.1. PowerPoint presentations should be emailed to the Secretariat a week before the hearing. The Secretariat will run a trial test to ensure the presentation works.

6.4. All changes to product literature should be shown using italics, underscoring etc. The final version of the summary of product characteristics (SPC) and Section 4 Additional Information (Manufacturing Process, Finished Product Specification and Drug Substance Specification) should also be submitted in Word format.

6.5. Do **not** send paper copies of the representation.

6.6. Virtual oral hearings are the expected practice and will be conducted via Teams. The procedures and protocols for virtual oral hearings are subject to change from time to time as the Commission deploy technological solutions, such as Zoom, Microsoft Teams, and adapt to the changing environment. Details of the software specific for the virtual hearing will be provided by the Secretariat.

[10] Please refer to regulation 343 of The Human Medicines Regulations 2012 (as amended).

Commission on Human Medicines

ANNEX 1

	Application Type	Relevant Regulation/ Schedule	CHM	Timeline to Submit Representation to the CHM (Written/Oral)	Extension Requests (max.)	Review Panel Rights
1	**New Applications** (including renewal / abridged / orphan)	Schedule 11, Part 1 The Human Medicines Regulations 2012	Proposal to refuse, vary, or suspend requires referral to the CHM	**Statutory:** 6 months	CHM may approve up to **12 months total** from original request date	**Yes**
2	**Type IB Variation**	Schedule 10A (outside Schedule 11) The Human Medicines Regulations 2012 (as amended)	Referral to the CHM at discretion of the LA	**Non-Statutory:** timeline set by CHM on a case-by-case basis	No statutory right to extension	**No**
3	**Type II Variation / Reclassification / Complex Variations**	Schedule 11, Part 2 The Human Medicines Regulations 2012 (as amended)	Referral to the CHM at discretion of the LA	**Statutory:** 6 months	CHM may approve extensions up to **12 months total** from original request date	**Yes**
4	**Paediatric Investigation Plans (PIPs)**	Schedule 11, Part 1A The Human Medicines Regulations 2012 (as amended)	Referral to the CHM at discretion of the LA	**Statutory:** 28 calendar days	CHM may approve extensions up to **56 calendar days total** from original request date	**Yes**
5	**Clinical Trial Application**	Schedule 5 to The Medicines for Human Use (Clinical Trials) Regulations 2004	Referral to the CHM at discretion of the LA	**Statutory:** 6 months	CHM may approve extensions up to **12 months total** from original request date	**Yes**