Audit of process efficiency in the replacement of the reporting platform for therapeutic products

Federal Office for National Economic Supply

Key facts

At the end of 2021, around 11,500 human medicines were authorised in Switzerland; the uninterrupted supply of these is not guaranteed. This is not a phenomenon of the recent COVID-19 pandemic, but has been an ever-increasing concern for the therapeutic products industry, hospitals and doctors for around 20 years.

The Confederation responded in 2015 by creating a reporting office for essential human medicines in the Federal Office for National Economic Supply (FONES). The definition of "essential" is based on a risk analysis and is set out in a list of the relevant active substances. At the time of the audit, this list comprised 250 active substances, which are contained in around 15% of all approved human medicines. For essential human medicines of this kind, the marketing authorisation holders have until now reported a maximum of 200 cases of supply difficulties per year. These reports are recorded on a platform by the therapeutic products reporting office.

The platform of the therapeutic products reporting office is part of the Information and Operation System of the Coordinated Medical Services. The Information and Operation System is currently being replaced, which means that the platform must also be recreated in the new Next Generation Information and Operation System. With this audit, the Swiss Federal Audit Office (SFAO) wanted to determine if this is being done with end-to-end digital processes and whether this is creating the greatest possible benefit for all stakeholders. This is not completely the case. With the revamping of the platform, certain optimisations should be examined and, if possible, realised. In addition, the FONES should maintain the option of using the new Information and Operation System to create the necessary comprehensive data basis on supply disruptions in the therapeutic products sector.

Replacing the platform of the therapeutic products reporting office is an opportunity

The FONES plans to transfer the platform to the new Next Generation Information and Operation System largely in its current state. There is a need for optimisation in the area of evaluations, interfaces and seamless operations. In the SFAO's view, however, the opportunity should be taken to address the current lack of data on the supply situation for human and veterinary medicines, as well as for selected medical devices. In principle, the platform and the comprehensive data basis require the same information. However, the data volume is likely to multiply through such development.

In recent years, various reports on the supply bottlenecks in the therapeutic products sector have been produced by the Confederation, as well as by other bodies. These reports have a common feature, despite the fact that the approaches to solving the problem differ in some cases: all of them point to the lack of reliable data on supply disruptions across all

therapeutic products. Although there are private initiatives that attempt to provide information on supply disruptions for a much broader range of medicinal products and medical devices, these are not complete either.

Needs of users and clients, and possible synergies, must be identified

In February 2022, the Federal Council adopted measures to improve the supply situation in the therapeutic products sector. These measures relate exclusively to human medicines and must now be explored in greater depth by a working group. Limiting the scope to human medicines means that one of the Federal Council's priority measures, namely the creation of an overall view of supply disruptions in therapeutic products, cannot be guaranteed. It would be desirable to extend the working group's mandate to veterinary medicines and medical devices, although this would lead to delays for human medicines. Therefore, the SFAO recommends drawing up a plan that shows how veterinary medicines and medical devices can be integrated into this overall view within a reasonable period of time. The SFAO also recommends planning the solution architecture of the Information and Operation System in such a way that, in addition to the platform itself, the comprehensive data basis can also be created with the corresponding mandate.

In the SFAO's view, the multiplication of information at the FONES that will be created can only be managed in collaboration with the therapeutic products sector. From the discussions held, it became apparent that it would support measures to improve the supply situation, but would only want to provide one point of contact with information on this topic. The aforementioned working group will examine whether the legal basis for a close involvement of third parties in data collection and processing is sufficient. However, the existing sovereign tasks, such as the release of compulsory stocks and quota allocation, must remain in the hands of the FONES.

Despite active exchanges between the FONES, the therapeutic products sector and the various service providers (hospitals, doctors, veterinarians), as well as other federal offices (Federal Office of Public Health, Federal Food Safety and Veterinary Office), the FONES should, in the SFAO's opinion, carry out an up-to-date, systematic survey of needs before creating the new platform. These should then be reviewed by the FONES for priority and feasibility.

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