Triennial review of medicines' SL prices: Lessons learned from appeals won against the FOPH

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Based on the current legislation since 2017, the Federal Office of Public Health (FOPH) reviews all medicines on the specialities list (SL) every three years to assess whether they still meet the requirements for inclusion in the SL, in particular whether they are still economical. If the latter is not the case, the FOPH orders a price reduction.

Since 2018, Walder Wyss has won a total of 18 cases before the Federal Administrative Court (FAC) and the Swiss Federal Court (FC). We take this opportunity to summarize the main lessons learned from these cases.

1. Overview of the legal framework

For a medicine to be included in the SL, it must be effective, appropriate and economical. The price review of a medicine is based on a comparison with:

– the price of the same medicine in nine reference countries (foreign price comparison, "Auslandpreisvergleich"; APV);

– the price of other medicines used to treat the same disease (therapeutic cross comparison, "Therapeutischer Quervergleich"; TQV).

After determining the average price in the reference countries in the APV and the average price of other medicines in the TQV, these two prices are weighted half each.

The cases won before the FAC and the FC can be grouped as follows:

– cases on the introduction of a limitation due to the reclassification of a medicine into another IT group (Section 2 below);

– cases on the packages and dosages to be used in the TQV (Section 3 below); and

– cases on the comparative medicines to be used in the TQV (Section 4 below).

2. Cases on the introduction of a limitation due to the reclassification of a medicine into another IT group

In cases regarding the reclassification of a medicine into another IT group, leading to a limitation of the medicine in question, the FAC has held that:

– a reclassification of a medicine and the introduction of a limitation are unlawful if they are not comprehensible, in particular when the medicine in question ranks higher in terms of appropriateness than the comparative medicines and when none of the comparative medicines in the TQV belong to the IT group which the medicine in question is supposed to be reclassified to (Decision C-6605/2018 from 4 November 2021; see our newsletter here);

– a reclassification of a medicine and the introduction of a limitation are unlawful if the FOPH does not carry out a comprehensive examination of the appropriateness of the medicine in question and if the principle of equal treatment is violated (Decision C-6601/2018 from 17 November 2021; see our newsletter here).

3. Cases on the packages and dosages to be used in the TQV

In cases regarding the packages and dosages to be used in the TQV, the FAC and the FC have held that:

- a TQV is unlawful if the dosages are not based on the product information or if they do not correspond to the dosage used in outpatient treatment, but rather to the dosage used in stationary treatment (Decision C-6115/2018 of 7 May 2020; see our newsletter here; Decision C-6116/2018 of 22 September 2021; see our newsletter here; Decision C-6117/2018 of 22 September 2021; see our newsletter here);
- a TQV is unlawful if the FOPH does not determine the usual dose of the medicines in the TQV based on the duration of therapy and the prevalence of the "therapy phases" (Decision C-5618/2020 from 30 August 2022);
- a TQV is unlawful if the FOPH only takes into account the low and medium dosage ranges, but not also the maximum dosage range according to the product information (Decision C-923/2020 of 24 May 2023);
- a TQV based solely on the NICE-guidelines is inadequate; the same holds true if the conversion of the equivalences into daily therapy costs are not comprehensible (Decision C-610/2018 of 12 October 2020);
- a TQV is unlawful if (i) it includes a medicine that is not on the SL at the time of the order by the FOPH and if (ii) it does not use the package with the lowest dosage (Decision C-613/2018 of 7 September 2021; cf. also Decision C-6117/2018 of 22 September 2021 and our newsletter here);
- a TQV is unlawful if it is based on the price of only one galenic form of the medicine in question instead of being based on the average price of both of its available galenic forms (Decision C-5955/2019 from 28 January 2022; see our newsletter here);
- a TQV must be based on the "usual dose", i.e. the recommended initial or maintenance dosage according to the respective product information; if exact dosage instructions can be found in the product information, these are to be used – and not the mean value of the whole dose range (Decision 9C_612/2020 from 22 September 2021; see our newsletter here).

4. Cases on the comparative medicines to be used in the TQV

In cases regarding the comparative medicines to be used in the TQV, the FAC has held that:

- a TQV is unlawful if it is based on a comparison with a medicine that is not a genuine therapeutic alternative to the medicine in question; when there are no comparable medicines at all, no TQV shall be carried out and the price review shall be based solely on the APV (Decision C-5979/2019 from 12 September 2022; Decision C-1791/2018 from 13 January 2023);
- a TQV is unlawful if it is based on a comparison with medicines that (i) do not cover the same dose range, (ii) are not applicable for the same patient age groups or that (iii) require additional and not pre-determinable dosages (Decision C-923/2020 of 24 May 2023);
- if no patent-expired comparative medicines are available for the TQV, a patent-protected medicine must be included in the TQV if it represents an available therapeutic alternative (Decision C-6896/2019 from 29 October 2021 and Decision C-6892/2019 from 28 October 2021; see our newsletters here and here);
- a TQV of a multi-indication medicine in which the pricing disregards any examination of the economic viability of other indications is unlawful (Decision C-7133/2017 of 16 February 2021; see our newsletter here);
- omitting a TQV despite the existence of numerous therapeutic alternatives is unlawful (Decision C-640/2018 of 6 January 2021; see our newsletter here);
- a TQV must take into account limitations of comparative medicines regarding the therapeutic line (first vs. second-line therapy) and regarding side effects (Decision C-6113/2018 of 29 September 2021; see our newsletter here).

Conclusion

Based on these cases, it becomes apparent that although the FOPH has wide discretion as to the triennial price review, it is worthwhile to carefully examine the FOPH's argumentation in each individual case.

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