Classification and Nomenclature of Digital Medical Devices: What Should We Know?

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INTRODUCTION

Digital and mobile technologies bring the promise to reshape the healthcare sector, and to some ex-tent the process has already started. However, digital healthcare technologies comprise a wide range of products and solutions, from telemedicine services to software products with medical purpose to be used by laypersons. In order to effectively protect patients' health, it is crucial to achieve consensus on definitions, nomenclature and a risk-based classification, based on which subsequent regulatory requirements depend.

Software that is intended to be used, alone or in combination, for a purpose as specified in the Medical Device Regulation (MDR) [1] or in vitro diagnostic medical device Regulation (IVDR) [2] is qualified as Medical Device Software (MDSW) [3]. MDSW is a very broad and heterogenous category: it comprises stand-alone software, which has its own intended medical purpose, thus meeting the definition of a medical device (MD) or in vitro diagnostic medical device (IVD) on its own or it may drive or influence a hardware MD, in addition to having a medical purpose on its own. This, along with the fact that existing EU level legal norms cannot consider either fundamental local aspects such as reimbursement policies or future developments, calls for further classification.

The aim of this work is to draw a subclassification of MDSW, along with a clarification on nomenclature and definitions, with view to identify categories for which reimbursement policies may be put in place and, although at first sight MDSW seem to be fully covered by existing EU Regulations and guidelines, highlighting the categories overlooked by existing legislation. The analysis may also help consumers and healthcare professionals to address potential oversimplification surrounding medical apps.

CLASSIFICATION OF MDSW

A first level of classification of MDSW, which has huge impact on reimbursement policies, can be drawn considering, on the one hand, MDSW intended by the manufacturers to be used by healthcare professionals and, on the other hand, MDSW intended to be used by laypersons (patients, caregivers). The latter category includes MDs that, although now not reimbursed by the National Health System, should be evaluated for reimbursement in the future. The software products in this category can be either stand-alone or connected to smart wearable devices and may be called ➡ **Patient-managed Digital Medical Devices (PDMDs)** (Figure 1).

As a second level of classification, the specific medical purpose should be considered. Indeed, **PDMDs** can provide information to be shared with a physician or to trigger a healthier lifestyle (e.g. blood glucose meter software), in which case they perform a diagnostic function, although it may lead to a therapeutic decision (Diagnostic **PDMDs);** or they can perform a direct therapeutic function, as in the case video game; or cover one of the other medical purposes listed in the MDR.

In the case of a direct therapeutic function, they should be called **Digital Therapeutics (DTx)** (Figure 2). Analysis of the legal status of **DTx** is particularly relevant, as some of these products are entering the EU market, but they still seem to be overlooked by existing legislation, in particular by Rule 11 of the MDR which focuses on software intended to provide information which is used to take medical decisions for diagnosis or therapeutic purposes, and does not seem to include software with a direct therapeutic effect, such as **DTx** .

Figure 2. Different levels of classification of Medical Device Software (MDSW), extrapolated from the MDR [1], MDCG guidance [3] and IMDRF guidance [4].

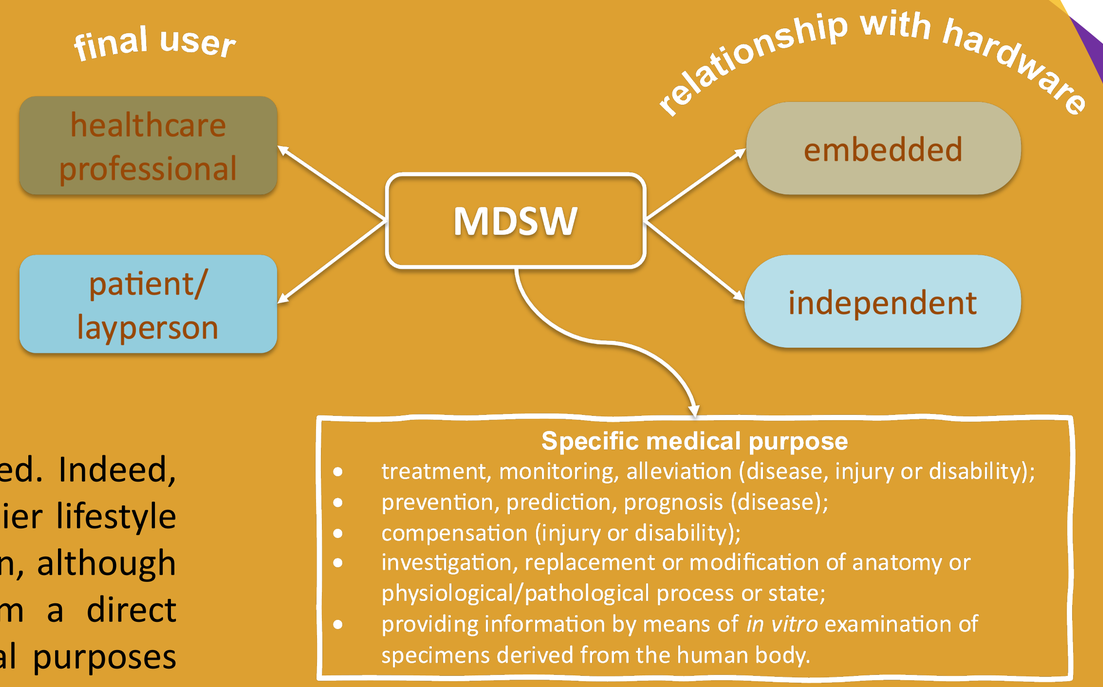
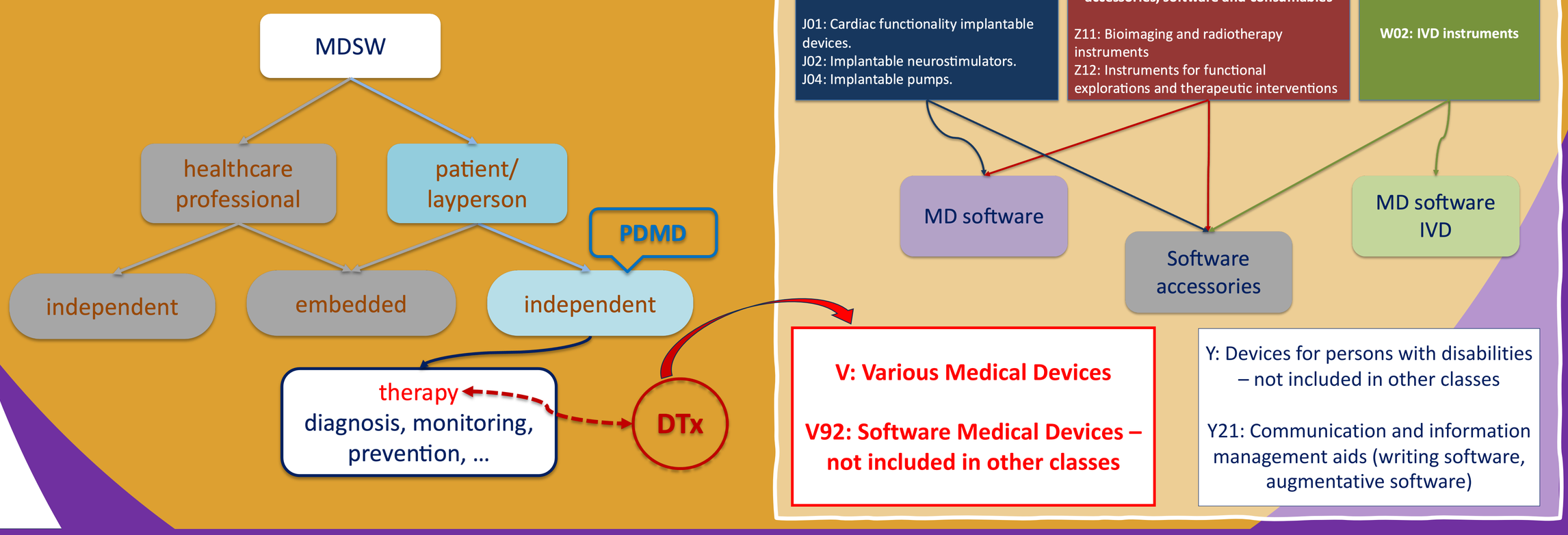


Figure 1. Classification of Medical Device Software (MDSW) integrating the MDR [1], MDCG guidance [3] and IMDRF guidance [4]. PDMD = Patient-managed Digital Medical Devices; DTx = Digital Therapeutics



CONCLUSION

While all DPMDs are Medical Devices (or in vitro Diagnostic Medical Devices), they are not all addressed with the same strength by existing regulations and guidelines. In particular, MDR Rule 11 focuses on software that is used to take medical decisions for diagnostic or therapeutic purposes, but seems to exclude direct therapeutic action, as well as other specific medical purposes (and this has direct consequences on classification). Analogously, in the European Medical Device Nomenclature EMDN) a class is not provided to accommodate DTx, which will eventually be comprised in class V: Various Medical Devices. To foster innovation in the field and as a basis for local regulations on pricing and reimbursement policies of PDMDs, an update of, at least, the MDCG Guidance and the EMDN is needed.

REFERENCES

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