

Reimbursement of medicinal products in Lithuania

Process map



Introduction

This regulatory process map aims to provide a concise yet comprehensive overview of the drug reimbursement process in Lithuania, from application submission to the reimbursement decision. The document is intended as a **practical tool** for pharmaceutical companies considering submitting applications for drug reimbursement in Lithuania.

The purpose of this document is to help industry better understand the Lithuanian reimbursement system, decision-making principles and the interaction between institutions, thereby enabling better preparation for reimbursement processes and dialogue with the responsible institutions.

The process map provides a visual overview of the main steps of the reimbursement process. This includes health technology assessment, reimbursement decisions, the negotiation process, contractual agreements, and the final inclusion in the lists of reimbursable medicines. It also outlines an additional step, applicable only in certain cases, during which the medicine is temporarily included in the reserve list of medicines. Below is an overview of each stage of reimbursement; detailed steps are provided in the map.

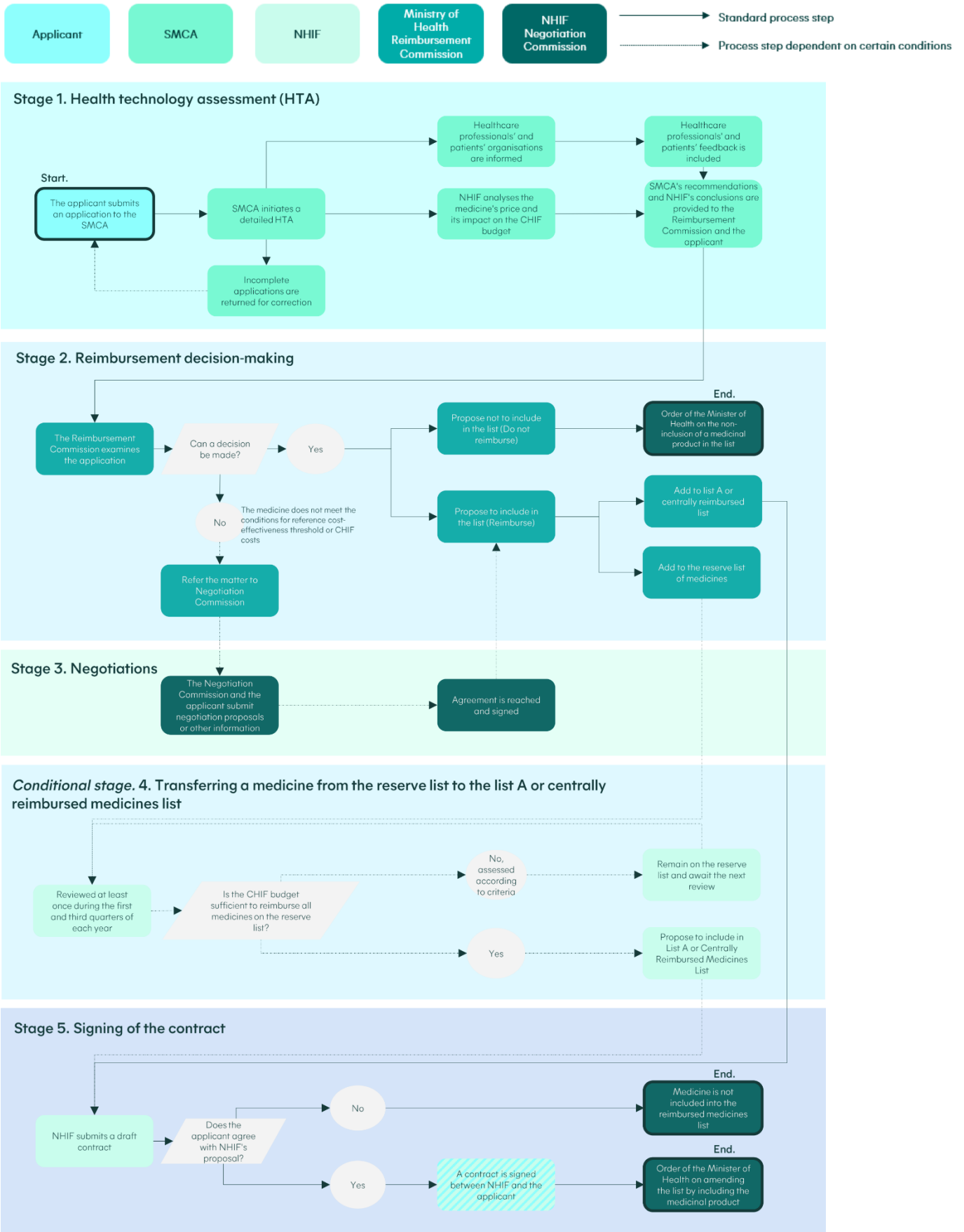
The document was prepared on 29 January 2026 in accordance with the legal acts in force at that time. Prepared on the basis of Orders No. 159, No. V-326, No. V-726 of the Minister of Health.

Abbreviations

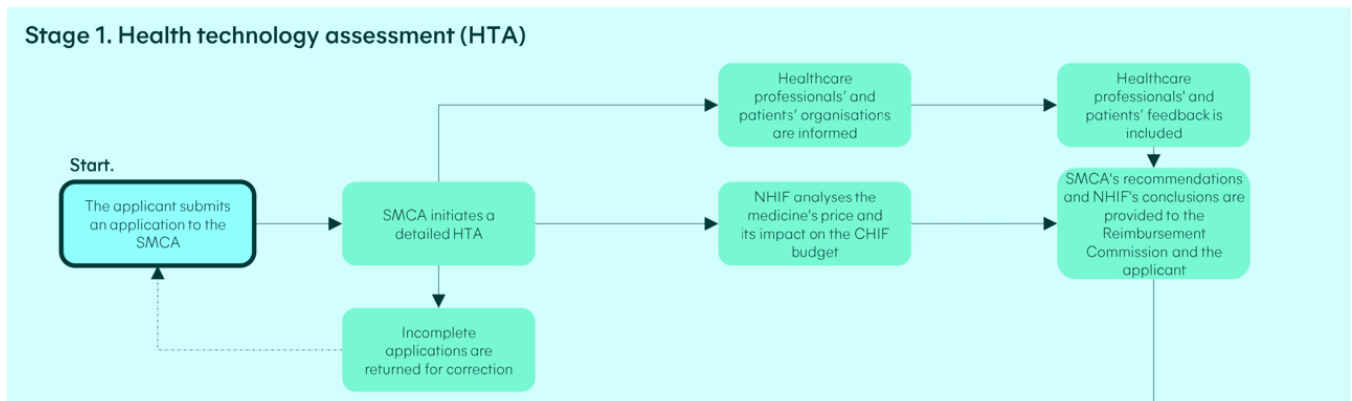
The following abbreviations are used in this document:

- PAS – Patient Access Scheme
- CHIF – Compulsory Health Insurance Fund
- MoH – Ministry of Health of the Republic of Lithuania
- HTA – Health Technology Assessment
- NHIF – National Health Insurance Fund under the Ministry of Health of the Republic of Lithuania
- SMCA – State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania

Overview of the reimbursement process



Stage 1. Health technology assessment (HTA)



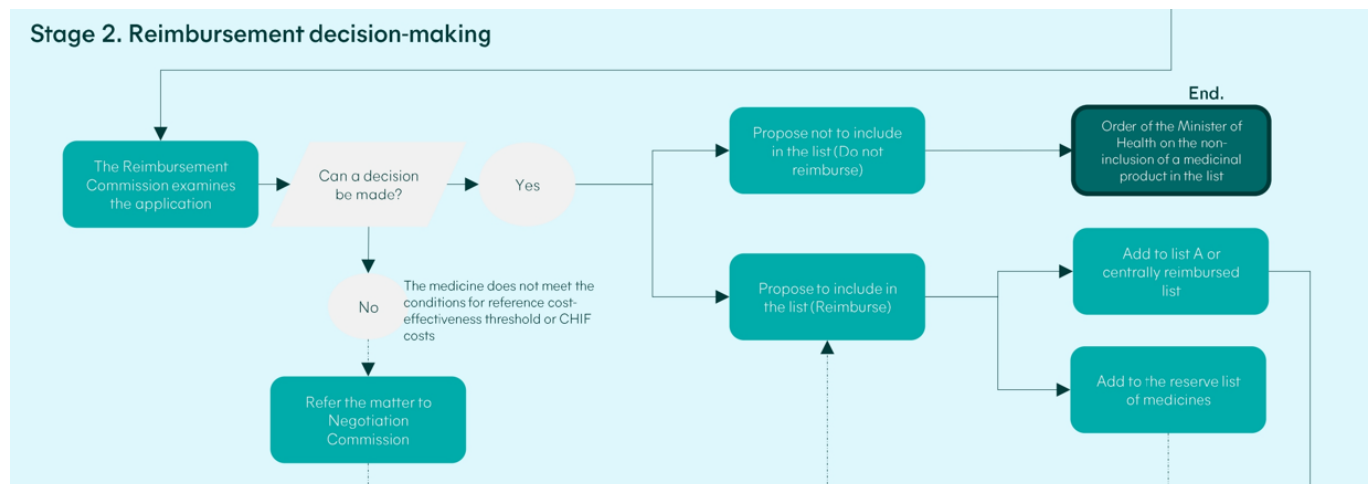
The HTA stage takes 90 days and is designed to assess the clinical and economic benefits of a medicinal product and its impact on the CHIF budget. The application for reimbursement may be submitted by the applicant (marketing authorisation holder, healthcare professionals' or patients' organisations). The HTA assessment is carried out by the SMCA, with the involvement of the NHIF. Healthcare professionals and patient organisations are also given the opportunity to provide their insights.

The HTA stage results in a summary of the HTA recommendations and NHIF conclusions, which are submitted to the Reimbursement Commission.

Responsible institutions: SMCA, NHIF

Legislation defining the stage: No. 159 On the approval of the description of the procedure for the inclusion of medicinal products and medical devices in the reimbursement lists and their modification

Stage 2. Reimbursement decision making



Reimbursement decision-making stage takes 50 days. During this time, the Reimbursement Commission makes a decision on the reimbursement of the medicinal product, which is based on the recommendations of the SMCA and the assessments of the NHIF and taking into account the PAS submitted by the applicant. The decision may involve inclusion in List A, the list of centrally reimbursed medicinal products, the reserve list of medicinal products, or a decision not to reimburse the medicinal product.

- Under certain conditions, and when the medicinal product does not meet the reference cost-effectiveness threshold (1, 3 or 5 GDP) or the CHIF costs are too high, the Reimbursement Commission may refer the matter to the Negotiation Commission in order to reduce the price of the medicinal product before making a decision.

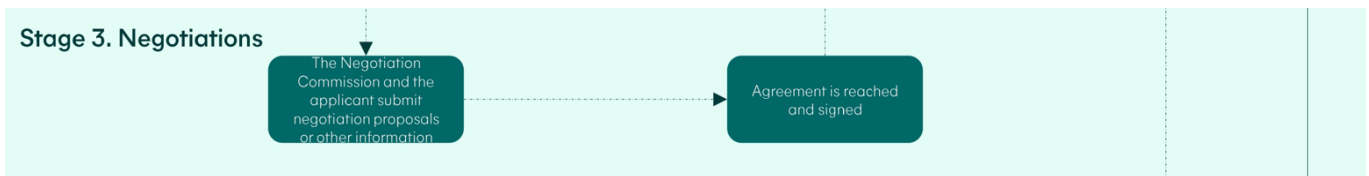
- The Reimbursement Commission decides whether to include a medicine on the list, based on its comparative effectiveness, the costs to the CHIF, the cost-effectiveness ratio compared to the reference cost-effectiveness threshold, or the outcome of negotiations.

The applicant has the right to appeal against a negative decision. During the appeal, the application may be returned for re-evaluation or rejected.

Responsible authority: MoH

Legislation defining the stage: No. 159 On the approval of the description of the procedure for the inclusion of medicinal products and medical devices in the reimbursement lists and their modification

Stage 3. Negotiations



Negotiations are conducted under certain conditions, before a reimbursement decision is made. During this stage, negotiation proposals are submitted and, depending on the course of the negotiations, an agreement may or may not be reached. If companies fail to provide the necessary information or refuse to negotiate, the negotiations are considered unsuccessful. The results of the negotiations determine whether or not the medicine will be included in the reimbursement list.

Responsible institution: NHIF

Legislation defining the stage: No. V-326 On the establishment of the Interinstitutional Commission for the Determination of Prices of Medicinal Products and Medical Devices and the approval of its rules of procedure

Conditional stage 4. Transferring a medicine from the reserve list to the A or centrally reimbursed medicines list

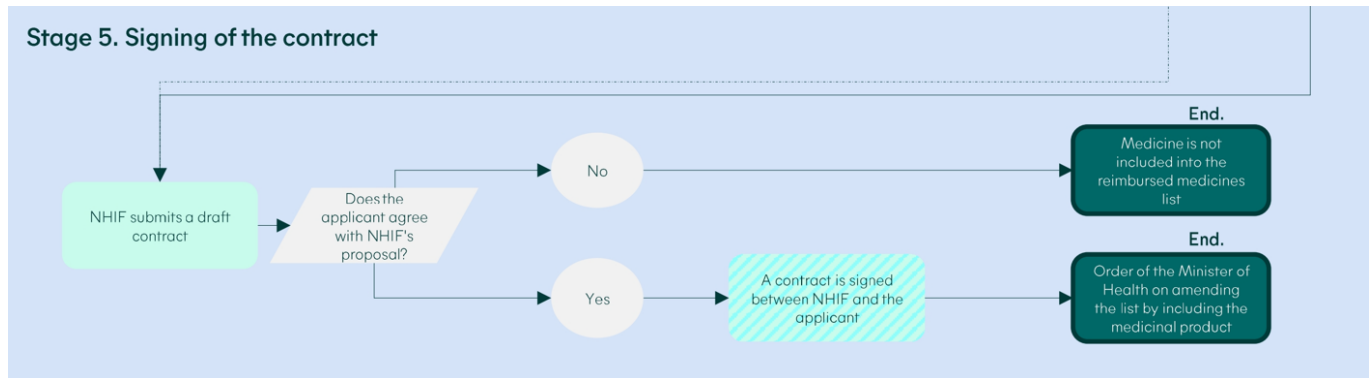


Medicinal products are moved from the reserve list to List A or centrally reimbursed medicines list in the first and third quarters of the year. The ability to transfer a medicinal product from the reserve list to the reimbursement list depends on the financial capabilities of the CHIF. If the funds are insufficient to move all medicinal products on the reserve list, the decision on which products to transfer is made after assessing additional criteria. These criteria consider additional quality-adjusted life years, costs, time spent on the reserve list.

Responsible institution: NHIF

Legislation defining the stage: No. 159 On the approval of the description of the procedure for the inclusion of medicinal products and medical aids in the reimbursement lists and their modification

Stage 5. Signing of the contract



During this stage, the reimbursement conditions are agreed between the NHIF and the marketing authorisation holder. Contracts are based on financial, clinical or mixed outcomes. Once the conditions have been agreed, a contract is signed and the medicine is included in the reimbursement system. In the event of disagreement, the medicinal product is not included in the list of reimbursable medicinal products. The legislation indicates that negotiations may be initiated in the event of disagreement, but in practice this is rarely done.

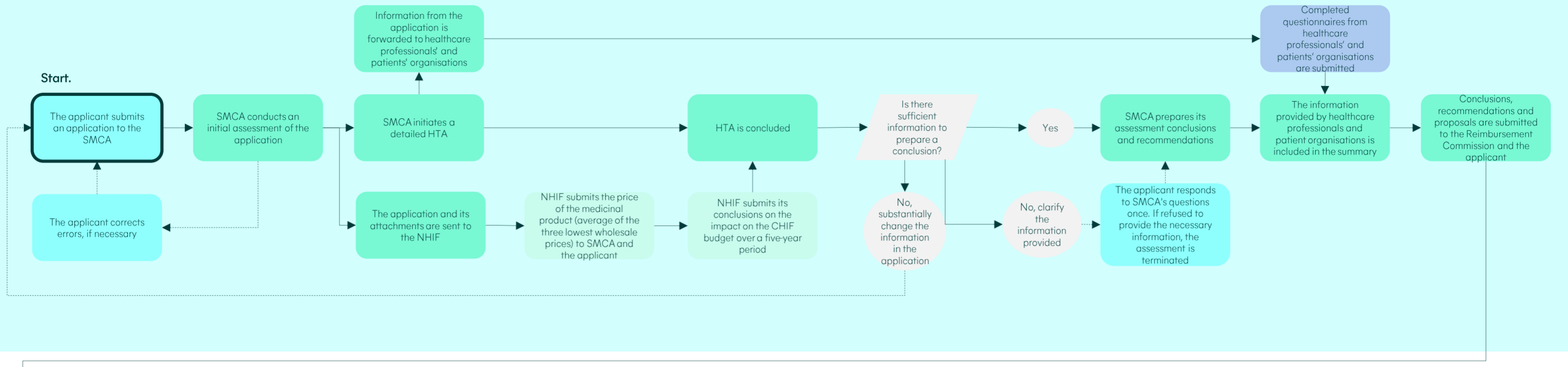
Responsible institution: NHIF

Legislation defining the stage: V-726 On the approval of the description of the procedure for the conclusion and implementation of agreements between the State Health Insurance Fund under the Ministry of Health and medicinal product manufacturers on improving access to treatment and risk sharing

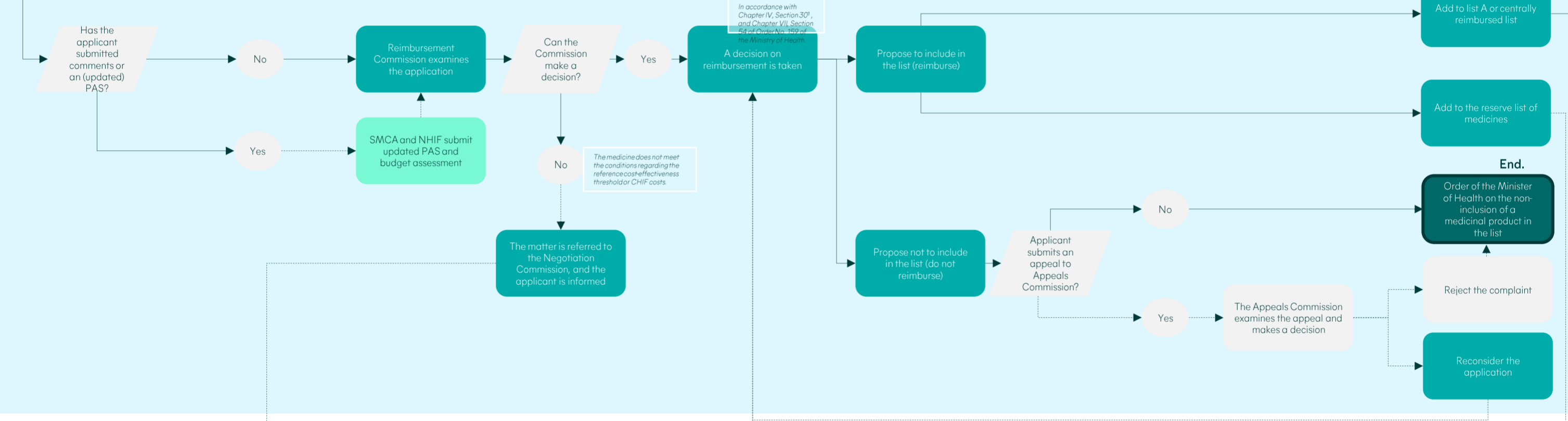
Legend



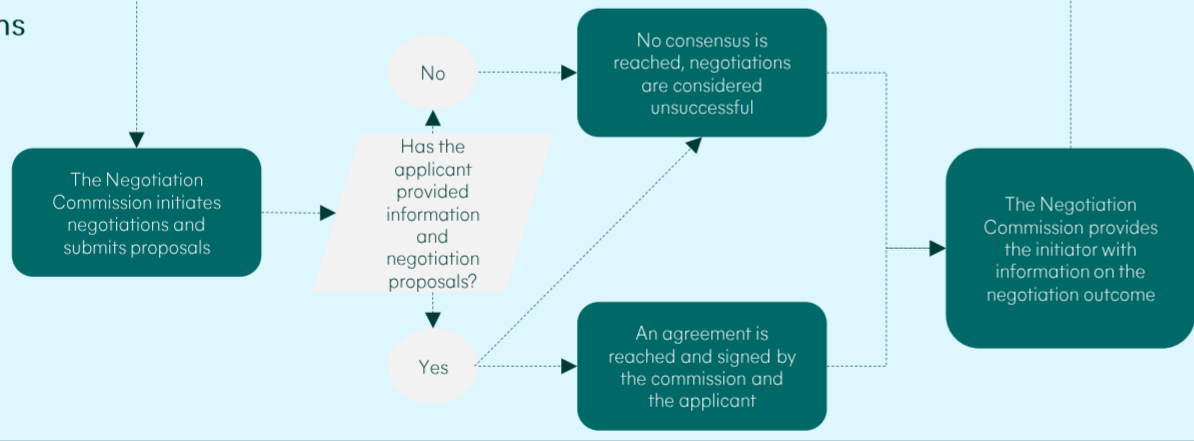
Stage 1. Health technology assessment (HTA) (90 days)



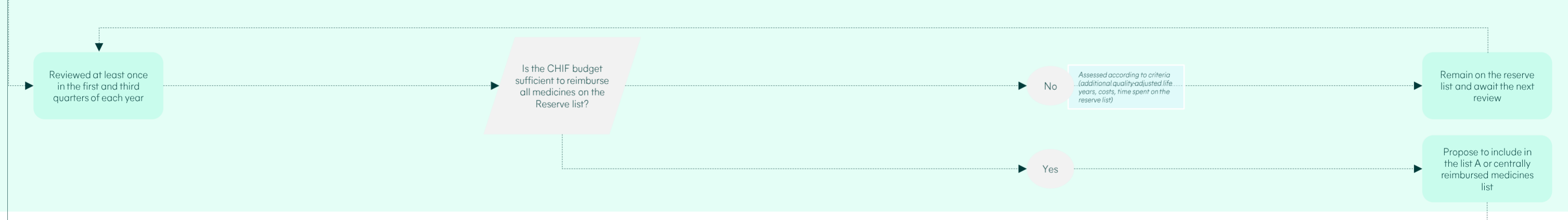
Stage 2. Reimbursement decision-making (50 days)



Stage 3. Negotiations



Conditional stage 4. Transferring a medicine from the reserve list to the list A or centrally reimbursed medicines list



Stage 5. Signing of the contract

