SIDLEY

Switzerland: Unequal Treatment of Patients With Rare Diseases

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"It can be said that the equal treatment of all health-insured persons is currently not guaranteed." This is the stark summary of a report ordered by Switzerland's Federal Office of Public Health (FOPH) and published at the end of last year. The report shows that measures introduced into law on March 1, 2011 with the objective to ensure that patients needing medicines either not authorized in Switzerland or authorized but not yet figuring on the list of reimbursable drugs could receive the medicinal therapy they need — an objective that clearly was not attained.

Swiss Health Insurance and Reimbursement System

The Swiss healthcare system is widely praised, and correctly so, for its quality. It is a very complex system. In a nutshell: Every Swiss resident is obligated to have basic health insurance coverage (BHI) that guarantees that a person receives immediate treatment by physicians and hospitals in cases of illness or accident without the need of previous administrative hassles, notably regarding costs. For their compulsory coverage, Swiss residents currently have the choice of 56 private health insurers approved by the FOPH. According to their needs and financial possibilities, consumers may take out additional insurance providing a higher level of comfort in an inpatient setting and securing the payment of therapies that are not covered by BHI (e.g., dental treatment).

With regard to the coverage of the costs for medicines, a two-tier system is in place. After a medicinal product has received its compulsory Swiss marketing authorization (Swiss MA) issued by Swissmedic, Federal Agency for Therapeutic Products, FOPH has to decide whether and, if so, for which indications, under which limitations, and at what price the product may be marketed if it is to be reimbursed by BHI. All products covered by BHI are entered into a list of specialities (SL) based on a decision by FOPH.
In some circumstances, however, therapies may not be covered by health insurers, such as (i) the off-label use of medicines, (ii) the use of medicines that have no Swiss MA, and (iii) medicines with a Swiss MA whose SL listing is still pending.

Regulatory Remedies

On March 1, 2011, a revision of the Federal Ordinance on Health Insurance (HIO) that was designed to fill these gaps in the coverage of medicinal therapy became applicable. In essence, the Swiss Federal Counsel decreed that in all the cases mentioned above, the BHI

would cover the costs, provided that the use of the product at hand is either (i) an indispensable prerequisite for the performance of another service covered by BHI and this service is clearly the primary focus, or, alternatively, (ii) the use of the drug is (a) expected to provide a major therapeutic benefit against a disease that may be fatal for the insured person or result in severe and chronic health impairments, and (b) no other effective and approved treatment method is available due to a lack of therapeutic alternatives.

For each case, that is, on a named-patient basis, based on a respective application submitted by the patient's treating physician, the health insurer of the patient decides whether the above conditions are met. With regard to the price of the medicine, the law requests that the health insurer consults the MA holder, but in essence it is the health insurer that decides on the price it is willing to reimburse (except for medicines with a foreign MA, where the price in the export country is reimbursed).

Evaluation of the Regulatory Remedies

Observers have raised numerous questions about this approach, notably about who should decide whether a medicinal therapy meets the legal conditions, decide whether it is expected to provide a major therapeutic benefit, and set the price for the therapy.

In its 125-page report on the evaluation of the 2011 revision of the HIO, the authors note that there are more and more cases of individual medicinal therapies to be decided by health insurers. The costs of the submission of and decision on coverage requests exceed 10% of the value of the medicines, which shows that the system is less than efficient.[1]

In addition to these cost considerations, however, the authors challenge how this system squares with the fundamental right to equal treatment:

For example, a test performed by the authors of the report consisted of submitting an identical application for cost coverage to 16 separate insurers, representing 80% of insured individuals. The authors found that the identical application was rejected 25% of the time, fully approved 20% of the time, and partially approved (in a trial setting) 40% of the time. The remaining applications did not receive a decision on the basis of the available information. The authors question the heterogeneity of these decisions in the light of the principle of equal treatment.[2]

The authors also questioned the overall rejection of 20% of patients' applications.[3]

[1] Report p. 15, Section 3.4.2.
[2] Report p. 20.
[3] Report p. 35, Section 6.1.

Remediating the Remedies

The report makes a string of suggestions for remediating the shortcomings of the regulation introduced in 2011.

In its comment on the report,[4] FOPH invites all stakeholders to evaluate the report's findings and communicates its plans to develop concrete measures to remediate the shortcomings of the current regulation in the first quarter of 2021 and to draft a project for a revision.

Patients and the industry are well advised to closely follow these developments. Stakeholder participation in the public consultation will inform the Federal Counsel's decision and enable it to assess the views of all stakeholders concerned.

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[4] To be found under https://www.bag.admin.ch/bag/de/home/das-bag/publikationen/evaluationsberichte/evalber-kuv.html (as only a German version of the report is published).