HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Applying for a Variation to a Blood Establishment Authorisation

1 SCOPE

This document provides guidance to blood establishments in applying for a variation to a blood establishment authorisation.

2 APPLYING FOR A VARIATION TO A BLOOD ESTABLISHMENT AUTHORISATION

Regulation 6(9) of S.I. No. 360 of 2005 states that 'A Blood Establishment shall not make any substantial change in the prescribed activities which it undertakes without the prior written approval of the IMB.'

Regulation 6(10) states that 'Any application by a Blood 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 blood establishment wish to change any detail of their authorisation, the Responsible Person should submit a completed application form to the Health Products Regulatory Authority (HPRA), together with the appropriate fee. Please see the 'Publications and Forms' section of www.hpra.ie.

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 blood 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 blood establishment to confirm that the variation has been approved. The blood 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.

4 CONTACT DETAILS

For further information or guidance, please contact:

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