Ricciardi W (2020) 01s: 16-18
https://doi.org/10.36118/pharmadvances.01.2020.04s

COMMENTARY Open Access

Commentary on "The concept of non-pharmacological mechanism of action in medical devices made of substances in practice: what pharmacology can do to promote the scientific implementation of the European medical device regulation"

(Commentary on Racchi M, Govoni S, The concept of non-pharmacological mechanism of action in medical devices made of substances in practice: what pharmacology can do to promote the scientific implementation of the European medical device regulation, Pharmadvances, 2020)

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Advances in medical device technology have been very important in recent years, resulting in an increased number of medical devices (M- Ds) estimated approximately in 500,000 different devices in Europe (1). The aims of EU policies with respect to public health include measures to establish and guarantee high standards of quality and safety for MDs. In this context, a new regulation was approved in Europe in May 2017: the Medical Device Regulation (MDR) (2). This new EU MDR (EU 2017/745) goes into effect on May 26, 2020 and governs all aspects of a MD's lifecycle. The new regulation aims to increase and strengthen confidence in the MDs' safety among EU healthcare professionals, patients and consumers.

The purpose of the regulators was to establish a more robust EU legislative framework to revise the current system for MD regulation in Europe. Historically, devices in Europe do not follow an approval process, but receive a conformity assessment by notified bodies, which, if approved, leads to the issue of a CE mark. In the conformity assessment, the goal to be achieved was "safety and performance as expected" (3). This goal is significantly different from the guarantee of safety and efficacy, that represents a standard requirement for public health. Under MDR, the requirements for devices approval, especially for those at high risk, in terms of clinical evidence will become greater to protect our patients.

Another important element of the new regulation concerns the improvement of transparency (4). In fact, the MDR requires that the manufacturer has to publish a summary of safety and clinical performance (SSCP) for

high risk devices and keep it updated on an annual basis. SSCP documents will be available on the European Union medical device database (EUDAMED). This database, previously accessible only to regulators, will now be publicly accessible. This represents an important element of the new system and underlines the need for transparency that is essential to ensure and support informed decisions on the use of new MDs.

In addition, the new MDR provides for the collection of post-marketing clinical follow-up data by manufacturers who will have to publish the results in a periodic safety update report. In parallel, vigilance procedures should be in place to allow the collection and judgment of adverse device events in clinical practice (4). Furthermore, the MDR improves the traceability of MDs by Unique Device Identification number and implant card for some implantable devices (2). Those described and others among the new indications of the MDR promise to offer greater safety for patients. Furthermore, one of the major changes of the MDR is linked to the extended definition of the term "medical device" that now will include products aimed to perform prediction and prognosis of diseases as well as those which do not have a direct medical intent (e.g. disinfection and sterilization products, fillers, condoms, software or implanted devices used for esthetic and cosmetic purposes) (5). In this innovative element characterizing the new regulation there is the inclusion of the 'Medical Devices Made of Substances'. In particular, Regulation 2017/745 identifies a specific classification rule (Rule 21: Substances or combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed) for MDs made of substances (2). This rule introduces MDs made of substances which need to be absorbed in order to achieve their intended action. This is an important similarity with medicinal products that requires the better definition of the differences between the two categories, in order to promote innovative interventions for the treatment of both established and new conditions.

These treatments differ from drugs and rather than having a pharmacological mode of action, they deliver their benefits through other means of action (such as chemical, physical, physiological), which generally have a particularly low risk profile.

Certainly, MDMS represent investments, research and innovation in health but need adequate regulation. Even the MDMS must be supported by scientific evidence for their commercialization. For this reason too, the new MDR represents an important landmark in the regulation of MDs in Europe. Therefore, it will be essential to promote a clear and homogeneous interpretation of the essential terms at the base of regulatory assessment of substance-based products. This represents a challenge for pharmacologists in order to face a complex definition problem both from a theoretical and experimental point of view (6). To give true effect to the MDR, all interested parties need to work together to achieve the high level of safety that patients expect. All these elements will also be necessary with a view to the value-based resources's allocation in our healthcare systems Healthcare. Systems today are under pressure to optimise the use of limited resources, as they face increasing costs associated with technological developments, increasingly complex patients with multiple chronic conditions and changing clinical practice. To meet the challenge to ensure the financial sustainability of universal healthcare and find resources to fund true innovations it becomes essential to switch resources from lower value to higher value healthcare (7). In this context, an useful evidence-based and value-based tool is represented by Health Technology Assessment (HTA). According to WHO (8) HTA is the systematic evaluation of properties, effects, and/or impacts of health technology. Its main purpose is to inform technology-related policy-making in healthcare, and thus improve the uptake of cost-effective new technologies and prevent the uptake of technologies that are of doubtful value for the health system.

HTA as a decision support tool has been most frequently formally established to evaluate pharmaceuticals (9). However, this methodology has been gaining interest also for MDs. Health technologies are essential for a functioning health system. MDs in particular are crucial in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation. For this reason, it will be essential to improve the application of the HTA methodology, also applying it to the evaluation of the MDs.

This is to achieve the WHO's strategic goal to ensure improved access, quality and use of medical products and technologies (8).

This objective can be achieved with the collaboration and skills of all stakeholders involved: healthcare professionals, institutions, regulatory bodies, policy and decision makers, industry, citizens and patients.

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