Audit of licensing and remuneration processes for medicines

Swissmedic and Federal Office of Public Health

Key facts

In Switzerland, a new medicinal product undergoes two processes: firstly, licensing for the Swiss market by Swissmedic; secondly, the remuneration process at the Federal Office of Public Health (FOPH) for acceptance onto the list of pharmaceutical specialties. This is the list of medicines that are paid for by the compulsory health insurance (CHI). In 2021, CHI expenditure on medicines amounted to around CHF 8 billion. The Confederation covers approximately CHF 600 million of these costs via individual premium reductions.

It is important that *both* processes are expedited as quickly as possible because, as a rule, the health insurance companies must only refund the cost of a medicine in Switzerland once it has gone through the licensing *and* the remuneration process. The Swiss Federal Audit Office (SFAO) examined both processes individually and together, in order to identify any potential for shorter turnaround times. The audit showed that, ideally, reductions of some 400 days are possible across the entire process chain (currently, the process for new medicines takes about 900 days in total).

Cooperation is essential, to exploit the potential for efficiency gains

Shorter times could be achieved by, among other things, improved international division of labour, parallel organisation of licensing and remuneration processes, and provisional remuneration directly after market authorisation. This potential for efficiency gains can only be achieved if the industry is on board. This audit shows that, cumulatively, the pharmaceutical companies submit their applications to Swissmedic and the FOPH around 300 days later than possible.

The SFAO is aware that short turnaround times are not the only criterion for these processes. Efficiency gains must not come at the expense of the quality and security of medicines, or impair the appropriate supply of medicines to Switzerland and economical pricing.

Swissmedic and the FOPH have internationally competitive turnaround times

In an international comparison of licensing authorities, Swissmedic is competitive. Internal targets are in place to achieve a further 10% reduction in turnaround times by 2026. At the applicant pharmaceutical companies, processing sometimes takes twice as long as required by Swissmedic. Swissmedic is dependent on the applicants to reach this target.

Switzerland's disadvantage lies in the so-called submission gap, which, according to a joint study by Swissmedic and the industry, is around 200 days for the year 2021 compared to the submission to the European Medicines Agency (EMA). In other words, companies submit their medicines to Swissmedic for licensing with a median lag of 200 days after their application to the EMA. This slows down the entire licensing process. Here, the solution lies partly in seeking international cooperation: Swissmedic is a participant in two initiatives (Orbis and Access). Under these programmes, companies submit their dossiers

simultaneously to all participating licensing authorities, which enables Swissmedic to substantially reduce the submission gap.

A data analysis by the SFAO revealed that the FOPH's processing times also hold up well against other European countries.

The FOPH spends up to 80% of the time negotiating prices with the pharmaceutical industry

The remuneration process at the FOPH is divided into three phases: assessment, appraisal and decision. In the assessment phase, a new medicine's effectiveness, appropriateness and economic efficiency are examined. This part of the process is efficient: assessment and appraisal take up 20% of the total processing time. However, at the end of the appraisal phase there is no categorisation of the benefits with a view to facilitating price-setting. In this regard, the SFAO recommended that the FOPH introduce a simple health economy model. This could shorten price negotiations during the decision phase, because the price ranges are already defined. Nonetheless, the duration of the process remains dependent on the price level demanded by the industry.

As an alternative, approaches involving time-limited low provisional initial prices are conceivable: remuneration would then be possible directly after Swissmedic licensing and would give the FOPH time to negotiate the final prices with the manufacturers. This could shorten the entire process by over 200 days. The SFAO recommended that the FOPH examine these two approaches.

Encourage cooperation between Swissmedic and the FOPH

The practice is shifting away from sequential and towards parallel working methods. Full parallel organisation of the processes would bring further time savings of over 200 days. Thus, medicines would be remunerated simultaneously with or shortly after Swissmedic licensing, even without provisional prices. Here too, the pharmaceutical industry would have to play its part and submit its dossiers to the FOPH around 200 days earlier. A pilot scheme was a success, and others are planned. A corresponding amendment of the ordinances on early process initiation at the FOPH and the requisite data exchange with Swissmedic is already envisaged.

Rethink the division of labour for generic medication and dismantle unnecessary hurdles

Individual hurdles exist in the Swiss licensing and remuneration for generic medication. For both processes, the branded preparation has to be licensed and remunerated in Switzerland. For around ten years now, generic status has been accorded not by Swissmedic, but by the FOPH. In the industry's view, there are coordination problems as a result of this division of labour between Swissmedic and the FOPH.

These are critical points which could stand in the way of further financial savings potential through alternative generic medication. The SFAO recommended that Swissmedic and the FOPH review the appropriateness and efficiency of the process.

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