

# Regulatory medical writing in Switzerland

Raquel Billiones

Clinipace Worldwide, Volketswil (Zurich), Switzerland

## Correspondence to:

Raquel Billiones  
Clinipace Worldwide  
rbilliones@clinipace.com

## Abstract

Switzerland is practically unknown in the drug/medical device regulatory landscape despite being home to some of the world's biggest pharmaceutical firms. This article briefly describes the regulations governing clinical trials in Switzerland and cites examples of Swiss-specific regulatory documents.

**Keywords:** Switzerland, Swissmedic, Regulations, Medical writing

Switzerland is not a member of the European Union (EU) or the European Economic Area. This makes this small country a minor player in the global drug/medical device regulatory landscape. However, in this issue on Medical Writing Around the World, I would like to place Switzerland on the medical writing map. Switzerland is my place of residence for now and this is where I spent most of my medical writing years. Switzerland is home to some of the world's largest pharmaceutical companies. Switzerland also hosts the secretariats of the International Committee on Harmonization (ICH), the Council for International Organizations of Medical Sciences Working Group, the International Standard Organization, and the World Health Organization - institutions and organisations which play vital roles in clinical research and drug/device regulations.

## Swiss regulations and regulatory body

The Swiss drug regulatory body is called Swissmedic (<http://www.swissmedic.ch>). Because of the country's many languages, its website is in German, French, Italian - and English. There is a fourth official country language, Raeto-Romanisch, but this is seldom used in written form. This multilingual setting makes English practically the regulatory lingua franca and makes life easier for non-Swiss medical writers.

The legislations governing clinical research in Switzerland are embodied in the Swiss Federal

Law of Therapeutic Products (HMG) and the Ordinance on Clinical Trials (VKlin),<sup>1</sup> roughly equivalent to the EU directives and the EU guidelines, respectively. HMG and VKlin require that clinical trials follow ICH E6 Guidelines on Good Clinical Practice. However, other ICH guidelines are not specifically mentioned.

Unfortunately, VKlin contains a lot of ambiguities that make life difficult for clinical researchers. It does not, for example, make a distinction between interventional trials and non-interventional or observational studies, so that both types of studies are subject to the same regulations. In addition, it does not address some aspects on medical devices, data protection, and biological samples.

## The GSASA dossier and the succinct statement

Working in Switzerland for the last 7 years, I have had the pleasure of writing Swiss-specific regulatory documents. The GSASA (*Gesellschaft Schweizerischer Amts- and Spitalapotheker*) Questionnaire for the Information of Hospital Pharmacist about Proprietary Drugs is one of them. The GSASA dossier is structured like a very much abbreviated Common Technical Document (CTD) of about 100 pages. Because the source documents are mainly in English, the GSASA dossier is usually written in English and then translated to German and French. The appendices include a copy of the drug packaging, the Swissmedic-approved summary of product characteristics in German and French, and the package inserts in German, French, and Italian.

The succinct statement (*gekürzte Fachinformation* in German) is probably the shortest and most concise regulatory document I have ever written. Varying from a quarter to a full page, it still covers all the essentials of therapeutic product information, from the formulation and posology, to contraindications, interactions, and packaging, and thus really lives up to its name. The trick in writing succinct statements is NOT using full sentences and using

as many commonly known abbreviations without defining them.

## The PEB protocol

PEB stands for *Praxiserfahrungsbericht*, a special type of clinical research project that is as observational as it can get but cannot be called an observational study. Translated by Swissmedic as ‘monitoring of use report’, a PEB documents data on therapeutic efficacy or safety within the framework of clinical practice.<sup>2</sup> I have seen other translations as a ‘field report’ or ‘clinical survey’.

Because VKlin does not distinguish between interventional and non-interventional studies, all studies have to go through the process of Swissmedic and independent ethics committee notification, approval, and reporting – except the PEB. For the PEB, only ethics notification is required, and informed consent is usually optional. A study protocol is needed, but a very short and abbreviated one at that. There is a catch though, as sponsors are very careful about the terms used in a PEB protocol, lest their project be elevated to observational study status. For example, the terms ‘study’, ‘treatments’, ‘visits’, ‘schedule’, and ‘follow-up’ may be deemed inappropriate for a PEB as they may connote intervention. Ever written a protocol without using these words?

## The clinical study report Swiss style

The clinical study report (CSR) is the bread-and-butter of many regulatory medical writers. Yet, writing a CSR as we know it, for Swiss trials, is not must.

I remember back in 2007, one of my very first freelance projects was to write a publication on a clinical trial. I asked for the CSR, and the client’s response was ‘the publication will be the report.’ To understand this rather cryptic statement without belying my ignorance, I researched a little deeper into the Swiss regulations, and this was what I found:

*Independently of whether the trial is a commercial or non-commercial one, and whether it ends normally or is prematurely discontinued, a final report must*

*always be submitted to Swissmedic. The time limit laid down in VKlin is 6 months following the end of the study[...] Swissmedic does not, however, stipulate any binding format for the report. The final report must nevertheless be in line with ICH GCP requirements (although it is not mandatory for it to be in ICH E3 format) and in accordance with current medical and scientific standards.<sup>2</sup>*

I must say many Swiss sponsors still go for the ICH E3-compliant report, especially if a trial is planned to be used in a marketing authorisation application somewhere. But I also know many who opt for the shortcut of submitting a publication *in lieu* of a CSR.

## Changes in 2013

At the time of writing, this is where Switzerland stands in terms drug and medical device regulations. However, a new law is expected to take effect in 2013. The Law on Human Research<sup>3</sup> will supersede the VKlin and redefine the roles and duties of the local independent ethics committee and Swissmedic in regulating clinical trials. The distinctions between different studies and therapeutic products will be clearer and critical issues such as research on embryos and cadavers will be addressed. How this will affect regulatory medical writing is hard to say. I will keep you posted!

## Disclaimer

The views and opinions expressed herein are those of the author alone and do not necessarily represent those of Clinipace Worldwide.

## References

1. Verordnung über klinische Versuche mit Heilmitteln (VKlin) [2001 Oct 17]. Available from: [http://www.admin.ch/ch/d/sr/812\\_214\\_2/index.html](http://www.admin.ch/ch/d/sr/812_214_2/index.html).
2. Swissmedic Information Sheet FAQ [2012 Dec]. Available from: <http://www.swissmedic.ch/bewilligungen/00089/00282/index.html>.
3. Bundesgesetz über die Forschung am Menschen (Humanforschungsgesetz, HFG) [30 Sept 2011]. Available from: <http://www.admin.ch/ch/d/ff/2011/7415.pdf>

## Author information

**Raquel Billiones** earned her BSc in Biology at the University of the Philippines and did her postgraduate studies (MSc and PhD) at the Free University of Brussels in Belgium. After completing her postdoctoral fellowship at the J.W. Goethe University Frankfurt in Germany, she switched to medical writing and never looked back. She

is currently working as a senior medical writer for the dCRO (d as in digital) Clinipace Worldwide at their EU headquarters in Zurich, Switzerland. Raquel has lived, studied and worked in five different countries in Asia and Europe.