

Home > News and media > PHI circulars

PHI 81/23 Prescribed List guidance material

Update on the Prescribed List of Medical Devices and Human Tissue Products Guide, and the Prescribed List webpages.

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Audience: Health sector

We would like to provide an update on the status of the:

- Prescribed List of Medical Devices and Human Tissue Products Guide
- Prescribed List webpage
- Prostheses List Reforms webpage.

The Prescribed List of Medical Devices and Human Tissue Products Guide (the Prescribed List Guide)

We are approaching the final stage in revising the Prescribed List Guide and plan on releasing an intermediate draft in late December. While this document is not yet finalised, we believe it contains helpful information and we expect it may assist sponsors in preparing and submitting their July 2024 Prescribed List applications by the due date in January 2024.

We will continue working on refining and professionally editing the draft and we plan to finalise and publish the Prescribed List Guide in the first quarter of 2024.

In the meantime, we have published a Prescribed List application training <u>presentation</u>, which provides summary of the guidance on the requirements, and explains the changes in the Prescribed List assessment process. We encourage stakeholders, and especially sponsors, to review the presentation.

Webpage restructure

We note that the Prostheses List (re-named to the Prescribed List) webpage is out of date and we are updating and restructuring all relevant webpages.

The restructured webpages will provide current and readily accessible information.

Stakeholders will be able to access the restructured webpages in early 2024.