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Sworn translator of the English language

Translation from the Polish language

Dz.U.12.388 → of 11 April 2012

REGULATION OF THE MINISTER OF HEALTH of 2 April 2012

on the minimum requirements to be satisfied by the analyses accounted for in the applications for reimbursement and setting the official sales price and for increasing the official sales price of a drug, a special purpose dietary supplement, a medical device, which do not have a reimbursed counterpart in a given indication

Pursuant to Article 24 par. 7 item 2 of the Act of 12 May 2011 on the reimbursement of medicinal products, special purpose dietary supplements and medical devices (Dz. U. No. 122, item 696 and of 2012 item 95) it is hereby ordered as follows:

§ 1.

The Regulation specifies the minimum requirements to be satisfied by the clinical analysis, economic analysis, the analysis of the impact on the budget of the entity responsible for financing benefits with public funds, and rationalisation analysis referred to in Article 25 par. 14 item c and Article 26 par. 2 items h-j of the Act of 12 May 2011 on the reimbursement of medicinal products, special purpose dietary supplements and medical devices (Dz. U. No. 122, item 696 and of 2012 item 95), hereinafter referred to as the "Act", included:

- 1) in the justification of the application for reimbursement and setting the official sales price of a drug, a special purpose dietary supplement, a medical device, which do not have a reimbursed counterpart in a given indication;
- 2) in the application for increasing the official sales price of a drug, a special purpose dietary supplement, a medical device, which do not have a reimbursed counterpart in a given indication.

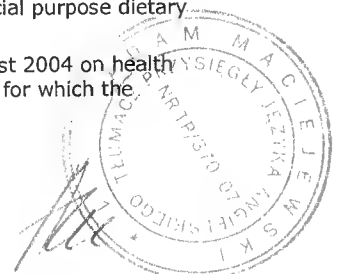
§ 2.

The information contained in the analyses shall be up-to-date as at the date of submitting the application at least with respect to effectiveness, safety, prices as well as level and method of financing of the technology for which the application was filed and optional technologies.

§ 3.

The terms used in the Regulation shall have the following meanings:

- 1) primary trial – a trial providing original data obtained based on the measurements made in the group of persons subject to the trial;
- 2) secondary trial – an analysis of the data derived from primary trials;
- 3) time horizon relevant for the economic analysis – a time perspective in which the health effects and expenditures related to using the technologies compared in the economic analysis are estimated, which enables the reflection of all relevant differences with respect to health effects and costs between the compared technologies in the analyses;
- 4) time horizon relevant for the analysis of the impact on the budget – a time perspective in which the expenditures of the entity responsible for financing benefits with public funds related to the use of the technology for which the application was filed are estimated, which comprises the forecast time interval sufficient to determine the market equilibrium and lasting at least 2 years from making the amendment arising from the competent minister's issuing the reimbursement decision referred to in Article 11 par. 1 of the Act or the price increase decision referred to in Article 11 par. 4 of the Act;
- 5) comparison – presenting the trials the object of which is proving or describing the differences between the technology for which the application was filed and the optional technology, and should there be no such trials – presenting separate trials referring to the technology for which the application was filed and optional technology or the natural course of the disease;
- 6) systematic review – a secondary trial conducted based on a set of consistently employed transparent predefined trial selection criteria in accordance with a described pattern enabling repetition, accounting for the reliability assessment of the selected trials and comprising a systematic objective review of the results of the selected trials;
- 7) reimbursed optional technology – an optional technology financed with public funds in the Republic of Poland consistently with the facts on the day of filing the application;
- 8) technology – a health technology as defined in Article 5 par. 42a of the Act of 27 August 2004 on health care benefits financed with public funds (Dz. U. of 2008 No. 164, item 1027, as amended) or a special purpose dietary supplement or a medical device as defined in Article 2 par. 21 and 28 of the Act;
- 9) optional technology – a medical procedure as defined in Article 5 par. 42 of the Act of 27 August 2004 on health care benefits financed with public funds applicable in a given clinical condition in the indication for which the



application was filed, which is available in the Republic of Poland, consistently with the facts on the day of filing the application;

10) application – the application referred to in Article 24 par. 1 item 1 or 2 of the Act.

§ 4.

1. The clinical analysis referred to in Article 25 par. 14 item c first indent and Article 26 par. 2 item h of the Act shall include:

- 1) a description of a health problem accounting for the overview of the epidemiological indicators available in the scientific literature, including incidence rates and prevalence of the clinical condition specified in the application, in particular referring to the Polish population;
- 2) a description of optional technologies with the reimbursed optional technologies listed and the method and the level of their financing specified;
- 3) a systematic review of primary trials;
- 4) selection criteria for the primary trials to be reviewed as stipulated in subpar. 3 with respect to:
 - a) characteristics of the population in which the trials were conducted,
 - b) characteristics of the technologies used for the trials,
 - c) effectiveness and safety parameters constituting the object of the trials,
 - d) methodology of the trials;

5) indication of the published systematic reviews satisfying the criteria referred to in subpar. 4 items a and b.

2. The review referred to in par. 1 subpar. 3 shall satisfy the following criteria:

- 1) consistency of the criterion referred to in par. 1 subpar. 4 item a with the target population indicated in the application;
- 2) consistency of the criterion referred to in par. 1 subpar. 4 item b with the characteristics of the technology for which the application was filed.

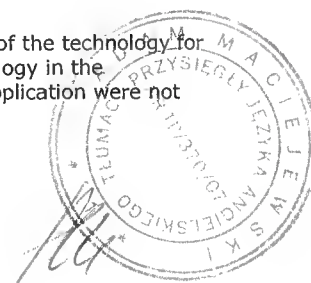
3. The review referred to in par. 1 subpar. 3 shall include:

- 1) a comparison with at least one reimbursed optional technology, and should there be no reimbursed optional technology – with another optional technology;
 - 2) an identification of all trials satisfying the criteria referred to in par. 1 subpar. 4;
 - 3) a description of the queries performed in bibliographic databases;
 - 4) a description of the trial selection process, in particular the number of publications excluded at the subsequent selection stages and the causes of the exclusion at the full text selection stage – in the form of a diagram;
 - 5) characteristics of every trial included in the review in a tabular form, with the account for the following:
 - a) a description of the methodology of the trial, including the indication whether a given trial was designed in the methodology enabling:
 - proving the superiority of the technology for which the application was filed over the optional technology,
 - proving the equivalence of technology for which the application was filed and the optional technology,
 - proving the non-inferiority of the technology for which the application was filed and the optional technology,
 - b) criteria of selecting participants in the trial,
 - c) a description of the procedure of allocating participants to technologies,
 - d) characteristics of the group of participants,
 - e) characteristics of the procedures to which participants were subject,
 - f) a list of all parameters subject to assessment in the trial,
 - g) information on the percentage of the persons who stopped participating in the trial prior to its completion,
 - h) indication of the sources of financing the trial;
 - 6) a specification of the results obtained in each of the trials to the extent compliant with the criteria referred to in par. 1 subpar. 4 item c in a tabular form;
 - 7) information on safety addressed to persons performing medical professions, which is up-to-date on the day of filing the application and that come in particular from the following sources: websites of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, the European Medicines Agency and the U.S. Food and Drug Administration.
4. Should there be no optional technology, the clinical analysis shall include a comparison with the natural course of the disease, in accordance with a given clinical condition in the indication for which the application was filed.

§ 5.

1. The economic analysis referred to in Article 25 par. 14 item c second indent and Article 26 par. 2 item h of the Act shall include:

- 1) a basic analysis;
- 2) a sensitivity analysis;
- 3) a systematic review of the published economic analyses, where health costs and health effects of the technology for which the application was filed were compared with the costs and effects of the optional technology in the population indicated in the application, and if the analyses for the population indicated in the application were not published – in a broader population than the one indicated in the application.

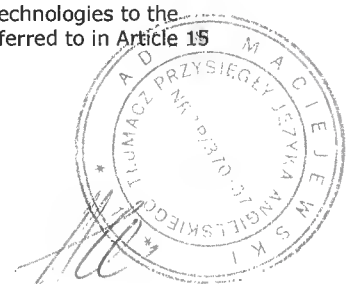


- a) comprising all patients in whom the technology for which the application was filed may be used,
 - b) target one specified in the application,
 - c) in the case of which the technology for which the application was filed is currently being used;
- 2) the estimation of the annual population number in the case of which the technology for which the application was filed will be used with the assumption that the minister responsible for health issues the reimbursement decision referred to in Article 11 par. 1 of the Act or the price increase decision referred to in Article 11 par. 4 of the Act;
 - 3) the estimation of the up-to-date annual expenditures of the entity responsible for financing benefits with public funds, incurred for treating patients in the clinical condition indicated in the application, with the specification of the expenditure component constituting the reimbursement of the price of the technology for which the application was filed, if applicable;
 - 4) a quantitative forecast of annual expenditures of the entity responsible for financing benefits with public funds, to be incurred for treating patients in the clinical condition indicated in the application, with the specification of the expenditure component constituting the reimbursement of the price of the technology for which the application was filed, with the assumption that the minister responsible for health does not issue the reimbursement decision referred to in Article 11 par. 1 of the Act or the price increase decision referred to in Article 11 par. 4 of the Act;
 - 5) a quantitative forecast of annual expenditures of the entity responsible for financing benefits with public funds to be incurred for treating patients in the clinical condition indicated in the application, with the specification of the expenditure component constituting the reimbursement of the price of the technology for which the application was filed, with the assumption that the minister responsible for health issues the reimbursement decision referred to in Article 11 par. 1 of the Act or the price increase decision referred to in Article 11 par. 4 of the Act;
 - 6) the estimation of additional expenditures of the entity responsible for financing benefits with public funds, to be incurred for treating patients in the clinical condition indicated in the application, constituting the difference between the forecasts referred to in subpar. 4 and 5, with the specification of the expenditure component constituting the reimbursement of the price of the technology for which the application was filed;
 - 7) the minimum and maximum estimation variant referred to in subpar. 6;
 - 8) tabular specification of the values based on which the estimations referred to in subpar. 1–3, 6 and 7 and the forecasts referred to in subpar. 4 and 5 were made;
 - 9) the specification of the assumptions based on which the estimations referred to in subpar. 1–3, 6 and 7 and the forecasts referred to in subpar. 4 and 5 were made, in particular the assumptions regarding the qualification of the technology for which the application was filed to the limit group and determination of the basis of the limit;
 - 10) an electronic document enabling the repetition of all calculations as a result of which the estimations referred to in subpar. 1–3, 6 and 7 as well as the forecasts referred to in subpar. 4 and 5 were obtained.
2. The estimations referred to in par. 1 subpar. 1–3, 6 and 7 and the forecasts referred to in par. 1 subpar. 4 and 5 shall be made in the time horizon relevant for the analysis of the impact on the budget.
3. The estimations referred to in par. 1 subpar. 1–3, 6 and 7 and the forecasts referred to in par. 1 subpar. 4 and 5 shall be made in particular based on the estimations referred to in par. 1 subpar. 1 and 2. Should it be impossible to present reliable estimations referred to in par. 1 subpar. 1 and 2, the analysis of the impact on the budget may include an additional variant in which these estimations were obtained based on other data.
4. Should the applied conditions for inclusion in the reimbursement comprise the risk-sharing instruments referred to in Article 11 par. 2 subpar. 7 of the Act, the estimations referred to in par. 1 subpar. 1–3, 6 and 7 and the forecasts referred to in par. 1 subpar. 4 and 5 shall be presented in the following variants:
- 1) with the account for the proposed risk-sharing instrument;
 - 2) without the account for the proposed risk-sharing instrument.
5. Should the applied conditions for inclusion in the reimbursement comprise establishing a new separate limit group, the analysis of the impact on the budget shall comprise the indication of the evidence of satisfying the requirements referred to in Article 15 par. 3 subpar. 1 and 3 of the Act.
6. Should the applied conditions for inclusion in the reimbursement comprise a qualification to the common existing limit group, the analysis of the impact on the budget shall comprise the indication of the evidence of satisfying the criteria referred to in Article 15 par. 2 and the requirements referred to in Article 15 par. 3 subpar. 2 of the Act.

§ 7.

1. The rationalisation analysis referred to in Article 25 subpar. 14 item c fourth indent and Article 26 subpar. 2 item j of the Act shall include:
 - 1) the presentation of the solutions referred to in Article 25 subpar. 14 item c fourth indent and Article 26 subpar. 2 item j of the Act together with the estimations proving the reasonability of these solutions;
 - 2) tabular specification of the values based on which the estimations referred to in subpar. 1 were made;
 - 3) the specification of all assumptions based on which the estimations referred to in subpar. 1 were made;
 - 4) an electronic document enabling the repetition of all calculations as a result of which the estimations referred to in subpar. 1 were obtained, as well as the calculation of these estimations upon the modification of any of the entered values and any of the correlations between these values.
2. Should the solutions referred to in par. 1 subpar. 1 comprise establishing separate limit groups for the reimbursed technologies, the rationalisation analysis shall include the indication of the evidence referred to in Article 15 par. 3 subpar. 1 and 3 of the Act.
3. Should the solutions referred to in par. 1 subpar. 1 comprise a qualification of reimbursed technologies to the common limit group, the rationalisation analysis shall include the indication of the evidence referred to in Article 15 par. 2 of the Act and the requirement referred to in Article 15 par. 3 subpar. 2 of the Act.

§ 8.



The analyses referred to in § 1 shall include:

- 1) the bibliographic data of all used publications, with the specificity level enabling unambiguous identification of each of the used publications;
- 2) the indication of other sources of information comprised in the analyses, in particular legal acts and personal data of the authors of unpublished trials, analyses, expert reviews and opinions.

§ 9.

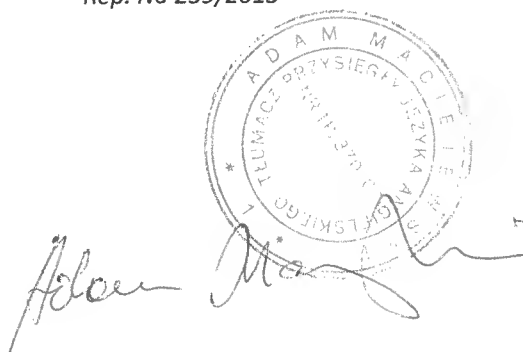
This Regulation shall enter into force on the date of publication.

MINISTER OF HEALTH

I, the undersigned, Adam Maciejewski, sworn translator of the English language, hereby certify that the above document is a true and correct translation of the original document presented to me in the Polish language.

Warsaw, 11 April 2013

Rep. No 239/2013



The image shows a handwritten signature in cursive script, which appears to read "Adam Maciejewski". To the right of the signature is a circular official seal. The seal contains the text "ADAM MACIEJEWSKI" at the top, "TŁUMACZ PRZYSIĘGI" in the middle, and "JĘZYK ANGIELSKI" at the bottom. There is also a small number "239" visible within the seal.