Audit of the monitoring system for medicines and vaccines

Swissmedic

Key facts

In Switzerland, no therapeutic product may be distributed without authorisation. Authorisation is granted by Swissmedic, the Swiss Agency for Therapeutic Products. The institute monitors the safety of therapeutic products sold in Switzerland. Swissmedic relies on a monitoring system for medicines and vaccines known as "pharmacovigilance". This consists of collecting reports of adverse reactions (ARs) and incidents likely to have an impact on consumer health, then examining them in order to take any necessary safety measures.

The Swiss Federal Audit Office (SFAO) examined Swissmedic's pharmacovigilance system. Its analysis focused on the reporting system and how reports are processed. In 2022, Swissmedic received 14,000 reports from manufacturers and 8,000 reports from healthcare professionals and patients. In the same year, Swissmedic carried out 700 in-depth examinations for possible safety measures. The full costs of Swissmedic's monitoring amounted to CHF 9.4 million in 2022 and this is financed 100% by the recipients of authorisations to market products. They mainly concern therapeutic products for humans. Monitoring also covers medicines and vaccines for animals, as well as blood and blood products (haemovigilance).

The SFAO found Switzerland's pharmacovigilance system to be efficient and effective, but also identified potential for increased reporting by healthcare professionals.

Better training and support for healthcare professionals

The likelihood of ARs or incidents identified by the pharmaceutical industry not being reported is low. This is because the industry is bound by safety requirements for therapeutic products when they are introduced onto the Swiss market. Healthcare professionals are also required to report serious or previously unknown ARs, any other incidents and any other observations of serious or previously unknown facts, as well as defects that are crucial to the safety of therapeutic products. A large proportion of these reports pass through specialist entities in public referral hospitals known as the Regional Pharmacovigilance Centres (RPC). Swissmedic has developed tools to facilitate the entry and forwarding of reports directly by doctors and patients. Since 2021, the institute no longer compensates the RPCs for their reports, but only for the in-depth examinations it commissions from them. This measure, together with the periodic public invitations to tender for these mandates, has made it possible to contain the costs of the RPCs at just over CHF 1 million.

Reports from healthcare professionals depend on their knowledge and motivation, and on support from the RPCs. In order to increase the number of such reports while maintaining their relevance and quality, Swissmedic should take the necessary steps to strengthen continuing professional development in pharmacovigilance for healthcare professionals.

Communication with healthcare professionals could be improved

Swissmedic's collection and processing of AR reports in Switzerland and abroad are efficient, transparent and effective. The measures taken to ensure the safety of medicines are appropriate and documented. Although they can be traced to the reports, this traceability is limited by the absence of an interface between the specific data on therapeutic products and the relevant individual pharmacovigilance reports (VigiOne). Safety measures consist primarily of amending package leaflets and informing healthcare professionals of the risks involved. In the absence of a national register of healthcare professionals and no unique electronic identification with Swissmedic, it is not possible to guarantee that potentially affected healthcare professionals will be fully informed. The SFAO notes that this is an issue in several areas of public healthcare.

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