Catarina Andersson Forsman – Swedish Medical Products Agency (MPA)

We must develop a system to work more efficiently with real-world data

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In a market where revolutionary treatments and new technologies threaten to introduce structural changes, the need for national authorities and regulators to adapt and catch up with the pace of the industry is of uttermost importance. Dr Catarina Andersson Forsman, director general of the Swedish Medical Products Agency (MPA), shares her unique perspective on the role that the agency must play in this regard going forward in addition to the strong commitment of Sweden to achieve the United Nation's sustainability goals.

What is the role of the Swedish Medical Products Agency in guaranteeing the safety and quality of medicines and medical products in the country?

The agency has the vision of being a leading force in the collaboration for better health, our task is to promote public health and animal health. The Swedish Medical Products Agency (MPA) is a national expert agency that operates under the Ministry of Health and Social Affairs. Our overarching goal is for individual patients and healthcare services to have access to safe and effective medicines of good quality, where benefits outweigh the risks. The mission also includes supporting pharmacies and the supervision of manufacturers of products within medical technology, cosmetic products, tattooing ink and the trade of falsified drugs.

Compared to other countries, where you have four or five agencies, our agency has many responsibilities and is fairly large in size with over 800 employees. As an agency, we have direct contact with the population through our Drug Information Center, which answers questions from the general public regarding medicines.

We also manage the Swedish Poisons Information Center, which advises the national healthcare providers and general public on the diagnosis and treatment of poisoned patients. The Center has proven to be useful for both the government and the population. For example, a few years ago, we had an issue with paracetamol because young people were using it in their attempt to commit suicide, the agency was informed through the Poisons Information Center and we were able to act rapidly. Those channels of communication are essential to promote dialogue and, in many cases, save lives.

As the national authority responsible for regulating and overseeing the development, manufacturing and marketing of drugs and medical products in Sweden, what are the main strengths of the country's healthcare system?

Sweden is considered a small country, but we work very closely together. We are looking at any kind of knowledge and information to obtain better healthcare outcomes. Compared to other countries, Sweden provides equal healthcare to the population, regardless of their geographical location; everyone is entitled to the same healthcare.

Within the pharmaceutical area, we have a national pharmaceutical strategy which translates into a yearly action plan. We host the centre for rational use of medicines that works to ensure that the action plan is implemented, which is an agreement between the Swedish Government and the Swedish Association of Local Authorities and Regions (SALAR). It is a rather unique setup because it includes the local authorities, the professional organizations, patient organizations and the state agencies.

Pharmaceutical companies and patient groups can sometimes exert pressure to regulators to bring new treatments to the market as soon as possible. How does the MPA manage the pressure and the issue of speed in the approval process?

That aspect comes close to the area where the regulatory system converges with the health technology assessment (HTA) and reimbursement system. As a regulator, we face many challenges

with new technologies and treatments, both with pharmaceuticals and medical devices. Today, we encounter large complex molecules that address a single patient, known as cell and gene therapies. It is a challenge, but we work together with the Dental and Pharmaceutical Benefits Agency (TLV), which determines whether a pharmaceutical product, medical device or dental care procedure should be subsidized by the state. The first thing that we focus on is the wellbeing of the population and we dedicate many resources to study and analyze new treatments and technologies.

Do you believe the agency is prepared for this new wave of new treatments and technologies?

Yes, but the MPA, as well as all other regulators, needs to seek the best tools to address the situation. We must develop a system to work more efficiently with real-world data. I am sure that the regulatory scene will evolve and be able to make correct determinations regarding new therapies. Expertise is another key component, and I see that the agency must continue to add experienced and talented people to the team.

Sweden would certainly like to be at the forefront of the changes, for example, we have discussed cell and gene therapies, but they have not evolved as fast as some of us thought. So, it is a balance between being prepared and having patience.

Since most of the legislation within the MPA's responsibilities is regulated at EU level, how does the agency handle potential conflicts on positions towards a substance or product with the EU?

Decisions are made in consensus. Discussing the issues is always positive, we share different points of view to reach wise decisions. Meetings happen at the EU level, but when the meetings conclude, collective decisions have been made.

A common concern among medtech companies in Sweden revolves around the new European medical device regulations set to start applying in 2020. How is the MPA working with the Swedish industry to make sure the companies are prepared by 2020?

Collaboration is a key word for us. The changes in regulations, with the added uncertainty of Brexit on top, can be too much for the system and industry. For example, every country in Europe has had to cope with the European General Data Protection Regulation (GDPR), which has not been easy, but the pharmaceutical and medical device industries are going through big structural changes with not one, but four new regulations. Two within medical devices, one in veterinary and another for clinical trials. Just implementing the regulations is an important amount of work; needless to say, the agency has been busy.

Since all the decisions within decentralized procedures are taken as a consensus opinion, we convey our position to Europe, and the Commission makes a formal decision. Any country can raise concerns in that scientific debate, which usually ends up with the best outcomes for everyone. I believe that the voice of Sweden is heard in the European Union.

Part of the United Nation's (UN) 2030 agenda is to fight the global antimicrobial resistance, reduce the environmental impact of drugs and achieve sustainable systems for industry and healthcare. What actions is the MPA taking to make sure the Swedish industry contributes to a sustainable future?

The agency is strongly committed to the UN's 2030 agenda. Our government is making an effort to ensure that everyone chips in and see the 17 goals achieved. The MPA has looked at which goals are within its responsibility. For example, we created the Center of Excellence for Medicines and Environment, which is an arena for dialogue to promote research and knowledge on the impact that pharmaceuticals have on the environment. I am happy to say that the industry is also making an effort toward sustainability. At the end of the day, we are all on the same boat.

As a regulator with decades of experience, what do you believe are the most important public health problems in society today?

One issue that sometimes holds back the healthcare system is that we have not built our primary care as we should, it is necessary to invest more. We certainly invest in hospitals, but Sweden needs to redirect funds so that patients go first through the primary care providers. It becomes an efficiency problem because people go to the emergency room when a visit to the local clinic would suffice. The MPA contributes to solving the problem with our centres of information where anybody can call and receive help, but the whole system needs to become involved in the effort.

On a positive side, what can other countries learn from the Swedish healthcare system?

Sweden is remarkably good in the collaboration area; it sets us apart. The system is built around different stakeholders sharing ideas, concerns and solutions for the benefit of everyone. Also, there is a concerted effort to support entrepreneurs and innovative companies, which helps the ecosystem grow.

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