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Broad Amendment to the Reimbursement Act - distribution aspects

A draft amendment to the Law on the Reimbursement of Medicines, Foodstuffs for Special Nutritional Purposes and Medical Devices and and certain other Acts (UD 187, "SZNUR") has been published on the website of the Government Legislation Centre.

Thirty days are provided for public consultation on the draft (until 20 June this year).

We are sending a directional analysis of the most important distribution aspects of the amendment to the SZNUR that are relevant to manufacturers, those being:

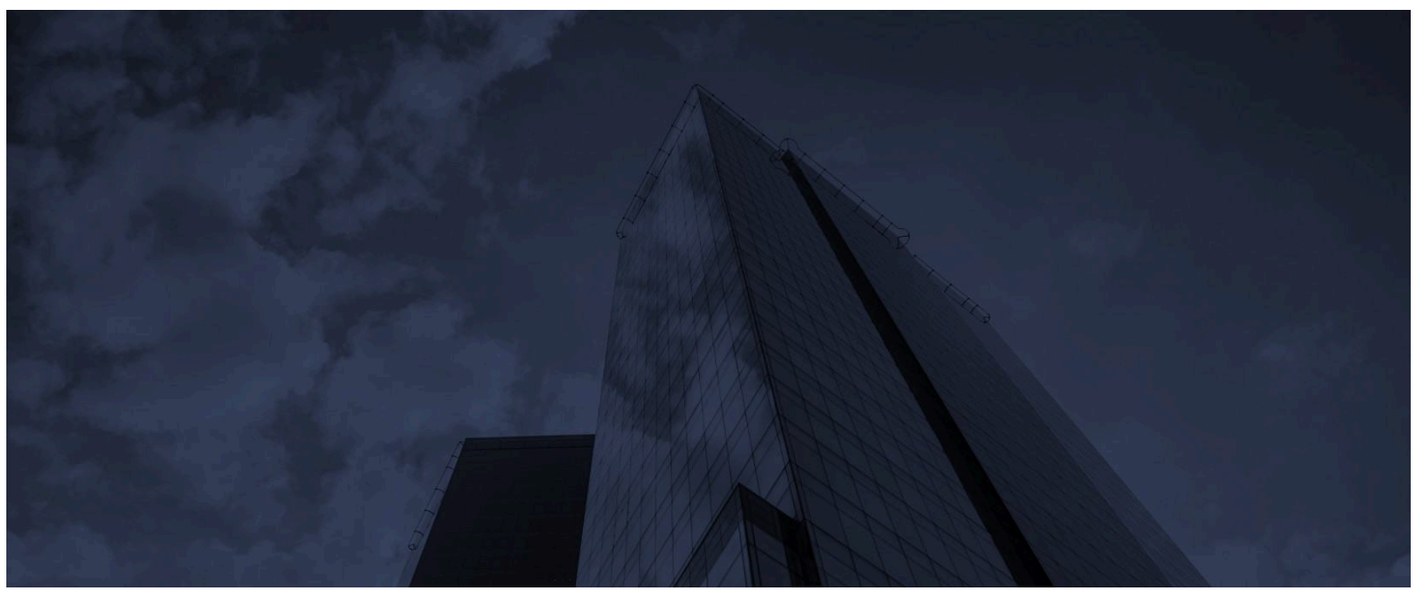
A) **changes to the wholesale margin** - increasing the minimum wholesale margin to 80 gr.;

B) **removal of the obligation to supply products at risk of non-availability to a minimum of 10 pharmaceutical wholesalers in equal shares;**

C) **amendments to ensure continuity of supply and rules on penalties for non-availability:**

- the applicant **will be able to avoid a penalty when it has proven that patients' needs have been met** (reverting to the previous wording of the rules),
- the penalty will apply **only to products included in what it known as the anti-exposure list** (for the period from when the medicine was included in said list),

- the penalty for discontinuity of supply will not apply to medicines reimbursed under drug programmes,
- **the entire distribution chain for all packages exempted in the territory of the Republic of Poland** (from the level of wholesalers, through pharmacies/pharmacy points or hospitals) will be examined as part of the verification of whether the obligation concerning the continuity of supply has been fulfilled,
- the President of the NFZ will check how many packs were introduced in a given quarter and take into account packs from previous quarters, and
- the penalty will be imposed by the President of the NFZ by way of an **administrative decision (with the possibility of appeal)** - however, the payment will be due within 30 days of the appeal failing and the issuance of a final decision;



D) insight of responsible entities into data on stock levels in ZSMPOL - the responsible entity will gain access to data in ZSMOPL on the number of unit packs in stock at businesses running pharmaceutical wholesalers, general pharmacies, pharmacy points, hospital pharmacies, hospital pharmacy departments or drug distribution departments - for products which it, itself, reports to ZSMOPL;

E) new rules for informing about the refusal of an order - the entity refusing an order for medicines (including those in the Rx category) will inform ZSMOPL about the refusal - the obligation to justify the refusal will be removed;

F) a broader obligation of responsible entities to report to ZSMOPL - responsible entities will be required to report to ZSMOPL on each fact of releasing a batch of medicinal product placed on the market in the territory of the Republic of Poland, and not, as until now, only on deficit products;

G) clarification that a financial penalty will also be charged for untimely or erroneous data submitted to ZSMOPL – the removal of doubts as to interpretation arising in the application of financial

penalties - the current wording of Article 127c, paragraph 1 of the Act - Pharmaceutical Law, stipulates that an entity conducting activity consisting in running a pharmaceutical wholesaler, which did not provide ZSMOPL with information on conducted transactions, inventories and warehouse transfers to other pharmaceutical wholesalers, is subject to a financial penalty. This wording of the provision allowed for the interpretation that the fine is related only to the failure to submit data to the system and does not cover the failure to submit data on time or the submission of incorrect data. The new wording is intended to remove ambiguity;

H) **changes to the return of medicinal products after "delisting"** - modification of the rules for the reimbursement of products that cease to be reimbursed will apply only to products purchased by pharmacies up to nine months prior to their "delisting", and for pharmaceutical wholesalers it will apply to products purchased up to 12 months prior to their "delisting";

I) **optional withdrawal of the authorisation to operate a pharmaceutical wholesaler in the case of export of scarce medicines without notification to the GIF** – the GIF will be able to refrain from withdrawing the authorisation to operate a pharmaceutical wholesaler if the GIF finds that the seriousness of the infringement is negligible;

J) **changes to meanings in the scope of reimbursements in the hospital channel** – the new, literal, wording of Article 9(1) of the Reimbursement Act implies that the elements indicated therein "form" the gross wholesale price;

K) **selected changes to the target and intervention import procedure** - the Minister of Health will confirm the absence of circumstances preventing the import of the product. The import procedure in the Target Import Service System has also been clarified and the rules for issuing prescriptions for target imports has been modified. A conditional possibility of importing medicines with an equivalent registered in Poland has been introduced; and

L) **removal of the requirement for the representative of the responsible entity to be based in Poland.**

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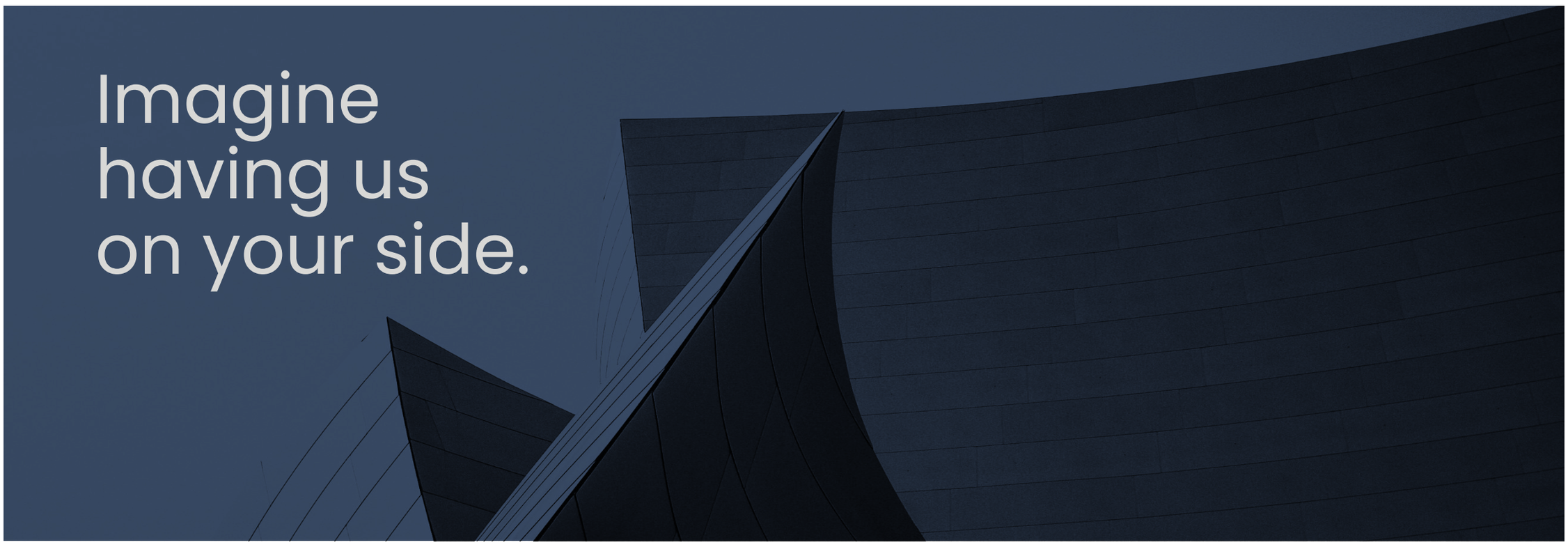

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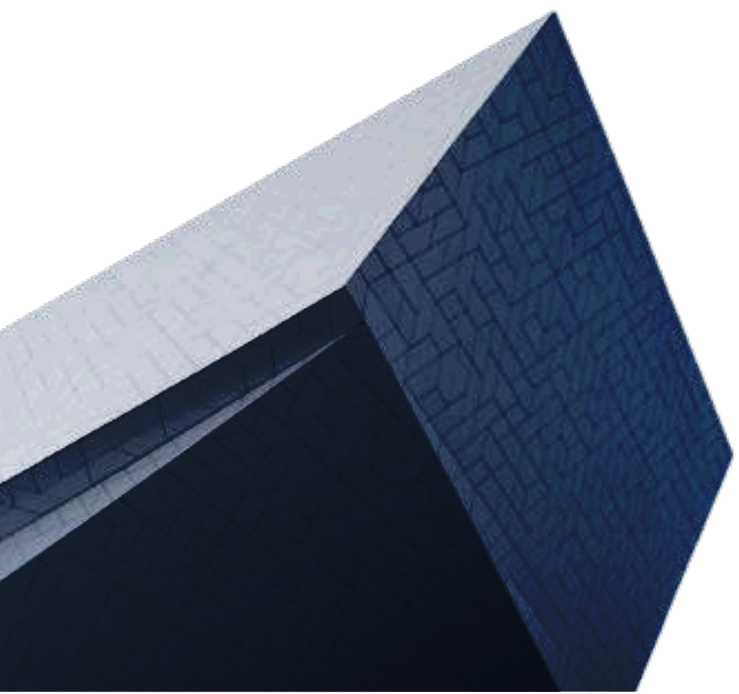

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