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Legal Update

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Poland: Amendment to the new Reimbursement Act

In brief

Recently, the Polish Minister of Health ("MoH") has resumed work on the largest amendment to the Polish Act on Reimbursement ("Draft") since its introduction into the Polish legal system in 2012. Although during almost eleven years of this Act being in force some areas requiring amendments have been identified, the Draft is all about something different.

In this issue

Key takeaways

The initial version of the Draft was published for public consultation by the MoH on 30 June 2021.

Analysis of the comments submitted within the public consultations took a long time as the MoH only sent the new version of the Draft to the Permanent Committee of the Council of Ministers on 26 August 2022. This means that work on the Draft has now resumed, although the expectation of the pharmaceutical industry was that the MoH would discontinue them.

The resumption of work 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, there are concerns that the new regulations would be detrimental to the Polish reimbursement system as a whole. It would hit hard particularly 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 cannot be reimbursed if this entity has not submitted the reimbursement applications for all presentations of the medicinal product authorised in the territory of the Republic of Poland. What is even more interesting is that the Draft requires the applicant to apply for the reimbursement of a new presentation of a medicinal product within three months of the date of its marketing authorization or face losing reimbursement decisions issued for the MAH's 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 of 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. This means that if the Draft comes into force in its current shape it will have an impact on certain medicinal products, therefore it is not welcomed by pharmaceutical companies.

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 becomes 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.

This 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 noted that these products have HIMT or MTHCV status only for the first reimbursement application. Therefore, this limitation would apply once applying for the continuation of reimbursement.

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

Current: Net selling price of a medicinal product, foodstuff intended for particular nutritional use or medical device agreed in the next reimbursement decision (continuation) may not be higher than the actual price.

Draft: The cost of one defined daily dose ("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. This is one of the most criticized changes by pharmaceutical companies as it may result in withdrawing certain products from reimbursement due to price referencing system in Europe.

5. Effective price as a rule for continuation of reimbursement

Current: The official selling price ("**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 as a rule. In cases 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 cannot be higher than in the previous one. The key question is how would it be calculated in case of more complicated RSS.

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, what has been often used by pharmaceutical companies, e.g. when the negative decisions was expected.

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

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

Draft: In case of disagreement 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. Pharmaceutical companies are very sensitive in this respect however, a couple of such reports from HIMT negotiations have been published and no confidential information is visible. Therefore, we are in the position that there is no reason to worry about this.

8. Obligatory price decrease following the LoE

Current: In case of the loss of market exclusivity ("**LoE**"), the 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. Pharmaceutical companies are against the current wording which forces pharmaceutical companies to cut the prices of medicinal products although there is no competition on the market. This change is definitely not welcomed by pharmaceutical companies as it is more unfavorable than the current version.

9. Payback

The MoH reversed a very significant change to 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, i.e. even if based on the regulations given applicant should be obliged to return certain amount as a payback, the fact that its reimbursement decision contains RSS results in no obligation to pay it.

Draft: RSS would generally 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 or medical devices 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 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. This means that one of motivators for consent to agree on RSS will no longer exist if payback applicants having it in their reimbursement decision would be subject to payback (although not in every situation).

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. This is something what the entities manufacturing medicinal products were fighting for. However, their expectations as to the benefits were different than the ones proposed by the MoH. Also, there are no doubts that these benefits are so unattractive that they would not convince any company to locate their manufacturing site in Poland.

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

Current: In general, medicinal products that have the same INN or different international names, but similar therapeutic effect and mechanism of action are classified in one "limit group". 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 cases these decision would be changed ex officio. We are in the position that the right of the MoH to make ex officio changes to the limit groups while the reimbursement decision is in force arguably disturbs the stability of the reimbursement conditions for applicants and patients. This is why this proposed change is widely criticized by pharmaceutical companies.

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 drug program descriptions. The applicants would only be entitled to present their non-binding opinions within 7 days as of the receipt of the draft. In fact this change would reflect the current practice of the MoH, where the applicant's opinions are also non-binding, but it is not that clearly provided in the law.

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 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 as customarily, in different kinds of proceedings where documents are delivered by a traditional mail, they are deemed to be delivered on the day of receipt by the addressee; it should be also noted that the system of notifying applicants about new documents in mailbox does not work properly.

14. Supply obligation and consequences of failure to comply

Current #1: In reimbursement applications, applicants are obliged to ensure uninterrupted supplies, specifying the annual volume of supplies, broken down on a monthly basis (subject to 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 mustbe 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 patients' demand the applicant is obliged to reimburse to the NHF the amount calculated by multiplying the number of undelivered packs and their official net sales price, unless the non-fulfilment of this obligation is a consequence of force majeure or the patient's 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 in 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 3 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. This obligation would not apply to medicinal products that 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, is that 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 (with no procedure to apply). The Draft envisages that an 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. The key concern is that off-label use is not properly verified and, consequently, out of pharmaceutical company's control. This is why this proposal is widely criticized as potentially creating a significant risk.

Conclusion

The key problem of the Draft is that the MoH and the pharmaceutical industry stakeholders differently define drug safety as ensuring availability of treatments to patients in Poland. In fact, the majority of the proposed changes could well result in the progressive withdrawal of certain medicinal products from the Polish market, which would result in the opposite effect to that anticipated.

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