

Regulatory Matters

SECTION EDITORS



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Editorial

Two years into the pandemic outbreak, our lives have changed one way or another. The pandemic not only has impacted our lifestyle, it might also have impacted our career at some level. We might find ourselves needing to venture out onto new paths, or to explore new areas within the existing paths. In this issue, we are pleased to have our first piece by Tiago Silva who talks about exploring regulatory writing for medical devices from the perspective of a

pharmaceutical regulatory medical writer. Tiago assures us that despite the core differences between the pharmaceutical and medical devices worlds, venturing into a medical device project may not be as daunting as we fear, as we already possess the necessary transferable skills that will get us through the process more easily.

The regulatory landscape of medical devices has continued to evolve during the pandemic. A new EU medical device regulation (MDR) has been fully implemented within the EU since May

2021. How is Switzerland, which is not part of the EU despite its central location in the continent, coping with the changes as a result of the new regulation? Our second piece by Joan D'souza throws some light on the Swiss medical device regulations from the Swiss Medical Devices Act to the conduct of clinical trials for medical devices in the country.

We hope you enjoy reading and derive useful insights from these articles.

Zuo Yen Lee and Clare Chang

From pharmaceuticals to medical devices: What are the transferable skills regulatory medical writers can rely on?

For several years, I have been a regulatory medical writer working with pharmaceutical medicines. Medical devices, however, is a field in which I have no experience. What would happen then, if suddenly a medical device document landed on my lap, along with all the regulatory timelines and constraints regulatory medical writers are all too familiar with? This certainly would not be an easy task, as many differences separate the two worlds. Fortunately, medical writers are used to finding creative solutions for all sorts of challenges on a routine basis. There are several skills an experienced pharmaceutical regulatory medical writer can transfer to developing a medical device document, even without much prior experience in this field.

Differences between pharmaceuticals and medical devices

The main differences between these two industries are briefly summarised below, pointing out some key topics that pharmaceutical medical writers may want to research before venturing on a medical device project.

Concepts and terminology

Medical devices have specific concepts, definitions,

and terminology. This includes the actual names of the regulatory documents that, although similar in scope to their pharmaceutical counterparts, have a different designation. Provided below are a few examples:

- Clinical investigation vs. clinical trial or study
- Clinical investigation plan (CIP) vs. clinical study protocol
- Clinical investigation report (CIR) vs. clinical study report (CSR)
- Clinical evaluation report vs. clinical overview and clinical summary (Modules 2.5 and 2.7 of the Common Technical Document)

More specific medical device terminology and concepts are discussed in the previous publications of Doerr et al. (2017)¹ and Billiones and Thomas (2019).²

Type of product, clinical development, and studies performed

According to the Medical Device Regulation 2017/745/EU,³ medical devices are defined as any kind of instrument, apparatus, appliance, software, implant, reagent, material, or other article used for specific medical purposes that do not achieve the principal intended action by pharmacological, immunological, or metabolic

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means, but which may be assisted in its function by such means. Naturally, being a different type of product compared to pharmaceutical medicines, their development is also different. Medical devices are conceived by medical and engineering experts to meet an identified clinical need. They are developed into prototypes tested at the bench and animal models and perfected before undergoing clinical investigation. Their clinical development is carried out at a faster pace and using smaller sample sizes than that for pharmaceutical medicines, which relies on a lengthier and more specific clinical development process through Phase I-IV clinical trials. The publication by Doerr et al. (2017)¹ further elaborates the main differences between the clinical development of pharmaceutical medicines and medical devices.

Regulations and guidance

Medical device development is governed by different regulations than pharmaceutical

medicines. In the EU, the Medical Device Regulation 2017/745³ is the main regulatory reference for these products. This regulation “harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market [...] sets high standards of quality and safety for medical devices by ensuring, among other things, that data generated in clinical investigations are reliable and robust and that the safety of the subjects participating in a clinical investigation is protected”. In other words, it states the requirements on the clinical development, marketing application, and post-marketing surveillance of medical devices (except for *in vitro* diagnostic medical devices, covered in the *In Vitro* Diagnostic Medical Device Regulation 2017/746).⁴

One key guidance is the international standard ISO 14155:2020,⁵ which establishes recommendations for the design, conduct, recording, and reporting of clinical investigations in human subjects using medical devices. This guidance also provides the template structures for key documents, such as the CIP, Investigator’s Brochure, and CIR.

Another important reference is the MEDDEV 2.7/1 revision 4,⁶ which establishes the main recommendations in the EU for the clinical evaluation of medical devices, including the development of the clinical evaluation report — the equivalent to Modules 2.5 and 2.7 of the Common Technical Document for pharmaceutical medicines.

The union of pharmaceutical medicines and medical devices produces combination/drug-device products (i.e., products that combine medicines, devices, and/or biological products).

Examples of combination products include pre-filled syringes or pens, corticosteroid inhalers, drug-eluting stents, and transdermal patches. According to the Medical Device Regulation 2017/745,³ combination products are regulated either under this regulation or under Directive 2001/83/EC of the European Parliament and the Council, and “the two legislative acts should ensure appropriate interaction in terms of consultations during the pre-market assessment, and of exchange of information in the context of vigilance activities involving such combination products”. When developing a combination product, both pharmaceutical and medical device regulations may need to be followed, and this should be addressed on a case-by-case basis.⁷

Transferable skills from the pharmaceutical to medical devices industry

Scientific knowledge and research skills

As a medical writer in an agency environment, I work with different pharmaceutical sponsors, indications, medicines, and regulations. It is not uncommon to start a new project on an indication or medicine that I know little about at first. Moreover, regulatory deadlines are often challenging, leaving writers little time to catch up with the scientific context of the project, which is necessary to tell an accurate and cohesive story in their document. Being able to quickly absorb and appraise new scientific information and

adapt to ever-changing realities is a core medical writing skill that is useful in both pharmaceutical and medical device industries.

Take the example of the combination product ABILIFY MYCITE® (Otsuka Pharmaceutical Co., Ltd/Proteus Digital Health), an aripiprazole tablet embedded with an ingestible sensor to measure medication compliance. If tasked with writing a CIR for it, I would divide my research into 2 components:

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- The pharmaceutical component (aripiprazole), which would be more familiar to me: the science behind the product, its development history, and the rationale behind this investigation.
- The technological component (ingestible event marker sensor) would require more research about the specific technological language and concepts. By applying the transferable skills in scientific research, synthesis, and critical appraisal, I could get familiar with this technology more efficiently and understand how this component works together with aripiprazole.

Knowledge of regulations, document templates, and guidance

A strong understanding of the International Council for Harmonisation (ICH) recommendations and applicable pharmaceutical regulations is required for medical writers working in the pharmaceutical industry. As stated above, most documents in the pharmaceutical



industry have their counterparts in the medical device industry that, despite some differences, have similarities in scope and even structure. This means that the writing of medical devices regulatory documents may not be as obscure as many medical writers who are used to working with pharmaceutical medicines might assume.

Say, for example, that I have been tasked to write a CIR for an investigation aimed primarily at comparing aripiprazole compliance with ABILIFY MYCITE® versus aripiprazole tablets alone in patients with schizophrenia and no detailed template or example CIR has been provided to me. Although I have never written a CIR before, I have written several CSRs for pharmaceutical medicines. I am familiar with the ICH E3⁸ guideline and the CORE Reference.⁹ Comparing the ICH E3 or CORE Reference with Annex D of the ISO 14155:2020

“...The writing of medical devices regulatory documents may not be as obscure as many medical writers who are used to work with pharmaceutical medicines might assume.”

(Table 1), a few things are noticeable:

- The ISO 14155:2020 is not as structured and detailed as its pharmaceutical counterparts, allowing for a more flexible approach, and
- The main sections (level 1 headings) are fairly similar. Using my CSR experience, I could plan the structure of the CIR and what to write in each section of the CIR, including writing important sub-headings, defining the level of detail in the text and the cross-references to other sections or external documents, deciding what important tables or figures to include, which source documents to use, and what to ask the subject matter experts.

For example:

- Section 6.1 of the CIR serves a similar purpose to Section 9.4 of the CSR, identifying the characteristics of aripiprazole and the

device component of ABILIFY MYCITE®.

- Section 6.2 of the CIR could include information similar to that in Sections 8 and 9 (excluding Section 9.4) of the CSR. The objectives, endpoints, assessments, and overall study design could be summarised using the ICH E3/CORE Reference as a structural reference.
- The ISO 14155:2020 only designates Section 7 for the investigation results. The ICH E3/CORE Reference could be used as a structural reference for level 2 and 3 sub-headings summarising the disposition of study subjects, results of the primary endpoints, secondary efficacy, safety, and other endpoints.

Project management and team leadership

As for pharmaceutical medicines, the development of medical device regulatory documents is part of a product development program that has its own timeline. They are also developed in a cross-functional environment, requiring regular discussion with and coordination of subject

Table 1. Structure of a clinical study report (CSR) based on the CORE Reference Version 1.0 versus clinical investigation report (CIR) based on ISO 14155:2020

CORE Reference: clinical study report (CSR)

1 Title Page	10 Study Subjects
2 Synopsis	10.1 Disposition of subjects
3 Table of contents	10.2 Protocol deviations
4 List of abbreviations	10.3 Data sets analysed
5 Ethics	10.4 Demographic and other baseline characteristics
5.1 IEC/IRB	10.5 Measurements of treatment compliance
5.2 Ethical conduct of the study	10.6 Extent of exposure
5.3 Subject information and consent	11 Efficacy and other evaluations
6 Investigators and study administrative structure	11.1 Efficacy results
7 Introduction	11.2 Results of statistical issues encountered during the analysis
8 Study objectives and endpoints	11.3 PK, PD, and other analyses results
8.1 Objectives	11.4 Efficacy results summary
8.2 Endpoints	12 Safety evaluation
9 Investigational plan	12.1 AEs
9.1 Overall design and plan	12.2 Analysis of deaths, other SAEs, and other clinically meaningful AEs
9.2 Discussion of study design, including the choice of control groups	12.3 Clinical laboratory evaluation
9.3 Selection of study population	12.4 Vital signs, physical examinations, and other observations related to safety
9.4 Treatment	12.5 Safety results summary
9.5 Efficacy and safety variables	13 Discussion and overall conclusions
9.6 Data quality assurance	14 Tables and figures
9.7 Statistical analysis methods planned in the protocol and determination of sample size	15 Reference list
9.8 Changes in the conduct of the study or planned analyses	16 Appendices

matter experts. Experienced pharmaceutical medical writers are used to running these projects like running a tight ship and are experienced in developing trusting relationships with the team, establishing roles and communication routes, and managing expectations. These skills are transferable to the medical device industry. For writing a CIR, the following could be proposed to the team from the start:

- Timeline: based on drafting, reviewing, approval, and publishing steps
- Data collection plan: based on source documents (CIP, statistical analysis plan, Investigator's Brochure), communication plan and route with subject matter experts' input, and identification of other sources. This also includes compiling and appraising information, identifying potential inconsistencies/conflicts, and proactively working toward their resolution.
- Meeting plan: kick-off meeting to present the project and align roles and expectations, data interpretation meeting to discuss the results and key messages of the investigation, and

comment resolution meetings to address outstanding cross-functional comments.

Technical writing skills

The objective, precise, lean, and unambiguous writing style used in pharmaceutical regulatory writing should also be applied in writing for medical devices. Pharmaceutical medical writers can transfer their technical writing skills to these new documents, keeping in mind the different terminology, ISO 14155:2020 recommendations for document structure, and applicable style guides.

Conclusion

There are significant core differences between the pharmaceutical and medical device industries that will require some level of adjustment by regulatory medical writers if they are to move from one to the other. Thankfully, our profession is one used to changes at a fast pace, whether in regulatory or technological settings or by working with different therapeutic areas and treatments. Experienced pharmaceutical medical writers will always find some common ground and make use of their pharmaceutical-acquired skills to smoothly transition to this parallel (but hopefully, not too strange) world.

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ISO 14155:2020 Annex D: clinical investigation report (CIR)

1	General
2	Cover page
3	Table of contents
4	Summary
5	Introduction
6	Investigational device and methods
6.1	Investigational device description
6.2	Clinical investigation plan
7	Results
8	Discussion and overall conclusions
9	Abbreviated terms and definitions
10	Ethics
11	Investigators and administrative structure of clinical investigation
12	Signature page
13	Annexes to the report

Abbreviations:

AE, adverse event; CORE, Clarity and Openness in Reporting: E3-based; CSR, clinical study report; IEC, Independent Ethics Committee; IRB, Institutional Review Board; PD, pharmacodynamics; PK, pharmacokinetics; SAE, serious adverse event.

Author information

Tiago Silva, MSc, has over 10 years of regulatory medical writing experience in the pharmaceutical industry. He is also the current vice president of the executive committee of the Portuguese Medical Writers Association.

Swiss medical device regulations

Introduction

In Switzerland, medical devices are controlled by various regulations; however, there is only one competent authority, Swissmedic, responsible for administering these regulations.¹ Some of the key regulations are presented in Table 1. A few recent changes in Swiss medical device regulations are discussed in this article.

As the world advanced, so did medical device regulations. The year 2021 was a historical year for medical device industries all over the EU. Switzerland is outside of the EU and not part of the common market in Europe; so, what implications did these changes have on the medical device industry in Switzerland? On May 26, 2021, the EU implemented new Medical Device Regulations (MDR); however, Swissmedic lacks official access to the central European medical device database (EUDAMED 3) required by the MDR due to the lack of an updated Mutual Recognition Agreement (MRA). What is the MRA? Since June 1, 2002, Switzerland has regulated medical devices with the EU through the MRA, which deals with all trading of goods, including medical devices.¹

EUDAMED 3 has been available since December 1, 2020 across Europe. EUDAMED 3 coordinates medical device information across the EU and thus increases transparency.² The EU

is prepared to negotiate with Switzerland over transitional provisions in the MRA related to MDR because the EU delegation represents Switzerland's interests in the International Medical Device Regulators Forum (IMDRF). Unfortunately, no agreement has been reached concerning the MRA, and consequently, Switzerland has implemented its own regulations under the revised Swiss Medical Devices Act.

Swissmedic requirements

According to the revised Swiss Medical Devices Act, the manufacturer must either have a registered place of business in Switzerland or appoint a natural and legal person domiciled in Switzerland to act as the company's representative. A Swiss authorised representative must be designated within specified times for specific devices (Table 2).³

In addition to designating an authorised person in Switzerland, the manufacturer must also have designated Swiss residents for three roles: one person responsible for regulatory compliance (PRRC); a distributor responsible for ensuring the device's availability in the Swiss market; and an importer responsible for placing the device from a foreign country onto the Swiss market.³ Each delegated representative has a fiduciary responsibility to the manufacturer and the Swiss authority to align with the mandate

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and, if required, terminate the mandate if the manufacturer acts contrary to the mandate. The manufacturer has the option of submitting the technical documentation file of the new medical device directly to Swissmedic upon contractual agreement with the authorised representative instead of keeping with the authorised representative. Nonetheless, most authorised representatives request the technical file from their manufacturers.

Clinical trials

Switzerland mandates human clinical trials for specific medical devices. The procedure for approval of a clinical trial for medical devices will depend upon the category of the clinical trial. These procedures are listed by category below:

- Category A clinical trials /post-market trials:
The devices used in this clinical trial have the CE label, and the devices used in this trial are used as stated in the CE-labelled instructions. Clinical trials falling under this category must be submitted only to the ethics committee.
- Category C clinical trials /pre-market trials:
The devices used in this clinical trial either do

Table 1. Swiss regulations

Description	Regulation	Reference
The Act guarantees safe and effective therapeutic products including medical devices.	The Federal Law (IDRAC 174478) on Therapeutic Products and Medical Devices (812.21)	Ch. 1, Art. 1 ; and Ch. 3.
The enforced ordinance provides all provisions related to medical devices. It forms the legal basis for placing medical devices in Switzerland.	Medical Devices Ordinance of Jul-01-2020 (IDRAC 315597)(MedDO)(812.213).	Ch.1, Ch. 2, Ch. 3, and Ch. 5.
The Act governs all requirements including ethics when human beings are involved in research.	The Federal Act (IDRAC 175144) on Research Involving Human Beings (810.30).	Ch.1, Sect.1, Art.1.
This ordinance regulates medical devices with respect to the conduct, procedure, duties, and responsibilities of the research ethics committee, and the registration of their clinical trials in accordance with the Article 1 Medical Devices ordinance of July 1, 2020.	The Ordinance (IDRAC 315596) on Clinical Trials for Medical Devices (ClinO-MD) (812.213.3). (German)	Art. 1.
This ordinance regulates the conduct, procedure, duties, and responsibilities of the research ethics committee, and the registration of the clinical trials.	The Ordinance (IDRAC 174400) on Clinical Trials in Human Research (ClinO)(810.305).	Ch.1, Sect.1, Art.1; and Ch.2, Sect. 1, Art. 20.



Illustration: Chris Monk www.yellowduck.net

not have the CE label, are not used per the CE-labelled instructions, or are prohibited in Switzerland. Clinical trials falling under this category must be submitted to both the ethics committee and to the Swissmedic.⁴

Before commencing the medical device clinical trial, it is essential to obtain the permission of both: (1) the cantonal ethics committee and (2) the Swissmedic, as well as to submit the trial on the ethics committee portal (“Basec”) and the Swissmedic portal (“eMessage”).⁴ It is also critical that submissions on both the portals are made on the same day. As per the rules implemented on May 26, 2021, Swissmedic will authorise only those trials that the ethics committee has approved. Once the submission has been made on both the portals, the complete document will be reviewed in 38 days.⁴ The manufacturer or its authorised representative must submit technical documentation to initiate a clinical investigation of a medical device.

Registration process

Furthermore, according to the new regulations, before placing the medical device on the market, all new medical devices must be registered

through the Swissmedic and receive a CE label through a designated body.³ The manufacturer, authorised person, or importer must register the device on the Swissmedic within 30 days of introducing the device in the Swiss market. Once the medical device is registered through the Swissmedic, the device obtains a unique device identification number (UDI). The Swiss Single Registration Number (CHRN) is a unique identification number that the Swissmedic assigns to Swiss manufacturers, authorised representatives, and importers upon request.³ The CHRN number must be obtained within 3 months of placing the device on the market.³ The CHRN improves the traceability of the device and enables ease of identification of the device. Once the MRA is updated, the process will change, and the manufacturers will receive their unique identification numbers through the EUDAMED 3.

Conformity assessment standard

Once the medical device is registered through the Swissmedic, the device must meet the conformity assessment standards before the device is placed in the Swiss market.³ The conformity standards are evaluated by a list of private

entities or designated bodies. Devices certified by notified bodies in a member state of the EU or the European Economic Area are equivalent to those certified by a Swiss notified body. The timelines for approval/clearance/certification of a product by a designated body will depend on the complexity of the medical device. Generally, the timeline for Class IIa/IIb categories will be 4 to 12 months, with a follow-up review within 3 years.³ Swissmedic must complete its clinical investigation in 60 days. Medical device compliance is attained once the device receives its CE label. The CE label on the medical device permits free transactions of the medical devices across the EU market. The device is ready for placement in the Swiss and EU markets upon receipt of its CE label/certificate. The CE label is valid for five years but may be extended several times.³ Swissmedic is continuously involved in the conformity assessment of medical devices by reviewing the documents issued by the designated bodies, auditing these bodies, and publishing the annual surveillance report of the audits on the Swissmedic website each year. The identification number of the designated body is placed beside its CE label.

Table 2. Timelines to designate a Swiss authorised representative

Medical devices	Class	Designation of a Swiss authorised representative by:
High-risk devices	Class III, IIb implantable, and active implantable medical devices.	December 31, 2021
Moderate-risk devices	Non-implantable Class IIb and Class IIa.	March 31, 2022
Low-risk devices	Class I.	July 31, 2022
Systems and procedure packs		July 31, 2022

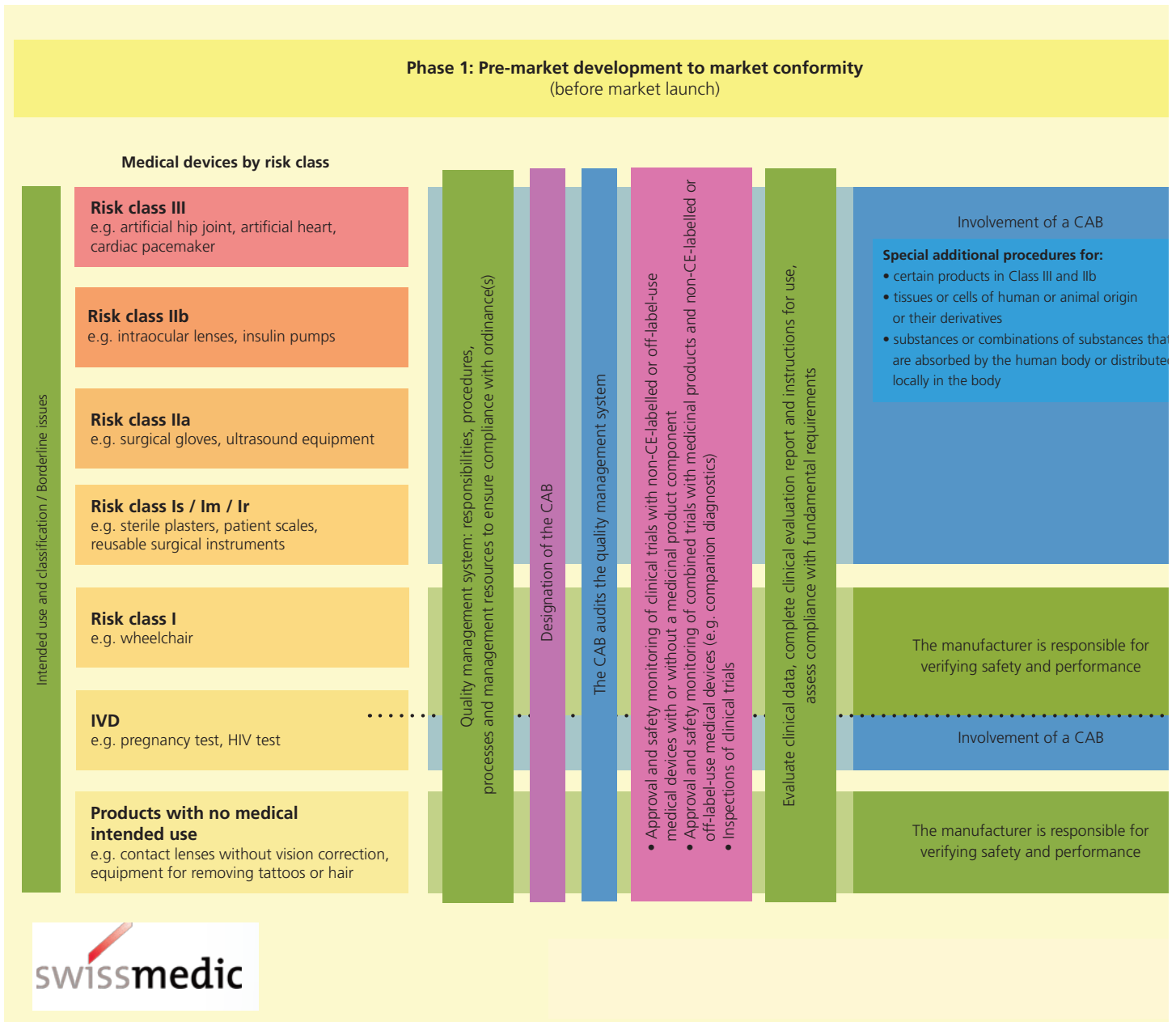


Figure 1. The tasks of Swissmedic – lifecycle of a medical device

The following are the designated bodies authorised to issue CE labels:

- The SQS (NB 1250) is the local Swiss designated body for issuing the CE label. CE labels issued under the old Medical Devices Ordinance (oMedDO) dated October 17, 2001 became void as of May 26, 2021. This means no new certificates can be issued under the oMedDO. However, certificates already issued under oMedDO will remain valid until their expiry date or until May 26, 2024.
- The Nando website offers a list of foreign notified bodies.³

Inspections

Swissmedic is responsible for continuous inspections of authorised representatives, importers, and manufacturers. Cantons carry out their inspections across multiple nursing homes and clinics, and the Swissmedic conduct relevant inspections in the hospitals. Foreign governmental inspections of medical devices are permitted in Switzerland provided the foreign body notifies the Swissmedic of its inspection at least 30 days before the planned inspection, receives a prior agreement of the company on the scope and the extent of inspection, and delivers a copy of the inspection within ten days after

issuing the report.⁵ If there are problems with the medical devices, it is mandatory for those first placing the medical device on the Swiss market to recall the device. The manufacturer also has an obligation to report to Swissmedic the measures they undertook to resolve the problem.

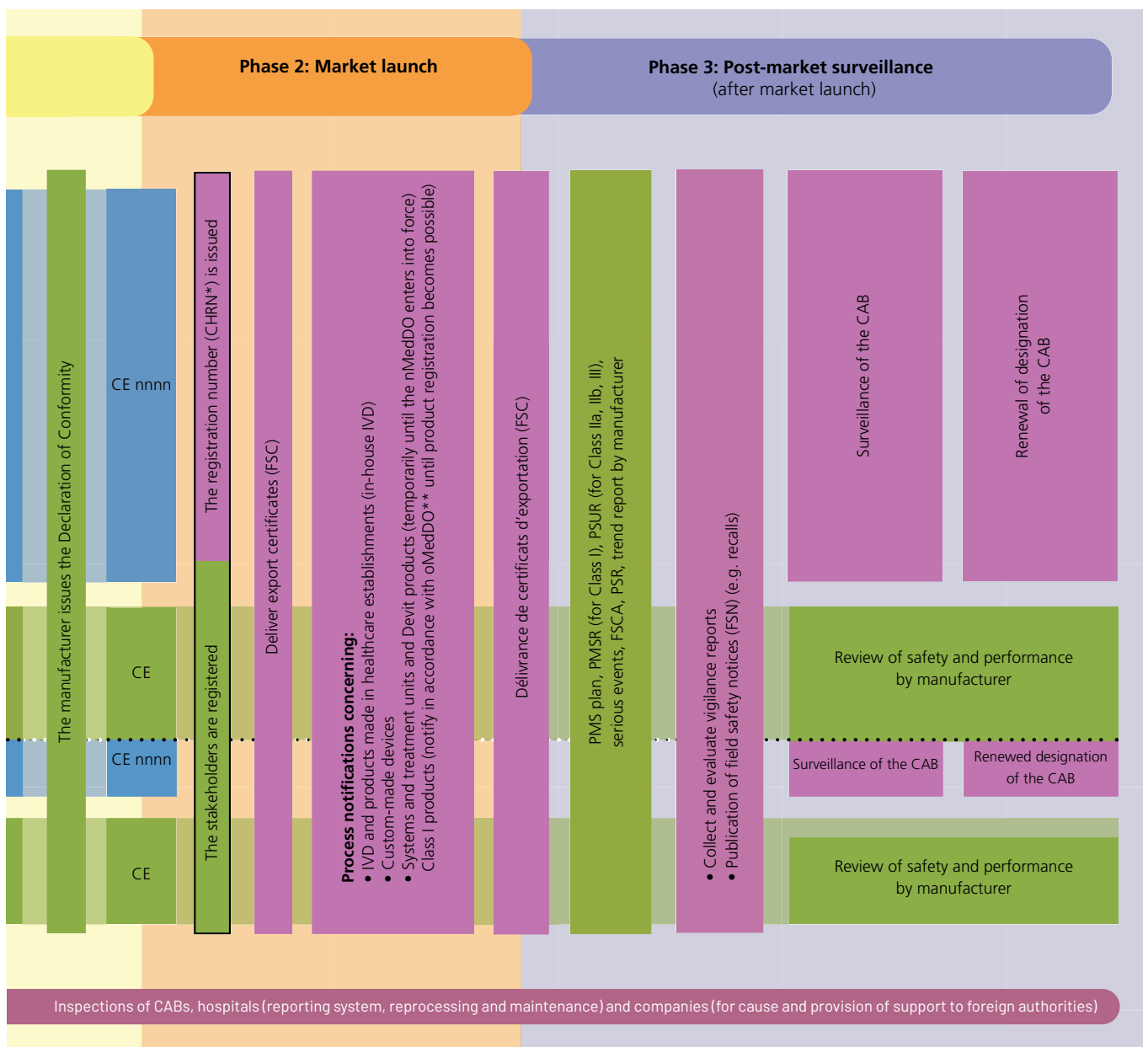
Conclusion

For now, Switzerland has worked its way through and looks forward to an updated MRA between Switzerland and the EU.

Disclosures and conflicts of interest

The author declares no conflict of interests.

The different stakeholders in the process: ● CAB / designated body ● Swissmedic ● Manufacturer



*CHRN = Swiss Single Registration Number. **Medical Devices Ordinance of 17 October 2001 (version of 1 August 2020)

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