

Legal alert

Publication in the SOLR of a communication on the submission of price offers after the issuance of a resolution of the Economic Commission

On 30 August 2024, a communication concerning the submission of price offers following the issuance of a resolution of the Economic Commission (the "Communication") was published in the System for Reimbursement Lists (Polish: System Obsługi List Refundacyjnych) (the "SOLR"). Given its small size, it is worth quoting it in full:

„We would like to remind you that, pursuant to Article 18a(1) of the Reimbursement Act, once the Economic Commission has made a resolution, the applicant may not modify the reimbursement application, especially with regard to the net selling price and risk sharing-schemes. Thus, the Ministry of Health urges the prudent submission of financial conditions for products at earlier stages of the process.

Modification of the financial offer after the Economic Commission has made a resolution is possible only pursuant to Article 18a(2) of the Reimbursement Act, if the Minister of Health considers it necessary to conduct additional negotiations with the applicant, due to the unmet needs of the beneficiaries and the payment capacity of the entity required to finance the benefits from public funds.

In view of the foregoing, the Ministry of Health announces that the submission of modifications of the reimbursement application after the issuance of the Economic Commission's resolution cannot be treated other than as a modification of the application and, at the same time, as additional negotiations.

Additionally, marketing authorisation holders participating in the Polish reimbursement system should bear in mind that the process of additional negotiations referred to in Article 18a(2) of the Reimbursement Act is not a rule, but an eventuality to be decided by the Minister of Health.”



At the outset, we would like to point out that the theses contained in the Communication represent an interpretation of the law as presented on the SOLR website. It is worth pointing out that the communications published to date by the Minister of Health, which seemed to be specifically aimed at ‘clarifying’ the provisions introduced by the Major Amendment to the Reimbursement Act^[1] and indicating the direction desired by the Ministry of Health in their interpretation, do not constitute a source of generally applicable law.

This does not mean that such communications can be disregarded by applicants, as they provide an important indication of how the authorities proceed under the Reimbursement Act^[2].

The content of the Communication appears to indicate that price negotiations depend primarily on discussions with the Economic Commission. The Communication also stressed that the submission of a new price offer after the issuance of the Economic Commission's resolution should be treated as a modification of the reimbursement application, and will be regarded as additional negotiations (referred to in Article 18a(2) of the Reimbursement Act). Furthermore, it was pointed out that the process of carrying out additional negotiations should be treated not as a rule, but as an eventuality “left to the discretion of the Minister of Health”.

[1] The Act of 17 August 2023 on the Amendment to the Act on the Reimbursement of Medicinal Products, Foods for Special Dietary Uses and Medical Devices, and some other Acts (Journal of Laws of 2023 item 1938 as amended; the “Major Amendment to the Reimbursement Act”).

[2] The Act of 12 May 2011 on the Reimbursement of Medicinal Products, Foods for Special Dietary Uses and Medical Devices (consolidated text in the Journal of Laws of 2024 item 930, as amended; the “Reimbursement Act”).

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As indicated in the Communication, Article 18a(2) of the Reimbursement Act **provides for the possibility of additional negotiations** with the Minister of Health (after the issuance of a resolution by the Economic Commission) if the authority “deems it necessary in view of the unmet needs of the beneficiaries and the paying capacity of the entity required to finance the benefits from public funds”.

However, to the best of our knowledge, in practice, applicants have so far been able to proactively submit new, in-depth proposals for reimbursement and pricing conditions even after the Economic Commission has issued a resolution. In addition, it so happens that such new proposals have been submitted several times – so as to reach a final agreement on access to therapy. As a rule, these activities have, so far, not been challenged by the Ministry of Health.

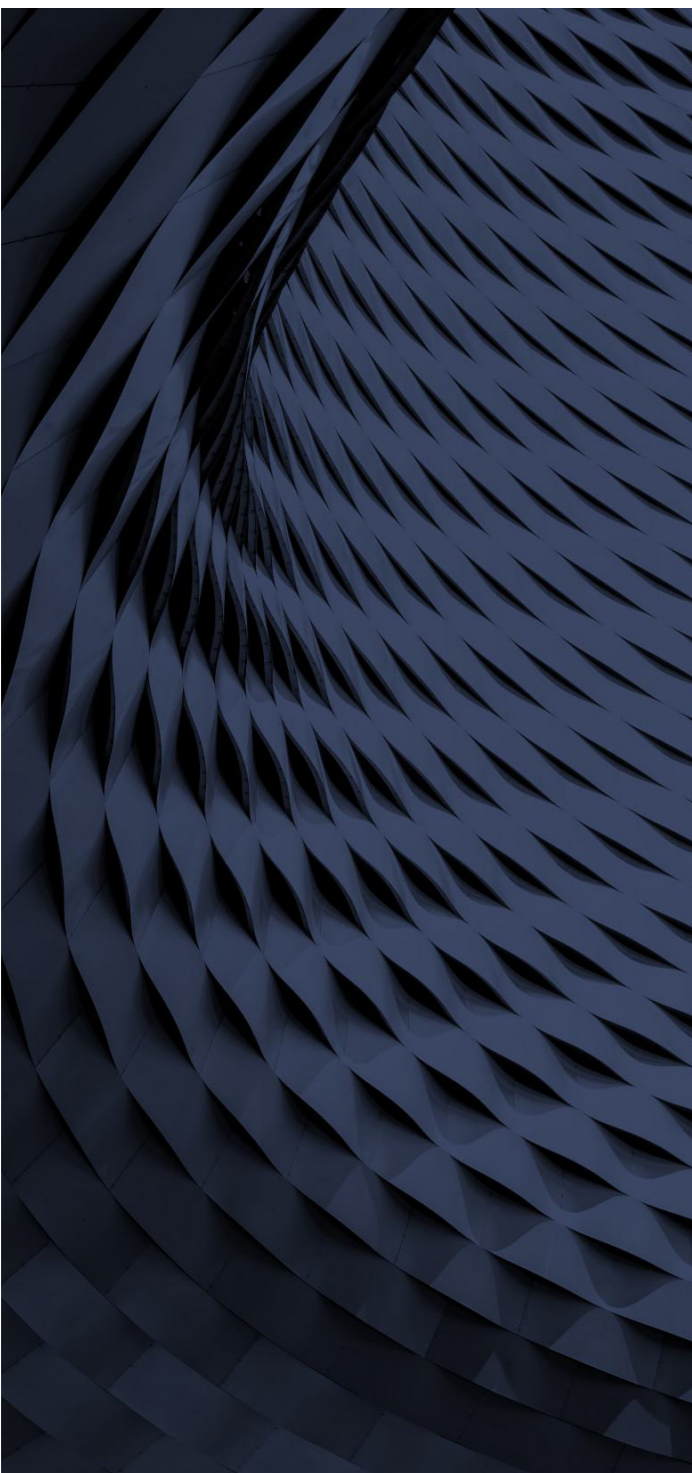
In view of the above, we hope that the interpretation provided in the Communication will not be considered as a restriction on the possibility for applicants to submit new price proposals after the issuance of the Economic Commission's resolution, and that this possibility will not be limited to only one offer.

In our opinion, a possible top-down restriction of the possibility to proactively submit price proposals after the issuance of a resolution by the Economic Commission would not be justified, both in view of access to therapy, the desire to negotiate the most favourable financial conditions from the payer's point of view and a purposive interpretation of the current provisions of the Reimbursement Act.

At the same time, we understand that the overriding aim of the Communication is to streamline the application procedure by limiting the possibility for applicants to submit new price proposals at the final stage of the procedure, which, in practice, may potentially affect the length of the application procedure. However, it should not be forgotten that the gist of the Reimbursement Act and the reimbursement proceedings conducted on its basis is to ensure adequate access to therapy for patients in Poland.

Therefore, it can be questioned whether the interpretation presented in the Communication at the SOLR website will not ultimately influence the issuing of a greater number of negative decisions by the Minister of Health, justified by the unsatisfactory price conditions proposed by applicants.

Should you have any questions or concerns, please do not hesitate to contact us.



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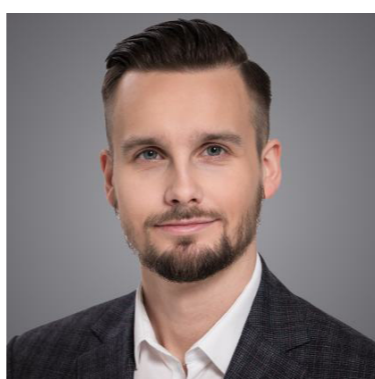
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