Interview: Petra Doerr – Head of Sector Communication & Networking, Deputy Executive Director, Swissmedic



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Petra Doerr, head of sector communication & networking as well as deputy executive director of Swissmedic, the Swiss surveillance authority for medicines and medical devices, discusses changes to the Swiss regulatory system and harmonizing the organization with its global counterparts.

Swissmedic has embarked upon a comprehensive overhaul of its regulations in response to changes to the Therapeutic Products Act that were finalized last year. This has included reviewing drug ordinances to simplify pathways to market. What progress has been made thus far?

This is a two-step process, the first stage of which was completed in March 2016 when the federal parliament signed off the revised version of the Therapeutic Products Act. Following amendments to this legislation we are now revising the ordinances so that they correspond to the new provisions of the Act. More than 10 ordinances have to be changed and the timeline for implementation has been set for the beginning of 2019. The main revisions relate to facilitating market access and introduce fresh procedures for products that have been authorized at the EU and EEA levels. They also strive to bring the Swiss regulatory framework up to date with and in closer alignment to the traditional use system of provision already in effect across the EU. Essentially, what we are expecting is a facilitated market access route for OTC products and generics.
One significant element with major internal consequences in the way that we carry out our business is the adaptation of our system for variations to the one of the EU. This is not dealt with

specifically in the revised Therapeutic Products Act, but was subject to additional parliamentary interventions. It has been agreed that we should align our system of classification and requirements for variations to that of the Europe Union. Now that we have made the categories the same, we can look closer at revisiting the timelines of approval, which is of course the aspect that will be most interesting to the pharmaceuticals industry and also patients.

Do you believe that there is sufficient harmonization between the Swiss regulatory framework and the rest of Europe? Some industry actors have pointed out that it is unnecessarily inefficient and burdensome to maintain two distinct systems, especially when the Swiss market remains comparatively small.

[Featured_in]

We are already closely aligned with the EU regulatory system because we base our requirements on the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines. The reason for retaining a distinct and separate system is simply that Switzerland is not an EU member state and therefore needs its own national regulatory regime, which is naturally well adapted to the local contextual environment. A distinct regulatory system also allows for the legislator to impose specific regulations in order to promote certain drugs by granting incentives that go beyond foreign regulatory systems (e.g. extended data protection periods for orphan drugs or pediatric drugs).

I would also point out that there are areas that are covered by the Bilateral Agreements between Switzerland and the EU and based on mutual recognition agreements. The medical device sector is a case in point. There is a free market whereby devices that are certified by a notified body here can freely circulate across the EU and vice versa. Unfortunately, we do not yet have any such comparable treaty governing market access for medicinal products.

That said, if you scrutinize our regular marketing authorization procedure, you will discover that it emulates the model of the centralized procedure of the EU. You start off with an initial phase of assessment with a list of questions followed by submission of answers to questions in the second stage of review and subsequently an approvable/non-approvable letter with a legal option of appeal. What we obviously don’t have is the Commission phase because this is very much a national authorization as opposed to a regional one. We additionally incorporate the option of considering the scientific assessments of competent, well-recognized regulatory authorities around the world. EU assessments very much fall into this category.

How do you judge whether another country’s regulatory authority is competent enough?

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The prerequisite is to have a comparable system for the control of medicines with comparable

standards to our own. As long as those conditions are met we are happy to use and refer to the scientific assessments of these competent authorities in the course of our own decision-making process.

Regulatory convergence and reliance seem to very much be the name of the game these days. How would you describe Swissmedic's international cooperation strategy?

I think that is absolutely right.

Over and above adhering to a baseline of harmonized requirements, Swissmedic is very attentive to identifying projects and initiatives for reliance and work sharing. Many national regulatory bodies are just now getting to grips with tools for reliance initiatives whereas I am proud to say that Swissmedic has had a legal basis for reliance on scientific assessments since as far back as 2002.

We also apply the concept to GMP inspections. Obviously, the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) have been around for quite some time now as international instruments help to synergize and unify different countries' pharmaceutical inspection authorities in the sense of promoting a commonly adhered to set of Good Manufacturing Practices, but we are also seeing a much greater level of inter-regulatory cooperation these days.

Swissmedic does not really have the depth of capabilities and workforce to be conducting GMP inspections abroad, so we leverage the capacities of other regulatory authorities that are PIC/S members and obviously our mutual recognition agreement (MRA) partners. Because we consider those entities to be broadly equivalent to our own standards we would not repeat an inspection undertaken by any of them. For example, if there is a manufacturer in China that has been inspected by the US FDA or EMA, then we will consider their inspection report as the basis to establish GMP conformity. This sort of phenomenon is going to become more and more common across the world as different regulatory regimes converge and become more streamlined. Personally, I believe this is a very positive development that injects efficiency into the regulatory process.

We hear that Swiss drug and API manufacturers will also soon be able to allow foreign regulators to inspect their facilities without needing to seek special SECO approval.

That is correct. Hitherto, quirks in our penal code meant that foreign officials were forbidden from conducting inspections within Swiss territory. In the pharmaceuticals sphere, outside regulators wishing to do inspections therefore had to secure a special waiver from the State Secretariat for Economic Affairs (SECO), the federal government structure for all core issues relating to economic policy. As of January 2018, this will no longer be the case. This is when the recent introduction of article 64a of the Therapeutic Products Act will come into force, which means that this layer of bureaucracy will be cut out.

In the future, foreign regulatory authorities will instead only need to notify Swissmedic and gain the consent of the manufacturer about to be inspected. There are some other provisions as well such as the fact that they are obliged to send us, Swissmedic, a report of their inspection findings no later than 20 days after the event. Again, this development fits very well with an increased emphasis on international cooperation and harmonization.

The drug development process is undergoing substantial upheaval with the advent of post-market access clinical studies, predictive modeling and the fast emergence of personalized therapies, for which the genetic variances make clinical evidence impossible. How are you going about modifying your internal organization in view of trajectory medical science is taking?

The way that drugs are being developed is indeed being rethought as new technologies become available and scientific awareness in areas like genetics increases. We do therefore feel a need to update and mature some of our legacy processes to make them more fit for purpose and in line with the current environment of drug development. To ensure that we are proactive in doing this we have implemented a system for horizon scanning that seeks to identify trends and developments likely to affect us in the future.

It is clear that we have to move with science and be flexible and versatile enough to react in time to unfolding developments. The beauty of horizon scanning is that it gives us the foresight to be able to build up the requisite capacity and knowhow and to rework our internal modus operandi.

Nor are we alone in doing this. On the contrary, horizon scanning stands as one of the core priorities of the International Coalition of Medicines Regulatory Authorities (ICMRA), a voluntary, executive-level, strategic coordinating, advocacy and leadership entity of regulatory authorities. Alongside our other partner agencies grouped together within the ICMRA, we are all joining forces and working together to address current and emerging human medicines regulatory and safety challenges globally and strategically in an ongoing, transparent, authoritative and institutional manner. The overarching idea is to share outcomes and best practice in facing these trends.

Margaret Hamburg, former commissioner of the FDA has been pretty outspoken about the need for regulatory agencies around the globe to do much more in terms of capability engineering in the sense of getting abreast of the brave new world of drug development. Where do you still identify room for improvement within Swissmedic on this front?

There is always an urgency to move with the times and get up to speed with the very latest developments in scientific and medicinal advancement. The move towards biologics is a good example of how the paradigm can shift and, as a regulatory authority, the onus is always on you to stay a few steps ahead and not be caught off guard. That means we always have to have one eye

on acquiring new capabilities, areas of expertise and skill sets.

We have implemented a system for knowledge management that assists us in navigating this process and in ensuring that we have the right sorts of personnel in place to handle evolving needs as and when they arise. I am happy to say that Swissmedic has always been very good in this respect. Partly this boils down to the manner in which we recruit and the type of candidates we find applying. Partly it's a consequence of the sheer strength of the Swiss talent pool in life sciences. Whereas the FDA tends to recruit graduates, train them up and then lose them to private industry, the reverse tends to be the case here in Switzerland. We possess a highly experienced staff in clinical expertise and scientific development and a part of our employees tend to join us on the back of distinguished careers in industry. This naturally equips us very well in facing the future.

We witness a rising tension between a demand for faster access to innovation from patients on the one side, and a call for enhanced regulatory stringency and oversight on the other. How do you practically go about balancing these competing interests of safety and innovation, flexibility and regulation?

The secret is all about forging common understanding from all sides. We have established a working group with representatives from different patient consumer organizations that meets 4-5 times a year to discuss precisely this sort of conundrum.

Right now, we are at the stage of exchanging insights and information so that all stakeholders around the table understand each other and the different motivations in play. There are ways to square the circle, but the starting point has to be common understanding. Pharma companies obviously want faster approval timelines, but this cannot come at the expense of safety. No one wants us to become a soft-touch regulator. Patients want speedy access to safe medicine and our national duty is to safeguard the interests of the patient.

At the end of the day, we have to strike an optimum balance between patient preferences and those of industry. And let's not forget, either, the social and economic significance of the pharmaceuticals industry to Switzerland as a whole. We're talking about an industry with a very strong R&D base that supports huge numbers of quality jobs. We therefore need to identify win-win solutions that satisfy all parties.

Industry actors regularly complain that an increased regulatory burden is making the drug development process slower, pushing up costs and thus ultimately raising the price of medicine. Do they have a valid point? And what can you, as a regulator, do about it?

It is undeniable that the regulatory burden today is more onerous that in the past and therefore we are sympathetic to their predicament. I would point out, though, that a more stringent regulatory regime is the natural consequence of enhanced patient safety. The two go hand in hand. The

solution is to work together to optimize the regulatory process without any reduction in standards. I think that a more pragmatic flexible approach to clinical trial design is the direction in which we are all headed. Already you see the FDA taking a lead in rethinking and reevaluating the parts of the clinical trial process to make it more fit for purpose under certain specific circumstances. Swissmedic can be expected to follow suit. Obviously, we do not have the resources at our disposal that the FDA does. We will not be attempting to reinvent the wheel. We are, however, watching very closely some of the experiments and pilot initiatives being conducted out in the United States and in the European Union and will be ready to embrace them if successful.

There are other compelling reasons why we need to be ready to adjust the manner in which we regulate and oversee the drug development industry. National health ministries, the WHO and EU executive are very concerned, for instance, about tendencies in antibiotic resistance. We have a role to play in this as well because we might have to start rethinking how antibiotics are being deployed in clinical trials. The main point is that institutions like us need to be ready and willing to embrace change and we are committed to ensuring Swissmedic's agility and flexibility.

We understand that Swissmedic has, itself, been a bit of a pioneer in experimenting with a premium, fast track approval process?

This came about as a direct result of our discussions and negotiations with industry. They were asking us to shorten our approval timeframes and we were explaining to them that this would only be possible if we could increase our capacity and have more resources at our disposal. As a result, we agreed to offer them a shortened procedure under a "pay for performance" rationale. Essentially, we offered an additional procedure for products not qualifying for fast track, whereby they would nonetheless still be dealt with quickly, but for double the fee. Whereas the regular fee sets a company back some 70,000 CHF, this premium service would cost 140,000 CHF.

Initially, for the first two years of operation, firms were slow to take up the scheme. There was a certain reticence, in some quarters, about paying more. Lately, though, we have noticed a surge in applications as companies begin to properly appreciate the full benefit of being in the market 2-3 months earlier compared to their competitors. Now that it is apparent that firms which have gone through the process have been reaping rewards, more and more developers of pharmaceuticals are demonstrating interest.

Swissmedic is often considered as one of the top regulatory authorities worldwide alongside peers such as FDA, EMA, PMDA and Health Canada. In your own opinion, in which aspects does Swissmedic perform especially well relative to its peers? And where could you be doing better?

The Centre for Innovation in Regulatory Science (CIRS) benchmarking studies tend to give a good indication of our ongoing performance relative to many of the other authorities that you mention.

Among the six major regulatory bodies that they benchmark, we have on average been the slowest apparatus for approval timelines.

Obviously, we can do better on that front, but you have to also take into account the size of our agency compared to the others and the volume of resources that we possess. Japan's Pharmaceuticals and Medical Devices Agency (PMDA) is noteworthy for having dramatically increased their approval speed in a very short space of time, but during that same time period they also almost doubled their capacity and staff. These are not options that we have at our disposal.

Our unique selling point is actually our efficiency. The Swiss pride themselves on efficiency and we know we have to be very smart about how we allocate and utilize our resources because we need to be able to achieve more with less. If you look at our fast-track procedure, you'll find that we are super competitive and on a par with even America's FDA. This is a major achievement and shows that we have a lean, effective, fine-tuned apparatus that is performing very well.

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