Baker McKenzie.

Major Reimbursement Act Amendment

November 2023

In brief

On 1 November 2023 (except for only a small number of provisions) the largest amendment to the Polish Act of 12 May 2011 on the Reimbursement of Medicinal Products, Foodstuffs Intended for Special Dietary Purposes and Medical Devices (the "**Act**") since the introduction of the act into the Polish legal system in 2012 finally comes in force (the "**Amendment**").

The Amendment has been widely criticized by the pharmaceutical industry as not only failing to make changes beneficial for patients and the industry but even as negatively affecting the functioning of the reimbursement system in Poland.

Key takeways

The Act is the key legal instrument regulating the principles by which the Republic of Poland finances the use of medicinal products, foodstuffs for special dietary purposes and medical devices to patients. At the time of its introduction into the legal system, the Act was intended to introduce a greater degree of transparency in the reimbursement activities of public authorities as well as to open up the reimbursement system to new innovative products while also rationalizing public spending on these products. **Its main objective was to transform the existing system so that, with the public financial resources available, it responds as fully as possible to current social demand for reimbursed products.**

It became apparent that the Act required changes in certain areas more than 10 years after its entry into force and during which time it was not amended to any significant degree.

In the summary of the Amendment (also referred to as its justification) the Minister of Health (the "**MoH**") maintained that it will, for example, ensure:

- a stable level of funding for reimbursed products
- enhance efficient use of public funds to achieve optimal health effects
- the systematic expansion of the reimbursed therapies with proven efficacy available
- optimization of the reimbursement system for medicinal products that are not yet regulated by the Act
- a systematic reduction in patient contributions to financing reimbursed products
- greater transparency of reimbursement decisions and more trust in dialogue

- a reduction in bureaucracy in certain areas
- an increase in what is termed the "medicinal safety of Poland", i.e. the set of benefits awarded to pharmaceutical companies manufacturing products and/or active pharmaceutical ingredients ("**API**") in Poland.

Unfortunately, experts' predictions are not so optimistic. Indeed, there are a couple of positive changes but in the main **the Amendment is expected to negatively impact the pharmaceutical industry** and, contrary to what the MoH believes, the situation of patients.

Among other things, the Amendment introduces regulations:

1. allowing the MoH to exercise manual control in certain areas, which might have an impact on the stability and certainty of administrative decisions (which is a general rule)
2. establishing incomprehensible supply obligations
3. significantly changing the process of creating drug programs (used for the most expensive products, including orphan and oncology medicinal products) and an increased role of coordinating teams in the treatment process.

Please find below a brief summary of the most important amendments proposed by the MoH. Please note that, except for certain amendments that will come into force on a different date (as indicated in this document), **the Amendment comes in force on 1 November 2023**.

Sections starting with "**Former**" refer to the previous wording of the Act, valid until 1 November 2023, whereas those starting with "**Amendment**" summarize the changes introduced in the Amendment, starting from 1 November 2023 (except for certain exceptions where the new regulations come into force later).

"**Rating**" refers to our subjective assessment (**Negative**, **Neutral**, **Positive**) of a particular change proposed in the Amendment from the point of view of the pharmaceutical industry.

"**Hint**" refers to an unofficial interpretation of the MoH, presented during workshops for marketing authorization holders (the "MAH") and their representatives, organized by the MoH on 18 October 2023.

In more detail

PRODUCT SUPPLIES

1. Supply obligations and non-compliance consequences

Former #1:

In the reimbursement applications, applicants (i.e. MAHs, their representatives or economic operators, in case of medical devices) are obliged to ensure uninterrupted supplies and to specify annual supply volumes broken down by month (subject to the actual issuance of a reimbursement decision).

Amendment #1:

Rating: **Negative**

The minimum annual supply volume for the only medicinal product reimbursed for a given indication that applicants undertake to provide must amount to no less than 110% of the estimated annual demand, whereas for a product for which at least one equivalent is reimbursed for a given indication, no less than the value resulting from the formula set out in the Amendment. It is obvious that in drafting these provisions, the MoH failed to take in account manufacturing or distribution capacity.

Hint #1:

One of the transitional provisions stipulates that existing regulations will apply to proceedings initiated but not completed before 1 November 2023, except for the provision regulating the new content of the reimbursement decision (e.g., that the reimbursement decisions will contain the annual supply volume) and the provision prohibiting the suspension of proceedings. However, the MoH claims that although the annual supply volume will be a part of the decision, it would not be calculated in accordance with the new rules. The MoH plans that before issuing a reimbursement decision, applicants will be informed about the expected annual supply volume which, however, should be in line with declarations made in reimbursement applications submitted before the Amendment came in force.

Hint #2:

The MoH claims that the annual supply volumes calculation formula should only be used by applicants for the purpose of declarations in the reimbursement applications. This does not, however, mean that the same supply volumes will be included in reimbursement decisions. While determining the actual supply volume obligation, the MoH will count the supply volumes of individual applicants in proportion to their market shares. If the market situation changes after the issuance of a decision (e.g., a new product enters the limit group), then it would

be possible to apply to the MoH to amend the decision (pursuant to Article 155 of the Code of Administrative Procedure; "CAP").

Former #2:

In the event of the failure to fulfil a supply obligation (annual volume or continuity of supply) followed by subsequent unmet patient demand, applicants are obliged to reimburse the National Health Fund (the only public payer in Poland; the "**NHF**") an amount corresponding to the number of undelivered packs multiplied by their official net sales price, unless the non-fulfilment of the obligation is the consequence of force majeure or patient needs have been satisfied by an equivalent.

Failure to meet a continuity of supply obligation is construed as the lack of turnover for a reimbursed product as determined on the basis of reports submitted daily to the electronic system for the monitoring of trade in medicinal products (pol. ZSMOPL).

Amendment #2:

Rating: **Negative**

The obligation to reimburse the NHF would no longer be linked to unmet patient demand or fulfilment by an equivalent unless the holder of a reimbursement decision has fulfilled the obligation referred to in the paragraph below. Moreover, irrespective of the obligation to reimburse the NHF, the holder of a reimbursement decision would need to cover NHF costs related to ensuring the availability of an equivalent.

Failure to meet a continuity of supply obligation would be construed as the lack of turnover for a reimbursed product stemming from the failure to supply the product to a healthcare services provider or pharmaceutical wholesaler located in Poland in the period of given quarter in quantities resulting from a supply obligation for this quarter and, in the case of an advanced therapy medicinal product, failure to comply with the obligation to ensure technological readiness for the manufacture of such product, unless the failure to perform this obligation is a consequence of force majeure event. Such obligation would not apply to: (i) medicinal products sourced under central tenders conducted by the NHF in the event that under a tender, a supplier of medicinal products for the entire patient population for a given reimbursement indication is selected for a period of at least 12 months and (ii) seasonal products.

The above obligation is planned to become effective as of 1 July 2024.

Hint:

The MoH is of the opinion that in order to fulfill the supply obligation, it is necessary and sufficient to demonstrate that there was a three-month supply of the product on the market in a given calendar quarter. Thus, it is not necessary to supply three months' stock to customers if the quantities of the product already available on the market are sufficient. Stock delivered in the previous quarter could also be used to document the fulfillment of the supply obligation. It is possible to present the amount of product at all levels of the wholesale trade – only except for products already in hospitals and outside of Poland.

Former #3:

No such regulation.

Amendment #3:

Rating: Negative

Another interesting change is that in the case of reimbursed medicinal products, foodstuffs or medical devices sold in pharmacies on a prescription basis and which are at risk of becoming unavailable, the applicant would be obliged to supply such products in equal quantities to at least 10 full-profile pharmaceutical wholesalers on the territory of Poland with the largest share of turnover with pharmacies that are open to the public.

The MoH will publish a list of products that are at risk of becoming unavailable (and update this list whenever required) and of the 10 wholesalers (annually by 30 April, based on data for the previous calendar year).

The above obligation is planned to become effective as of 1 January 2024.

Hint:

The MoH is not yet sure if it will publish a list of products and wholesalers from the very outset. Also, during the meeting at the MoH it was stated that lack of supply to a listed wholesaler due to lack of payment is a mitigating circumstance. Similarly, if certain wholesalers do not wish to purchase products, that constitutes an objective reason for which a given entity may not be penalized.

CONFIDENTIALITY

2. Publication of the result of negotiations along with negotiation protocols if there is disagreement with the Economic Committee ("EC")

Former #1:

The details of the negotiations process and information about it (excluding information constituting company secrets) is published by the MoH where there is disagreement between an applicant and the EC during a highly innovative medicinal technology ("**HIMT**") or medicinal technology of high clinical value ("**MTHCV**") reimbursement process and the EC adopts a negative resolution regarding a recommendation for reimbursement.

Amendment #1:

Rating: Negative

In the event of a disagreement between an applicant and the EC (over 90% of negotiations regarding innovative products), 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. In other words, the Amendment assumes that an EC negative recommendation would trigger the disclosure of the outcome of negotiations and negotiations protocols in the reimbursement process for every product, not only HIMT or MTHCV. Examples of such reports regarding HIMT negotiations are available here: https://www.gov.pl/web/zdrowie/fmltowpi.

Former #2:

No such regulation.

Amendment #2:

Rating: Negative

New regulations envisage reimbursement secrecy by indicating the subjective and objective scope thereof. However, at the same time an exemption linked with the "*execution of the provisos of international agreements, bilateral agreements or resolutions regarding an exchange of information connected to reimbursement of medicinal products, foodstuffs intended for special nutritional purposes and medical devices*".

Hint:

According to the MoH, the provision envisaging a bilateral exchange of pricing information results from discussions emerging in the EU about the possibility of mutual exchange of reimbursement information, potentially including RSS. Hence, this provision was introduced in order to enable such exchange in the future.

3. Reimbursement confidentiality

Former:

No specific provisions regarding the confidentiality of the reimbursement process, save for the general rules and situation described in point 2 above.

Amendment:

Rating: Negative

The Amendment contains new provisions regulating the scope of reimbursement confidentiality, i.e. what information is subject to confidentiality, as well as who is obliged to observe confidentiality (e.g. employees of authorities having access to confidential information). However, the Amendment also contains a provision indicating situations in which the MoH, ministry employees and other authorized persons are exempt from this obligation. Such situations include the performance of international or bilateral agreements or arrangements regarding the exchange of information on reimbursement. This could lead to a broader (compared with the current status quo) exchange of information between Poland and any EU Member State regarding the reimbursement conditions for a given product.

PRICING

4. Effective price as a rule for continued reimbursement

Former:

The official selling price set in a new reimbursement decision (continuation) cannot be higher than the one set in the previous decision.

Amendment:

Rating: Negative

It is proposed that such effective price should become the rule. In cases where a risk sharing scheme ("**RSS**") agreed in a given reimbursement decision would reduce the net selling price (effective price), the effective price included in the new reimbursement decision would not be higher than in the previous one. The key question is how this would be calculated in the event of a more complicated RSS, as the proposed regulation is not precise in this respect.

5. Obligatory price decrease following loss of market exclusivity or patent protection expiry

Former:

In the event of the loss of market exclusivity ("**LoE**"), the official selling price set in an initial reimbursement decision issued after LoE may not be higher than 75% of the official selling price set in the previous decision ("**obligatory price decrease**").

Amendment:

Rating: Positive*

It is planned that an obligatory price decrease will be linked not only to LoE but also to the expiry of patent protection, whichever occurs first.

Whereas the current wording does not assume the existence of an RSS, the proposed wording is more aligned with the market reality. The basic scenario would remain the same, i.e. in the case of a reimbursement decision without an RSS, the net selling price (the Amendment generally changes the reference point used by the Act from the official selling price (net selling price + VAT) to net selling price) would need to be set at the level of 75% of the net selling price established by the previous decision.

However, the Amendment assumes an option whereby an applicant would agree with the MoH on setting up an RSS to decrease the confidential effective price instead of the net selling price.

* ***Rating: Rather positive, except for additional link to the expiry of patent protection***

Example: *Let's assume that the net selling price=100. In such case, the applicant might agree with the MoH that the net selling price would remain at the level of 100 but that the newly established confidential effective price would not be higher than 75. Therefore, an actual decrease in the cost of reimbursement would be achieved by decreasing the confidential price, not the official one, and that is beneficial in the light of the reference pricing system.*

The last option would apply to a reimbursement decision containing an RSS decreasing the net selling price (confidential effective price) and envisages two scenarios: (i) an obligatory price decrease of at least 25% applicable to such confidential effective price or (ii) an obligatory price decrease of at least 25 percentage points divided between the net selling price and the confidential effective price.

Example: *It is difficult to predict how this would work in practice. However, let us assume that the net selling price=100 and the confidential effective price=80. Considering the proposed wording, we can imagine a net selling price decrease to 85 and a confidential effective price decrease to 70 (25 pp. in total).*

Hint:

In cases where the date of the obligatory price decrease would occur earlier than subject to the former regulations, the MoH would not shorten the reimbursement decisions.

6. Creating separate or joint limit groups during validity of a reimbursement decision

Former:

In general, medicinal products that have the same INN or different international names but similar therapeutic effect and mechanism of action are treated as belonging to one "limit group". Limit groups remain unchanged as long as a reimbursement decision remains valid.

Amendment:

Rating: Negative

Limit groups could be changed (by way of creating separate or joint limit groups) while a reimbursement decision is valid and in such cases, these decisions would be changed ex officio with immediate effect. Our position is that the right of the MoH to make ex officio changes to limit groups while a reimbursement decision is in force arguably disturbs the stability of the reimbursement conditions for applicants and patients. For this reason, the proposed change has been widely criticized by pharmaceutical companies.

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

Former:

No such provisions.

Amendment:

Rating: Neutral*

An 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 the case of point (iii)) administrative or economic benefits envisaged by the Amendment. This is something that entities manufacturing medicinal products have been fighting for. However, their expectations as to benefits were different from the benefits proposed by the MoH. Moreover, there is little doubt that these benefits are so unattractive that they would not convince any company to locate a manufacturing facility in Poland.

* *Rating: Neutral* ***(neither an incentive to consider manufacturing medicinal products or API in Poland, nor a real benefit for those already manufacturing them in Poland)***

8. Wholesale and pharmacy margins

Former:

Formerly, the wholesale margin is 5% and is fixed for products sold in open pharmacies and is the maximum in the case of products sold to hospitals. In pharmacies the margins are calculated on the basis of algorithm, depending on the wholesale price of the medicinal product.

Amendment:

Rating: Positive

The wholesale margin will be increased to 6% but will also be limited to PLN 150 (~EUR 33) in the case of products sold in pharmacies that are open to the public and PLN 2,000 (~EUR 444) in the case of products reimbursed in connection with drug programs and chemotherapy. The Amendment also assumes that the obligation to accrue a wholesale margin will apply regardless of the delivery destination (i.e. will also apply to sales abroad). Pharmacy margins will be increased as compared to their current levels in accordance with the expectations of the industry associations.

9. Potential ex officio reimbursement of medical devices available under publicly financed healthcare services

Former:

Medicinal products and foodstuffs intended for particular nutritional use which are used in connection with publicly financed healthcare services may be subject to an ex officio reimbursement decision issued by the MoH, if they constitute a significant cost component of such services (otherwise, the reimbursement is subject to an application). In such cases, prices could be arbitrarily set by the MoH without the prior submission of an application by an authorized entity.

Amendment:

Rating: Negative

The scope of products that could be subject to such ex officio reimbursement decision would also include medical devices. The MoH expects this change to provide broader access to innovative medical devices used as a part of publicly financed healthcare services (i.e. hospitals would not only use the cheapest devices). However, according to industry associations, this could have the opposite effect, that is, a lack of availability due to parallel exports or cutting supplies to Poland. Of course, such ex-officio reimbursement does not mean that there are no negotiations with the MoH at all, but lack of agreement between the parties may result in blocking the market for a given device.

REIMBURSEMENT PROCESS

10. Prohibition to change a reimbursement application after an EC resolution and limiting the number of applicant representatives

Former:

No such provisions.

Amendment:

Rating: Negative

Modifying an application, including net selling prices and RSS provisions, following an EC resolution would be prohibited. While the MoH will be entitled to conduct additional negotiations, it is no secret that today only negotiations with the MoH are relevant for the actual determination of the reimbursement conditions.

The Amendment also envisages that an applicant could be represented by a maximum of three individuals. Currently, applicants without a local presence are supported by local Polish speaking experts (medical, HTA, lawyers) but also want to participate themselves.

Therefore, a team of 5-6 persons participating in negotiations on behalf of the applicant is not unusual.

11. Obligation for foreign applicants to appoint a MAH representative

Former:

In case of medicinal products only two categories of entities may apply for reimbursement – MAH or its representative. A MAH representative is defined as a natural or legal person designated by MAH to perform its rights and obligations in Poland.

Amendment:

Rating: Negative

One of the transitional provisions provides that in the absence of the appointment of the MAH representative within the meaning of amended Article 2.35a of the Pharmaceutical Law, an applicant not having a registered office in Poland, who has obtained a reimbursement decision, is obliged to appoint this representative by 1 February 2024. The revised definition clarifies that the representative must be domiciled (natural person) or have its registered seat (legal person) in Poland. The above obligation applies also to reimbursement proceedings initiated and not completed before 1 November 2023. Each proceedings initiated by a foreign applicant, in the absence of a Poland-based MAH representative, will be suspended until such representative is appointed and discontinued if no representative has been appointed by 1 February 2024.

Hint:

The MoH clearly indicated that the above pertains not only to already issued reimbursement decisions and ongoing proceedings (as it is provided by the abovementioned transitional provision), but also to future ones (however, lack of appointment of the MAH representative in connection with the proceedings initiated after 1 November 2023 has not been covered in the Amendment)). According to what has been stated, it will not be prohibited for a foreign MAH to be an applicant and holder of the reimbursement decision (also being represented by the local attorney); however, such foreign MAH will need to have a local representative appointed anyway (by way of a formal agreement submitted to the Polish authorities). Foreign MAHs used to be represented by local attorneys (proxies) and they were not appointing any local representatives. Consequently, the MoH experienced problems with reaching out to certain applicants with issues not related to a specific reimbursement proceedings, for the purpose of which an attorney has been appointed (e.g. due to a limited scope of the power of attorney). This is why the aim of the MoH is to have a specific and officially appointed Poland-based person/entity, who/which exercises the rights and obligations of the MAH in Poland and can be contacted in connection with any issues that might arise.

12. Changes to reimbursement applications and decisions

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

#1:

Rating: Negative

The obligation to update certain documents and information (referred to in Article 24.2 of the Act) during the entire reimbursement proceedings (including information on reimbursement conditions in other EU/EFTA member states).

Hint:

According to the MoH, updates should be made before important reimbursement proceedings milestones.

#2:

Rating: Negative

Obligations to submit a "patent document" along with the reimbursement application. The problem is that the patent document is not defined, as often there are a number of medicinal product elements that are subject to patent protection.

Hint:

According to the MoH, it could be a patent online system printout; however, it is still not stated which patent should be provided. We can, however, state that in our view it should be the last patent actually withholding the market entry of a generic product.

#3:

Rating: Negative

In the case of an application seeking an increase in 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 sought would be required.

Hint:

According to the MoH it should be an official document, not an unverifiable statement.

#4:

Rating: Negative

An application to increase a net selling price submitted while a reimbursement decision remains valid until loss of exclusivity or patent protection and within 12 months of the first reimbursement decision issued after such circumstances would have no legal effect.

#5:

Rating: **Positive**

Proof of availability in the "ordinary" reimbursement proceedings - finally, in the case of an advanced therapy medicinal product (ATMP), an applicant would only need to commit to ensure that it is technologically ready for manufacture at the time of submission of an application.

#6:

Rating: **Negative**

Decisions, orders and other letters issued during the course of proceedings conducted using the SOLR system (electronic system used for the whole reimbursement proceedings in Poland) would be deemed to have been delivered when signed and placed in the recipient's mailbox, which is incomprehensible as customarily, in different kinds of proceedings where documents are delivered by traditional mail, they are deemed to have been delivered on the day of receipt by the addressee; it should also be noted that the system for notifying applicants about the appearance of new documents in mailboxes does not work properly.

#7:

Rating: **Positive**

A rationalization analysis will no longer be required as part of the dossier submitted together with a reimbursement application.

#8:

Rating: **Negative**

An HTA dossier will only be valid for a period of one year from the date on which a reimbursement application is submitted and for no more than three years from the date of preparation.

#9:

Rating: **Negative**

Reimbursement proceedings must be discontinued if an HTA dossier is not supplemented within the requisite time limit (at least 21 days). Currently, if an HTA dossier is not compliant with the rules, the MoH requests the applicant to supplement. However, delays cause proceedings to be delayed as whole without there being such severe consequences.

#10:

Rating: **Negative**

Reimbursement proceedings must be discontinued in cases in which an HTA Agency recommendation implied the need to meet additional conditions in order for a product to be reimbursed and the fulfillment of those conditions were not confirmed by an applicant within the prescribed period (up to three months).

#11:

Rating: **Negative**

The suspension of reimbursement proceedings at the request of an applicant will not be possible. The Amendment assumes that only the MoH will be able to suspend proceedings and for a period of up to 90 days. The suspension of reimbursement proceedings was often used by pharmaceutical companies, e.g. when the negative decisions was expected and a company wanted to internally discuss the new proposal in order to manage MoH expectations.

Hint:

The MoH claims that applicants will be entitled to request a suspension of the proceedings in justified cases.

#12:

Rating: Negative

Criminal liability for false data or false information provided in an application on the part of an applicant's representative who signs the reimbursement application. The Amendment contained this new provision from the very beginning. Recently, the MoH decided to soften it slightly by excluding the HTA dossier from the scope of data and information covered by such sanction.

#13:

Rating: Positive

A drug program description would no longer constitute an attachment to a reimbursement decision, meaning that any changes to such drug program description would not require the consent of all the holders of reimbursement decisions whose products are available under such program. Sometimes, pharmaceutical companies used this to delay the completion of the reimbursement process for a new medicinal product that was about to enter a drug program. As the reimbursement lists are published every two months, failure to finalize the process before the publication of the final list for the upcoming two-month period means that the reimbursement would be delayed by two months. Therefore, some companies sought to obtain two additional months of reimbursement without there being another competitor in the drug program.

13. Changes regarding drug program descriptions

Former #1:

The drug program description constitutes an appendix to the reimbursement decision. Previously , pharmaceutical companies used to occasionally delay the completion of the reimbursement process for a new medicinal product that was about to enter a drug program. As the reimbursement lists are published every two months, failure to finalize the process before the publication of the final list for the upcoming two-month period means that the reimbursement would be delayed by two months. Therefore, some companies sought to obtain two additional months of reimbursement without there being another competitor in the drug program.

Amendment #1:

Rating: Positive

A drug program description would no longer constitute an attachment to a reimbursement decision, meaning that any changes to such drug program description would not require the consent of all the holders of reimbursement decisions whose products are available under such program.

Former #2:

Drug program descriptions are proposed by an applicant and jointly agreed by the applicant and the MoH during the course of reimbursement proceedings.

Amendment #2:

Rating: Negative

An applicant would still be obliged to propose a drug program description, but the provisions regulating the process of agreeing its content with the participation of the applicant and the MoH would be repealed and substituted with ones envisaging that the MoH would create and change drug program descriptions. Applicants would only be entitled to present a non-binding opinion within seven days as of the receipt of a draft. In fact, this change would reflect the current practice of the MoH, in line with which an applicant's opinions are also non-binding although this is not specifically stipulated in law (of course, not in each and every case but quite often). The MoH will also amend the drug program description what is widely regarded as an important threat to the stability of reimbursement conditions (e.g., RSS is often linked with the drug program description – changes that could be introduced by the MoH almost anytime might influence the conditions agreed during the negotiations). Before, pharmaceutical companies had greater control over the changes in the drug programs, as their consent was required.

Hint:

In the interim period (proceedings initiated before 1 November 2023), the MoH will still agree with the applicant on the content of the drug program despite the fact that the program description will no longer be attached to the reimbursement decision. Drug program descriptions will be established after the verification analysis and HTA Agency recommendations are issued.

14. New procedure for identifying non-reimbursed products recommended in clinical guidelines (including OTC products)

Former:

An Rx medicinal product may not be reimbursed if it has an OTC equivalent, unless it requires use of more than 30 days under specific clinical conditions.

Amendment:

Rating: Neutral*

The MoH could issue a reimbursement decision for a medicinal product (including OTC products requiring use for more than 30 days under specific clinical conditions) that is recommended in clinical guidelines in cases where no reimbursement application has been submitted so far and market exclusivity for this product has already expired. An initial list of such products would be prepared by the HTA Agency. Following consultations with the Transparency Council, national consultants and the Patients Ombudsman, the MoH

would publish a final list and inform respective MAHs about the possibility of submitting a reimbursement application. Such applications would be exempted from the HTA Agency recommendation, meaning that the reimbursement process would be faster and cheaper for the applicant. However, some experts point out that the proposed wording is quite vague in terms of whether such reimbursement decision would be issued by the MoH ex-officio or based on an application. Our position is that it is rather clear that the MoH's intention (also unofficially confirmed by the MoH) is to leave decision regarding the submission of a reimbursement application solely in the hands of the MAH.

** Rating: Rather neutral, but such significant change in approach expanding the catalog of products that can that are reimbursable may have an impact on the ability to reimburse products which this system is really designed for (e.g. innovative medicines which would remain unavailable without public funding).*

Hint:

Reimbursement of an OTC medicinal product results in a ban on public advertising of such product.

15. Reimbursement lists publication dates

Former:

Reimbursement lists are published every two months.

Amendment:

Rating: **Positive**

Reimbursement lists would be published every three months. This means that if a reimbursement decision is issued before the reimbursement list publication date it will not enter into force until the date of the entry into force of this next list. However, this is in line with proposals presented by the entire pharmaceutical industry with a view to making the reimbursement system more stable: Four reimbursement lists instead of six annually would result in less frequent changes in the limit groups that influence patient co-payment. Lists will be published on 1 January, April, July and October.

Hint:

Starting from 2024 the reimbursement decisions' validity period might not be linked with reimbursement lists publication dates (e.g., a reimbursement decision is valid until 30 April 2024, i.e., one month after the previous and two months before the next reimbursement list publication date), the Amendment assumes an ex lege extension of these decisions until the end of a given reimbursement lists' validity period (i.e., until 30 June 2024 in the above example). However, in order to do so, the MoH expects the decision holders to submit a request for a change of the reimbursement decision (based on Article 155 of the CAP), aimed at updating the RSS.

OTHER

16. Reimbursement decision revocation

Former:

The MoH is obliged to revoke a reimbursement decision in the event of: (i) a lack of declared therapeutic efficacy; (ii) the risk of use being disproportionate to the therapeutic effect; (iii) the reliability and precision of the criteria estimates on the basis of which a reimbursement decision was issued being compromised; (iv) the commitment to ensure continuity of supplies or the annual volume of supplies is not met and patient needs will not be met.

Amendment:

Rating: **Positive**

The key change is abandoning the mandatory revocation of reimbursement decisions. At the same time, the list of situations that might result in such revocation will be extended and is as follows: (i) a lack of declared therapeutic efficacy; (ii) the risk of use being disproportionate to the therapeutic effect; (iii) the reliability and precision of the criteria estimates on the basis of which a reimbursement decision was issued are compromised; (iv) the commitment to ensure continuity of supply is not met; (v) the annual supply volume commitment is not met and there is a failure to meet the needs of patients; (vi) the applicant no longer meets the conditions for benefits related to manufacturing in Poland; and (vii) the notifying body withdraws the certificate of conformity for a medical device.

Also, in the event that an off-label decision is issued for a given medicinal product, such off-label decision will also become invalid in the event of expiration, revocation or shortening of the „main" decision.

**** Rating: Rather positive, as abandoning the mandatory revocation of a reimbursement decision is more important than the extended list of situations which may lead to such revocation.***

17. Possibility to return the product

Former:

No such provision.

Amendment:

Rating: **Positive**

In instances where the product is no longer reimbursed (for whatever reason) the wholesaler and pharmacies that bought the product before will be entitled to return it and request a refund. Therefore, in case of a price decrease, the previously used mechanisms for price adjustments can remain in force.

18. Extended scope of situations when medicinal products could be supplied in foreign or limited packages/leaflets

Former:

Where justified on public health grounds and when there are serious difficulties in the availability of restricted use Rx medicinal products, hospital medicinal products or vaccines, except for vaccines intended for obligatory or recommended vaccinations in Poland, the President of the Office for Registration, taking into account safe use of the medicinal product, may, for a specified period of time, grant an exemption: (i) from the obligation to include certain particulars on the package/in the insert, or (ii) in whole or in part from the obligation to supply such product with a Polish language package/leaflet.

Amendment:

Rating: **Positive**

The Amendment assumes that apart from restricted use Rx medicinal products and hospital medicinal products, where no changes have been proposed, any medicinal product could basically be exempted from the obligations indicated above if there are significant problems with its availability. This means that under the new regulations e.g. any vaccine could be supplied to the Polish market with foreign packaging unless the President of the Offices refuses to grant an exemption.

19. Extension of the MoH authority to restrict the sale of certain products in pharmacies

Former:

The MoH is entitled to restrict the issuance of certain products in case of unavailability due to an epidemic state or in the event of a danger of the spread of an infection or infectious disease that may pose a threat to public health, by determining the maximum amount of a product that can be dispensed to a patient in a given period.

Amendment:

Rating: **Neutral**

The MoH's authority could apply to the maximum amount that can be dispensed to a given patient at a given time or for a given indication. In addition, a novelty could be restrictions on any product that is reimbursed or on a so-called "anti-export list," without reference to an epidemic state (or other threat associated with the spread of an infection or infectious disease), but only in connection with the possible unavailability of such a product within the territory of Poland.

20. Other changes in the Pharmaceutical Law

Changes to the "do not substitute" information.

Rating: Negative

If the "do not substitute" information is included on the prescription, the prescriber will additionally include in the patient's medical records a detailed justification for prescribing a specific product to that patient. At the same time, at the patient's request or with the patient's consent, it will be permissible to dispense a medicinal product other than the one prescribed by the prescriber - if the total amount of the active substance or substances contained in the medicinal product dispensed corresponds to the total amount of the active substance or substances contained in the medicinal product prescribed in the prescription, and these products also have the same indications and the same manner of administration. In practice, this means that it will be quite easy to ignore information from a physician regarding the legitimacy of dispensing a particular drug prescribed on the prescription. In addition, having to justify the prescription of a particular product may also discourage doctors from doing so.

Limitations on prescriptions.

Rating: Negative

Under a single prescription, a patient will be able to receive drugs/devices for a maximum of 120 days of use, calculated based on the dosage specified on the prescription. If on a prescription there is more than the amount of a drug/device for 120 days of use, the next amount needed for the subsequent 120-day use period will be available to the patient after three-fourths of the period for which the prescription was filled.

Conclusion

After almost 12 years of applying the provisions of the Act, which although not ideal were well tested and provided a framework within which most of us had learned to operate, the appearance of some chaos is something that cannot be excluded.

Of course, it is normal to slightly over-predict the negative effects of new regulations during the legislative process in order to convince the authors of such regulations to refrain from implementing certain changes.

However, the experts might actually be right this time. It is significant that during the legislative process, the MoH decided to reject a number of negative changes, e.g. obligatory refusal to reimburse a product for which the cost of QALY exceeds six times GDP per capita in Poland or the price corridors for reference products.

Consequently, the Amendment is not as unfavorable as some of its previous version, but it still changes so many areas, that actual effects for the patients and pharmaceutical industry would need some time for assessment.

Contact us

Juliusz Krzyżanowski

Counsel | Head of Healthcare and Life Sciences Practice

Juliusz.Krzyzanowski@bakermckenzie.com

Disclaimer