CAU-08 verze 0

Requirements on structure of technical documentation that is to be submitted together with applications for reimbursement of medicinal products and foods for special medical use

This instruction has been valid since 9 September 2019.

This instruction is created to:

- introduce uniform standards therefore reducing the number of deficiencies and missing data, and facilitating the evaluation process
- facilitate communication between parties to the proceeding and the Institute
- facilitate preparation of supporting evidence for the applicant
- improve intelligibility of key documentation and facilitate orientation of the Institute's technical staff in the submitted evidence
- accelerate the evaluation process

The instruction is issued on the basis and in line with the provisions of Section 39f of Act No. 48/1997 Coll., On Public Health Insurance and Section 45 of Decree No. 376/2011 Coll.

This instruction is a recommendation in nature.

A common structure as defined in the Submission Template is recommended for those individual administrative proceedings or those complex revisions of reimbursement, in which a comprehensive clinical benefit assessment or cost-effectiveness or budget impact evaluation need to be carried out in accordance with applicable legislation.

The common structure will therefore not be required in case of applications for short proceedings of so called similar medicinal products (specific defined cases of entry of generic and biosimilar medicines), etc.

Based on the experience gained so far in the assessment phase of submitted evidence, these obstacles have been identified:

- The submitted evidence or documentation significantly varies in structure according to the marketing authorisation holder or author of the submission
- The submission sometimes consists of several inconsistent documents
- Important information or scenarios are absent or vary between documents submitted

The Institute expects that the introduction of a common structure for the submission of technical documentation will have a positive impact on all entities affected by the specific administrative proceeding. More specifically, the improvements listed at the beginning of this instruction are expected to take place.

During preparation of the Submission Template, representatives of all stakeholders concerned by the process of setting or changing reimbursement price and reimbursement conditions were consulted. These representatives had the opportunity to comment on the document and make suggestions. In addition, a roundtable meeting was organized for the external experts in Autumn 2018 where both the intention to introduce this Submission Template and the first draft were presented. The organisations addressed, in alphabetical order, were:

- Association of Innovative Pharmaceutical Industry
- Association of Clinical Nutrition Manufacturers
- Czech Association of Pharmaceutical Companies
- Czech Medical Society of Jan Evangelista Purkyně
- Czech Society for Pharmacoeconomics and Health Technology Assessment
- General Health Insurance Company of the Czech Republic

- Institute for Health Economics and Technology Assessment
- Ministry of Health
- Patient Council at the Ministry of Health
- Union of Health Insurance Companies of the Czech Republic

Annexes:
Annex no. 1: Submission Template