LIFE SCIENCES BRIEFING

Regulatory Consideration for Software/Hardware Medical Device Combinations

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Regulators are approving more medical device software (MDSW) every year (e.g., the U.S. Food and Drug Administration cleared 135 MDSWs in 2023, 56% more than 2022). One in four medical devices is estimated to be either MDSW themselves or contain medical device software. The Medical Device Coordination Group (MDCG) published guidance in October 2023 explaining the regulatory options available to manufacturers combining MDSW with hardware or hardware components. This post summarizes the key takeaways from the guidance.

Types of MDSW and hardware combination

It is commonplace for MDSW apps to receive and process data inputs from hardware or hardware components to produce a medical or therapeutic output. These hardware components can be *external*, providing input data to a MDSW app. The MDCG guidance gives the example of a dermal patch with an embedded sensor. Upon purchase of the dermal patch, a customer is prompted to download a MDSW app and pair the two. The sensor collects and relays data to the MDSW app that processes it and creates medical outputs that are displayed to the user and can be shared directly with a healthcare professional.

Alternatively, the hardware can be *incorporated* within a smartphone or wearable connected to a MDSW app. Such a device could be a watch that incorporates a sensor that collects the relevant data. Users then download a MDSW app that processes the data and displays the monitored medical information.

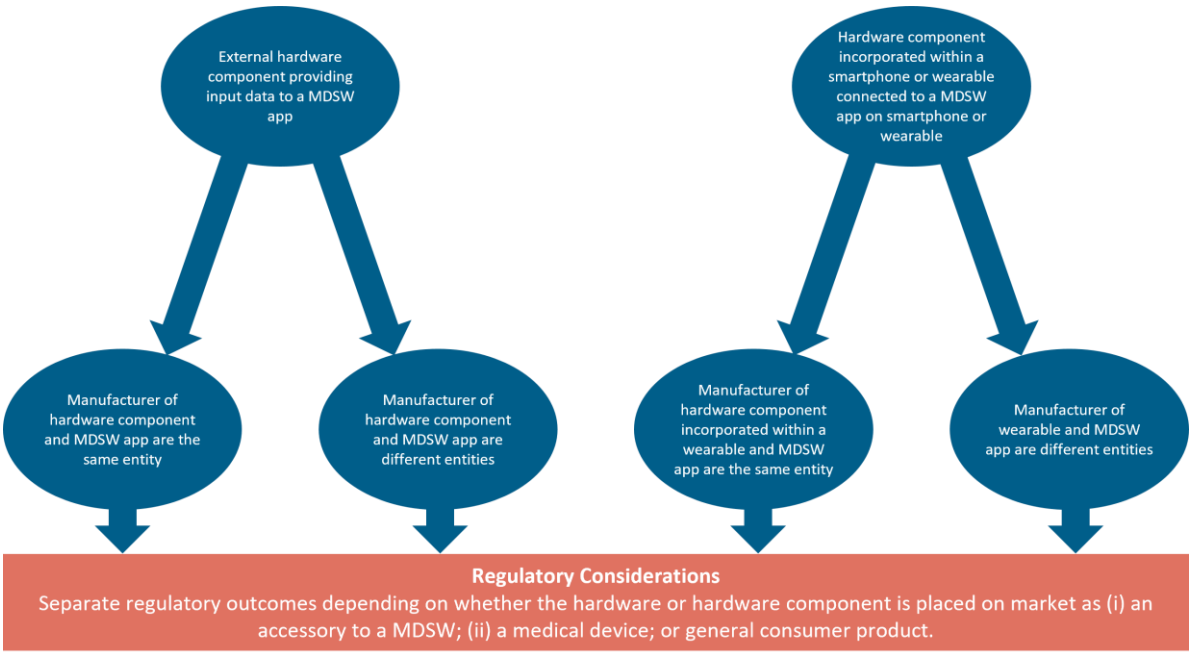

Figure 1 - Overview of MDSW and hardware combinations

In both of the above examples, and as portrayed on Figure 1 above, the manufacturers of hardware and MDSW apps can be either the same or a different entity.

Regulatory considerations

The regulatory considerations for manufacturers of devices combining MDSW and hardware depend on the regulatory route by which that hardware or hardware component is placed on the market. The guidance outlines the following three options:

- **Option 1:** The hardware or hardware component is placed on the market as *an accessory to a MDSW*.

- **Option 2:** The hardware or hardware component is placed on the market as a *medical device* either (i) as part of a system (*Article 22, EU MDR*), (ii) as a combination with another medical device (*Article 2(1), EU MDR*), or (iii) as an integral part of medical device.

For options 1 and 2, the guidance reiterates that any manufacturer of a medical device or of an accessory to a medical device must demonstrate compliance with the provisions of the MDR, for example, with the MDR Annex I on general safety and performance requirements (the GSPRs). Furthermore, manufacturers of MDSW are required to verify safety features, compatibility, and interoperability of medical devices with which the MDSW works in combination. Importantly, when the hardware itself is compliant under MDR as a medical device or an accessory to a medical device, the MDSW manufacturers may rely on the compliance of the hardware with the MDR including the GSPRs when used according to the MDSW's intended purpose. As part of the risk management and postmarket surveillance process, the MDSW manufacturers must ensure that sufficient systems are in place to identify and report incidents relating to the hardware, hardware component, or accessory.

- **Option 3:** The hardware or hardware component is an integral part of a *general consumer product or wearable digital product* and is not a medical device or an accessory to a medical device and has no intended medical purpose (*Article 22(4), EU MDR*).

When the hardware is not a medical device, the manufacturer of the MDSW cannot rely on its compliance with the MDR, and the hardware must be subject to the relevant conformity assessment procedure. Pursuant to Article 22(4), EU MDR, "Where the system or procedure pack incorporates devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose […] the system or procedure pack shall be treated as a device in its own right and shall be subject to the relevant conformity assessment procedure [.]"

Accordingly, the guidance provides four primary considerations for products in this category. First, in the MDSW's *technical documentation*, the MDSW manufacturer needs to outline all the relevant non-medical-device hardware or hardware components intended to be used in combination with the MDSW. Second, the MDSW manufacturer needs to draw up a detailed *risk management plan* for both the MDSW and the hardware that may influence the safety and performance of the MDSW. Third, *clinical*

evidence must be provided for all configurations in which the MDSW and combination hardware could be used. Fourth, the MDSW manufacturer is responsible for postmarket surveillance of both the MDSW itself and the hardware that may affect MDSW safety, performance, and compatibility.

Manufacturers should be cognizant of these different scenarios when developing an MDSW/hardware combination product. In particular, manufacturers should be cautious of the scenario described in Option 3, in which a hardware component, which itself has no intended medical purpose and is not CE marked, is intended to be used in combination with MDSW that does have an intended medical purpose. In such circumstances, the combined product will need to be subject to a conformity assessment.