Baker McKenzie.

Legal Update

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Poland: Amendment to the new Reimbursement Act

In brief

Since late 2020 a reimbursement fast-track program for the most innovative oncology and rare disease treatments (defined as highly innovative medicinal technologies (HIMT)). For example, the first ever HIMT has become reimbursed for this new procedure in less than two years since its authorization. We also observe an increasing number of rare disease therapies being reimbursed in a standard procedure and the Minister of Health (MoH) has recently reported progress in the implementation of the Plan for Rare Disease for 2021-2023. The above significantly changes the perception of Poland as one of the last countries where fast reimbursement of such therapies is possible.

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Key takeaways

On 30 June 2021, the initial draft of the largest amendment to the Polish Act on Reimbursement of 2012 ("**Draft**") since its introduction into the Polish legal system was published for public consultations by the MoH.

Analysis of the comments submitted within the public consultations took quite a long time as the MoH sent the new version of the Draft to the Permanent Committee of the Council of Ministers on 26 August 2022. This means that the works on the Draft have resumed, although the expectations of the pharmaceutical industry were that the MoH would discontinue them.

The resumption of works is all the more problematic as the MoH has chosen to leave in place most of the unfavorable proposals that have been criticized by the industry. If adopted in its current shape, the new regulations would be detrimental to the Polish reimbursement system in whole. It would also obviously hit hard on oncology and rare disease drugs by introducing solutions, summarized in this newsletter, setting up real barriers for their reimbursement in the future.

Below please see a brief summary of the most important amendments proposed by the MoH.

In more detail

1. Obligation to apply for all the presentations of the medicinal products

Current: No such regulation.

Draft: Medicinal product of the marketing authorization holder (MAH) or its parent or subsidiary could not be reimbursed in case this entity has not submitted the reimbursement applications for all presentations of this medicinal product admitted to trading in the territory of the Republic of Poland. What is even more interesting is that the Draft requires the applicants to apply for the reimbursement of a new presentation of medicinal products within three months as of the date of its marketing authorization under the pain of revoking the reimbursement decisions issued for other, already reimbursed presentations.

2. Exclusion from reimbursement of Rx (subject to prescription) medicinal products having OTC equivalent

Current: Rx medicinal product may not be reimbursed if it has an OTC equivalent unless it requires use for more than 30 days in a specific clinical condition.

Draft: Exclusion from reimbursement of Rx medicinal products having an OTC equivalent of the same MAH or its parent or subsidiary, regardless of the length of treatment.

3. Obligatory refusal if QALY cost is >6x GDP per capita

Current: One of the criteria taken into account by the MoH while deciding on the reimbursement is the amount of the cost threshold for obtaining an additional quality-adjusted life year (QALY), set at three times the GDP per capita in Poland or if this cost cannot be determined, the cost of obtaining an additional life year.

Draft: The abovementioned criteria would remain unchanged however, the MoH would become obliged to refuse to reimburse a given product (except for the reimbursement of the highly innovative medicinal technologies (HIMT) or medicinal technologies of a high clinical value (MTHCV)) if the amount of the threshold of the cost of obtaining an additional QALY exceeds six times the GDP per capita in Poland, or if it is not possible to determine this cost - the cost of obtaining an additional life year.

The abovementioned amendment would likely set up an obvious barrier to reimburse many therapies used in rare diseases and/or oncology, which by their nature very often exceed this threshold. The exception will be HIMTs and MTHCVs, which will not be affected by this restriction, but it should be assumed that only in connection with the first reimbursement decision.

4. Price limits for medicinal products available in pharmacies and having reimbursed equivalents

Current: Net selling price of a medicinal product, Foodstuff or MedDev agreed in the next reimbursement decision (continuation) may not be higher than the actual price.

Draft: The cost of one DDD of a medicinal product availability in pharmacies could not exceed: (i) 150% of the DDD cost of the limit base if the medicinal product being subject to continuation proceedings is an equivalent of the medicinal product constituting the limit base; (ii) 150% of the DDD cost of the cheapest equivalent, if the medicinal product being subject to continuation proceedings is not equivalent to the medicinal product constituting the limit base.

5. Effective price as a rule for continuation of reimbursement

Current: The OSP set in the new reimbursement decision (continuation) cannot be higher than the one set in the previous one.

Draft: The abovementioned concept of the effective price is proposed to be a rule. Precisely, in case where there was an RSS agreed in a given reimbursement decision resulting in a decrease of the net selling price (effective price), the effective price included in the new reimbursement decision could not be higher than in the previous one.

6. Prohibition to change the reimbursement application after the Economic Committee's (EC) resolution and to suspend the reimbursement proceedings

Current: No such provisions.

Draft: Prohibition to modify the application, including the net selling price and the RSS following a resolution of the EC. While the MoH will be entitled to conduct additional negotiations, it is not a secret that today it is only the negotiations with the MoH that are relevant to the actual determination of the reimbursement conditions.

The Draft also envisages a prohibition to suspend the proceedings.

7. Publication of the result of negotiations with the negotiations protocols in case of lack of agreement with the EC

Current: Only in case of lack of agreement between the applicant and the EC with respect to HIMT or MTHCV negotiations process its outcome and information on the course of negotiations, excluding information constituting company secrets, is published by the MoH.

Draft: In case of lack of agreement between the applicant and the EC, the result of the negotiations together with the negotiation protocols, excluding information constituting company secrets, would be published by the MoH following any reimbursement proceedings.

8. Obligatory price decrease following the LoE

Current: In case of the loss of market exclusivity (LoE), the official selling price (OSP) set in the first reimbursement decision issued after the LoE may not be higher than 75% of the OSP set in the previous decision ("**Obligatory price decrease**").

Draft: Obligatory price decrease is planned to be linked not only with the LoE, but also with the patent protection or supplementary protection certificate (SPC), whatever occurs first. Moreover, if the reimbursement decision contains the risk sharing scheme (RSS) decreasing the net selling price (NSP) (effective price), the obligatory price decrease of 25% would apply to this effective price.

9. Payback

The MoH resigned from a very significant change of the current payback regulations proposed in the initial version of the Draft. In general, the MoH decided to leave one important amendment.

Current: RSS agreed in the reimbursement decision exempts from payback.

Draft: RSS would generally be exempt from payback, except for the situation where calculated payback would be higher than (i) the amount of receivables which the obligation to transfer to the National Health Fund (NHF) results from that RSS - in case of medicinal products, foodstuffs intended for particular nutritional uses ("**Foodstuff**") or medical devices ("**MedDev**") available in pharmacies upon prescription; (ii) the actual value (savings or total benefits) obtained by the NHF as a result of that RSS - in the case of the products available within the drug programs or chemotherapy. However, the difference resulting from the reduction of the "payback" amount per applicant in a given limit group by the amounts indicated above is to be reimbursed.

10. Benefits for medicinal products manufactured in Poland or from API manufactured in Poland

Current: No such provisions.

Draft: Entity applying for reimbursement of a medicinal product: (i) manufactured in Poland, (ii) manufactured from API manufactured in Poland or (iii) manufactured in Poland from Polish API, would be entitled to choose up to two (in case of point (iii)) administrative or economic benefits envisaged in the Draft.

11. Creation of separate or joint limit groups during the reimbursement decision validity period

Current: Limit groups remain unchanged during the reimbursement decision validity period.

Draft: Limit group could be changed during the reimbursement decision validity period and in such case this decision would be changed ex officio. The right of the MoH to make ex officio changes to the limit groups while the reimbursement decision is in force disturbs the stability of the reimbursement conditions for applicants and patients.

12. Changes in the drug program descriptions creation and changing processes

Current: Drug program descriptions are proposed by the applicant and jointly agreed between the applicant and the MoH during the reimbursement proceedings.

Draft: The applicant would still be obliged to propose a drug program description, but the provisions regulating the process of agreeing its content between the applicant and the MoH would be repealed and substituted with the ones envisaging that MoH would create and change the drug program descriptions. The applicants would only be entitled to present their non-binding opinions within seven days of the receipt of the draft.

13. Changes in the reimbursement applications

The Draft envisages certain changes in the requirements regarding the reimbursement applications:

- In case of application to increase the net selling price - evidence of an increase in the manufacturing costs of a medicinal product, foodstuff or medical device and an economic analysis of the manufacturer's manufacturing and operating costs justifying the increase requested would be required.
- An application to increase the net selling price submitted during the duration of the reimbursement decision lasting before the LoE or patent protection and during the period of 12 months of the first reimbursement decision issued after these circumstances would have no legal effect.
- Proof of availability in the "ordinary" reimbursement proceedings - finally, in case of advanced therapy medicinal product, an applicant would need to commit to ensure that it is technologically ready to be manufactured at the time of submission of the application;
- Decisions, orders and other letters issued in the course of proceedings conducted using the SOLR system would be deemed to have been delivered when signed and placed in the recipient's mailbox, which is an incomprehensible idea;

14. Supply obligation and consequences of failure to comply.

Current #1: In the reimbursement applications, applicants are obliged to ensure uninterrupted supplies, specifying the annual volume of supplies, broken down on a monthly basis (subject to the actual issuance of the reimbursement decision).

Draft #1: The minimum annual volume of supply for the only medicinal product reimbursed in a given indication the applicants would be obliged to ensure shall be no less than 110% of the estimated annual population, and for a product for which at least one equivalent is reimbursed in a given indication, no less than the value given by the formula indicated in the Draft. It is obvious that while drafting these provisions, the MoH has not taken into account the manufacturing or distribution capacity.

Current #2: In case of failure to comply with the supply obligation followed by unmet patient demand, the applicant is obliged to reimburse the NHF the amount calculated by multiplying the number of undelivered packs and their official net sales price unless the non-fulfillment of this obligation is a consequence of force majeure or the patients need has been fulfilled by its equivalent.

Failure to meet the obligation for continuity of supply is understood as the lack of turnover of a reimbursed product determined based on reports submitted daily to the ZSMOPL electronic system.

Draft #2: The obligation to reimburse the NHF would no longer be linked with unmet patients demand or fulfilled by its equivalent.

Failure to meet the obligation for continuity of supply would be understood as the lack of turnover of a reimbursed product consisting of failure to supply the product to a healthcare services provider or pharmaceutical wholesaler located in Poland in quantities not less than for a period of three months resulting from the obligation of monthly supply and, in the case of an advanced therapy medicinal product, failure to comply with the obligation to ensure technological readiness for its manufacture. The above obligation would not apply to medicinal products which are subject to central tenders conducted by the NHF in the event of selection in this tender of a supplier of medicinal products for the entire patient population in a given reimbursement indication for a period of at least 12 months.

What is also interesting, in the case of reimbursed medicinal products, foodstuffs or medical devices availability in pharmacies upon prescription, the applicant would be obliged to supply these products in equal quantities to at least 10 pharmaceutical wholesalers with a full profile in the territory of Poland, with the largest share of turnover with pharmacies open to the public.

15. Reimbursement lists publication dates

Current: Reimbursement lists are published every two months.

Draft: Reimbursement lists would be published every three months. This means that if the reimbursement decision is issued before the reimbursement list publication date it will not enter into force until the date of entry into force of this next list.

16. Full responsibility of MAH for off-label reimbursement

Medicinal products in Poland can be reimbursed off-label only ex-officio by the MoH (no procedure to apply). The Draft envisages that MAH which has obtained the off-label reimbursement decision would, irrespective of the SMPC content, assume full responsibility for the adverse effects of the medicinal product concerned for the indications covered by that reimbursement decision.

Conclusion

The key problem of the Draft is that the MoH and the pharmaceutical industry stakeholders differently define the drug safety defined as ensuring availability of treatment to patients in Poland. The majority of proposed changes might likely result in progressive withdrawal of certain medicinal products from the Polish market which would result in opposite effect to the anticipated one.

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