*Gazette* is a condition on the exercise of the minister's power to declare that a law is a 'corresponding state law'.

1.153 However, neither the instruments nor their explanatory statements indicate whether a notice was published in the *Gazette* when the instruments were made. It is therefore unclear to the committee whether the condition in subsection 7(1) of the RIHE Act was satisfied.

**1.154 The committee seeks the minister's advice as to whether a notice was published in the *Gazette* in relation to each of the instruments and:**

- **if so, which *Gazette* or *Gazettes* contain the relevant notices, and where they can be accessed; or**
- **if not, the power relied on to make the instruments.**

| | |
|---|---|
| **Instrument** | **Therapeutic Goods Legislation Amendment (2018 Measure No. 3) Regulations 2018 [F2018L01434]** |
| **Purpose** | Amends the Therapeutic Goods Regulations 1990 to reduce regulatory burden for hard surface disinfectants, and to lower the application fee for marketing approval applications for export only Class 1 medical devices |
| **Authorising legislation** | *Therapeutic Goods Act 1989* |
| **Portfolio** | Health |
| **Disallowance** | 15 sitting days after tabling (tabled Senate 17 October 2018). Notice of motion to disallow must be given by the second sitting day of 2019[108] |

## Unclear basis for determining fees[109]

1.155 Item 1 of Schedule 1 of the instrument sets out the application fees payable under the Therapeutic Goods (Medical Devices) Regulations 2002 (Medical Device Regulations) to include certain classes of medical devices in the Australian Register of Therapeutic Goods.

1.156 The explanatory statement explains that the fee for export only devices in paragraph (f) has been reduced from $530.00 to $90.00, to reflect changes to the way in which the applications for these devices are processed.[110] However, the

108 In the event of any change to the Senate's sitting days, the last day for the notice would change accordingly.

109 Scrutiny principle: Senate Standing Order 23(3)(a).

110 Explanatory statement, p. 1, 4.

explanatory statement does not explain the basis on which the other fees listed in item 1 are calculated.

1.157 The committee's longstanding view is that, unless there is specific authority in primary legislation to impose fees in delegated legislation, fees imposed by legislative instruments should be limited to cost recovery. Otherwise, there is a risk that such fees are more properly regarded as taxes, which require specific legislative authority.

1.158 Consequently, the committee's expectation in cases where an instrument carries financial implications via the imposition of or change to a charge, fee, levy, scale or rate of costs or payment is that the relevant explanatory statement will make clear the specific basis on which an individual imposition or change has been calculated.

1.159 The committee acknowledges that the instrument replicates the application fees for other classes of medical devices in the Therapeutic Goods (Medical Devices) Regulations 2002. However, the fact that provisions replicate those in a previous instrument, or in similar instruments, will not, of itself, address the committee's scrutiny concerns.

**1.160 The committee requests the minister's advice as to the basis on which the application fees in paragraphs (a) to (e), (g) and (h) in item 1 of Schedule 1 have been calculated.**