Transition Management Tool: From MDD to MDR

Whilst doing her best in terms of accurate representation of the new Regulation on medical devices, the author reserves the right not to be held responsible for the correctness, completeness and adequacy of the content provided in the text. Accordingly, readers may not hold the author liable.

In this paper, we present seven techniques for a smooth transition of manufacturers (MF) to the new EU regulatory framework on medical devices — REGULATION (EU) 2017/745 (new Regulation).

It is to be noted that none of the techniques presented here is applicable in each and every case. There might even be some extreme cases where *none* of the techniques can be applied. However, it can be claimed that, on average, more than one technique can be applied to each type of device.

Technique n°1: Customisation

Article 21 of the new Regulation precludes member states to create obstacles to put custom-made devices in the market provided certain conditions are fulfilled.

The requirements under the new Regulation are lower (except for certain aspects of Class III custom-made devices) than those for ordinary devices. In particular, the conformity assessment burden is substantially reduced.

On top of this, there are more and more devices for which the needs of patients differ, especially when it comes to implantable devices. Based on a prescription requesting personalisation, a manufacturer can decide to personalise and adjust a device so that it perfectly fits a specific patient, e.g. in terms of length, thickness and material (allergy-friendly). This may shortly become even more economically advantageous in view of the future widespread of **3D-printing**.

However, the manufacturer needs to keep in mind the fact that only custom-made devices, which are not mass-produced ("*industrial scale*") or in the framework of an "**industrial process**", can follow lighter provisions of the new Regulation. The Court of Justice of the EU (ECJ)…

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Technical documentation (Annex II and III)	NO	YES	YES

Conformity assessment procedures	YES for	YES –…	YES –…

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2)
3)
4)
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8)

Technique n°2: Selling 3D-Datasets Instead of Devices

3D-printing is becoming increasingly useful and advantageous for the sector of medical devices because it facilitates a) manufacturing of complex medical devices with multiplex elements, in addition to saving costs compared to the traditional method; and b) meeting particular needs of a specific patient, i.e. customisation of medical devices such as tracheal splint, artificial eyes, maxillofacial prosthesis, etc.

There are success stories with regard to 3D-printing, and it is expected that the technique will spread further[1]. First of all, 3D-printing is a manufacturing technique like any other technique, but there is something special about this particular system.

3D-printing might open the door to a new business model for some manufacturers of medical devices. It might also offer the possibility to sell blueprints/datasets instead of physical devices,

[1] http://www.digitaljournal.com/article/345215

thus not being a "manufacturer" in the meaning of the new Regulation, but leaving physical manufacturing to the users, patients or independent service providers involved in these. However, it is not certain yet whether and to what extent this possibility exists. It is not yet clarified by the courts whether a virtual blueprint/dataset (instructing the 3D-printer what to print) is legally to be considered a medical device or not. Moreover, the new EU Regulation remains silent when it comes to a device manufactured through the 3D-printing technique. The new Regulation covers "software", however dataset is not considered software.

It remains open for the courts to decide at which stage of the process of 3D-printing a product is to be considered as the end product, i.e. a medical device…

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Technique n°3: Use of (own) Distributors

Article 120 (4) is among the transitional provisions of the new Regulation, which prolongs the lifecycle of "old regime" medical devices after the application date of the new Regulation (25 May 2020). It permits that devices

- lawfully placed on the market prior to 26 May 2020; or
- certified under the Directives prior to, but placed on the market from 26 May 2020

continue to be made available on the market (put into service) until 27 May 2025.

The meaning of the expressions used in the regulatory text such as "placing on the market" and "making available on the market" differs and this distinction is important as it implies the extent

to which the requirements of the new Regulation need to be respected.

“Placing a device on the market” is a subtype of “making available on the market”, which is defined as any supply of a device for consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. This includes selling, renting and providing access to devices, including via the Internet. It also can happen many times. Contrary thereto, “placing on the market” can only occur once, because it is defined as the first making available on the EU market. “Placing on the market” implies a decision of a manufacturer or of an importer to give away a product, either to clients or to distributors or to provide access to the product otherwise.

Thus, if a product has been placed on the market before 26 May 2020, only certain obligations of the new Regulation apply, e.g. post-market surveillance, vigilance and registration obligations. However, a product as such must not comply with the new Regulation and the “old” certificates and conformity assessment procedures of the Directives suffice.

Given that devices placed on the market before 26 May 2020 fall mostly under the old legal regime, the manufacturer might have an interest to…

Technique n°4: Singling out Devices for Clients

Point 14 of the Commission Interpretative document: *Placing on the market of medical devices*, issued on the occasion of the entry into application of Directive 2007/47/EC, contains a hint which can be used as an independent legal transition management technique,... This considers that a device, which has not yet left the manufacturer's premises but was singled out in view of a concrete client based on a contract and identified as such, as already placed on the market as "the product was transferred from the stage of manufacture". Hence manufacturers can sell already manufactured devices to clients e.g. hospitals, distributors etc., prior to 27 May 2020, but keep the devices in their premises in a separate area or on a separate shelf or singled-out in another unequivocal way.
Evidently, this technique can best be used for devices which…

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Technique n°5: Use of Certificates Issued Under the Directives

This technique is in line with the transitional provisions of the new Regulation, namely its Article 120(3). This provision allows using the certificates issued under the Directives after the application date of the new Regulation (25 May 2020)—provided certain conditions are fulfilled. For instance, the CE-marketed device needs to continue to comply with the Directive and there may not be any significant changes in the design and intended purpose. At the same time, certain provisions of the new Regulation apply, i.e. post-market surveillance, market surveillance, vigilance, and registration of economic operators and of devices. We would only add—in a situation where the Eudamed is not available—the respective part cannot be applied.

The "hybrid regime" mentioned above gives privilege not only with regard to the certificates as such but also with regard to the substantial requirements (the Annex I of the Directives applies, not Annex I of the new Regulation) and …

Technique n°6: Certificate of Free Sale to Prepare Sell-off in Third Countries

A manufacturer might consider **stockpiling** free sales certificates under the Directives and have them renewed quite closely before the sell-off in 3rd countries. That would be in early 2020, late 2019.
As a side note, "the most recent" free sale certificates will have a higher likelihood to be recognised by the 3rd countries.

Here we present two options:

Technique n°7: Insisting on Equal Treatment of Tenderers

A manufacturer who is using the technique of the distributor as a buffer or the "old" certificates beyond 25 May 2020 (the new Regulation application date) might be confronted with public tenders that call for conformity with the new Regulation. Such a manufacturer and their offer might be rejected for this particular reason.

The Court of Justice of the European Union (ECJ) has ruled…

Technique n°8: Product Identity Planning

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In the view of generating new **clinical data**, a manufacturer has the possibility to add several small modifications to a device, e.g. regarding chemical composition of components, or design modifications. When doing so, he should not combine two or three change parameters but add only one modification at a time, unless one modification requests necessarily another.

The idea of the present technique is not only to cut big changes into series of small changes, but to declare each time a new product identity and generate new clinical data by post-market clinical follow-up (**PMCF**), thereby avoiding the need to undertake a new clinical investigation. By a series of small changes which are carefully explored by PMCF, a manufacturer can generate the clinical data needed and can avoid costly and cumbersome clinical investigations which take 2–5

years. Clinical investigations take place in a climate of legal uncertainty and will not happen without many problems. Nobody knows yet how the Article 62 of the new Regulation will be applied in future.

Applying this technique, the manufacturer needs to consciously plan…

Technique n°9: Public Interest Provision

Article 59 of the new Regulation authorises member states to exempt devices from the severe requirements of the new Regulation, i.e. from the need to undergo a conformity assessment procedures governed by Article 52. These devices may be placed on the market / put into service on grounds of public health or patient safety or health.

The reasoning behind Article 59 is to avoid shortage of medical devices, which would—already in small percentages—lead to a serious distortion in the normal functioning of hospitals and result in negative consequences for the patients. Accordingly, the provision is beneficial for both users and producers. Nevertheless, it is not up to manufacturers to call for the application of this provision.

However, a manufacturer can…

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Dear reader,