Agenda Item 13.7: Standardization of medical devices

Australia recognises the need to support standardising international medical devices classification and nomenclature.

We appreciate the World Health Organization’s (WHO) presentations at International Medical Devices Regulators Forum (IMDRF) meetings, as well as at the Member State briefing session held in April this year. Members of IMDRF raised concerns with the WHO analysis and sought clarification on the rationale for WHO’s support to the (not yet established) European Medical Device Nomenclature (EMDN).

Australia remains concerned about meaningful engagement with all relevant stakeholders, including regulators, peak industry representative bodies and manufacturers, to understand the impact of their proposal.

Australia recommends the WHO consider the following actions:

1 – Validate the WHO analysis mapping exercise of existing nomenclatures against the WHO principles (with the owners of the nomenclatures) and provide the results to Member States.

2 – Provide a timeline for when and how the proposed WHO mapping of EMDN and Global Medical Device Nomenclature (GMDN) will be undertaken and validated. Mapping the new nomenclature to the existing GMDN system is required to minimize the impact of a duplicate nomenclature system on Member States, medical device manufacturers and other industry stakeholders.

3 – Undertake a costing exercise. Sustainability is an important consideration moving forward for this nomenclature to become and, once established, remain useful for Member States and other stakeholders. The creation of a new nomenclature system will require significant resources, both financial and in the form of technical expertise. Member States who already utilise an existing nomenclature, will have additional costs to accommodate another nomenclature. More importantly, manufacturers who supply to various markets globally will need to label and categorise their medical devices in a number of different ways, adding to costs for supplying medical devices.

4 – Provide an overview of the involvement and feedback the WHO has received from medical device manufacturers and industry stakeholders thus far in the process in the comparative analysis and the identification of impacts of a new nomenclature, including any technical barriers to trade. We encourage the WHO to be more transparent with these efforts and engage in a broader multi-stakeholder consultation.