Australian Government

Australian Small Business and Family Enterprise Ombudsman

14 July 2021

Personalised Medical Devices
Medical Devices and Product Quality
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2602

via email: *PersonalisedDevices@health.gov.au*

Dear Sir/Madam

Proposed refinements to the regulation of Personalised Medical Devices

We welcome the proposed refinements to the Personalised Medical Devices (PMD) framework as these refinements would offer an improved regulatory model for small businesses who supply personalised medical devices. As such, we offer the following comments:

1. We support introducing an exemption for class 1 medical devices and offering an alternative conformity assessment procedure for class 2a medical devices for small businesses that are sufficiently qualified. These refinements will provide small businesses with a low cost and less burdensome (ie a 'right sized') version of the regulatory framework.
2. We recommend the TGA's list of qualifications be a dynamic list that is continuously updated as new appropriate qualifications arise. The proposed prescriptive list may exclude small businesses who hold appropriate expertise but do not have the exact qualifications listed. To ensure that small business qualifications accurately reflect their ability to obtain exemptions and alternative assessment procedures we recommend the TGA regularly review and update this list.
3. The TGA should review the application of risk classifications on personalised medical devices to ensure that they apply an appropriate level of regulation on small businesses. Small businesses have raised concerns that low risk medical devices may have higher risk classifications than a qualified professional would accept. To ensure that the TGA are not overburdening small businesses with regulation, the TGA should review how risk classifications apply to personalised medical devices.
4. We recommend the TGA publish guidance material so that small businesses have clear guidance on the application of the PMD framework, and an interface be developed similar to that of the "*What classification is my medical device?*" interactive tool on the TGA's website.

We thank the TGA for engaging with our office on the PMD framework and for the opportunity to comment. If you would like to discuss this matter further, please contact Mr Paul Buckingham on [redacted] or at [redacted]

The Hon. Bruce Billson
Australian Small Business and Family Enterprise Ombudsman