Positive Decisions by Minister of Health to Increase Ex-Factory Official Price of Publicly Funded Drugs in Poland Lack Content-Related Justifications - an Analysis of Quality of Justifications of Decisions on Increasing Prices of Reimbursed Drugs

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PRESENTED AT:

1. BACKGROUND

Decisions to increase price of reimbursed drugs may be a matter of business life and death for smaller pharmaceutical companies. Within the always limited public budget they may therefore severely impact patients' access to drugs.

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 publicly funded drug will have its ex-factory price increased.

Procedure

The process is initiated by a pharmaceutical company which has to submit application to increase the official ex-factory price of its reimbursed drug. The new price has to submitted together with a budget impact analysis and some minor requirements.

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 by the resolution of the Economic Commission.

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

Requirements for administrative decision on price increase

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 increase ex-factory price of a publicly funded drug

Since Poland joined the EU on 1 May 2004 she was obliged to implement the Transparency Directive 89/105/EWG which stipulates in art. 3 that objective and verifiable criteria of price increase of a publicly funded drug have to be established.

On Jan 1, 2012 the law on drug reimbursement went into force. It sets 3 criteria to be taken into account when increasing ex-factory price of a reimbursed drug defined in the article 13 of law on drug reimbursement.

There are formally two separate clauses in the article 13, one to set ex-factory price of a drug without reimbursed equivalents (art. 13.1) and the other for a drug with at least one reimbursed equivalent (art. 13.5).

As the objective of this study is to verify quality of justifications based on those criteria, it is reasonable to provide it in full with clauses 13.1 and 13.5 combined.

"The Minister of Health sets the official ex-factory price of a drug, having taken into account the following criteria:

1) Resolution of the Economic Commission

2) Recommendation of the President of the AOTMiT (only if price increase is justified based on additional health benefit provided)

3) Price competitiveness

- taking into account balancing interests of patients and entrepreneurs who produce and sell drugs, financial capabilities of the NFZ and R&D/Investment activity of the applicant in the field of health care in Poland and other countries of EU/EFTA."

Analysing the decision making practice

The decisions to set prices of drugs have come under closer scrutiny as a reaction to steady and steep increase of launch prices of innovative drugs in the recent decade.

Usually the real (effective) ex-factory price of an innovative publicly funded drug in a given country is not known to the public because of confidential rebates.

Some say that every registered drug is worth public funding but at a fair price.

It is therefore essential to verify if a demanded price is actually fair and justified. There are institutions and organisations which do this job for some drugs, e.g. Institute for Clinical and Economic Review in US [www.icer.org] or Patented Medicines Prices Review Board in Canada [http://pmprb-cepmb.gc.ca/home].

One may claim that such a job in Poland is partially done by the Agency for Health Technology Assessment and Tarriff System [www.aotm.gov.pl] but their involvement is limited only to verification and recommending the innovative drug prior to the decision to include it in public funding. In regard to price increase the Agency is only involved if the increase is justified by additional health benefit (see criteria above).

The ultimate institution to make decision whether a given price increase of a publicly funded drug in Poland is acceptable is MoH. Therefore justifications of such decisions could provide a great insight into the way in which MoH is balancing competing interests of patients and drug producers/sellers.

To the best of our knowledge this is the first study to extensively and systematically assess the quality of content-related justifications (C-RJ) of decisions to increase ex-factory prices of reimbursed drugs 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 increase ex-factory prices of reimbursed drugs.

3. METHODS

All decisions on increasing a price of reimbursed drugs requested and received under Polish Freedom of Information Act by the Foundation for Transparency and Predictability of Administrative Decisions in 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 considerable ex-factory price increase of a publicly funded drug within each new reimbursement announcement published every two months.

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 situation in positive decisions on including drugs in public funding where MoH actually makes copy-paste of the paraphrased art. 12 of the law on drug reimbursement without a claim to art. 107.4.

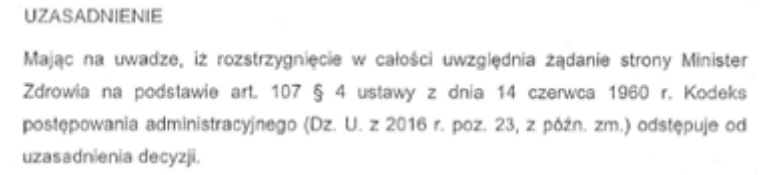
Number and percentage of decisions in each category was calculated separately for positive and negative decisions.

4. RESULTS

The study included 75 decisions of which 42 were positive and 33 negative.

100% (42/42) positive decisions lacked C-RJ with a claim to article 107.4 (C).

Every positive decision was justified in the same way (see figure below).



UZASADNIENIE

Mając na uwadze, iż rozstrzygnięcie w całości uwzględnia żądanie strony Minister Zdrowia na podstawie art. 107 § 4 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz. U. z 2016 r. poz. 23, z późn. zm.) odstępuje od uzasadnienia decyzji.

It says: "Taking into account that the decision fulfills all the demand of the applicant, on the basis of art. 107.4 of the code of administrative procedure the Minister of Health waives justification of the decision.

100% (33/33) 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).

5. CONCLUSIONS

Our study proves that Minister of Health in Poland uniformly and persistently does not provide content-related justifications in positive decisions to increase ex-factory official prices of drugs in public funding. MoH uses art. 107.4 of the code of administrative procedure and claims it may actually waive any justification because they fully accepted the demand of the applicant.

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 permit the whole or part of the price increase requested” shall contain a statement of reasons based upon objective and verifiable criteria.

Therefore based on art. 4 the Transparency Directive explicitly requires C-RJ not only in negative ("no price increase") decisions but also in positive decisions when initially requested increase was negotiated downwards and some price increase was accepted and implemented.

Such a requirement for justification of decision on increasing drug prices using “objective and verifiable criteria” brings about several consequences the most obvious being to establish such criteria. It is reasonably impossible for such criteria to be applied only to negative decisions, i.e. rejecting any price increase. These criteria have to be used regardless of the outcome of the decision making process – in order for this outcome to be reached.

To verify whether price increases accepted in positive decisions in our dataset were equal to those initially demanded was outside the scope of study.

Even if the Transparency Directive does not provide a direct and explicit requirement for a C-RJ to be included in positive decisions where initially demanded price increase is fully accepted, 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 fundamental question is whether decisions to increase reimbursed drug prices resolve conflicting interests. It is obvious that manufacturers of drugs compete against one another for the reimbursement budget. As the budget is limited, that competition is a zero-sum game - the more one company gets, the less is available for the others to sell their drugs for. One may also claim that similar competition exists among groups of patients with different diseases.

In our opinion decisions to increase a given drug's ex-factory price resolve conflicting interests among manufacturers and patients. It seems that the Polish Parliament shares this opinion as they voted the law on drug reimbursement with explicit statement in the art. 13.1 and 13.5 (quoted in "1. Background" chapter) that the MoH should "balance the interests of patients and entrepreneurs who produce and sell drugs". If those interests were not conflicting, no balancing would be necessary.

Therefore positive decisions on price increases are not a situation when art. 107.4 of code of administrative procedure could be used and no justification provided in the administrative decision.

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 of waiving justification based on art. 107.4 should no longer be continued.

The Foundation has taken several actions to point at this problem and the twin one of no C-RJs in positive decisions on including innovative drugs in public funding 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.