Labor Senators' Additional Comments

1.1 While not opposing the Committee's recommendation that the Bill be passed, Labor Senators remain concerned about some aspects of the Bill and wish to note the following comments.

Legislative approach

1.2 Labor has offered in-principle support to the recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation. However, as many submitters and witnesses noted, faster access to therapeutic goods comes with significant risks that need to be carefully managed during implementation.

1.3 In this context, the Government's decision to progress a bare-bones Bill, with implementation details left to regulations that have not been drafted, makes it difficult for Senators to assess the Bill. Time and time again during the hearing on this Bill, the Department of Health and other witnesses said that Labor Senators' questions could only be answered once the regulations were available.

1.4 In essence, the Government is asking the Parliament to pass the Bill and trust that the Government will sort implementation details later. The last time this approach was adopted in the Health portfolio was on the National Cancer Screening Register Bill. Labor Senators note that the Register and the improvements to the National Cervical Screening Program that it will support have now been delayed – potentially putting women's lives at risk.

1.5 In its submission, the Department of Health notes that one argument for this legislative approach is the availability of disallowance provisions. Labor Senators reserve their right to scrutinise the eventual regulations closely, and to disallow any regulations that do not strike an appropriate balance between access and safety.

Third party conformity assessment of medical devices

1.6 Labor Senators are particularly concerned by the Bill's lack of detail around third party conformity assessment of medical devices (Schedule 2). As the Department of Health notes in its own submission, even basic details of this process are yet to be settled:

> Details of applications for designation as conformity assessment bodies (including the criteria for becoming such a body), application forms, information that must accompany the application, processes for assessing the competence of applicant companies, information about fees, conditions that may apply in respect of a body's designation, the lapsing of applications and provision for the Secretary to revoke or vary a designation as a conformity assessment body will be set out in regulations.[1]

1.7 The Department of Health notes that conformity assessments for many of the therapeutic goods available in Australia are currently conducted by European

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1 *Submission 22*, p. 6.

regulators or third parties. Nonetheless, the shift to conformity assessments by Australian corporations is a significant one that comes with risks as well as opportunities. In light of the dangerous and high-profile failures of some implantable medical devices in recent years, Labor Senators will scrutinise regulations made under Schedule 2 of the Bill with particular rigour.

1.8 Labor Senators note that at this stage the Government appears to have ignored the Consumers Health Forum of Australia's (CHF) recommendation that third party conformity assessment be limited to lower-risk medical devices and not applied to high-risk implantable devices.

Post-market monitoring

1.9 Labor Senators note that the inquiry demonstrated widespread support—including from industry—for stronger post-market monitoring. Submitters and witnesses argued that this was an essential complement to quickening access to medicines and devices by streamlining regulatory arrangements. For example, the CHF noted that:

> Our support for a move to a limited third party conformity assessment regime is contingent on the improvements to the post marketing [sic] arrangements…[2]

1.10 The Government states that it is implementing Recommendation 27 of the Expert Panel Review via this Bill. However, Labor Senators note that Recommendation 27 is made up of five sub-recommendations on post-market monitoring, not all of which appear to be addressed by this Bill.

1.11 Labor Senators also note that the Department of Health was unable to clarify (but has taken on notice) how much of the 2016-17 Budget measure Improving the Regulation of Therapeutic Goods in Australia will be allocated to post-market monitoring.

1.12 Labor Senators join submitters and witnesses in calling on the Government to strengthen post-market monitoring in implementing this Bill.

Senator the Hon Lisa Singh **Senator Murray Watt**

2 *Submission 27*, p. 5.