Interview: Giovan Maria Zanini – Board member, Swissmedic Cantonal Pharmacist and President of Ethics Committee, Ticino, Switzerland

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An expert in the implementation of Swiss federal laws within Switzerland's constituent cantons, Giovan Maria Zanini discusses the evolution of Swiss pharma regulatory framework and efforts to strengthen and protect the country's world leading innovation environment.

Dr. Zanini, you have been described as "the expert in the cantonal implementation of federal law." Could you please introduce yourself and explain your expertise in this area to our readers?

My current "day job" is working for the public administration of canton Ticino, where I now hold the position of cantonal pharmacist. In this regard, one of my main responsibilities is to take federal law pertaining to pharmaceutical products foster the right adaptation and strict implementation of these laws at the cantonal level. As a reminder, Switzerland only adopted a countrywide regulatory framework for medicines in 2002, as beforehand medicine regulation was formally managed by the cantons. As part of this reform, strategic regulatory areas such as medicine approval and manufacturing as well as international trade are now handled at national level, while some specific fields are still controlled by the 26 cantons of our country. In this regard, the main local priorities notably revolve around the regulation of the retail market, which includes fighting illegal e-commerce and the distribution of counterfeit products, but also ensuring healthcare law

enforcement in the health sector.

This relatively new approach based on a sound balance between centralized processes and the persistence of a strong local power has also been replicated to the R&D part of the value chain, with the release of the Human Research Act (HRA) in 2014. This regulatory update clearly set up which part of the research process approval now falls within Swissmedic *[the Swiss surveillance authority for medicines and medical devices, e.d.]* or the cantonal jurisdiction. In this vein, seven local ethics committees were created, and I was appointed president of the ethic committee of the Italian speaking part of Switzerland. Obviously, the fundamental objective is to better protect the individual's dignity, psychological integrity and health; and in the grand scheme of things, one of the main objectives of the HRA was also to simplify and streamline process approval for clinical research by implementing harmonized requirements at the confederation level, while the seven local ethics committees in charge of reviewing new application files closely collaborate to ensure our country's historical federalism doesn't hinder the efficiency of our overall approval processes.

Finally, in January 2015, I also had the honor to be appointed member of the strategic council of Swissmedic. In this regard, the Swiss Parliament recently promulgated a deep reform of the 2002 pharma regulation, and we are notably in charge to ensure updated regulations will allow to actually reach the outcomes targeted by the parliament. We are then comprehensively adapting Swissmedic's processes, while the overall regulatory update should last at least two more years.

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What are the main strategic areas impacted by this reform?

We introduced new regulations improving the population's access to medicinal products and the conditions for biomedical research and industry. As an incentive for research, authorization holders will benefit from a data protection period of 15 Years for pediatric medicinal treatments and orphan drugs. Simplification of market access was also a goal, especially for well-known APIs, alternative medicines and similar therapeutic approaches. In the meantime, we have been adapting medicine classification by notably moving some pharmaceutical products from the GP to the pharmacist' area of competency.

We also look at ramping up approval for treatments already approved by regulatory agencies such as the FDA or the EMA. In this regard, the Article 13 of our regulation stipulates that clinical trials data and application files submitted to other international regulators should be more taken into account by Swissmedic.

This important regulatory update leads us to the question of the overall positioning of Swissmedic among the international landscape. From a technical point of view, Swissmedic nurtures very close and satisfactory relationships with its counterparts. Nevertheless, these relationships are also impacted by the evolution of the broader political context in Switzerland – and 'isolationist' politics have been gaining support, as proven by the recent referendum on mass immigration. This political trend unfortunately comes in contradiction with the international collaboration that is moving forward the research and regulatory fields all over the world.

Switzerland obviously continues to recognize and apply all the most important international norms and regulations, which stand as the fundamental basis that has allowed our domestic companies and the overall industry to strive beyond our borders. As one of the most innovative countries in the world, we need to ensure our standards remain at the forefront of the industry, which I think we managed to do with the HRA. With the HRA, we based our strategic thinking on the international regulations while translating it to our national specificities. One of the overarching objectives was to build a modern regulatory framework that would improve Switzerland's attractiveness in terms of clinical trials investments.

Two years after the HRA was initially released, what has been the impact of this important reform?

We will probably need to wait a bit longer to truly assess the impact of this reform. Nevertheless, before 2014, the number of clinical studies approved in Switzerland was continuously decreasing, while it is now slightly picking up again.

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I am utterly convinced of the positive effect of this reform, although it is difficult to compare the evolution of the clinical research eco-system before and after the implementation of the HRA, as it introduced many structural transformations that make it not easy to find similar metrics. For example, before the release of the HRA all clinical studies had to be reviewed by Swissmedic, while now only the studies displaying a given level of risk have to receive Swissmedic's approval. In this regard, Switzerland was probably among the first countries in the world to implement such risk-based approach for clinical study evaluations. This milestone perfectly illustrates how Switzerland has been recently strengthening its regulatory leadership, while medicine approvals moreover are provided within 30 days – two times shorter than for the EMA, for example.

When we met with Walter Hölzle, he said his objective would be to decrease drug development timelines from eight to four years. From an ethical and technical point of

view, do you consider this objective reachable in the near future?

In terms of innovative drug development, we basically hold a two-fold margin for maneuver: first, on the clinical development part, and, second, on the regulatory side of the process. Considering the regulatory improvements already implemented over the past years, reducing clinical development timelines would mean that the level of data and information we hold when assessing and approving a new molecule would also decrease accordingly.

Fundamentally, reducing drug development timelines would then imply that our society as a whole is willing to accept a slightly higher level of risk. To improve timely access for patients to new medicines, we are already discussing adaptive licensing approaches, a prospectively planned process starting with the early authorization of a medicine in a restricted patient population, followed by iterative phases of evidence gathering and adaptations of the marketing authorization to expand access to the medicine to broader patient populations.

As a pharmacist by trade, I look at this interesting approach from a patient perspective: the latter undoubtedly want to access groundbreaking medicines under development as early as possible, while in the meantime it would allow the industry to more swiftly bring their most innovative treatments to the market. Nevertheless, we see that the main hindrance remains at the public opinion level, while patients probably are already ready to accept a slightly higher level of risk. At this point, we then notice a discrepancy that set apart patients from the healthy part of the population, which would be more reluctant to support a decreasing of the requirements imposed to the industry for the development of new treatments.

Nevertheless, I believe regulatory experts see adaptive licensing as a development option that needs to be seriously considered, although it could probably not be implemented for all kinds of drugs currently under development.

Given your three-fold responsibility, what are the main objectives you want to have achieved over the upcoming five years?

After the recent upgrade of the federal law for medicines and the implementation of the HRA, we now need to ensure updated regulatory processes and requirements will allow delivering the expected outcomes. Ensuring our processes become more efficient and easier to navigate is our priority, but we should not overlook the importance to endlessly strengthen the trust that our citizens holds for our institutions and quality of our medicinal products. In this regard, the concrete implementation of these two crucial regulatory milestones will be fundamental to further develop the trust we have managed to build over the past decade.

What would be your final message to our international readers?

Switzerland holds a very interesting position among the global research and innovation landscape. This positioning should not be seen as an achievement, and we need to continuously nurture and move our eco-system forward to ensure we remain at the forefront of the industry in this regard.

In this endeavor, we face several, fundamental challenges to which we will have to find a well-balanced answer, whether it concerns innovation pricing and reimbursement or accelerating the development of genetic research without compromising human dignity. Furthermore, in an industry context where regulatory and administrative burdens are still accused of hindering innovation access, we need to ensure regulations are applied with a reasonable level of flexibility, still maintaining the same high level of safety.

Talking about Switzerland specifically, I am particularly optimistic we will manage to maintain the leadership position we currently hold. Over the past few years, we have managed to introduce a sound level of centralization that helped us to render our processes more efficient. Swiss federalism, strongly based on well-balanced consensus, has also been honing our capacity to close highly satisfactory multilateral agreements, and this ability will undoubtedly stand as a strong competitive advantage.

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