Standardization of medical devices nomenclature

And IFMBE's intervention

Marc Nyssen, Maurice Page

Introduction

WHO's Executive Board 148 took place in Geneva as a "virtual meeting", January 19th – January 26th 2021. Marc Nyssen and Maurice Page registered and were accepted as IFMBE representatives. In particular point 11 of the agenda required our attention and intervention:

11. Standardization of medical devices nomenclature
Document EB148/13

The agenda handling was rather confusing with modifications happening the day self so that continuous attention was required; agenda point 11 was even not mentioned on the Saturday "Programme of work" that was published for Saturday 23rd, although corrected later.

Standardization of medical devices nomenclature was treated together with the agenda point 10:

10. Substandard and falsified medical products

point 10, only two NGO's had sent in a statement, for point 11, IFMBE was the only one, please note also that NGO speakers are given only one minute to make their contribution, therefore it must be very short and focused on the main points.

Comments by WHO member states (EB members and non-EB members)

After a brief intro by the chairman, comments of member states were immediately summoned, here we present a brief summary of the remarks they made.

Austria: recognizes the importance of the need for a standard medical devices nomenclature

Russian Federation: mentions the support for the need for a standard medical devices nomenclature

Australia: acknowledges the importance of this topic but warns for the risk of confusion created by the introduction of yet another nomenclature

India: stresses the need for an international forum on medical devices

United Kingdom: states that medical devices are a complex matter and the need to involve the "regulators" , concretely via the engagement of the IMDRF forum and UK wants clear and in-depth explanations why existing nomenclatures are not satisfactory

Israel: only comments on "substandard and falsified medication"

USA: about nomenclatures, requests the secretariat to add an analysis about the concerns about existing nomenclatures and regrets the lack of a briefing towards the Member States about this topic. Also the lack of involvement of regulatory bodies is regretted; why not use the GMDN? There is need for harmonisation with

the regulators forum.

Colombia: Nomenclatura is an important matter.

Korean Republic: mostly on falsified medication, also mentions nomenclature is important.

Oman: concerns about falsification only.

Indonesia: applies a system with license numbers and local nomenclatures for requests for offers regarding medical devices; acknowledges the need for international harmonisation but sees many obstacles in several countries.

Germany: lists the 8 fundamental requirements / characteristics that an international medical device nomenclature must fulfil:

1. global, normative by WHO
2. acceptance by regulators
3. stable, without changes
4. freely available
5. available to everybody
6. accessible to small innovative companies
7. transparent, as public good, not private
8. multi-lingual.

Moreover he stressed: « not outsourced »; for regulators by regulators », not for private interests dominated by industry » and expressed appreciation for WHO's work, above private interests.

Brazil: requires overlap with GMDN, which is now freely available since 2019, so there is no need for a new nomenclature.

Thailand: supports the WHO's actions regarding medical devices nomenclature standardisation.

Canada: OK with the goal, but concerns with the creation of incidental confusion, as WHO's efforts are not known to regulators, need of involvement of the Intl. Med. Dev. Regulatory Forum; also not clear with the concerns WHO expresses about existing nomenclatures: please elaborate on these shortcomings.

Zambia: only about falsified medicines

Turkey: only about falsified medicines

Spain: only about falsified medicines

Dominican Republic: on covid-19 and welcomes back USA; did not know we were on Agenda Point 10 and 11?

Austria (2nd intervention): representing EU and European Member States: requests the Secretariat to hold a Forum on the nomenclature topic.

IFMBE was the only NGO that had sent in a statement, following statement was made (within the one minute time limitation for NGO contributions):

Statement regarding
WHO EB-148 agenda item 11:
Standardization of medical devices nomenclature

Made by Prof. Marc Nyssen and Maurice Page
on behalf of:

The International Federation for Medical and Biological Engineering (IFMBE)

STATEMENT: Dear Chairperson, Director General, distinguished Delegates, ladies and gentlemen,

IFMBE fully supports WHO's proposal to adopt the European medical device nomenclature once it will be finalized.

As IFMBE counts among its member associations biomedical and clinical engineers world-wide, greatly needing a freely usable and well managed nomenclature as a cornerstone for sound management and maintenance of medical devices.

We are available to join WHO in its efforts to finalize, deploy and maintain the needed standardized medical device nomenclature, by proposing the assistance of representative experts among which several from our European member societies.

IFMBE intends to actively participate in the Nomenclature subgroup of the Medical Device Coordination Group MDCG.

This should be done now.

Thank you for your kind attention.

WHO Secretariat's response by Assistant Director General Dr. SIMAO:

States that WHO is very committed to the subject of the nomenclature for medical devices, thanks Member States for their guidance on this matter, states that this is a complex matter due to more than 7000 types of medical devices in usage, while more than half of the member states don't have a nomenclature in use. Moreover she mentioned GMDN and stressed that this nomenclature does not fulfil at all the countries' requirements. She finally stated that discussions with IMDRF should resume and promised briefings with member states on this matter.