

French breast implants, the Medical Device Regulation, and a theoretical case study

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Abstract

The 2010-2011 Poly Implant Prothèse scandal triggered a review of the Medical Device Directive. This resulted in a new Medical Device Regulation that was approved this year. It contains many changes, and many questions will arise when medical device companies start certifying their medical devices per the new regulation. The solution to many unclear cases will depend on how the new regulation is interpreted. Medical writers can play a key role by creating precedents that are coherent, well documented, and useful for all stakeholders.

Poly Implant Prothèse (PIP) was a French manufacturer of silicone gel breast implants. The company was founded in 1991 and liquidated in 2010 after it became public that they had been using low-quality industrial silicone gel for the implants. The company sold an average of 100,000 sets of breast implants per year over 20 years. After a site inspection in 2000, the FDA prohibited sale of PIP's silicone breast implants on the US market, which led to a considerable decrease in sales worldwide. PIP reacted with dramatic cost cuts and by replacing the high-medical quality silicone gel with low-quality industrial silicone without following the regulations for production of medical implants or performing preclinical tests. The new implants had a 500% higher risk of breaking or losing content and were considered to be related to



several deaths and to have caused breast cancer. December 23, 2011, the French government recommended surgical removal of PIP breast implants, affecting 30,000 women in France.¹ An estimated 30,000 - 40,000 women were affected in the UK, 1,000 in the Netherlands, 2,500 in Sweden, and many women in other European countries, Latin American countries, and Australia.² After this scandal, breast implants were reclassified as Class III (high risk) medical devices.

PIP was not the only "bad guy" in the market: the M-Implants manufactured by the Dutch company Rofil and the TiBREEZE breast implants manufactured by the company formerly known as GfE Medizintechnik GmbH were also found to be of low quality. Obviously, something in the marketing approval process and post-market surveillance was wrong and made it easy to get low quality devices approved.

The advent of the Medical Device Regulation (MDR)

As a result of the PIP scandal, the public, European governments, and competent authorities all asked for more transparency in the

medical device market and an improved marketing approval process. Finally, in 2011-2012, the competent authorities started working on the topic, resulting in the MDR in 2017,³ which ultimately should increase the patient and user safety.

As I mentioned in my other article in this issue ("The Medical Device Directive: a necessary step towards more patient and user safety", page 25), how the MDR will affect the medical device market and whether it will improve the patient and user safety remains to be seen. This depends on how the notified bodies and the competent authorities interpret each and every word, paragraph, and definition in the directive's text. Just only one word might make quite a difference.

A case study

To illustrate this uncertainty, I would like to go through one "case study". A small but interesting difference between the MDD and the MDR is found in the Annex 1 Essential Requirements under the General Requirements:

"...devices can be made available to the market if they are safe and effective..."



The word “effective” was not used in the MDD, which instead said that a device could be marketed if it was safe and performed according to its “intended use” as defined by the manufacturer. Does this mean that manufacturers will have to demonstrate clinical efficacy when the intended use is intimately related to the treatment of a specific disease or symptom as is the case of cardiac pacemakers? Will medical device companies be more cautious when defining the intended use of new devices? For example, will the implantable pump that delivers intrathecal baclofen now do only that and no longer “relieve spasticity symptoms due to cerebral palsy”?

Assume that a manufacturer wants to market a new and revolutionary wonder device that “stimulates the increase of factor XXX thereby shortening the healing time of acute non-infected wounds”. What type of efficacy evidence will be required by the notified bodies? Only in vitro studies that show that the device effectively stimulates the increase of factor XXX? Or at least one serious clinical study that shows that the healing time of acute non-infected wounds to be shorter when compared to the standard treatment? As a scientist, I would answer, “Yes, exactly that”. Just for the sake of understanding what this means, try to define what an acute non-infected wound is. One idea: surgical wounds are acute and non-infected (or at least should not be!). So, it is clear: the manufacturer should run a clinical study with surgical wounds ... but, in which surgical wounds would a clinical study

make sense? The surgical wound after a thoracotomy? Or a limb amputation? Or a simple appendectomy? Should the clinical study include thousands of patients with all types of surgical wounds? Will the manufacturer be able to derive from one surgical wound to all the rest? Or will the intended use end up being “stimulates the growth of XXX thus shortening the healing time of the surgical wounds that result of the following procedures: X, Y and Z”?

One could argue that the same would apply to a new wonder drug, with the same difficulties arising when the correct set of pre-clinical and clinical studies must be defined, but there is a great difference: pharmaceutical companies have a different financial capacity, years of experience in evidence-based medicine, infrastructure to provide study centres with investigational products, and very long planning processes. Medical device companies are often small, have very little experience in clinical research, investigational devices are often only a few prototypes, and the manufacturers have very short timelines in their marketing plans. So, the wonder device manufacturer will probably think twice before embarking on such an adventure.

You might think that this is a very specific case (and a theoretical one), but as I mentioned before, this “case” is the result of only a one-word difference. Most probably, a long list of questions will arise from the many differences between the MDD and the MDR. I believe that the answers will slowly crystallise from sets of precedent cases and accumulated practical experience in working

with the authorities and the notified bodies.

How medical writers can help

Medical writers can play a significant role. What and how the notified bodies and competent authorities decide for difficult cases will be the result of the quality of the documents provided by the manufacturers and us, the medical writers responsible for writing clinical evaluations, clinical study plans, and market surveillance documents. Complying to the most possible extent with the requirements of the MDR and clearly explaining, in specific cases, why we cannot will be key to creating sets of precedent cases that are coherent, well documented, and useful for all stakeholders.

References

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Author information

Claudia Frumento holds a PhD in medical technology. She has more than 17 years of experience in international medical device corporations and has been a freelance medical writer since 2006. She leads the EMWA workshops on medical writing for medical devices.