REIMBURSEMENT OF DRUGS IN POLAND
CONTENTS

3  Introduction
4  The reimbursement system – Underlying ideas and means of operation
4  Reimbursement proceedings in Poland – General rules
5  Commencement of proceedings for inclusion in the reimbursement scheme
7  The proceedings
10 The reimbursement decision
13 Reimbursement availability categories
13 Patient contribution levels
14 Limit groups
17 The fixed prices and fixed margins system
20 Risk-sharing instruments
22 Pay-back mechanism
22 Proper relationships in the pharmaceutical market
23 Summary
24 Contact
On 1 January 2012, the Act of 12 May 2011 regarding reimbursement of drugs, foods for special medical purposes, and medical products (Journal of Laws of 2011, No 122, item 696), hereinafter referred to as “the Reimbursement Act”, came into force in Poland. The Reimbursement Act comprehensively regulates issues pertaining to reimbursement for drugs, foods for special medical purposes, and medical products. The solutions which it introduced revolutionised operation of the drug reimbursement system in Poland, and its coming into force was accompanied by myriad controversies and fears. Today, two years since the Reimbursement Act was implemented and after the intervening opportunity to test its operation in practice, there are grounds for concluding that, all in all, the Act amounts to a cohesive body of legal regulations which imposed some order on the Polish drug market. There are nevertheless certain aspects of its operations which require adjustment. In this article, I hope to outline the main rules governing reimbursement for drugs in Poland and to discuss the problems affecting this system in practice.
The reimbursement system
– Underlying ideas and means of operation

Naturally, establishing a transparent system for drug reimbursement is a priority for the state authorities. The two main aspects of the matter which must somehow be reconciled are the interests of the patients on the one hand and fiscal stability on the other. Other interests which come into play are those of the marketing authorisation holders and of entities which actually deal in the medicines, such as pharmaceutical wholesalers. The goal of the Reimbursement Act lay in rearranging the Polish reimbursement system so that, within the applicable financial constraints, it addresses the needs of Polish patients, unambiguously regulates relationships between the business enterprises active in the domestic drug market, and conforms with Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems Official Journal L 040, 11/02/1989 P. 0008 - 0011.

Reimbursement proceedings in Poland
– General rules

Rational proceedings for inclusion of a specific drug in the national reimbursement scheme are ensured by a multi-stage procedure conducted by the Ministry of Health geared at assessment of the product in question (and its effectiveness) and of its financial aspects, conducted in accordance with the Polish Administrative Process Code. This procedure must conform with:

1. The rule of law – the competent administrative authorities must proceed on the basis of, and within the bounds of, applicable laws;
2. The rule of objectively verifiable truth – the public administrative authorities, proceeding ex officio or at the application of the parties concerned, should take any and all actions in order to establish the factual status and to rule on the issue with due heed for the public interest and the legitimate interests of the citizens;
3. The principle of increasing trust – public administrative authorities ought to proceed and rule in a manner which contributes to trust in the public authorities among the citizenry;
4. The access to information rule – the public administrative authorities are legally obligated to provide the parties with due, exhaustive information about the

---

1 Reasoning for the governmental draft of the Reimbursement Act – Sejm printing office document no 3491.
3 Article 6 of the Administrative Process Code.
4 Article 7 of the Administrative Process Code.
5 Article 8 of the Administrative Process Code.
factual and legal circumstances which may impact upon definition of their rights and obligations falling within the ambit of the administrative proceedings at hand;

5. The active participation of the parties principle – the public administrative authorities must ensure that the parties may actively involve themselves in every stage of the proceedings and state their position with respect to the assembled evidence and materials, and the demands formulated, before the decision is handed down;

6. The principles of conviction – the public administrative authorities ought to explain to the parties concerned their rationale in ruling on the case.

Compliance with the basic principles set out above is subject to judicial review.

Commencement of proceedings for inclusion in the reimbursement scheme

Commencement of proceedings for inclusion of a product in the reimbursement scheme involves filing an application for inclusion in the reimbursement scheme and for definition of an official sale price with the Ministry of Health. Such proceedings may be initiated by a limited circle of entities, namely:

1. The marketing authorisation holder, defined in article 2.24 of the legislative Act of 6 September 2001 – the Pharmaceutical Law (consolidated text: Journal of Laws of 2008, No 45, item 271 with subsequent amendments) as the entity which secured authority to introduce the given drug to market dealing;

2. The marketing authorisation holder’s representative, defined in article 2.35 of the Pharmaceutical Law as a natural person or a legal person designated by the marketing authorisation holder for performance of its duties, and exercise of its rights, in Poland by way of a written contract defining the representative’s mandate and obligations;

3. An entity which secured permission to conduct parallel imports.

The detailed contents of the application for inclusion of a drug in the national reimbursement scheme are defined in the Reimbursement Act. The required elements of the application include:

---

6 Article 9 of the Administrative Process Code.
7 Article 10 § 1 of the Administrative Process Code.
8 Article 11 of the Administrative Process Code.
9 Under certain circumstances strictly defined in the Reimbursement Act, the Minister of Health may proceed on an ex officio basis to decide on reimbursement for a drug with clinical data, indications, dosage, or means of administration other than defined in the Medicinal Product Characteristics (i.e. off-label use) where this is necessary to protect the life and health of patients, where there are no other medical procedures financed from public funds which might be resorted to in the given clinical condition (article 40 of the Reimbursement Act).
10 Article 35a.2 of the Pharmaceutical Law.
11 Article 2.27 of the Reimbursement Act.
1. Information (up-to-date as at filing of the application) concerning reimbursement of the drug in question in any Member State of the European Union or of the European Free Trade Association (EFTA), specifying the level of reimbursement and the applicable conditions and limitations (including the risk-sharing instruments). This information must be confirmed in appropriate documents, accompanied by sworn translations into Polish. Legitimate questions have been raised as to whether this requirement to present translations does not amount to a bureaucratic redundancy and as to the added value, if any, presented in translating reams of documents from several different countries (and languages). It may be posited the Ministry of Health may just as well glean the same knowledge about the terms of reimbursement for the drug applied in other countries (and the prices adopted for this purpose) by way of a simple declaration. Also, it might be noted that article 24.2.1 of the Reimbursement Act stipulates that the documents submitted include the risk-sharing instruments implemented in other countries. Risk-sharing instruments are oftentimes subject to confidentiality clauses agreed between the marketing authorisation holders and the competent authorities, so the requirement of presenting them may be questioned as an attempt at putting the Polish regulations above those of other countries, and at requiring the marketing authorisation holders to contravene obligations assumed by them in other jurisdictions. A rational approach would be to require disclosure of risk-sharing instruments only if they are not subject to confidentiality obligations.

2. For drugs which do not have reimbursed equivalents for the given therapeutic indication, there is the requirement to submit documentation for the purpose of health technology assessment (HTA) which includes:
   a) A clinical analysis;
   b) An economic analysis, formulated from the perspective of the entity obligated to finance services out of public funds and from the perspective of the services recipient;
   c) An analysis of the impact on the budget of the entity obligated to finance services out of public funds;
   d) A rationalisation analysis, setting out reimbursement solutions for drugs whose inclusion in the reimbursement scheme will free up public funds in an amount, at the very least, corresponding to the increase of costs indicated in the budget impact analysis – to be presented where the budget impact analysis points to an increase of the reimbursement costs.

12 Article 24.2.1 of the Reimbursement Act.
13 These issues have been raised by the Employers’ Union of Innovative Pharmaceutical Companies INFARMA in its letter to the Minister of Health dated 24 August 2011 (ref ZPIFF/83/PSZ/2011).
14 Such an analysis is also submitted for a drug which has a reimbursed equivalent in the given clinical indication – article 25.4.b of the Reimbursement Act.
The proceedings

Following its submission, the application for inclusion of a drug in the reimbursement scheme ought to be considered by the Minister of Health within a basic deadline of 180 days16 (circumstances justifying extension of this deadline are described below). The reimbursement proceedings as such comprise the following stages:

1. Examination of the application in its formal aspects.
   If there are any elements missing from the submitted documentation, the Minister of Health may call upon the applicant to rectify these shortcomings within a seven-day deadline. The time for rectification of formal shortcomings is not counted towards the duration of the proceedings as such, so the overall duration is extended. If the applying party does not present the missing documents within seven days, the entire application will be left without consideration17.

2. Where the application concerns reimbursement of a drug within a drug programme, the drug programme as such must be defined.
   A drug programme is a health care programme comprising drug technology in which the active substance is not a cost component of other services guaranteed within the national health care scheme. Drug programmes are resorted to in order to finance particularly expensive drugs for patients afflicted by strictly defined clinical states. The details of such a programme are set out in an appendix to the reimbursement decision; they should include, in particular, the criteria for inclusion of a patient in the programme, criteria for exclusion, the dosage plan, and the terms for performing diagnostic tests in the course of treatment. The programme ought to be formulated so that enrolment in the treatment regimen and its monitoring is attended to by an independent body. The deadline for drawing up a drug programme is 60 days; as with submission of missing documents, this time is not counted towards duration of the proceedings as such, which are duly extended. In the event that no drug programme is agreed between the applicant and Minister of Health, the Minister of Health issues an administrative decision refusing inclusion in the reimbursement scheme18.

3. Assessment of the HTA documentation by specialised bodies, viz the Transparency Council affiliated with the Agency for Health Technology Assessment in Poland and by the Agency for Health Technology Assessment’s President;
   Such assessment is performed for drugs which do not have a reimbursed equivalent for the same clinical indications. The Transparency Council as well as the President of the Agency for Health Technology Assessment in Poland present their position concerning inclusion of the given drug in the reimbursement scheme.


---

16 Article 31.4 of the Reimbursement Act.
17 Article 64 § 2 of the Administrative Process Code.
18 Article 31.11 of the Reimbursement Act.
Such negotiations are a mandatory element of the reimbursement proceedings for every drug. Their object comprises definition of the official sale price, the level of own contributions by the patients purchasing the drug, the clinical indications for which reimbursement will be available, and the risk-sharing instruments. It is worth noting that the parameters and solutions finally arrived at by way of such negotiations may depart significantly from those originally proposed by the applicant, for instance as regards the risk-sharing mechanism. The negotiations are conducted between the applicant on the one hand and a five-member team from the Economic Commission on the other. The latter then presents the negotiation results to the Economic Commission in its full composition, and a final position on the part of the Economic Commission is formulated. The negotiation results are duly documented in a document signed by both parties; on this basis, the Economic Commission adopts a resolution which it promptly passes on to the Minister of Health.\(^{19}\) The Reimbursement Act is not clear as to whether the Economic Commission may adopt a resolution different from that set out in the minutes documenting the negotiations. In practice, we have seen situations where the reimbursement terms (first and foremost the product price) agreed between the applicant and the negotiation team are subsequently not accepted by the Economic Commission as such.\(^{20}\)

5. The applicant must then have the opportunity to state its position with respect to the evidence assembled and demands made. Before issuing his decision, the Minister of Health must afford the applicant the chance to peruse all of the evidence and materials assembled in the case.\(^{21}\) In particular, the applicant must have the chance to peruse the case files and to file its final position.

6. The Minister of Health then hands down a decision concerning inclusion of the drug in the reimbursement scheme or, alternately, refusing such inclusion.

In accordance with article 12 of the Reimbursement Act, the Minister of Health – with a mind to obtaining the best health effects possible given the available funds – issues an administrative decision concerning inclusion in the reimbursement scheme and definition of an official sale price taking into account the following criteria:

1) The position adopted by the Economic Commission;
2) The recommendation of the President of the Agency for Health Technology Assessment in Poland;
3) The significance of the clinical state to which the application for reimbursement refers;
4) Clinical and practical effectiveness of the drug;
5) Safety of use;
6) Ratio of health benefits offered by the drug to the risks associated with its use;

---

\(^{19}\) Article 18.3 of the Reimbursement Act.

\(^{20}\) S. Łajszczak, Co może być wynikiem negocjacji refundacyjnych? [What are the possible results of reimbursement negotiations?],

\(^{21}\) Article 10 § 1 of the Administrative Process Code.
7) The proportion of costs to the health benefits obtained of the drug covered by the application in juxtaposition to drugs already in use;
8) Price competitiveness;
9) Impact on expenditures of the entity obligated to finance services out of public funds and of the service recipients;
10) Existence of any alternative medical technologies and their clinical effectiveness and safety of use;
11) Dependability and precision of assessment of the criteria specified under items 3) through 10) above;
12) Health priorities defined in the legislative instruments promulgated on authority of article 31a.2 of the legislative Act of 27 August 2004 regarding health care services financed out of public funds (consolidated text: Journal of Laws of 2008, No 164, item 1027, as amended);
13) The threshold of quality-adjusted life year (QUALY), defined in terms of three times the gross domestic product per inhabitant or, where this cost cannot be defined, the cost of winning an additional year of life;
- taking into account other medical procedures which may be applied in the given clinical state which may be replaced by the drug to which the application refers.

It should be borne in mind that, in issuing the reimbursement decision, the Minister of Health takes into account the above criteria taken as a whole – in other words, the Minister enjoys considerable leeway in weighing the various factors. It should also be noted that the Minister of Health is not bound by the position adopted on the case by the Economic Commission or by the recommendation by the President of the Agency for Health Technology Assessment in Poland.

---

22 These priorities include, in particular, reducing incidence of, and premature deaths caused by, cardiovascular diseases, malignant tumours, and chronic respiratory diseases, reducing injuries in accidents, preventing and treating (also at the rehabilitation stage) of psychological disorders, bone and joint diseases, contagious diseases and infections, reduction of detriment to health caused by use of alcohol, psychoactive substances, and smoking, preventing obesity and diabetes, limiting the health effects of noxious agents, improving the quality and effectiveness of maternal and obstetric care and of health care of children aged up to 3, preventing the most common health problems among schoolchildren, developing long-term care and improving the quality and effectiveness of geriatric care.

23 The Reimbursement Act does not envisage special rules for any particular drug categories, in particular for orphan drugs as discussed in Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, Official Journal L 018, 22/01/2000 P 0001 – 0005. As a result, there persists the risk that many orphan drugs (and, in general, many drugs used in treatment of rare conditions) may, as it were, fall through the cracks in the system in that they will not meet the cost effectiveness criterion.

The reimbursement decision

The reimbursement proceedings are concluded by a reimbursement decision issued by the Minister of Health. The reimbursement decision ought to include the following components:

1. Details of the applicant, i.e. the applicant’s business name, registered seat and/or place of operations;
2. The name and identification details of the drug;
3. The reimbursement availability category and, in the case of a drug used as part of a drug programme, a description of the drug programme;
4. The patient contribution level;
5. The official sale price;
6. The date on which the decision shall come into force, the decision’s validity period;
7. The risk-sharing instruments (where applicable);
8. Definition of the limit group.

Under article 127 § 3 in reference to article 129 § 2 of the Administrative Process Code, an applicant dissatisfied with the reimbursement decision may, with a deadline of fourteen days following receipt of same, apply to the Minister of Health for renewed consideration of the case. Also, the Minister of Health may – either on an ex officio basis, or at the request of the party concerned – correct clerical and calculation mistakes and any other manifest errors.

A reimbursement decision may be issued for one of the following periods:

1. Five years – for drugs for which an administrative decision concerning inclusion in the reimbursement scheme remained in force for an uninterrupted period of five years, or for drugs for whose equivalent reimbursed within the same reimbursement availability category and the same clinical indication an administrative decision concerning inclusion in the reimbursement scheme remained in force for an uninterrupted period of five years;
2. Three years – for drugs for which an administrative decision concerning inclusion in the reimbursement scheme remained in force for an uninterrupted period of three years (but shorter than five years), or for drugs for whose equivalent reimbursed within the same reimbursement availability category and the same clinical indication an administrative decision concerning inclusion in the reimbursement scheme remained in force for an uninterrupted period of three years (but shorter than five years);
3. Two years – for drugs for which an administrative decision concerning inclusion

---

26 Article 113 § 1 of the Administrative Process Code.
in the reimbursement scheme remained in force for an uninterrupted period shorter than three years, or for drugs for whose equivalent reimbursed within the same reimbursement availability category and the same clinical indication an administrative decision concerning inclusion in the reimbursement scheme remained in force for an uninterrupted period shorter than three years, and also for drugs for which this is the first administrative decision concerning inclusion in the reimbursement scheme;

- subject to the reservation, in each and every instance, that the validity period of the decision may not exceed the period of the drug’s market exclusivity. The Reimbursement Act does not provide for any extension of the original validity period of a reimbursement decision, meaning that once a reimbursement decision elapses, a new one must be applied for in accordance with the procedure outlined above. The practical implication is that, in order to have any hope that continuity of reimbursement for a given drug will be maintained, an entity must apply for a new reimbursement decision well before the original one has elapsed.

Particular attention should be devoted to the question of amending reimbursement decisions. The Reimbursement Act does not provide for expanding the list of clinical indications for which any given drug is reimbursed. Where the relevant entity wishes to seek reimbursement for a new clinical indication, it must file a new reimbursement application and obtain a new decision for that indication. Considering that every reimbursement decision is issued for a fixed period of time, one may easily picture a situation where reimbursement decisions for different clinical indications will expire at different times.

The Reimbursement Act expressly regulates the following circumstances under which amendment of the original reimbursement decision is possible:

1. Increase of the official sale price for the reimbursed drug;
2. Decrease of the official sale price for the reimbursed drug;
3. Shortening of the period in which the decision will remain valid.

The absence of any express regulations concerning amendment of an issued reimbursement decision within a different scope than specified above may give rise to considerable difficulties in practice. Such problems may arise even in the event of a seemingly simple technical issue such as change of the name of the entity to whom the reimbursement decision has been issued – let alone more complex situations such as adjustments to the obligation to ensure annual deliveries of a certain quantity or change of the marketing authorisation holder. Recourse may be sought in article 155 of the Administrative Process Code, which provides that a final decision pursuant to which a party has acquired a right may be, at any time, repealed or amended by the administrative authority which had issued that decision with the

---

27 Article 11.3 of the Reimbursement Act.
permission of the party concerned, provided that no applicable laws stipulate otherwise and that there are public interest grounds, or legitimate interests of the party concerned, militating in favour of such repeal or amendment. Yet this will be of little use when it comes to change of the very identity of the origina applicant. The lines of authority established by the Polish administrative courts with respect to application of article 155 of the Administrative Process Code make it clear that any changes based upon article 155 are possible only if the identity of the party remains unchanged. The Regional Administrative Court in Olsztyn, for example, stated in its verdict of 18 August 2011 (case ref II SA/Ol 397/11): “The legal possibility of applying the procedure provided for in article 155 of the Administrative Process Code is predicated upon pursuit of the proceedings within the same legal and factual status and with the participation of the same parties. Accordingly, use of this procedure to amend a decision as regards the addressee of the decision or the legal basis for the outcome is impermissible”. In other words, change of the entity to which a reimbursement decision has been issued is possible only by repealing the original decision and securing of a new one, issued to the new entity.

The Reimbursement Act also provides for repeal of a reimbursement decision by the Minister of Health in situations where:

1. It is established that the drug in question lacks the declared therapeutic effectiveness;
2. It is established that the drug poses risks which are incommensurate to its therapeutic effect;
3. Dependability and precision of assessment of the criteria discussed in articles 12.3 through 12.10 of the Reimbursement Act is put into question;
4. The party concerned does not fulfil its obligations concerning continuity of supply or annual deliveries, with the effect that patient demand for the drug is left unmet.

In such instances, the Minister of Health acts on an ex officio basis.

---

29 Please see J. Adamski, K. Urban, E. Warmińska, Refundacja leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych, Komentarz [Reimbursement of foods for special medical purposes and medical products – Commentary], Wolters Kluwer, Warsaw, 2013, p. 278.
30 Article 33.1 of the Reimbursement Act.
Reimbursement availability categories

As already mentioned above, one of the elements of the reimbursement decision is comprised in definition of the reimbursement availability category – a key point as regards defining the patient co-payment level and the rules governing use of the drug. The applicant is well advised to ponder the reimbursement availability category which it will seek early on in the entire process. Article 6.1 of the Reimbursement Act defines the following reimbursement availability categories:

1. For drugs available on a prescription basis from pharmacies:
   a) For the entire range of registered indications and applications;
   b) For a specific indication associated with a specific clinical state\(^31\);
2. For drugs used within a drug programme:
3. For drugs used in chemotherapy:
   a) For the entire range of registered indications and applications;
   b) For a specific indication associated with a specific clinical state;
4. For drugs used in provision of guaranteed health care benefits other than as specified under items 1-3 above.

Patient contribution levels

Under article 14.1 of the Reimbursement Act, in issuing the reimbursement decision, the Minister of Health qualifies the drug to one of the following patient contribution levels:

1. Free of charge – for drugs with proven effectiveness in treatment of malignant tumours, psychotic states, mental retardation, developmental problems, or contagious diseases posing an especial epidemiological risk for the population, and also for drugs used within drug programmes;
2. Flat payments\(^32\) – for drugs:
   a) Requiring, in accordance with the current medical state of the art, use over a period exceeding 30 days and whose monthly cost for the service recipient, given a co-payment of 30% of the financing limit, would exceed 5% of the minimum monthly wage applicable in Poland\(^33\); or
   b) Classified for flat payments on the basis of regulations applicable prior to the coming into force of the Reimbursement Act; or
   c) Requiring, in accordance with the current medical state of the art, use over a maximum period of 30 days and whose monthly cost for the service recipient, given a co-payment of 30% of the financing limit, would exceed 5% of the minimum monthly wage applicable in Poland.

---

\(^{31}\) Please note that “indication associated with a specific clinical state” may refer to indications included in the Medical Product Characteristics as well as to off-label use.

\(^{32}\) Under article 6.6 of the Reimbursement Act, the flat fee is 3.20 PLN.

\(^{33}\) In accordance with the Regulation concerning the minimum remuneration for labour in 2014 promulgated by the Council of Ministers on 11 September 2013 (Journal of Laws for 2013, No 1074), the minimum monthly salary for full-time work in 2014 is 1,680 PLN gross.
recipient, given a co-payment of 50% of the financing limit, would exceed 30% of the minimum monthly wage applicable in Poland;

3. 50% - for a drug requiring, in accordance with the current medical state of the art, use over a maximum period of 30 days;
4. 30% - for a drug not classified in the co-payment levels specified under items 1-3 above.

Subsumption under the appropriate category, as outlined above, proceeds under the presumption that one daily drug dose ("DDD"), as defined by the World Health Organisation, is administered every 24 hours. Where no DDD has been formulated for the given drug, classification proceeds in reference to the monthly therapy cost. In this connection, it should be noted that definition of the patient contribution level refers to the financing limit set for the given limit group, and that it is but a basis for calculation of the price ultimately remitted by the recipient of health care services, i.e. by the patient. The latter pays the difference between the retail price and the financing limit. To illustrate, this means that, with respect to a given product classified in the relevant reimbursement decision as “free of charge,” the patient may still be asked to pay some amount as he/she purchases the product from her pharmacist. This will be the case, for example, where reimbursement is extended to two products classified within a single limit group, e.g. an innovative product and a generic product. In the hypothetical situation where the prices of two products defined as free-of-charge and falling within the same limit group (defined in reference to the WHO’s DDD) are, respectively, 100 and 75, and the price of the less expensive product defines the basis of the limit, then the patient wishing to purchase the more expensive product must cover the difference out of his/her own pocket. Thus, in order to assess the actual co-payment level for any given drug, regard must be had not only to the patient contribution level for that drug, but also for the drug’s position within its given limit group.

**Limit groups**

In issuing the reimbursement decision, the Minister of Health defines the limit group in which the given product is classified, i.e. the group of drugs covered by a shared financing limit (article 2.9 of the Reimbursement Act). A single limit group comprises drugs which have the same international name, or different international names but similar therapeutic effects and operating mechanisms, with due heed for the following criteria:

1. The same clinical indications or applications for which reimbursement applies;
2. Similar effectiveness.

---

34 With a view to safeguarding patient interests, the person dispensing drugs at a pharmacy is under a duty to inform the patient of the possibility of purchasing a drug other than the prescribed one which has the same international name, dosage, pharmaceutical form, and therapeutic parameters but which falls within the financing limit (or, simply put, is less expensive); the pharmacy is also obligated to provide access to such a cheaper alternative (article 44.1 of the Reimbursement Act).

35 Article 15.2 of the Reimbursement Act.
The general rule adumbrated above is supplemented by specific authority of the Minister of Health who, upon consultation with the Transparency Council – and referring, in particular, to juxtaposition of the costs of obtaining a similar health effect, or of an additional health effect – may decide to:

1. Create a separate limit group, where the means of administration or pharmaceutical form of the drug materially impacts upon the health effect, or additional health effect, of the drug;
2. Create a shared limit group, where a similar health effect, or similar additional health effect, is obtained despite different mechanisms of the drugs’ operation.

Please bear in mind that, while subsumption within the same limit group of drugs having the same international name and the same means of administration seems innocuous enough (this is a solution which, by all appearances, ought to encourage use of less expensive products), the bringing together within the same limit group of drugs with different international names may give rise to doubts. In particular, the statutory concept of “similar therapeutic effect and similar operating mechanisms” may be considered imprecise, leaving considerable leeway for discretionary action. Such statutory provisions open the way for creation of “jumbo groups” bringing together a wide variety of active substances covered by a shared financing limit. While beneficial enough for the public authorities financing the national healthcare scheme, such a solution exposes patients to additional co-payments caused by the fact that the limit is based upon a different active substance; patients may end up unable to purchase a drug containing a specific active substance and falling within the financing limit.

Classification of specific products within a single limit group enables definition of the financing limit for that group. Within a given limit group, the limit basis is taken as the highest among the lowest wholesale prices per DDD of the drug attaining, in aggregate, 15% of the quantitative turnover by DDD achieved within that limit group in the month preceding by three months the Minister of Health’s announcement of the list of reimbursed drugs. As a result of this mechanism’s application, the basis of the limit is tied not only to the lowest price, but also to the turnover volumes. This is rational enough in that such a solution avoids situations where the limit basis would be defined by a drug which may be inexpensive, but whose availability is limited, so the net effect is that patients benefit from access to the drug within the limit price. It should be borne in mind that, with the passage of time, the limit basis value may

36 Article 15.3 of the Reimbursement Act.
37 Please see “Do trzech razy sztuka” – Ustawa Refundacyjna po publikacji trzech pierwszych wykazów [Three tries - The Reimbursement Act after publication of the first three lists], p 13.
38 In accordance with article 37 of the Reimbursement Act, the lists of drugs reimbursed under the national scheme are published every two months and constitute a summary of the reimbursement decisions then in force.
39 Article 15.4 of the Reimbursement Act.
change, particularly due to endeavours on the part of the applicants (marketing authorisation holders et al) to change the price.

The above rule, however, is subject to significant exceptions. In the event that it is decided to provide reimbursement for the first equivalent reimbursed for the given clinical indication, the basis for the limit within the given limit group is comprised in the wholesale price per DDD of such equivalent. In this connection, the official sale price of the first equivalent in reference to DDD may not exceed 75% of the price of the first product. Where reimbursement is extended to further equivalents, the basis of the limit may not exceed the wholesale price per DDD of the first equivalent\(^{41}\).

A separate set of rules applies to drugs used in drug programmes and in chemotherapy. Here, the basis for the limit within the given limit group is taken as the highest among the lowest wholesale prices per DDD of the drug topping up, as per the declaration filed in the application for inclusion in the reimbursement scheme, 110% of the quantitative turnover (calculated in reference to DDD) achieved in this limit group for the preceding year or, in the case of a drug for which a new limit group will be established, 100% of the estimated requirements\(^{42}\).

The original classification of a drug in a given product group may be subject to subsequent change. In particular, creation of a new limit group may become necessary if there appear new active substances. Where issue of a reimbursement decision for such a new drug necessitates establishment of a new limit group also encompassing products previously classified within another limit group, the Minister of Health – proceeding on an ex officio basis – issues new administrative decisions changing the original limit group of the given product\(^{43}\).

\(^{41}\) Article 15.7 of the Reimbursement Act.
\(^{42}\) Article 15.11 of the Reimbursement Act.
\(^{43}\) Article 16 of the Reimbursement Act.
The fixed prices and fixed margins system

One of the basic premises of the Reimbursement Act is constituted in establishment of a mechanism of fixed prices and fixed mark-ups at every stage of dealing in medicinal products. The idea is that any discounts along the line running from the drug’s manufacturer to the wholesaler, the pharmacy and, in due course, to the patient must be prevented44. An exception to this basic rule is provided for in article 9 of the Reimbursement Act, which provides that, for purchases of drugs by medical service providers (i.e. hospitals) for the purpose of providing guaranteed medical services, the official prices and margins constitute maximum figures. In other words, the only point within the drug distribution system where discounts of any sort are permitted under Polish law is in sales to hospitals. At any and all other points, the entities participating in the distribution system are bound by law to apply:

1. The official sale price;
2. The official wholesale price (the official sale price + the wholesale margin);
3. The official retail price (the wholesale price + the retail margin).

The Reimbursement Act defines in detail the formulas for calculating the wholesale price and the retail price (to be applied, respectively, by wholesalers and by pharmacies). And thus:

1. Business enterprises engaging in wholesale medicine dealing (i.e. pharmaceutical wholesalers and consignment warehouses) are obligated to apply a fixed margin corresponding to 5% of the official sale price. This 5% margin is enforced irrespectively of the number of wholesalers (intermediaries) involved in the chain of supply; where a greater number of entities is involved, this margin may be split between the individual wholesalers (article 7.3 of the Reimbursement Act), but under no circumstance may the aggregate margin exceed 5%;
2. Entities conducting retail dealing in medicines (i.e. pharmacies) are under a legal duty to apply the official retail margin. This margin is regressive in character and is calculated on the basis of the wholesale price of the given drug constituting the basis of the limit within the given limit group, taking into account DDD. The underlying rationale of such a solution lies in supporting discharge of information duties with respect to generic substitution in retail trade45 – the pharmacist

44 “(…) it is the premise of the legislative draft to rearrange the reimbursement system based on the sale price as a fixed, official price negotiated with the applicant and specified in the reimbursement decision issued by the Minister of Health (…) Obviation of discounts along the line running from the owner of rights in the drug to the wholesaler and onwards to the retailer enables definition of a rational price for the drug by way of negotiations involving the entity and the competent authority and geared at attainment of a compromise. This should render the rights owner more willing to reduce the price of the drug in recognition of competitive pressures in the market” (reasoning for the governmental draft of the amendments to the Reimbursement Act – Sejm printing office document no 3491).
has no financial gain in recommending drugs which are more expensive than the limit base. The mechanism for calculating the retail margin is as follows:

<table>
<thead>
<tr>
<th>Wholesale price from</th>
<th>Wholesale price to</th>
<th>Margin</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>5.00 PLN</td>
<td>40%</td>
</tr>
<tr>
<td>5.01 PLN</td>
<td>10.00 PLN</td>
<td>2 PLN + 30% x (x - 5.00 PLN)</td>
</tr>
<tr>
<td>10.01 PLN</td>
<td>20.00 PLN</td>
<td>3.50 PLN + 20% x (x - 10.00 PLN)</td>
</tr>
<tr>
<td>20.01 PLN</td>
<td>40.00 PLN</td>
<td>5.50 PLN + 15% x (x - 20.00 PLN)</td>
</tr>
<tr>
<td>40.01 PLN</td>
<td>80.00 PLN</td>
<td>8.50 PLN + 10% x (x - 40.00 PLN)</td>
</tr>
<tr>
<td>80.01 PLN</td>
<td>160.00 PLN</td>
<td>12.50 PLN + 5% x (x - 80.00 PLN)</td>
</tr>
<tr>
<td>160.01 PLN</td>
<td>320.00 PLN</td>
<td>16.50 PLN + 2.5% x (x - 160.00 PLN)</td>
</tr>
<tr>
<td>320.01 PLN</td>
<td>640.00 PLN</td>
<td>20.50 PLN + 2.5% x (x - 320.00 PLN)</td>
</tr>
<tr>
<td>640.01 PLN</td>
<td>1,280.00 PLN</td>
<td>28.50 PLN + 2.5% x (x - 640.00 PLN)</td>
</tr>
<tr>
<td>1,280.01 PLN</td>
<td></td>
<td>44.50 PLN + 1.25% x (x – 1,280.00 PLN)</td>
</tr>
</tbody>
</table>

- with x denoting the wholesale price of the drug constituting the basis for the limit, taking into account DDD.

As regards dealing in a reimbursed drug, the basic price (referred to in calculating the wholesale price) is constituted in the official sale price, which is defined in the context of the decision concerning inclusion in the reimbursement scheme. Under article 2.26 of the Reimbursement Act, the official sale price constitutes the sale price specified in the administrative decision concerning inclusion in the reimbursement scheme, VAT included. Please note that the Reimbursement Act is not explicit as to which participant in the distribution chain ought to apply the official sale price46, a fact which may engender interpretational controversies in practice. It is clear enough that a manufacturer which secured a reimbursement decision for its drug and is the first entity introducing it to the market (by selling it to a wholesaler) ought to apply the official sale price. If, however, the business model is a more complex one, the applicant which received the reimbursement decision may be an entity other than the producer – or, indeed, other than the marketing authorisation holder. Such situations where the respective roles of marketing authorisation holder and manufacturer are assigned to different entities are quite common in practice. For instance, in the case of a hypothetical multinational pharmaceutical company,

---

46 Rather, the statute limits itself to a general guideline, defining the net sale price as the price (without VAT) at which the drug is sold to authorised entities – article 2.6 of the Reimbursement Act.
a foreign marketing authorisation holder may be represented in Poland by a local entity charged with attending to all aspects of sales in the Polish market, and this entity is neither the manufacturer nor the marketing authorisation holder but, rather, an entity licensed to operate a wholesale unit or a warehouse into which it receives products manufactured by the foreign manufacturer. In such a case, there arises the question of whether deliveries to such a local representative ought to be settled for in accordance with the official sale price, or whether the entities concerned – belonging as they do to a single corporate group – may apply an “internal” price (with due heed for any applicable transfer pricing regulations). From a rational perspective, such “pre-wholesale” deliveries within a single corporate group ought to be viewed as neutral for purposes of the Reimbursement Act, with the official sale price coming into play only once sales are effectuated “outside”, to an independent wholesaler\(^{47}\). Yet the regulatory authority has, by way of communiqués issued by the Ministry of Health, leaned towards the position that the official sale price ought to be applied by the marketing authorisation holder in sales to any wholesaler – even a wholesaler belonging to the marketing authorisation holder’s own corporate group\(^{48}\). These interpretational questions must somehow be taken into account in the devising of drug distribution models, and they may be a significant motivation for foreign marketing authorisation holders to avoid inclusion of their Polish representatives in their distribution chains.

It should be borne in mind that a considerable amount of time may elapse from the moment in which a medicinal product is purchased by a given entity within the distribution chain, e.g. a pharmacy, until the moment of that product’s sale to the end user, and that the intervening period may witness some change in the official sale price. The binding sale prices are announced on a bi-monthly basis by the Minister of Health in an announcement listing reimbursed:

1. Drugs;
2. Special purpose comestibles;
3. Medical products.

In order to adhere to the objectives of the Reimbursement Act, the prices and margins specified in the then-current announcements should always be applied, irrespectively of the actual price at which the goods were purchased\(^ {49} \). Violation of the legal duty to apply the fixed prices and fixed margins renders the offender liable


\(^{48}\) The interpretation offered by the Ministry of Health in its document of 16 August 2011 (ref MZ-PLO-460-10817-52/MZ/11 and MZ-PLE-460-12215-5/GB/11) explicitly states that “in accordance with the definition set out in article 2.6 of the Reimbursement Act, the net sale price is the price at which the marketing authorisation holder effectuates sale to the first entity licensed to deal in drugs on a wholesale basis”.

\(^{49}\) Please see J. Adamski, K. Urban, E. Warmińska, Refundacja leków, środków spożywczych specjalnego przeznaczenia żywniowego oraz wyrobów medycznych, Komentarz [Reimbursement of foods for special medical purposes and medical products – Commentary], Wolters Kluwer, Warsaw, 2013, p. 147.
for a fine corresponding to the value of the drugs, etc. sold contrary to the Reimbursement Act plus up to 5% of the turnover achieved in the previous calendar year in products for which the reimbursement decision has been issued. This translates into a considerable risk for pharmacies and wholesalers, which can never be entirely certain as to the exact price at which they can sell their stocks of medicinal products, in that:

1. Where the sale price is increased at some moment, the pharmacy or wholesaler will achieve an additional profit (the product was originally purchased at a lower price, but the margin was calculated in reference to the new, higher basis);
2. Where the sale price is decreased, the pharmacy or wholesaler will suffer a loss (the product was originally purchased at a higher price, but the margin was calculated in reference to the new, lower basis). In an extreme scenario, this loss will proceed beyond sale at a margin lower than the official one – the entity may actually find itself selling the product for less than it paid for it.

The Reimbursement Act does not provide for any mechanism under which a wholesaler or pharmacy might demand return with respect to products whose price has been decreased. This risk is left to lie with the wholesalers and pharmacies in what is an indubitable shortcoming of the Reimbursement Act.

Risk-sharing instruments

One of the possible elements of the reimbursement decision is comprised in definition of risk-sharing instruments. The entity concerned may, already at the stage of applying for reimbursement, propose a risk-sharing mechanism concerning, for example:

1. Tying the revenue of the applicant to the health effects actually achieved;
2. Tying the official sale price to deliveries at a lower price agreed in the course of negotiations;
3. Tying the official sale price to the turnover level;
4. Tying the official sale price to return of a part of the reimbursement obtained to the entity obligated to finance health care services out of public funds;
5. Other reimbursement terms geared at increasing availability of guaranteed medical services and/or reducing their cost.

Various risk-sharing instruments may be combined with one another. The applicant's proposals concerning risk-sharing instruments are subject to evaluation by the Transparency Council and by the President of the Agency for Health Technology Assessment in Poland, and they may be negotiated with the Economic Commission. If risk-sharing instruments are not included in the original application for inclusion in

---

50 Articles 50.1 and 50.2 of the Reimbursement Act.
51 Please see the Ministry of Health's information concerning certain provisions of the Reimbursement Act from 4 August 2011 (ref MZ-PLE-460-12214-3/GB/11).
the reimbursement scheme, they may be raised at subsequent stages of the proceedings, particularly in negotiations with the Economic Commission.

Risk-sharing instruments may constitute a particularly attractive proposition for the Minister of Health in situations where:

1. The exact size of the patient population (and, accordingly, the exact treatment costs) is unknown;
1. Uncertainty persists as to the health effects of the product in question.

In some situations, it will be the applicant who will be keen to agree some sort of risk-sharing mechanism. For example, this may be the case where, given the reference prices in force in various countries and a desire to avoid parallel exports\(^{52}\), the applicant is unwilling to see the reduced price of the product disclosed in the Minister of Health’s announcement\(^{53}\). In such an event, the official sale price will be set at a higher level, and its real-terms reduction will be effectuated by way of a risk-sharing instrument\(^{54}\) (e.g. by returning some of the reimbursement to the authority).

A significant consideration in favour of risk-sharing instruments is comprised in the fact that statutory pay-back mechanisms (as discussed below) do not apply if the reimbursement decision institutes a risk-sharing mechanism\(^{55}\). Such a solution is beneficial from the perspective of the applicant’s strategic planning and price policies in that it eliminates the element of uncertainty inherent in pay-back mechanisms as to whether or not a return will have to be remitted and to the amount of such return. On the other hand, an applicant which agrees to be bound by risk-sharing mechanisms but then fails to observe their terms is subject to a penalty corresponding to twice the amount of the costs borne by the public authority due to failure to abide by the terms of the reimbursement decision\(^{56}\).

---

53 While the Reimbursement Act does not elaborate on questions of confidentiality of risk-sharing instruments, practice indicates that, generally, the details of risk-sharing instruments are not disclosed to the public.
55 Article 4.11 of the Reimbursement Act.
56 Article 50 of the Reimbursement Act.
Pay-back mechanism

With an eye to fiscal discipline, the Polish legislature has decided that the aggregate budget for reimbursement of medicinal products shall be not more than 17% of all the public funds earmarked for guaranteed services in the financial plans of the National Health Fund. Article 4.1 of the Reimbursement Act provides that, where this aggregate budget is exceeded while implementing the financial plan of the National Health Fund with regard to reimbursements under the Act discussed here, an overrun amount for the given limit group shall be defined and an applicant which has received a reimbursement decision shall repay to the authority an amount proportional to the share of its drug in the overrun for the given limit group.

As already indicated above, this pay-back mechanism does not apply to products for which risk-sharing instruments have been defined.

Proper relationships in the pharmaceutical market

Given application of the fixed margins and fixed prices for medicinal products, as discussed above, less scrupulous market participants may be tempted to attempt shaping the market in their favour. The Reimbursement Act seeks to prevent irregularities in this regard by way of certain provisions devised to counteract corruption.

First of all, the Reimbursement Act prohibits the following actions by business enterprises which manufactures and/or sells drugs, foods for special medical purposes, and/or medical products covered by the national reimbursement scheme:

1. Predicating the execution of contracts concerning such drugs, foods, or products – or the terms of such contracts – upon acceptance or fulfilment by:
   a) Another business enterprise manufacturing and/or selling drugs, foods for special medical purposes, and/or medical products covered by the national reimbursement scheme;
   b) Pharmacy operators;
   c) Pharmacy managers;
   d) Persons dispensing drugs, foods for special medical purposes, and/or medical products covered by the national reimbursement scheme;
   - of benefits (including financial benefits or personal favours) not associated with the object of such contract;
2. Application of varying contract terms with respect to such entities.

---

57 Article 3.1 of the Reimbursement Act.
58 Article 49.1 of the Reimbursement Act.
Contracts running afoul of these statutory proscriptions are considered invalid. Without prejudice to the above, the Minister of Health may also punish an offending enterprise with a fine corresponding to 3% of the net turnover of the product covered by the reimbursement decision achieved in the previous financial year.

The Reimbursement Act furthermore forbids:

1. Entities manufacturing and/or selling drugs, foods for special medical purposes, and/or medical products covered by the national reimbursement scheme;
2. Pharmacy operators, pharmacy managers, and persons dispensing drugs, foods for special medical purposes, and medical products subject to reimbursement in connection with filling prescriptions for such drugs, etc;
- from offering contingent sales, all and sundry discounts and rebates, loyalty schemes, gifts, prizes, prize draws, incentive travel, games of chance or wagers, use of goods, combined transactions, coupons, and any and all other financial or personal benefits to patients or to physicians. If, however, a given reimbursement decision incorporates risk-sharing mechanisms involving any of the above, the general statutory proscription shall not apply with respect to those specific risk-sharing instruments.

Breach of the above proscription invokes liability for a penalty applied by the competent regional pharmaceutical inspector. This penalty may be up to 5% of the net turnover in products covered by a reimbursement decision achieved in the preceding calendar year; where the offending entity has not posted such turnovers, the penalty corresponds to one hundred times the value of the illegal benefit offered.

Summary

While the Reimbursement Act generally amounts to a cohesive instrument regulating reimbursements for medicines in Poland, it has not been impervious to certain “teething pains” which only became apparent in practice. In particular, some of the formulations used in the text of the Act have proved to be imprecise, opening the way for differences in interpretation; a key area of such doubts concerns the question of which entities within the drug distribution chain are bound to apply the official sale price. Application of the Reimbursement Act may also read to situations at odds with common sense, for example where pharmacies or wholesalers may be forced to sell products for less than they paid for them. The Polish legislature is currently contemplating amendments to the Reimbursement Act as now in force, and it might be hoped that some of these imperfections will be remedied.

59 Article 49.2 of the Reimbursement Act.
60 Article 52.2 of the Reimbursement Act.
61 Article 49.3 of the Reimbursement Act.
62 Article 53.2 of the Reimbursement Act.
63 Articles 50.4 and 50.5 of the Reimbursement Act.
CONTACT:

Dorota Bryndal
Partner, Attorney at law
tel. + 48 22 318 69 44
e-mail: d.bryndal@gessel.pl

Adam Kraszewski
Attorney, Managing associate
tel. + 48 22 318 69 18
e-mail: a.kraszewski@gessel.pl