Positive Decisions by Minister of Health on Reimbursement of Innovative Drugs in Poland Lack Content-Related Justifications - an Analysis of Quality of Justifications of Decisions to Include Drugs in Public Funding

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1. BACKGROUND

Decisions to fund highly priced innovative drugs within a national health care system are crucial for patients' access in Poland and many other countries.

National Health Fund (NFZ) is a single payer in the Polish health care system and it is the Minister of Health (MoH) who makes a decision whether a drug is funded from public sources.

Procedure

The process is initiated by a pharmaceutical company which has to submit application for public funding of a drug. If the drug is innovative and no equivalents are already reimbursed in Poland, the application has to be accompanied by HTA analyses.

Those analyses are verified by analysts at the Agency for Health Technology Assessment and Tariff System (AOTMiT).

The first appraisal is made by the Transparency Council, a group of 20 experts and representatives appointed by MoH, proposed by NFZ, Office for Registration of Medicinal Products and Patient Ombudsman. They issue a statement on public funding of a drug, which is then taken into account by the President of AOTMiT who issues a recommendation. Both statements and recommendations are extensively justified and published on the AOTMiT website www.aotm.gov.pl.

The next stage is negotiations between the applicant company and the Economic Commission, a group of officials appointed by the MoH and NFZ, concluded with a resolution.

Then the MoH may arrange for additional negotiations with the applicant company. The proceedings are concluded by the decision of MoH not bound either by the statement of Transparency Council, the recommendation of the President of AOTMiT or the resolution of the Economic Commission.

The whole proceedings to include a drug into reimbursement in Poland are formally an administrative procedure regulated by the general law (code of administrative procedure) and specific law (on drug reimbursement).

Requirements for administrative decision on reimbursement

There are several formal requirements for an administrative decision, one of which is to include a content-related justification (C-RJ) called a factual justification. As stated in the article 107.3 of the code of administrative procedure, this justification in particular has to indicate the facts considered as proven by the administrative authority, the evidence on which the authority based the decision and the statement of reasons for other evidence to be denied credibility and decisive power. The article 107.4 of the code stipulates that the authority may waive justification if the decision fulfils the whole demand of the applicant unless conflicting interests or appeal are decided upon.

Criteria to include a drug in reimbursement

Since Poland joined the EU on 1 May 2004 she was obliged to implement the Transparency Directive 89/105/EWG which stipulates in art. 6 that objective and verifiable criteria to include a drug into public funding have to be established. As at that time there were no objective and verifiable criteria of inclusion into public funding and the process to make a decision took much longer than 180 days, Poland was under an infringement procedure by European Commission for failure to implement the Transparency Directive.

On Jan 1, 2012 the law on drug reimbursement went into force. It sets 13 criteria to be taken into account when including a drug into reimbursement defined in the article 12 of law on drug reimbursement.

As the objective of this study is to verify quality of justifications based on those criteria, it is reasonable to fully quote it.

"Art. 12. Aiming to obtain the most health effects within the available public funds, the Minister of Health issues the administrative decision to include into reimbursement and set the official ex-factory price, having taken into account the following criteria:

1) Resolution of the Economic Commission

2) Recommendation of the President of the AOTMiT

3) Importance of the clinical state that the submission concerns

4) Clinical efficacy and effectiveness

5) Clinical safety

6) Relation of health benefits to risks

7) Relation of costs to achieved health effects of currently used drugs as compared to the submitted drug

8) Price competitiveness

9) Impact on the expenditures of the public payer and patients

10) Existence of alternative medical technology, its clinical effectiveness and safety

11) Credibility and precision of estimates of criteria set out in points 3-10

12) Health priorities

13) Level of threshold to achieve additional quality adjusted life year, set at three times per capita gross domestic product; in case such cost is not possible to be calculated – the cost of additional year of life

- taking into account other medical procedures possible in the given health state which could be replaced by the drug."

Analysing the decision making practice

The reimbursement decision making practice in Poland has been explicitly analysed since January 2016 initiated by NW [www.inar.pl/pl/2016/01/, most recent www.inar.pl/pl/2021/03/]. The bi-monthly analyses concerned statements of Transparency Council, recommendations of the President of AOTMiT and decisions of MoH categorized into positive, negative and conditional. It is a screening and helicopter view tool without going into details of justifications.

To the best of our knowledge this is the first study to extensively and systematically assess the quality of content-related justifications of reimbursement decisions by the MoH in Poland.

2. OBJECTIVES

This study assessed the quality of content-related justifications (C-RJ) which Minister of Health is legally obliged to provide in decisions to include a drug in reimbursement in Poland.

3. METHODS

All decisions to include a drug in reimbursement requested and received under Polish Freedom of Information Act by the Foundation for Transparency and Predictability of Administrative Decisions in the years 2017-2020 were identified.

Increasing number of these decisions and other documents related to reimbursement proceedings in Poland is published by the Foundation in a Database of Administrative Decisions called DecyBaza on its website www.dlaprzejrzystosci.pl/decybaza.

It has to be noted that over the years the Foundation developed a Reimbursement Decisions Transparency Program, within which since October 2019 they continue to request decisions on every innovative drug included in public funding within each new reimbursement announcement published every two months.

In Poland formally an administrative decision on including a drug into reimbursement can be issued in four following situations:

(1) a drug without reimbursed equivalents (usually the original) is applied for inclusion in public funding,

(2) a reimbursed drug without reimbursed equivalents (usually the original) is applied for a decision for its public funding to be continued,

(3) a drug with reimbursed equivalents (usually a generic/biosimilar) is applied for inclusion in public funding,

(4) a reimbursed drug with reimbursed equivalents (usually a generic/biosimilar) is applied for a decision for its public funding to be continued.

The decisions in the analysed set have been issued in all these circumstances with majority concerning innovative drugs (without reimbursed equivalents). Nevertheless the obligation for such a decision to be justified in a content-related manner is valid in all these situations.

We anticipated that assessment of quality of justifications would require an extensive classification to discern minor quality differences and two independent assessors as is the case in systematic reviews.

After initial overview of the available decisions we have come to conclusions that the quality of justifications is very uniform and undoubtful and requires a relatively simple classification applied by one reviewer (NW).

Every decision was assessed and classified into one of four categories:

(A) content-related justification (C-RJ) included and verifiable,

(B) C-RJ probably included but not verifiable due to redactions,

(C) lack of C-RJ with a claim to article 107.4 of the code of administrative procedure,

(D) lack of C-RJ without a claim to article 107.4 of the code of administrative procedure.

Additional breakup of a “lack of C-RJ” category into two: with and without a claim to article 107.4 of the code of administrative procedure is associated with the parallel study on quality of justifications in decisions on increasing the ex-factory official price of publicly funded drugs where MoH actually waived any justification claiming that the decision fulfils all the applicant requested.

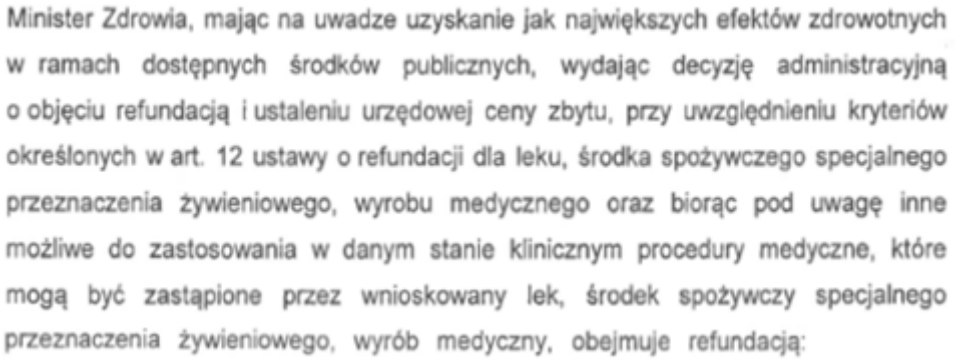
Number and percentage of decisions in each category was calculated separately for positive and negative decisions.

4. RESULTS

The study included 122 decisions of which 118 were positive and 4 negative.

100% (118/118) positive decisions lacked content-related justifications (C-RJ) without a claim to article 107.4 (D).

In every justification of the positive decisions the most C-RJ resembling excerpt was identical paraphrased clause from article 12 of the law on drug reimbursement.


Minister Zdrowia, mając na uwadze uzyskanie jak największych efektów zdrowotnych w ramach dostępnych środków publicznych, wydając decyzję administracyjną o objęciu refundacją i ustaleniu urzędowej ceny zbytu, przy uwzględnieniu kryteriów określonych w art. 12 ustawy o refundacji dla leku, środka spożywczego specjalnego przeznaczenia żywieniowego, wyrobu medycznego oraz biorąc pod uwagę inne możliwe do zastosowania w danym stanie klinicznym procedury medyczne, które mogą być zastąpione przez wnioskowany lek, środek spożywczy specjalnego przeznaczenia żywieniowego, wyrób medyczny, obejmuje refundacją:

It says: "Aiming to obtain the most health effects within the available public funds, issuing the administrative decision to include into reimbursement and set the official ex-factory price, having taken into account the criteria set in art. 12 of the Reimbursement Law on drugs, foods for particular nutritional uses and medical devices, also having taken into account other medical procedures possible in the given health state which could be replaced by the drug (food for particular nutritional uses or medical device), the Minister of Health includes into reimbursement" [then goes the name of the drug, pharmaceutical presentation, package, dose].

One may easily see the similarity with article 12 of the law on drug reimbursement qouted in chapter 1 Background of this study.

100% (4/4) negative decisions were extensively redacted in contrast to positive decisions with usually only personal applicant data redacted. Based on the length of justification by far exceeding that in positive decisions they were all classified as (B).

We have to note that the proportion of positive to negative decisions in the analysed set does not reflect the actual proportions in real life. The set of decisions is heavily overrepresented by positive decisions as a result of FOIA requests issued predominantly as a reaction to announced inclusions of new drugs into reimbursement in Poland. Therefore no conclusions can be drawn based solely on that proportion as to how often positive reimbursement decisions are taken in Poland.

5. CONCLUSIONS

Our study proves that Minister of Health in Poland uniformly and persistently does not provide content-related justifications in positive decisions to include drugs in public funding.

The Directive 89/105/EEC of 21 December 1988 (also called “the Transparency Directive”) sets out several requirements relating to the transparency of measures regulating the pricing of medicinaI products for human use and their inclusion in the scope of national health insurance systems.

In regard to justifications the Transparency Directive requires that decisions “not to include” shall contain a statement of reasons based upon objective and verifiable criteria including expert opinions or recommendations on which the decision is based.

Such a requirement brings about several consequences the most obvious being to establish “objective and verifiable criteria” of including a drug into reimbursement. It is reasonably impossible for such criteria to be applied only to negative decisions. These criteria have to be used regardless of the outcome of the decision making process – in order for this outcome to be reached.

The Transparency Directive stipulates a direct explicit requirement for providing justification (“statement of reasons”) in negative decisions. This however may not be interpreted as a way of allowing not to justify positive decisions as the directive does not refer to justifications of positive decisions at all.

In the absence of any regulation by the directive one has to assume that a given country’s regulations apply. These regulations in Poland (i.a. art. 107.3 and 107.4 of the code of administrative procedure) provide for a requirement for a content-related (factual) justification in all administrative decisions regardless whether positive or negative. The exception to waive a justification is for those decisions which fulfil the whole demand of the applicant unless conflicting interests or appeal are decided upon.

The reimbursement criteria were extensively and thoroughly discussed in the years following EU accession of Poland in 2004 as the European Commission kept pushing Polish government to conform with Transparency Directive.

In 2005 a report by the Expert Group to Develop Changes to Drug Reimbursement System was published for public consultation [https://www.katowice.oia.pl/files_news/news_303/files/450_zal_kier_zmian_refundacja_leki.pdf].

The Employers' Union of Innovative Pharmaceutical Companies INFARMA in Poland published their own proposition of changes to reimbursement system in 2008 [https://biotechnologia.pl/farmacja/od-poczatku-roku-ministerstwo-zdrowia-mowi-ze-jest-przygotowany-projekt-zmian-w-systemie-refundacji-lekow,5514?month=1&year=2020]. They proposed 4 criteria to include a drug in reimbursement and two modes for setting a price. The whole process would be concluded with an individual administrative decision with a justification.

We must note that even the most objective and verifiable criteria will not ensure fair competition for public funds and fair reimbursement decisions if their fulfilment is not fully reflected in content-related justifications. Therefore we understand that the identified and documented practice of MoH not to provide content-related justifications in positive decisions on inclusion of drugs into reimbursement should no longer be continued.

Based on the rule of legitimate expectation the decions made so far may be used to predict the outcome in a given new process. This would lead to more consistent decision making practice based solely on performance of a drug on official criteria, resulting in actual equal and fair treatment of small and large companies and various groups of patients. In the absence of C-RJs it is severely impeded to identify what decision to legitimately expect.

The Foundation has taken several actions to point at this problem and the twin one of no C-RJs in positive decisions on increasing ex-factory prices of publicly funded drugs in Poland, and to have the current practice changed, i.a.:

(1) open letter to MoH, answered with claims that the practice is legal [www.dlaprzejrzystosci.pl/minister-zacheca-fundacje-do-skierowania-braku-merytorycznych-uzasadnien-decyzji-refundacyjnych-do-sadu-administracyjnego/],

(2) an apeal to pharma and medical device industry groups in Poland to confirm that MoH is obliged to justify positive decisions [summary of responses www.dlaprzejrzystosci.pl/podsumowujemy-inicjatywe-3xtak/],

(3) a petition to Polish Parliament [www.dlaprzejrzystosci.pl/fundacja-sklada-petycje-do-sejmu-i-senatu-w-reakcji-na-przekonanie-ministra-zdrowia-ze-nie-musi-uzasadniac-merytorycznie-pozytywnych-decyzji-refundacyjnych/].

The petition is still proceeded as of 7 May 2021 now awaiting completion of a legal opinion.

We look forward to make the Polish Minister of Health change practice of not justifying positive pricing and reimbursement decisions on drugs which is evidently embarassing for Polish experts and may be harmful for Polish citizens.

DISCLOSURES

No external funding was received for this study.