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PHI 68/23 Prescribed List cost recovery charges

This circular provides clarification on timing and details for payment of the annual Prescribed List levy.

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We are issuing additional information about the timing and details for the new Prescribed List (PL) levy:

- 1. From 1 July 2023, the two current ongoing PL listing fees (usually due in March and September) were replaced with an annual cost recovery levy.
- 2. The first time the new cost recovery levy will be charged will be around September 2024. The exact date from when the levy is payable will be communicated in early 2024.
 - 1. This timeframe will enable sufficient time for the department to consider the cost model that will inform the levy amount, and to conduct the relevant administrative processes.
 - 2. We will undertake stakeholder consultation about the amount and the administrative process before implementing the levy.
- 3. Sponsors with devices already listed on the PL before 1 July 2023 will not be charged any ongoing listing fee during the 2023/24 financial year. Instead, they will be subject to the new levy around September 2024.
 - 1. The department recognises that this streamlined approach will result in an underrecovery of costs for the 2023/24 financial year.

- 4. Sponsors with devices listed between 1 July 2023 and September 2024 will be charged the new levy for the first time around September 2024.
- 5. All other cost recovery fees outlined in the Medical Devices and Human Tissue Products Rules (e.g. application fees) are still payable.

The cost recovery levy will cover the general administration and management of the PL, as the services are provided to a group of individuals or organisations (sponsors with products listed on the PL). This includes costs for administration and depreciation of the relevant PL IT systems. From 1 July 2026 the levy will also cover compliance activities and post listing review costs.

The charges are consistent with the <u>Australian Government Charging Framework</u>. We will document regulatory charging activities through a Cost Recovery Implementation Statement, which will be updated twice a year. All charging activities will also be reviewed at least every five years.