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Federal Supreme Court Confirms Leading Case regarding the Examination of Drug Prices

In a judgment of 14 December 2015, the Swiss Federal Supreme Court considered the current practice of the Swiss Federal Office of Public Health (FOPH) regarding the re-examination of drugs which are reimbursed by the mandatory health insurance as unlawful. The re-examination, which is exclusively based on external reference pricing, does not comply with the Federal Health Insurance Act (HIA). With its decision, the Swiss Federal Supreme Court confirms the judgment of the Swiss Federal Administrative Court of 30 April 2015. In its triennial review, the FOPH had assessed drug prices in the context of periodical re-examinations exclusively based on external reference pricing, without considering drug pricing references in Switzerland. Furthermore, and in light of this leading case, certain amendments regarding the drug pricing regime that came into force on 1 June 2015 come into conflict with the requirements of the HIA.

Previous Practice of the Federal Office of Public Health

According to art. 65*d* para. 1 of the Ordinance on Health Insurance (OHI), the Federal Office of Public Health (FOPH) reviews all drugs included in the list of reimbursable pharmaceutical specialties (Specialties List/SL) every three years in order to determine whether they still comply with the conditions for being listed, that is, whether they are effective, appropriate and efficient. In principle, the fundamental benchmarks to evaluate a drug's efficiency are the Internal Reference Price (IRP) as well as the External Reference Price (ERP), each weighted at 50% (art. 65*b* para. 2 OHI). However, during the periodic re-examination to be conducted every three years, the ERP is taken into account almost exclusively according to art. 65*d* para. 1bis OHI. The IRP is only taken into consideration in exceptional cases, that is, when a comparison with drug prices of reference countries is not feasible. Depending on whether the IRP is included in the examination, the approved drug prices vary.

Limited Examination is not in Accordance with the Law

The proceedings concerned an order of the FOPH that imposed to reduce the price of a specific drug in the context of the triennial review by almost 26% only based on the ERP, without consideration of the IRP.

In its decision C-5912/2013 of 30 April 2015, the Swiss Federal Administrative Court had approved an appeal submitted by the license holder against the respective order. Subsequently, the FOPH submitted an appeal to the Federal Supreme Court. With its decision 9C_417/2015 of 14 December 2015, the Federal Supreme Court confirmed the decision of the Federal Administrative Court and rejected the appeal lodged by the FOPH.

The Federal Supreme Court firstly examined the meaning of the term efficiency and concluded with regard to the prevailing theory and settled case law that one can only decide whether a certain cost-benefit-ratio is favorable or unfavorable by comparing different cost-benefit-ratios. The Supreme Court's case law shows that a comparative rating of various drugs was always a key element of the evaluation of the drugs' efficiency. The Federal Supreme Court therefore supports the argument of the Federal Administrative Court stating that the IRP is to be understood as an essential evaluation criteria regarding a drug's efficiency. The Federal Supreme Court held that a limited assessment of the efficiency, which is only based on the comparison of the ERP, does not consider the cost-benefit-ratio.

The Federal Supreme Court pointed out that with the abandonment of the IRP, possible changes on the SL cannot be taken into consideration, in particular new and more efficient drugs or a new study regarding the efficiency of the drug that is under review. Consequently, the legislator's aim to sort out services which do not meet the requirements set out in article 32 para. 1 of the Federal Health Insurance Act (HIA) is not fulfilled.

The respective weighting of the IRP and the ERP and the question whether an IRP which is higher than the ERP has to be considered as well, were not addressed by the Federal Supreme Court as these issues had not been discussed by the Federal Administrative Court either.

In contrast to the Federal Administrative Court, the Federal Supreme Court did not discuss a possible violation of the constitutional guarantee of economic freedom. Because article 65d para. 1bis lit. a OHI violates the constitutional principle of legality and because, therefore, the appeal had to be dismissed anyway, the question of the applicability of the right to economic freedom could be left open.

Amendment of the OHI and the OSCHI Entered into force on 1 June 2015

On 1 June 2015 various amendments of the OHI and the Ordinance on Services in the Compulsory Health Insurance (OSCHI) with regard to drug pricing entered into force. These amendments shall be applied for the first time within the examination of drug prices in 2016. However, the new rules still do not take the IRP and the ERP into consideration equally:

- When assessing the efficiency with respect to the admission of a drug to the SL, the ERP shall be weighted twice and the IRP only once. As a rule, the newly fixed price may exceed the ERP by no more than 5%.
- In the context of the triennial review, the ERP must be taken into account for two thirds and the present price for one third. However, the margin of tolerance of 5% currently applicable shall be rescinded. The IRP shall continue to be applied only exceptionally, in particular, if the ERP cannot be carried out at all or only in less than three reference countries.

In view of the Federal Supreme Court's judgment of 14 December 2015, these regulations also come into conflict with superior law.

Conclusion

In its new leading case, the Federal Supreme Court held that the FOPH has to adhere to the requirements of the HIA, and the court follows the argumentation of the Federal Administrative Court. When conducting the triennial review, the efficiency of a drug is to be assessed based on the same criteria that apply when a drug shall be first admitted to the SL. Both the IRP and the ERP must be applied.

Neither the Federal Supreme Court nor the Federal Administrative Court made a statement regarding the respective weighting of the ERP and the IRP. In this respect, some uncertainty remains and will only be sorted out in the course of other appeals proceedings.

The new rules which entered into force on 1 June 2015 and which do not consider the IRP and the ERP equally appear to be unlawful as well.

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