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Interchangeability and Incentives – Switzerland Aims at Encouraging Use of Biosimilars and Generics

The Swiss government wants to encourage the use of biosimilars and generics with the aim of decreasing the costs of healthcare. Recent regulatory and legislative changes will make it easier to replace reference products by biosimilars and incentivize patients to choose generics and biosimilars when available.

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A. Background

On September 22, 2023, the Swiss Federal Council (Government) published a bill to amend two Federal Ordinances related to mandatory health insurance, which will enter into force on January 1, 2024. The bill is part of recent legislative and regulatory activities that aim at increasing the use of generic and biosimilar pharmaceutical products in Switzerland.

As per the Federal Council, generic and biosimilar pharmaceutical products are not used as often in Switzerland as in comparable developed countries, which results in higher costs for mandatory health insurance. Among the aims of the changes is to decrease the costs of health insurance by encouraging the replacement of original or reference products by generics and biosimilars.

The latest developments include a change of the relevant regulatory environment on interchangeability of biosimilars and more restrictive rules on pricing and reimbursement of both generics and biosimilars.

The bill also includes measures related to reimbursement of pharmaceuticals that have not yet received pricing from the Federal Office of Public Health and the optimization of the process to obtain such pricing. These issues will not be further addressed in this Newsflash.

B. Interchangeability of Biosimilars with Reference Products

On June 22, 2023, the Swiss Agency for Therapeutic Products (**Swissmedic**) published an amendment of its Guidance document "Authorisation biosimilar" (the "**Biosimilar Guidance**"). The amendment is based on Swissmedic's experience from market surveillance on the safety and efficacy of biosimilars. Swissmedic's experience confirms the results of the European Medicines Agency's analysis of April 2023, supporting the interchangeability of biosimilar medicines with corresponding reference products.

Under the previous version of the Biosimilar Guidance, only the physician attending the individual patient could decide whether the reference product or a specific biosimilar be used. A replacement by another person (in particular the pharmacist or the patient) was not possible. The new version of the Biosimilar Guidance sets forth that the "medical professional" (a term that includes, among others, physicians and pharmacists) can decide to replace the prescribed reference product by a biosimilar (or the prescribed biosimilar by another biosimilar), "in consultation with the patient".

C. Incentives to Use Generics and Biosimilars

The amended Ordinance on mandatory health insurance (*Krankenversicherungsverordnung / Ordonnance sur l'assurance-maladie*) provides for a more differentiated computation of minimum price differences between reference products and biosimilars. While a biosimilar was previously deemed "economical" if its ex factory price was at least 25% below the price of the reference product, the minimum difference now depends on the yearly turnover of the reference product in Switzerland. For instance, if the yearly turnover is above CHF 25 million, the expected minimum price difference will be 35%.

The amended Ordinance on healthcare benefits (*Krankenpflege-Leistungsverordnung / Ordonnance sur les prestations de l'assurance des soins*) increases the patient's deductible when using an original or reference product in spite of generics or biosimilars being available. Currently, the patient's deductible is 10% of all costs above the patient's minimum yearly contribution ("*franchise*") and 20% upon purchasing medicinal products where a cheaper generic product would have been available. This deductible will be increased to 40% and will also apply when a cheaper biosimilar would have been available.

D. Comment

These legislative and regulatory changes are designed to address an acute concern of the Swiss population. According to a recent survey, the costs of healthcare currently constitute the biggest concern of Swiss residents (before pensions, migration or energy supply). Whether these changes will have the intended consequences (the Federal Council expects a decrease in costs of about CHF 250 million per year) will not be known before several years.

The interchangeability of biosimilars with corresponding reference products is in line with similar policies in other European jurisdictions and follows guidance published by the EMA. The doubling of the health insurance deductible when purchasing original or reference products may lead to a stronger shift towards generics and biosimilars, which in turn could lead to increased litigation activity when original or reference medicinal products approach the patent cliff.

Please do not hesitate to contact us if you have any further questions on this subject.

Legal Note: The information contained in this Smart Insight newsletter is of general nature and does not constitute legal advice.

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