



GUIDANCE AND PROCEDURES FOR NOTIFICATION AND ASSESSMENT OF SIGNIFICANT CHANGE TO AN APPROVED UNDERGRADUATE OR SPECIALIST MEDICAL EDUCATION /TRAINING PROGRAMME AND/OR BODY.

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Comhairle na nDoctúirí Leighis
Medical Council

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MEDICAL COUNCIL GUIDANCE AND PROCEDURES FOR NOTIFICATION AND ASSESSMENT OF A SIGNIFICANT CHANGE TO AN APPROVED UNDERGRADUATE OR SPECIALIST MEDICAL EDUCATION/TRAINING PROGRAMME AND / OR BODY.

1. PURPOSE OF THIS GUIDANCE

The purpose of this guidance is to outline what a significant change is, when a significant change request can be made and what the process is for a *Body to notify the Medical Council of any significant change. This guidance describes the process that must be followed to ensure that proposed new developments to a **Programme or Body are in accordance and comply with the Medical Council standards.

** Body/Bodies denote Medical School and /or Postgraduate Training Body.*

*** Programme/Programmes denote a medical degree Programme and a Programme of specialist training.*

2. THE ROLE OF THE MEDICAL COUNCIL IN MEDICAL EDUCATION AND TRAINING

The Medical Council's purpose is to protect the public by promoting and ensuring high standards of education, training, conduct, and continuing professional development amongst doctors. The Medical Council regulates medical doctors in the Republic of Ireland by maintaining the 'Register of Medical Practitioners' and investigates complaints made against medical doctors.

[Part 10](#) of the [Medical Practitioners Act 2007](#) (the MPA 2007) sets out our responsibilities with regard to medical education and training.

- * We set standards and produce guidelines for medical education and training which all: basic medical degree, intern, and Programmes of specialist training in Ireland are required to meet. We assess and monitor adherence to those standards.
- * We approve the bodies that can issue basic medical degrees or specialist medical qualifications ('Body' or 'Bodies')
- * We issue Certificates of Experience to medical graduates who successfully complete intern training in Ireland and;
- * We inspect clinical sites where medical training is provided ('clinical training sites').

Accreditation Standards

Hereinafter any reference to "accreditation" of a Programme means approval by the Medical Council of a Programme within the provisions of sections 88(2)(a)(i)(I) or 89(3)(a)(i) of the MPA 2007. The current standards for undergraduate accreditation are the [World Federation of Medical Education Global Standards in Basic Medical Education \(2015\)](#). The current standards for postgraduate accreditation are the [Medical Council Accreditation Standards for Postgraduate Medical Education \(2011\)](#).

Basic medical education Programmes are normally accredited on a five-year cycle, on expiry of which the approved Body must apply to the Medical Council for re-accreditation. Postgraduate Programmes are accredited through a cyclical process of accreditation. Postgraduate Programmes which require a formal re-accreditation upon expiration of the accreditation approval period will be contacted by the Medical Council to arrange a reaccreditation. However, the Medical Council must be notified throughout the lifetime of a Programme of important details, such as performance data (via annual returns), challenges and any proposed significant change to the Programme or body, which may impact on the continuation of existing accreditation status.

3. WHAT IS A SIGNIFICANT CHANGE?

A significant change is one which creates a perceived risk that changes to the Programme or Body will result in the Programme and Body no longer complying with the Medical Council Standards and/or the conditions of accreditation.

The Medical Council Rules supporting the Medical Practitioners Act state any significant alterations to the design and delivery of the Programme, as approved, will require the prior approval of the Medical Council. Furthermore, any significant alterations to the status and/or structure of the body, as approved, will require the prior approval of the Medical Council.

A significant change may include changes to:

- The curriculum,
- Duration of Programme,
- Assessment structure.

It is the responsibility of all Bodies to give careful consideration to all proposed changes to a Programme (and if appropriate seek external review), as to whether it is a significant change as defined above. If a Body has any doubt as to whether a proposed change represents a significant change and a risk of not complying to the Medical Council standards and/or the conditions of accreditation, this must be discussed with the Medical Council at an early stage of planning.

The Medical Council is seeking assurance that a Body can justify a proposed significant change to a Programme and continue to meet the Medical Council's standards. Any changes to the Programme not deemed 'significant' should still be carefully considered and reported via the annual returns process.

Some examples of what a significant change can look like:

- A PGTB moving to an outcomes-based curricula.
- A PGTB requesting to change the amount of prior experience required for entry to a specialty.
- A major change to the curriculum of an undergraduate Programme.

4.WHEN CAN A SIGNIFICANT CHANGE BE MADE?

The Medical Council must be informed in advance of a significant change planned for a Programme or Body. A significant change proposal can be submitted to the Medical Council at any point throughout the year. The sooner a Body informs the Medical Council the better, but a Body should notify the Medical Council of proposed significant change **at least 12 months** in advance of a proposed significant change being implemented. This is to allow sufficient time to fully assess the change and conduct an evaluation, if deemed necessary. This will avoid risk to the continuing approval status of the Programme and body, and the potential for any adverse impact on the students and/or trainees.

In addition, all Bodies will be reminded via the annual returns process to notify the Medical Council of any significant change requests.

Please note: a Body should not wait until their Programme is due for re-accreditation to inform the Council of a significant change. When a Body envisages the introduction of significant change to an approved Programme, they are required to inform and seek the prior approval of the change.

In circumstances where approved Programmes and/or Bodies experience disruptions of any kind which pose a risk to the delivery of the Programme, they are required to inform Council as soon as possible and set out a plan to address the risk. The Council will endeavour to support the Programme and/or Body, and if necessary, may propose amendments and/or monitor progress.

5.PROCESS FOR NOTIFYING THE MEDICAL COUNCIL OF A SIGNIFICANT CHANGE

A Body must complete the Medical Council's "Notice of Intention to Change an Accredited Programme" form. The proposed significant changes can be submitted with the Body's annual return or at any time to the Medical Council if doing so complies with the required notice period. A link to the form can be found [here](#).

The following information must be provided when a body submits a significant change request (or provide justification if not included), as applicable:

- Broad outline of the revised Programme, clearly highlighting the proposed change and rationale for it, and consideration of any changes to assessment processes and Medical Council standards.
- The benefit of the significant change and timeline of implementation; plans for transition and details of change management process.
- Mapping of current curriculum and assessment framework to the revised curriculum so the Medical Council assessment processes via significant change are facilitate, if applicable to significant change request.
- Details of impact analysis conducted, including the anticipated impact of the change on access and Equality & Diversity, to existing students, trainees and educators, and any benefits/risks for patients if applicable.
- Clinical or other teaching resources available to deliver the revised Programme.
- Resource implications of the change for healthcare facilities.
- Details and outcome of stakeholder consultation concerning the change, including with students and/or trainees and trainers.
- Planned evaluation process including monitoring outcomes, the effects of change and a clear 'feedback loop' for all stakeholders, with timescales for monitoring and responding.
- Risks identified as a result of the change, i.e., quality of teaching, level of supervision, patient safety etc.
- Any other details considered relevant.

6. HOW WILL THE SIGNIFICANT CHANGE BE ASSESSED?

Significant change requests will primarily lie with the Executive for review. In exceptional cases where a request is deemed complex in nature, the Executive will seek expertise (an assessor team or a specialist expert) in the review of the application to help inform the recommendation that will then be submitted to ETC.

The Medical Council will decide whether it is necessary to reconsider a Body and Programme's accreditation status or whether an accreditation should be triggered in light of the forthcoming implementation of the approved significant change.

The Executive or assessor team may seek a meeting with the Body for further clarity. The Executive will make a recommendation, ideally within 3 months, as far as feasible, to the Medical Council's Education and Training Committee, for consideration.

The ETC will consider the recommendation and decide if the proposed change is justified and provide a clear rationale for any decision made.

Although the Executive will make every effort to ensure there is clarity in relation to the proposal and that the relevant questions have been answered, ETC may decide to request further information from the Body. In this case, the ETC has a further 3 months to make a decision following the receipt of the additional information.

If approving a significant change, the ETC has the right to seek measures to gain additional reassurance where reasonable, for instance, in cases where the significant changes are complex or may pose significant impact on trainees and/or patients. This may include some monitoring post approval.

The Body will then be notified that ETC has either approved or declined the Significant Change request with clear rationale for their decision. If the significant change is approved, ETC is responsible for determining when the change comes into effect, if the change can be applied retrospectively, and any recommendations for monitoring of the change. This will be done on a case-by-case basis by the ETC. If the Medical Council decides not to approve the proposed significant change, the Body must not make the change to the existing accredited Programme.

In some cases, it is possible ETC may make quality improvement recommendations. If applicable, the recommendations will be included in writing with the decision. If ETC makes any recommendations for quality improvement, the recommendations will be added to the annual returns with a specified timeline for completion.

7. OUTCOME

The Body will be given notice in writing of the decision, the date on which the decision was made, as well as the following:

- In the case of a refusal, the reasons for the decision.
- In the case of approval, the reasons for the decision and the date from which the change comes into effect.
- Where applicable, monitoring or quality improvement recommendations.

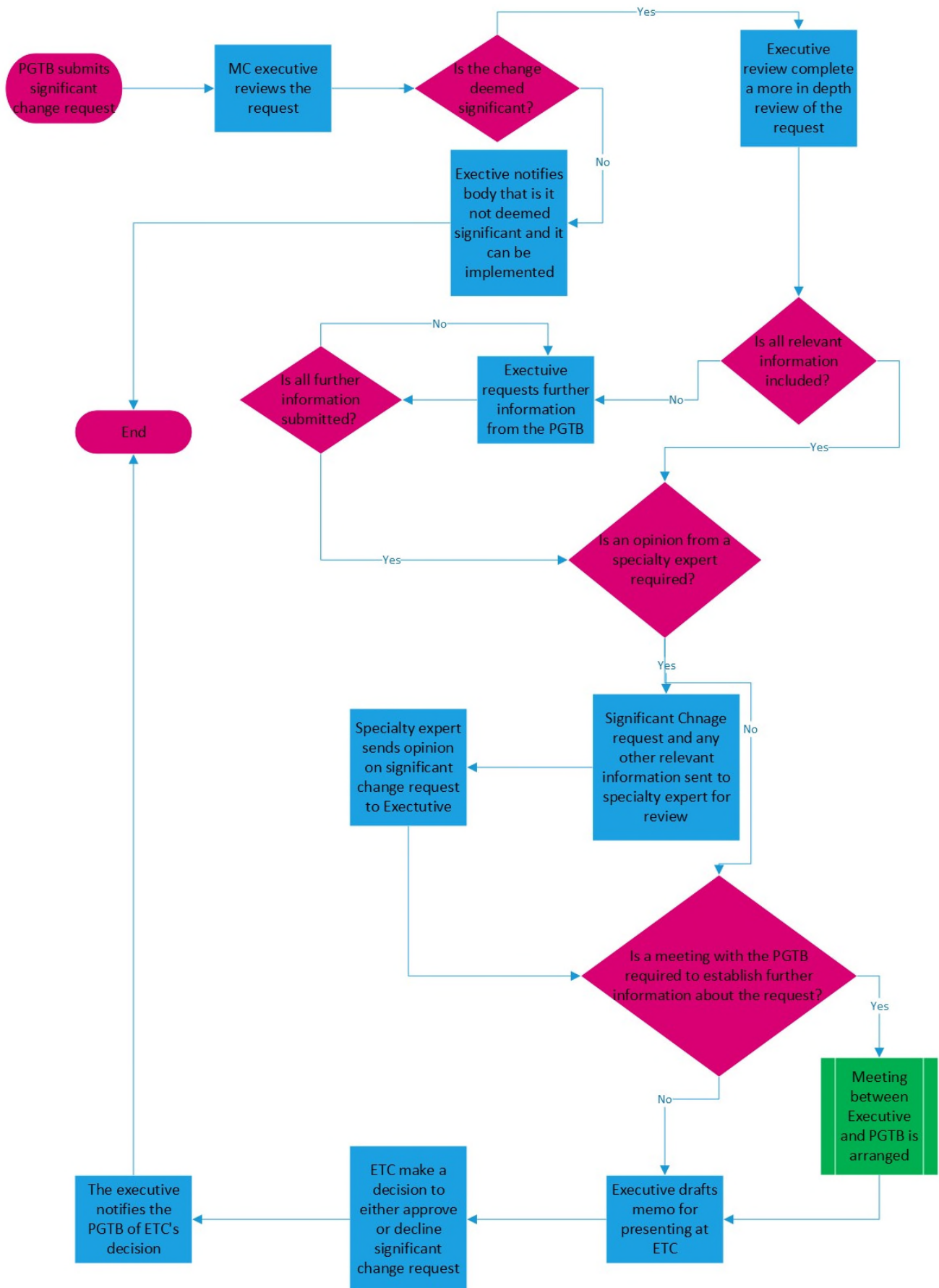
PLEASE note: If the Medical Council decides not to approve the proposed significant change, the Body must not make the change to the existing accredited Programme.

Appealing a Significant Change Decision

In the case the change is deemed significant and is not approved, the Body can resubmit an amended significant change request to the Medical Council after 6 months. The amended significant change request will only be assessed in such circumstances whereby the Body has considered the reasons for not approving the significant change and has amended the significant change request to reflect an updated proposal which takes into account the previous reasons for the decision.

SIGNIFICANT CHANGE PROCESS MAP

Timeframe - from notification of significant change to recommendation made to the ETC – approx. 3 months.





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