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Swissmedic's main building showing the entrance on Hallerstrasse in Bern, Switzerland

Research-oriented Switzerland needs an independent, competent and internationally recognised therapeutic products agency

Swissmedic emphasises international cooperation

The complexity of a medicinal product's life cycle from its development through authorisation, marketing and market surveillance should not be underestimated. Today every aspect of the process is generally networked globally. Efficient international cooperation is vital for a small regulatory agency like Swissmedic if it wants to keep up with the rapid pace of developments.

Peter Balzli and Cordula Landgraf, Swissmedic, Bern, Switzerland

Introduction

Seventy-two different languages were the Lord's punishment for the arrogance demonstrated by the people who had attempted to build the tower of Babel. The project failed because their many languages had made mutual comprehension and therefore coordination and cooperation impossible. The number of languages spoken in the pharmaceutical regulatory environment worldwide is similar, yet, in contrast to the unfortunate builders of Babel, those working in pharmaceutical medicine have realised that harmonisation and cooperation are essential. For example, the regulators in three regions – the EU, USA and Japan – agreed on a shared goal with the pharmaceutical industry as long ago as 1990: they decided to harmonise the technical requirements for the authorisation of medicinal products. The initiative, known as the International Council on Harmonisation, or ICH for short, is a success story. Today the Common Technical Document (CTD or eCTD) developed by the ICH is a global standard.

Formerly, if a medicinal product had been authorised in country A, it was quite likely that the company in question would have to completely restructure its regulatory dossier to submit the same

product in country B. The authorities in each country had their own national rules and regulations determining what regulatory dossiers had to look like. This meant an enormous administrative effort for all concerned, something that neither the regulators nor the pharmaceutical industry were happy about. This provided the impetus for everyone to develop a standardised format. The result is widely known: the CTD and eCTD have gone a long way towards eliminating bureaucratic hurdles and duplication.

Terminology that was also developed by the ICH, the Medical Dictionary for Regulatory Activities (MedRA), even allows countries to speak a "common language".

Yet international collaboration is vital in other areas of medicinal product authorisation too.

The reasons why international cooperation is becoming ever more important are obvious. The therapeutic products industry today nearly always develops and manufactures medicinal products and medical devices on a global basis. In addition, healthcare research and development are constantly generating new findings, therapeutic approaches and technologies that have to be integrated into the regulatory environment. The increasing complexity of products, the supply chain and the operating environment combined with budgetary constraints makes it difficult even for larger authorities to fulfil their oversight functions on their own.

In this context, cross-border exchange is vital if effective protection that reflects the current state of science and technology is to be provided for the individual patient and for the population as a whole. The Swiss Therapeutic Products Agency, Swissmedic, and other internationally recognised regulators have therefore established collaboration with the authorities in other countries on various levels and using a number of instruments, and are now in the process of implementing this collaboration efficiently.

Background

The development of Swissmedic's international collaboration can be divided into two phases. In the period between Swissmedic's establishment in 2002 and 2014, international collaboration was gradually built up and expanded. This was the period during which bilateral collaboration was established with internationally recognised authorities. In the coming years, Swissmedic will be using this basis to focus more closely on implementation of this collaboration and on the benefits for the Agency.

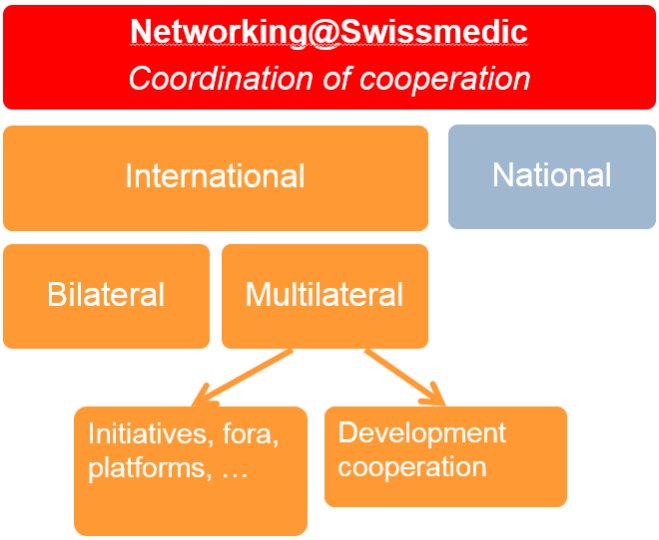
Hereby, the following principle applies: Swissmedic is internationally acknowledged as a well-networked therapeutic products authority and a professional, reliable partner. For this purpose, the Agency aligns itself with international standards and uses the relevant bilateral collaborations and international networks.

Categorisation

International collaboration can be divided into two categories: bilateral and multilateral. Development cooperation is separate from international collaboration, being an activity that the Swiss Federal Council added to Swissmedic's performance mandate in 2013 with a separate budget and different objectives (see "Development cooperation" further below).

Overarching activities are coordinated by Networking (see Figure 1 on the next page).

Figure 1: Swissmedic's international cooperation

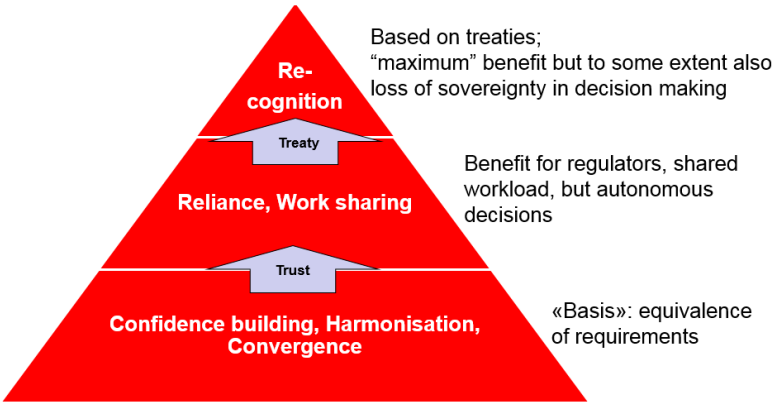


International cooperation covers the following main activities:

- Information and experience sharing with partner authorities
- Participation in working groups/task forces/forums, follow-up and knowledge transfer
- Participation in international conferences and workshops

Cooperation is viewed as an ongoing process at different levels that build on each other. Sharing information and experience at the start of a cooperation builds confidence in the partner's way of working; the next step is to consider the potential to share work, e.g. by using results generated by the partner authority (see Figure 2 below).

Figure 2: Levels of cooperation



Bilateral cooperation with partner authorities

Bilateral cooperation with partner authorities is generally based on an agreement or a declaration of intent with no legal force. Switzerland and the European Union signed a declaration of intent of this kind in July 2015, for example. The declaration states that the parties to the agreement will "share non-public information on the safety, quality and efficacy of medicines, already authorised or under review, both in Switzerland and in the European Union (EU), in order to enhance public health protection".

Swissmedic has signed a total of sixteen bilateral agreements of this kind with regulatory agencies on all continents. The documents are published on the Swissmedic website [1].

Multilateral cooperation with international organisations and initiatives

International cooperation on the regulation of therapeutic products is not only occurring at the bilateral level between individual authorities, it is increasingly taking place multilaterally on different platforms. Multilateral platforms to harmonise regulatory requirements may take the form of international initiatives or private associations (see Table 1) set up and supported by several national therapeutic products authorities or international organisations such as the World Health Organisation (WHO) or the Council of Europe. They cover the entire spectrum of therapeutic products regulation.

Table 1: Swissmedic's multilateral cooperation with international organisations and initiatives (not exhaustive)

ACSS Consortium Australia-Canada-Singapore-Switzerland Consortium	Australia-Canada-Singapore-Switzerland Consortium (ACSS Consortium)
Council of Europe	Council of Europe (www.coe.int)
EUPATI European Patients' Academy on Therapeutic Innovation	European Patients' Academy on Therapeutic Innovation (EUPATI – www.eupati.eu)
ICMRA	International Coalition of Medicines Regulatory Authorities (ICMR – http://icmra.info)
ICH harmonisation for better health	International Council on Harmonisation (ICH – www.ich.org)
IGDRP International Generic Drug Regulators Programme	International Generic Drug Regulators Programme (IGDRP – www.igdrp.com)
i-p-r-f.org International Pharmaceutical Regulators Forum	International Pharmaceutical Regulators Forum (IPRF – www.i-p-r-f.org)
OECD BETTER POLICIES FOR BETTER LIVES	Organisation for Economic Co-operation and Development (OECD – www.oecd.org)
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S – www.picscheme.org)
World Health Organization	World Health Organization (WHO – www.who.int)

Swissmedic is actively involved in the committees and working groups pertinent to the Agency's role that have been set up by these platforms. The precondition for the Agency's active participation is a concrete benefit in terms of fulfilling its legal mandate to ensure the protection of public health.

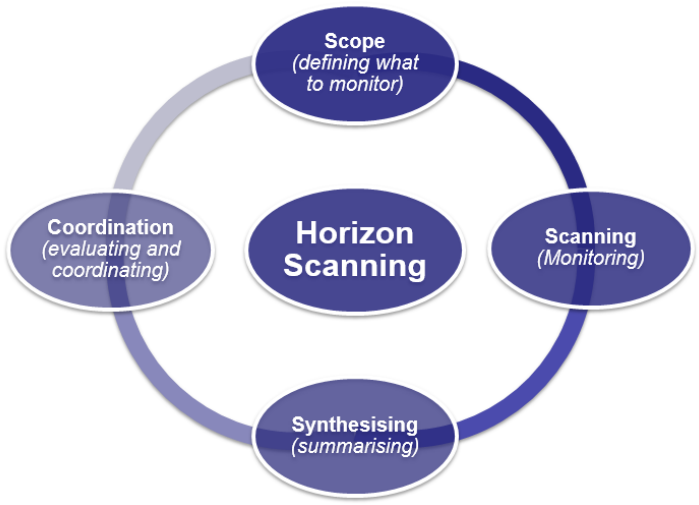
In the light of this, involvement in the ICH has been one of Swissmedic's top priorities since the Agency was established. For many years, Swissmedic had observer status representing the European Free Trade Association (EFTA). It was granted full membership in June 2014 in recognition of its many years of active participation and is now represented in the new ICH organisational structure both in the Assembly and in the Management Committee [2].

A further example of multilateral cooperation is the ACSS Consortium (ACSS stands for **A**ustralia, **C**anada, **S**ingapore, **S**witzerland) established in 2007 as a collaborative undertaking between the regulatory authorities of the four countries.

This example is a good illustration of the different levels of cooperation. To begin with, the focus was on experience and information sharing, which provided an opportunity to get to know the other regulators' way of working; now a number of projects have been set up to enable the Consortium to review and test options for sharing the workload. Confidence in the partner's way of working is a vital prerequisite here.

Benefit-oriented cooperation means that it is important to analyse the individual activities regularly for the benefits they offer and to adapt them as necessary. Horizon scanning can be an extremely useful tool here. This is a process in which the regulatory environment is monitored and evaluated to identify new developments and trends (see Figure 3).

Figure 3: Swissmedic's "Horizon Scanning"



Development cooperation

Development cooperation is a relatively new activity for Swissmedic. It focuses on the memorandum of understanding signed in January 2014 by the Bill & Melinda Gates Foundation, the Federal Department of Home Affairs (FDHA) and the Federal Department of Foreign Affairs (FDFA).

The overriding priority of this partnership is to accelerate and improve access to high-quality, life-saving medicines for people in low-income countries. The aim is to enhance the efficiency of the

regulatory review and approval procedure by having stakeholders focus on activities with high added value and reinforcing the ability of the regulatory authorities to protect the health of the people they represent. The primary emphasis is initially on regulators in the sub-Saharan countries, although other regions may be subsequently included.

Conclusion

If it did not network internationally, Swissmedic would lose touch with the constantly changing regulatory environment. This would also have repercussions for Switzerland as a centre of pharmaceutical research in which an independent, competent and internationally recognised domestic therapeutic products agency plays a major role.

A clear strategic alignment for cooperation is therefore important for a small agency like Swissmedic. Clear objectives and criteria are vital in view of the complexity of the task. Cooperation is only sustainable if it involves both give AND take. For efficiency reasons, Swissmedic is increasingly focusing on initiatives approached through multilateral cooperation.

It is clear that NO therapeutic products agency today can handle all tasks on its own. A smoothly functioning, efficient regulator that is not internationally networked is inconceivable today.

Authors

Peter Balzli is Head of Communication at Swissmedic. An economist by training, he was previously a journalist and has worked as Swiss Television's foreign correspondent in Paris and London.

Cordula Landgraf has been Head of Networking at Swissmedic since August 2007. A pharmacist by training, she has over 15 years of experience in Regulatory Affairs.

Contact
networking@swissmedic.ch

Sources

[1] Swissmedic: Agreements on information exchange. URL: www.swissmedic.ch via the menu “About us > Collaboration > International collaboration > Bilateral collaboration with partner authorities > Agreements on information exchange" (last accessed: 20 May 2016).

[2] Swissmedic: ICH meeting in Indianapolis - Swissmedic and Health Canada included as new members. URL: www.swissmedic.ch via the menu “News > Announcements > 9 July 2014" (last accessed: 20 May 2016).