

Evaluation of authorisation and control of medicines in compulsory health insurance

Summary of the report of the Parliamentary Control of the Administration for the attention of the Council of States Control Committee

of 13 June 2013

Overview

Pharmaceutical drug prices are a recurring topic in discussions about rising health service costs. The parliamentary control committees have therefore requested the Parliamentary Control of the Administration (PCA) to assess how medicines covered by compulsory health insurance are authorised and reassessed. On 19 April 2012, the Council of States Control Committee's relevant sub-committee decided on the exact approach to be taken in the investigation.

Overview of results

The evaluation highlights a number of legal shortcomings in the process of authorisation and control, as well as difficulties in its implementation. The criteria for assessing medicines are not precise enough, the procedures and responsibilities are unclear, the recently introduced review of previously authorised medicines is not effective enough and the pricing system for generic medicines contains legal inconsistencies. It is clear that the current procedures only achieve the objective of supplying medicines cost-effectively to a limited extent: the number of medicines whose cost is reimbursed by health insurance has doubled over the past 15 years and prices of new medicines on the list of pharmaceutical specialities (SL) have risen continuously.

Imprecise assessment criteria and unsystematic benefit evaluation

Health insurance companies only reimburse the cost of medicines on the 'specialities list' (SL), which is issued by the Federal Office of Public Health (FOPH). To be listed, a drug must be effective, fit for purpose and cost-effective. These three criteria are always applied by the FOPH and the Federal Medicines Committee (FMC) when an application is made for authorisation of a new drug. However, these criteria are not defined in sufficient detail by the authorities. For example, the benefit a medicine brings is not assessed sufficiently or according to unified criteria.

This can have an effect on the price established for a drug. There are problems with both instruments employed to set prices. In a comparison with six other countries, list prices are sometimes taken which are considerably higher than the actual prices paid. This leads to excessive prices being fixed in Switzerland. The second instrument, a comparison with similar drugs on the Swiss market, would generally be more suitable to establish prices. However, it is not clearly defined which medicines are used in the comparison. The results it produces are therefore controversial. These imprecise assessment criteria weaken the FOPH's position in the face of the pharmaceutical companies, which frequently have greater scientific and legal resources.

Unclear procedures and responsibilities

There is no clear structure to the authorisation procedure for pharmaceutical drugs in Switzerland; no clear distinction is made between an assessment based on medical criteria and one made on health-policy criteria. Both the FOPH and the FMC are responsible for assessing medicines, and there is no clear allocation of responsibilities between the two. Furthermore, both the FOPH and the FMC have too few resources to carry out procedures adequately, as a comparison with other countries shows. The results of each step in the procedure are not made sufficiently transparent, either to those submitting drugs for authorisation or to the general public.

Limited assessment with little effect

Medicines are now reassessed every three years to determine whether they should remain on the SL to be reimbursed by health insurance. The first such assessment carried out in 2012 showed that the only criterion tested is price, a comparison being made with prices abroad. Medicines are not reassessed for their effectiveness and on whether they are fit for purpose, although new information about the drug may be available. In view of the resources available to the FOPH section concerned, a more extensive assessment is not realistic. The assessment procedure can therefore have at best a limited effect on medicine prices, whilst less effective medicines remain on the SL.

Generic medicines pricing system not cost-effective

The aim of mandatory health insurance is to provide a high level of healthcare at as low a cost as possible. This aim is not achieved with the current pricing system for generic medicines.

Whereas abroad the price of an original drug is lowered when a comparable generic medicine is authorised, in Switzerland its price remains the same, even once the patent has expired. The price of a generic drug in Switzerland is the price of the original minus a fixed percentage. Health insurers do not simply pay for the cheapest drug, they are also prepared to reimburse the cost of a comparable but more expensive medicine, a system which is clearly not cost-effective. Furthermore, even once the fixed percentage has been deducted, generic medicines in Switzerland are still considerably more expensive than similar products abroad.

Assessment procedure

The procedure for authorising and checking medicines paid for by mandatory health insurance was considered from three different viewpoints: from a legal perspective, in terms of its implementation and by international comparison. Two of these assessment components, the legal opinion and the international comparison, were carried out externally. The PCA considered the way the procedure is implemented by looking at individual medicines and conducting discussions with the authorities and other players involved.

The full report is available in German and French; the Italian version should be ready around March 2014: www.parlament.ch > Organe und Mitglieder > Kommissionen > Parlamentarische Verwaltungskontrolle