Personalized Medical Devices Working Group 2020 Update

Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Therapeutic Goods Administration—Department of Health
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Working group overview

Working group rationale:

Technology has progressed to where it is now possible to ‘mass produce’ individualised medical devices, for example, 3D-printing of devices based on patient CT scan data.

Original GHTF documentation does not adequately address these types of devices.

Work item timeline

- November 2018: Published N49—Definitions for Personalized Medical Devices
- March 2020: Published N58—Personalized Medical Devices—Regulatory Pathways (Approved)
- Proposed NWIE—Personalized Medical Devices—Considerations for validating design envelopes and personalized medical device production systems

Working Group Meeting in Canberra
October 2019
Benefits of reform

• Addresses an emerging trend towards personalized treatments in the medical devices sector.
• Ensures an appropriate level of regulatory oversight is undertaken.
• Leads to harmonisation of requirements for safety, performance and manufacturing of these products.
• Provides a basis for consistent and transparent requirements across multiple jurisdictions.
• Aligns with IMDRF Strategic Priorities.
Final regulatory pathways document (N58)

The goal of this project was to develop a technical document that provides recommendations to support a harmonised approach to regulating medical devices that are manufactured for individuals.

- Two-month public consultation held 24 May 2019 through 24 July 2019
- 17 submissions including from Australia, Canada, Europe, Singapore, Taiwan, USA
- 150 Individual comments
- Working group meeting in Canberra October 2019 to review comments and update the document
- Final document delivered and agreed by IMDRF Management Committee
# Regulatory pathways

<table>
<thead>
<tr>
<th>Custom-made</th>
<th>Patient-matched</th>
<th>Adaptable</th>
<th>Medical device production system (MDPS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorising health professional takes responsibility</td>
<td>Matched to a patient</td>
<td>Mass produced</td>
<td>A collection of components designed to work together to produce devices</td>
</tr>
<tr>
<td>Bespoke design for a person</td>
<td>Manufactured within a validated design envelope</td>
<td>Can be adapted or modified after supply</td>
<td>To be used by health professionals</td>
</tr>
<tr>
<td>Not patient matched or adaptable</td>
<td></td>
<td></td>
<td>Production process validated by the manufacturer</td>
</tr>
</tbody>
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Regulatory pathways

Custom-made medical devices
- Highest level of detail
- Recognises unique pathway for custom-made devices

Patient-matched medical devices
- Reliance on usual regulatory requirements, according to the device regulatory classification
- Focus on validation of design envelope

Adaptable medical devices
- Reliance on usual regulatory requirements, according to the device regulatory classification
- Focus on validated instructions for the adaptable features

Medical device production system (MDPS)
- Considered to be a medical device in its own right
- Reliance on usual regulatory requirements, according to the device regulatory classification of device produced
- Focus on validation of production process
Annexes

Annex 1—Additive and subtractive manufacturing considerations
- Introduces MDPS
- Clarifies status of raw materials for additive manufacture vs materials that are medical devices

Annex 2—Considerations for point-of-care manufacture
- Manufacturing under special arrangements (e.g. exemptions)
- Using medical device production systems
- Fully regulated manufacturing as per the GHTF/IMDRF model
Next steps—PMD validation guidance

• for consideration by the IMDRF Management Committee in 2020
Thank you