HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Applying for a Variation to a Tissue / Importing Tissue Establishment Authorisation

1 SCOPE

This document provides guidance to tissue / importing tissue establishments in applying for a variation to a tissue / importing tissue establishment authorisation.

2 APPLYING FOR A VARIATION TO A TISSUE / IMPORTING TISSUE ESTABLISHMENT AUTHORISATION

~~Regulation 6(9) of S.I. No. 158 of 2006 as amended states that 'A Tissue Establishment shall not make any substantial change in the prescribed activities which it undertakes without the prior written approval of the IMB.'~~

~~Regulation 6(9A) states that 'An importing tissue establishment shall not make any substantial changes in the importing activities it undertakes without the prior written approval of the Health Products Regulatory Authority'.~~

~~Regulation 6(10) states that 'Any application by a Tissue Establishment or Importing Tissue Establishment for approval to make a substantial change in its activities must be made in writing to the IMB and accompanied by the appropriate fee.'~~

Regulation 6(9) of S.I. No. 158 of 2006, as amended, states that 'A tissue establishment shall not make any substantial change in the prescribed activities which it undertakes without the prior written approval of the IMB.'

Regulation 6(9A) states that 'An importing tissue establishment shall not make any substantial changes in the importing activities it undertakes without the prior written approval of the Health Products Regulatory Authority'.

Regulation 6(10) states that 'Any application by a tissue establishment or ~~Should a tissue /~~ importing tissue establishment for approval to make a substantial change in its activities must be made in writing to the IMB and accompanied by the appropriate fee.'

Should a tissue/importing tissue establishment wish to change any detail of their authorisation, the ~~Responsible Person~~responsible person should submit a completed application form to the Health Products Regulatory Authority (HPRA), together with the appropriate fee. ~~Please see www.hpra.ie.~~Please go to the HPRA website at www.hpra.ie for more information.

3 GENERAL NOTES

- Variation applications must be submitted **prior** to the authorisation holder implementing the change.

- Depending on the variation type, supporting documentation is required as specified in the application form. Additional documents may be required to support the review of the application. Electronic versions of supporting documents are preferable.

- The HPRA can create a shared folder on OneDrive for the submission of requested documents. You are requested to advise the HPRA in advance of the application if this is required and provide the email addresses of the personnel who require access to upload documents.

- If the supporting documentation is incomplete or follow up documentation is not provided in a timely manner, the application may be rejected.

- Variations to the tissue~~/~~/importing tissue establishment authorisation can be classified as **administrative** (requiring a limited amount of assessment by an inspector) or **technical** (requiring significant assessment by an inspector with possible scheduling of a site inspection). The fee required depends on the variation type. The fee code for administrative variations is 330. The fee code for technical variations is 331.

- Following approval of the variation by the HPRA, an endorsed authorisation containing the updated variation will be issued to the authorisation holder indicating the date from which the endorsed authorisation is effective.

- Authorisation holders should retain their original authorisation on file and exhibit the endorsed authorisation as appropriate.

- In certain circumstances, the HPRA may send an email to the tissue~~/~~/importing tissue establishment to confirm that the variation has been approved. The tissue~~/~~/importing tissue establishment should attach a copy of the email to their current authorisation until their new endorsed authorisation is issued. Please note that this procedure will only be followed in exceptional circumstances.

- Please note that the average time to review and approve variations is two to three months and this is dependent on the information provided/submitted and on other work priorities and may take longer. We will endeavour to review variations as soon as practical.

4 CONTACT DETAILS

For further information or guidance, please contact the HPRA at:

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HPRA
~~18 September 2025~~26 June 2026