

STATE INSTITUTE FOR DRUG CONTROL	SP-CAU-003 - W	Version: 11 / Effective date: 05.11.2018 page 1 of 27
Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes		

1. OBJECTIVE

To establish the procedure (course of administrative procedure) for the determination/change of maximum ex-factory price and/or the amount and terms of reimbursement of a medicinal product/food for special medical purposes.

2. USERS

Price and Reimbursement Branch staff.

3. DEFINITIONS OF TERMS AND ABBREVIATIONS

ADM DTB	an employee of the VAS department in charge of entries in the information system (DMP), a web service for CAU
ADM SECR	an assistant of the CAU Branch in charge of distribution of documents in SSL AA
ADM SŘDLP	an employee of the VAS department in charge of the functionality of the SŘDLP for users (schedules, stages, forms)
ADM UNI	an employee of the VAS department in charge of universal administrative support, a person responsible for formal correctness
ADM VAL	an employee of the VAS department in charge of the input control of applications for determination/change/revocation of MP/ACR
CAU	Price and Reimbursement Regulation Branch
PEA	Pharmaco-Economic Analysis team
ASSR	assessor (expert employee of MTA) – a person responsible for expert and content correctness, except for parts pertaining to pharmaco-economic (hereinafter referred to also as “PE”) analyses, if PE analyses were assessed by PEA ASSR - an assessor of the PEA team – a person responsible for expert and content correctness of parts pertaining to pharmaco-economic analyses)
STP ASSR	an STP assessor (expert employee - coordinator) – a person responsible for process, expert, and content correctness
AR	assessment report
CT	control table with the codes of medicinal products/FSMPs which contains data for SCAU
COO	administrative procedure coordinator (an APC employee) – a person responsible for process and legal correctness
CBA	Department of Preparation of Complex Source Materials and Analyses
APC	Department of Administrative Procedure Coordination
MedP	medicinal product
MP	maximum price
MoH	Ministry of Health of the Czech Republic
EiF	entry into force
MTA	Department of Medical Technology Assessment
DDA	Department of Data Analyses
PS	professional society
DSD	Documentary Service Department
FSMP	food for special medical purposes

STATE INSTITUTE FOR DRUG CONTROL	SP-CAU-003 - W	Version: 11 / Effective date: 05.11.2018 page 2 of 27
Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes		

DLLA	Department of Legal and Legislative Activities
DEC	decision
CAU D	Director of the Price and Reimbursement Branch
DIR	Director of the Institute
CAU S	CAU secretariat
APC S	secretariat of the Department of Administrative Procedure Coordination
STP S	secretariat of Department of Selected Types of Administrative Procedures
SCAU	List of prices and reimbursements of medicinal products/foods for special medical purposes
SCUP	List of medicinal products/foods for special medical purposes used in institutional care only
SThP	specific therapeutic programme
SSL AA	electronic documentary service AthenA
AP	administrative procedure
SŘDLP	an application for the conduct of administrative procedures
COMPL	Notification of completion of source material identification
Institute, SÚKL	State Institute for Drug Control
APC M	Administrative Procedure Coordination Department Manager
MTA M	Medical Technology Assessment Department Manager
VAS M	Validations and Administrative Support Department Manager
STP M	Selected Types of Administrative Procedures Department Manager
VAS	Department of Validations and Administrative Support
ACR	amounts and conditions of reimbursement
PHI Act	Act No 48/1997 Coll., on Public Health Insurance, as amended
BR	basic reimbursement

4. RELATED INTERNAL REGULATIONS

This version does not contain any links to internal regulations or forms.

5. RELATED GENERALLY APPLICABLE LEGAL REGULATIONS, STANDARDS AND EU REGULATIONS

Act No. 500/2004 Coll., Rules of Administrative Procedure, as amended ("Administrative Code")

Act No. 378/2007 Coll., on Pharmaceuticals and Amendments to Some Related Acts, as amended (Act on Pharmaceuticals)

Act No. 48/1997 Coll., on Public Health Insurance and Amendments to Some Related Acts, as amended

Act No. 634/2004 Coll., on Administrative Fees, as amended

Decree No. 384/2007 Coll., on the list of reference groups, as amended

Decree No. 385/2007 Coll., on determination of the list of active substances intended for support or supplementary treatment

Decree No. 376/2011 Coll., implementing some of the provisions of the Act on Public Health Insurance

Act No. 265/1991 Coll., on the Competence of Czech Authorities Concerning Prices, as amended

Act No. 526/1990 Coll., on Prices, as amended

Price Decision of the Ministry of Health 1/13-FAR, stipulating a list of ATC groups of medicinal products and foods for special medical purposes not subject to producer price regulation

STATE INSTITUTE FOR DRUG CONTROL	SP-CAU-003 - W	Version: 11 / Effective date: 05.11.2018 page 3 of 27
Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes		

Price regulation of the Ministry of Health 1/2013/FAR, on the regulation of prices of medicinal products and foods for special medical purposes, as amended

Act No 499/2004 Coll., on Archival and Documentary Service and on Amendment to Some Acts, as amended

Decree No 259/2012 Coll., on details regarding documentary service operation

Act No 372/2011 Coll., on Healthcare Services, as amended

6. PROCEDURE

The procedure governing the processing of applications for maximum price determination/change and/or the amount and conditions of reimbursement of a medicinal product/food for special medical purposes is outlined in Tables A and B, and in the flow chart provided under Annexes 1 and 2.

The responsibility for the administrative procedure shall lie primarily with the person who is specified in SSL AA as well as in SŘDLP as the dossier owner (COO/STP ASSR).

Within the scope of APC (Table A), fixed and predefined listed COO-ASSR couples to cooperate within an administrative procedure are established.

All of the documents sent for review shall be in the Word format.

The CT for SCAU shall be in the excel format.

The procedure shall be applicable to administrative procedures upon request referred to by the provision of Section 39f of the Act on Public Health Insurance and conducted in compliance with the provision of Section 39g (except for paragraph 9 of this provision) of the PHI Act, by the **APC department (ALTERNATIVE A)** and by the **STP department (ALTERNATIVE B)**.

The STP conducts administrative procedures that do not require a cost-effectiveness and budget-impact analysis.

An assessment of whether an administrative procedure lies within the powers of the APC or STP department shall be completed upon application validation; cases more complex in terms of identification shall be assessed by STP M or MTA M.

In case the MoH revokes a CAU decision and returns the matter for new negotiation, the dossier shall be transferred to the APC appointed COO and, where STP is involved, to the STP appointed STP ASSR.

Where the procedure mentions medicinal products, this shall be understood as including also foods for special medical purposes.

Where a timeline for an activity is mentioned, a day shall mean a working day.

ALTERNATIVE A (APC)

Activity	Specification	Conducted by	Document/aid/ SŘDLP
1. Dossier take-over	The APC S shall electronically take over the dossier from VAS via the SŘDLP and SSL AA applications following the application completeness check. The dossier shall be handed over from VAS to the APC S also with unsupported payment of the administrative fee (to be	APC S VAS ADM VAL	SŘDLP SSL AA

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	tracked and safeguarded by the ADM VAL).		
2. ASSR and COO appointment	The ADM SECR shall hand over the information about the dossier to the MTA M and APC M, the MTA M shall appoint the ASSR, and with regard thereto, the ADM SECR shall transfer the dossier to the respective COO (the MTA M, APC M, ASSR, and COO shall be all advised of the hand-over).	ADM SECR MTA M	SŘDLP SSL AA e-mail
3.1. Data check	The COO shall assess the provided dossier to check whether it contains the necessary data. (This step runs concurrently with step 3.2.) If the necessary data are available, step 4 of the procedure shall follow. If any of the particulars are not available, step 3.1.1. of the procedure shall follow.	COO	
3.1.1. Invitation for amendment (where shortcomings are identified upon hand-over to the APC)	Depending on the nature of the matter, the COO shall draft an invitation to eliminate shortcomings (missing particulars or other defects) in the application (an expert rationale, where applicable, shall be drafted by the ASSR and checked by the MTA M), and shall hand it over for review and signature to the APC M. The invitation shall be published on the Institute's notice board. Where an invitation for the elimination of shortcomings is being sent, the administrative procedure shall be suspended by resolution. Once the amending information is delivered, step 3.1.2. of the procedure shall follow. This invitation does not rule out an invitation in the validation stage.	COO (ASSR-MTA M) APC M	F-CAU-003-06R SŘDLP SSL AA
3.1.2. Receipt and assessment of the amendment	The COO in cooperation with the ASSR shall assess the provided amending documentation. If the amendment contains the necessary data and the administrative procedure has been suspended, the COO in cooperation with	COO ASSR ADM UNI APC M	F-CAU-003-22R SŘDLP SSL AA

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p>the ADM UNI shall draft a notice on resumed administrative procedure and shall hand it over to the APC M for signature. An ADM UNI employee shall enter the signed document into the dossier and shall publish it on the Institute's notice board.</p> <p>If the amendment does not contain the necessary data, the COO in cooperation with the ASSR may draft another invitation for amendment within timeline which shall be published thereby on the Institute's Notice Board as per step 3.1.1. of the procedure, or, in case the shortcomings have not been eliminated from the application, the COO shall issue a resolution terminating the administrative procedure and the ADM UNI shall publish this fact on the Institute's Notice Board.</p>		F-CAU-003-18R
3.2. Search for price references, calculation of the maximum price and amount of reimbursement	<p>Upon being informed that a file has been allocated thereto, the COO, in cooperation with the ASSR, shall file a request with the CBA department for the search of price references for the administrative procedure, incl. the prepared relevant form (control table), and a request for the drafting of the protocol on the MP/ACR determination, cc ASSR.</p> <p>Where the conditions for the determination of a fixed reimbursement as referred to by Section 39c, paragraphs 7 and 8 of the PHI Act have been met, the request for the search of price references and drafting of the protocol for the determination of the reimbursement shall not be made.</p> <p>The search shall be completed within 21 days of the commencement of the administrative procedure.</p> <p>An appointed CBA employee shall hand over the form with retrieved price references to the ASSR and COO via the SŘDLP application and shall inform them</p>	ASSR CBA employee COO	SP-CAU-001 SP-CAU-002 SP-CAU-010 F-CAU-001-04 F-CAU-001-04N F-CAU-002-01N F-CAU-002-14N e-mail SŘDLP

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p>about the entry of these source materials by e-mail. The COO shall enter the retrieved price references in the dossier and shall sign them. Prior to the entry in the dossier, the source materials from CBA may be checked by the ASSR. Where a protocol on the MP/ACR determination is concerned, the same procedure shall be applied. It shall be included in the dossier no later than together with the AR.</p>		
<p>4. Receipt of motions from parties to the procedure</p>	<p>As of the first day of the commencement of the administrative procedure (date of application submission = day 0) the receipt of motions from parties to the procedure shall run on a continuous basis. Documents coming through the SSL AA shall be handed over to the APC S via the ADM SECR and thereafter distributed to the position of the concerned COO.</p> <p>The COO, having reviewed the document, shall enter it in the dossier, conclude it and inform the ASSR. With a view to the nature of the provided evidence or proposal, the COO shall act as necessary. With a view to the nature of the motions from parties to the procedure, the COO may request opinions from the MTA, CBA, or PEA. In case the document has been delivered by a party to the procedure directly to the e-mail address of the COO, ASSR or another employee, the COO shall be forthwith informed of such document and he/she shall create a new external document in the SSL AA, shall enter it in the respective file, and shall inform the ASSR by means of a copy. If the content of the document is labelled as a business secret, prior to the conclusion of the document the COO shall ask the ADM UNI to arrange for this information to be hidden.</p>	<p>A mail-room employee ADM SECR APC S ADM UNI COO ASSR MTA M APC M</p>	<p>SSL AA SRDLP e-mail</p>

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p>Where the proposals are incomplete, the COO, after agreement with the ASSR, shall draft an invitation for cooperation and after a review thereof by the APC M or MTA M (depending on its nature) shall send it to the ADM UNI, who, after the APC M's signature shall arrange for its publication.</p> <p>A request for an expert opinion by a professional society shall be signed and sent by the MTA M, cc ASSR and COO, who shall place the request in the dossier. The opinion of the professional society shall be sent by the MTA M to the assessor and coordinator, the COO shall enter it in the dossier.</p>		F-CAU-003-08R
5. Determination of maximum price/basic reimbursement/reimbursement per package	<p>A CBA employee appointed, on the basis of the request, to draft the MP/ACR determination, shall draft a protocol on the MP/ACR determination in compliance with effective methodologies.</p> <p>The CBA employee shall hand over the aforementioned protocol on the MP/ACR determination together with any source materials for the MP/ACR determination to the ASSR and COO via the SŘDLP application and shall inform them about the entry of those source materials by e-mail.</p> <p>The protocol on the MP/ACR determination shall be placed in the dossier no later than together with the AR in the same manner as referred to under section 3.2. of this procedure.</p>	CBA employee	<p>Relevant forms of the F-CAU-001 and F-CAU-002 series</p> <p>SŘDLP e-mail</p>
6. Assessment report drafting	<p>Once the timeline for the provision of evidence and submission of motions expires, no later than on day 20/40 of the administrative procedure commencement, the ASSR in cooperation with the COO shall draft the AR, where the proposals and evidence provided by parties and, if applicable, by professional societies, shall be addressed by the type thereof, and, if necessary,</p>	ASSR COO MTA M	F-CAU-003-04R e-mail

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p>shall request cooperation from the CBA and/or PEA departments. They shall enter the determined MP/ACR in the AR.</p> <p>The ASSR shall forward the AR by e-mail to the MTA M for review, cc COO and PEA ASSR.</p> <p>In the aforementioned e-mail message, the ASSR shall enter a brief information on the respective administrative procedure, emphasising whether the AR is subjected to reporting to CAU D or the DIR.</p>		
<p>7. AR review</p>	<p>The AR shall be reviewed by the MTA M. In case of shortcomings the MTA M shall return it to the ASSR or COO for amendment or re-processing; thereafter the ASSR shall re-send the amended AR to the MTA M for review. The procedure shall be repeated until the MTA M approves the AR.</p> <p>The APC shall provide an e-mail information (cc ASSR, PEA ASSR – where PE analyses were assessed, COO, and APC M) on the results of AR review specifying whether the AR is subjected to reporting. In case the AR is subject to reporting, the MTA M shall prepare the reporting and shall send an e-mail also to CAU D who shall safeguard the hand-over of the reporting to the DIR (repeated requests for opinion shall be also sent by the MTA M to CAU D).</p> <p>Following approval by the MTA M, the COO shall send the AR to the APC M for review, cc ASSR (and PEA ASSR, if PE analyses were assessed).</p> <p>Following the approval of the AR by the MTA M, the ASSR shall complete the source materials which are to be filed in the dossier and shall inform the COO.</p>	<p>APC M MTA M COO ASSR</p>	<p>e-mail</p>

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	In case of shortcomings, the APC M shall return the approved AR to the COO for amendment or reprocessing, thereafter the COO shall again send the amended AR to the APC M for review. The procedure shall be repeated until the APC M issues his/her approval of the AR, always cc ASSR (PEA ASSR, if PE has been assessed), and MTA M.		
8. Control of the status of MedP marketing authorisation and parties to the procedure	<p>The COO shall instruct the ADM UNI to review the status of the marketing authorisation of the medicinal product and parties to the procedure at least one working day prior to the issue of the COMPL.</p> <p>The ADM UNI shall review the status of the MA code of the medicinal product under which the administrative procedure was initiated, a review of their parallel codes, verification of the holder in case of centrally authorised products, a review of the holders (or importers/domestic manufacturers/SThP submitters, where applicable) and of powers of attorney/authorisations.</p> <p>Where a shortcoming/non-compliance is identified, he/she shall contact the COO who shall safeguard the elimination of the shortcoming/non-compliance. Where incorrect data about the holder or their authorised representative are identified in SŘDLP, the ADM UNI shall contact a responsible employee of the DDA/DLLA department who shall ensure that the situation is remedied.</p>	COO ADM UNI	SŘDLP e-mail
9. Notification of completion of source material identification	The COO shall send the approved AR to the ADM UNI for verification of correctness of the specified parties to the procedure and parallel codes, cc ASSR, together with a reference to the location of the source materials which are to be included in the dossier, or with other evidence collected by SÚKL, and concurrently shall instruct the ADM UNI	COO ADM UNI APC M	F-CAU-003-05R SŘDLP SSL AA e-mail

Title: **Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes**

to file them in the dossier and to prepare the COMPL in SŘDLP.

By means of a resolution which forms part of Notifications within administrative procedures initiated prior to 30 November 2011, a 10-calendar day timeline for the provision of an opinion on source materials shall be established. Appeal from this resolution may be filed; in such a case, the procedure outlined under step 11 shall be also employed.

The ADM UNI shall file the source materials or other evidence, if applicable, in a document called "Evidence collected by SÚKL" in SSL AA and shall generate the COMPL in SŘDLP. He/she shall enter the AR into SŘDLP, selecting the "Assessment Report" option from the "Element Info" tab, and shall inform the COO about the entry of the source materials/evidence, the prepared AR for signature, and the COMPL for review. The final Word AR shall be saved by the ADM UNI in the relevant file of the administrative procedure on the shared disk.

The COO shall check the entry of all source materials and COMPL review. The COO shall sign any evidence that needs to be signed in the SSL AA and shall sign the AR in SŘDLP. The COMPL shall be handed over by the ADM UNI via SŘDLP for signature to the APC M, and following signature, the ADM UNI shall arrange for its publication on the Institute's Notice Board and, concurrently, shall conclude the documents with source materials/evidence and the AR (no later than on day 40/120 of the commencement of the procedure)

Stage: Once the document is generated in the SŘDLP and published on the Institute's Notice Board (COMPL), the stage will be automatically changed to "Send DEC", the web will show "COMPL".

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p><i>Specification of products: the COMPL shall not specify parallelly imported products or parallel codes.</i></p> <p><i>The AR shall mention the parallelly imported products and parallel codes in a commentary only.</i></p> <p><i>The ADM UNI in cooperation with the COO shall, concurrently, record all of the data in so called "Specific part of the subject matter" in SŘDLP.</i></p> <p><i>The COO shall safeguard the assignment of the SRS subject matter to the administrative procedure in SŘDLP.</i></p>		
10. Objections on AR	<p>Within the 10-day timeline of the date of delivery of the COMPL, the documents coming via SSL AA shall be forwarded via the ADM SEC to the position of the concerned COO, who shall be automatically alerted of the new document by e-mail.</p> <p>Following review, the COO shall file the document in the dossier and conclude it and shall forthwith inform the ASSR of the new document. Where the document has been delivered by a party directly to the e-mail address of the COO, ASSR or another employee, the COO shall be forthwith informed about this document and following control, the COO shall create a new external document in SSL AA and shall file it in the respective dossier and shall inform the ASSR by means of a copy. The procedure shall continue with step 12.</p>	COO ADM UNI ADM SECR	SSL AA e-mail
11. Monitoring of sent appeals	<p>Has an appeal from the resolution mentioned in the COMPL been delivered within 15 days of the delivery? If it has, step 18 shall continue. Appeal from the resolution shall have no suspensory effect.</p>	COO	SSL AA
12. Drafting of the decision	<p>Following the expiry of the timeline specified by the COMPL, or by Section 39g, paragraph 5 of the PHI Act, the COO shall draft the decision /the ASSR shall draft a new AR; depending on the type of delivered opinions, cooperation with the</p>	COO ASSR Employee of CBA/PEA ADM UNI	F-CAU-003-02R F-CAU-003-04R SŘDLP

Title: **Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes**

	<p>ASSR or a CBA and/or a PEA employee shall be carried out.</p> <p>Prior to the drafting of the decision the COO (or the ADM UNI, if invited to do so by the COO) shall check the status of the marketing authorisation and the validity of payment for all codes and, where applicable, the COO shall suspend the procedure, either completely or partially. Furthermore, parallel codes shall be checked.</p> <p>When drafting the decision, the SŘDLP application shall be used. The ADM UNI in cooperation with the COO shall, concurrently, update any data in so called Specific part of the subject matter in SŘDLP.</p> <p>It is expected that prior to the control of the final draft decision by the MTA M/APC M, the legal aspects of the draft will have been validated by the COO and the expert ones by the ASSR. In case of a new AR step 6 of the procedure shall follow. (No later than on day 60/150 of the commencement of the administrative procedure.) <i>Specification of products: within the scope of the decision, the parallel codes shall be mentioned both in the operative part of the decision and the rationale of the operative part for the "active" code. Parallely imported products shall be mentioned only in the rationale of the concerned operative part of the decision.</i></p>		e-mail
13. Review of the decision by the MTA M	<p>Following finalisation, the ASSR shall forward the proposed decision to the MTA M for review, cc ASSR. The e-mail shall include also a brief summary of the issues within the AR.</p> <p>In the e-mail through which the ASSR forwards the DEC to the MTA M for</p>	MTA M ASSR COO	e-mail

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p>review, the ASSR shall provide brief information on the concerned administrative procedure, pointing out whether the DEC is subjected to reporting to CAU D or the DIR. The criteria for DEC reporting and its further processing shall be the same as those governing the AR reporting as referred to under section 7 of this procedure.</p> <p>The review shall be performed and in case of shortcomings, the MTA M shall return the DEC to the ASSR and COO for amendment or re-processing, thereafter the ASSR shall send the amended DEC back to the MTA M for review. The procedure shall be repeated until the MTA M approves of the decision. The approval of the MTA M shall be sent to the COO as well as the ASSR (incl. PEA ASSR, if PE analyses were assessed). Following approval by the MTA M, the COO shall send the decision to the APC M for review, cc ASSR (incl. PEA ASSR, if PE analyses were assessed).</p> <p>In case the DEC is subject to reporting, the MTA M shall send an e-mail also to the CAU D, who shall safeguard the hand-over of the reporting to the DIR (repeated requests for opinion shall be also sent by the MTA M to the CAU D).</p>		
14. Review of the decision by the APC M	In case shortcomings are identified, the APC M shall return the approved draft to the COO and, if applicable, also to the ASSR for amendment or re-processing; thereafter the COO shall send the amendment back to the APC M for review. The procedure shall be repeated until the APC M approves of the decision, cc ASSR (incl. PEA ASSR, if PE analyses were assessed), and MTA M.	COO ASSR APC M	e-mail
15. Signature of the decision	After the APC M approves of the decision, he/she shall instruct the ADM UNI to check the parties, status of marketing authorisation of the medicinal	APC M COO ADM UNI	SSL AA SŘDLP e-mail

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p>products, incl. parallel codes, at least one day prior to the issue of the decision. The ADM UNI shall check the holders and powers of attorney as per step 8 of the procedure. Following the check of the powers of attorney/authorisations regarding the products subjected to the administrative procedure, he/she shall enter these powers of attorney/authorisations in the dossier and via SŘDLP shall enter them in the dossier and forward for signature by the APC M; following the signature, the ADM UNI shall arrange for publication on the Institute's Notice Board.</p> <p>The e-mail shall be sent cc COO and ASSR.</p> <p><i>Specification of products: within the scope of the decision, the parallel codes shall be mentioned in the operative part of the decision for the "active" code. Parallely imported products shall be mentioned only in the rationale of the concerned operative part of the decision.</i></p>		
16. Publication of decision	<p>The ADM UNI shall publish the decision on the Institute's Notice Board (no later than on day 75/165 of the commencement of the administrative procedure) via SSL AA. Following publication, he/she shall arrange for and check the change of stage in SŘDLP (possibly also on the following day). He/she shall save the Word version of the decision in the relevant file on the shared disk.</p> <p><i>Stage: Once the document is generated in SŘDLP and published on the Institute's Notice Board (Decision), the "Decision" option being selected in the "Element Info" tab, the stage will be automatically changed to "Awaiting EiF"; the website will display "DEC" (decision).</i></p>	ADM UNI	SSL AA SŘDLP
17. Reporting to SCAU/SCUP	<p>Once the decision is published, the dossier shall stay at the COO position. Concurrently with the publication of the</p>	COO ADM DTB	SSL AA SŘDLP e-mail

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p>decision, the COO shall send a CT containing also all of the parallel codes and parallelly imported medicinal products for SCAU/SCUP together with the Word-format decision or with information that the decision has been generated in SŘDLP and the date as of which the decision becomes final/is provisionally enforceable, to the ADM DTB.</p> <p>The procedure outlined in SP-CAU-023 shall apply to the entry of data (implied by the decision) into SCAU/SCUP.</p> <p><u>Timeline:</u> as required by the ADM DTB, no later than within the 15th day of the month preceding the issuance of the SCAU.</p>		SP-CAU-023
18. Delivery of appeal	<p>Delivered appeals shall be forwarded from the Institute's mail-room to the APC S; the ADM SECR shall inform the COO (or appointed COO for MTA dossiers; the MTA dossier shall be transferred to the APC) who shall assess them and arrange for their inclusion in the dossier. Thereafter, procedure outlined in SP-CAU-030 shall follow. In case no appeal has been delivered, step 19 of the procedure shall follow.</p> <p>In case the MoH, on the basis of an appeal, decides to revoke the decision and to return the matter for new processing, following the return of the dossier the COO shall draft a resolution stipulating the timeline after the return from the MoH in the duration of 10 days of the date of delivery for providing an opinion and thereafter the relevant step of the procedure shall follow (3.2.).</p>	COO APC S ADM SECR	SSL AA SP-CAU-030 F-CAU-003-21R
19. EiF indication	<p>The COO shall monitor the timelines for the entry into force of the decision, shall inform the ASSR, and, concurrently, shall hand the dossier over to CAU S. The ADM DTB shall indicate the EiF date in the decision as instructed by the COO (section 17 of this procedure refers),</p>	COO ADM DTB	SŘDLP SSL AA e-mail SP-CAU-030 SP-CAU-023

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p>shall electronically sign it, and enter in into the dossier in SSL AA via the SŘDLP application. .</p> <p><i>The stage will change to "DEC – Eif" (decision – entry into force) and this information shall also appear on the website. Furthermore, where a ruling on the substance is concerned, in respect of which at least the usual therapeutic daily dose basic reimbursement section has come into force, the ADM DTB shall indicate in the content in "Element Info" that a "final decision" is concerned. A document labelled in this manner shall be sent to DSD via AA to the website together with the information on the date of the Eif, which shall be completed by the ADM DTB in SŘDLP – in case of a partial Eif the information shall be indicated in the subjects only, in case of a complete decision Eif the current status shall always be changed in the subjects from pending to removed after entry into force, or in the Element Info in the option "Basic Data" on the AP.</i></p>		
20. Transfer and archival of the dossier	The ADM DTB shall transfer the dossier to the CAU archive position, and shall alert the COO, ASSR, and ADM SECR of the indication of the clause and of stage settings in SŘDLP.	ADM DTB COO	SSL AA
21. Filing the dossier in the Reference Registry	The ADM SECR shall file the dossier in the CAU Reference Registry and shall indicate its location.	ADM SECR	Reference Registry

STATE INSTITUTE FOR DRUG CONTROL	SP-CAU-003 - W	Version: 11 / Effective date: 05.11.2018 page 17 of 27
Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes		

ALTERNATIVE B (STP)

Activity	Specification	Performed by	Document/ SŘDLP	Aid/
1. File take-over	The STP S shall electronically take over the dossier from VAS via the SŘDLP and SSL AA applications following the application completeness check. The dossier shall be handed over from VAS to the STP S also with unsupported payment of the administrative fee (to be tracked and safeguarded by the ADM VAL)	ADM VAL STP S VAS	SŘDLP SSL AA	
2. STP ASSR appointment	The STP S shall hand over the information about the dossier to the STP M, who shall appoint the STP ASSR. The STP S shall forward the dossier to the appointed STP ASSR.	STP S STP M	e-mail SSLP AA SŘDLP	
3.1. Data check	The STP ASSR shall assess the provided dossier to check whether it contains the necessary data. (This step runs concurrently with step 3.2.) If the necessary data are available, step 4 of the procedure shall follow. If any of the particulars are not available, step 3.1.1. of the procedure shall follow.	STP ASSR		
3.1.1. Invitation for amendment (in case the STP ASSR identifies a shortcoming)	Depending on the nature of the matter, the STP ASSR shall draft an invitation for elimination of shortcomings of the application or an invitation for amendment, and shall hand it over for review and signature to the STP M. The invitation shall be published on the Institute's Notice Board. Where an invitation for the elimination of shortcomings of an application is being sent, the administrative procedure shall be suspended by resolution. Once the amending information is delivered, step 3.1.2. of the procedure shall follow. This invitation does not rule out an invitation in the validation stage.	STP ASSR STP M	F-CAU-003-06R SŘDLP SSL AA	
3.1.2. Receipt and assessment of the amendment	The STP ASSR shall assess the provided amending documentation. If the amendment contains the necessary data	STP ASSR ADM UNI STP M	F-CAU-003-22R	

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p>and the administrative procedure has been suspended, the STP ASSR in cooperation with the ADM UNI shall draft a notice on resumed administrative procedure and shall hand it over to the STP M for signature. The ADM UNI shall enter the signed document into the dossier and shall publish it on the Institute's Notice Board.</p> <p>If the amendment does not contain the necessary data, the STP ASSR may draft another invitation for amendment within a timeline which shall be published thereby on the Institute's Notice Board (as per step 3.1.1. of the procedure), or, in case the shortcomings have not been eliminated from the application, the STP ASSR shall issue a resolution terminating the administrative procedure and the ADM UNI shall publish this fact on the Institute's Notice Board.</p>		<p>SŘDLP SSL AA</p> <p>F-CAU-003-18R</p>
<p>3.2. Search for price references, calculation of the maximum price and amount of reimbursement</p>	<p>Upon being informed that a file has been allocated thereto, the STP ASSR shall file a request with the CBA department for the search of price references for the administrative procedure.</p> <p>In case of an ACR procedure, where the conditions for the determination of a fixed reimbursement as referred to by Section 39c, paragraphs 7 and 8 of the PHI Act have been met, the request for the search of price references for the determination of the reimbursement shall not be made.</p> <p>The search shall be completed within 21 days of the commencement of the administrative procedure.</p> <p>An appointed CBA employee shall hand over the form with retrieved external price references to the STP ASSR via the SŘDLP application and shall inform him/her about the entry of these source materials by e-mail.</p>	<p>STP ASSR CBA employee</p>	<p>SP-CAU-001N SP-CAU-002N SP-CAU-010</p> <p>F-CAU-001-04 F-CAU-001-04N F-CAU-002-01N F-CAU-002-14N</p> <p>e-mail SŘDLP</p>

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	The STP ASSR may check the source materials from CBA and subsequently shall enter the retrieved price references to the dossier and shall sign them.		
4. Receipt of motions from parties to the procedure	<p>As of the date of the commencement of the administrative procedure (date of application submission = day 0) the receipt of motions from parties to the procedure shall run on a continuous basis. Documents coming through the SSL AA shall be handed over from the mail-room to the S STP and thereafter distributed herefrom to the position of the concerned STP ASSR. The STP ASSR, having reviewed the document, shall enter it in the dossier and with a view to the nature of the provided evidence or proposal shall act as necessary. With a view to the nature of the motions from parties to the procedure, the STP ASSR may request opinions from the CBA, APC or MTA.</p> <p>In case the document has been delivered by a party to the procedure directly to the e-mail address of the STP ASSR, STP M, or another employee, the STP ASSR shall be forthwith informed of such document and he/she shall request the ADM UNI to create a new external document in the SSL AA and to enter it in the respective dossier.</p> <p>If the content of the documents is labelled as a business secret, the STP ASSR shall ask the APC for assessment and, prior to the conclusion of the document, the ADM UNI to arrange for this information to be hidden.</p> <p>Where the proposals are incomplete, the STP ASSR shall draft an invitation for cooperation which shall be sent thereby to the STP M for review and signature; the</p>	A mail-room employee ADM UNI STP S STP ASSR COO STP M	SSL AA SŘDLP e-mail
			F-CAU-003-08R

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p>STP M shall arrange for its publication following signature.</p> <p>A request for an opinion by a professional society shall be processed by the STP ASSR, sent via e-mail to the STP M (cc STP ASSR and MTA M), and entered in the dossier by the ADM UNI once instructed by the STP ASSR. The STP ASSR shall be forthwith advised of the delivered opinions from professional societies and shall ask the ADM UNI to create a new external document in SSL AA and to file it in the respective dossier.</p>		
5. Determination of maximum price/basic reimbursement/reimbursement per package	<p>A CBA employee appointed to draft the MP/ACR determination shall draft a protocol on the MP/ACR determination in compliance with effective methodologies.</p> <p>The CBA employee shall hand over the aforementioned protocol on the MP/ACR determination together with any source materials for the MP/ACR determination to the STP ASSR via the SŘDLP application and shall inform him/her about the entry of those source materials by e-mail.</p> <p>In case of an ACR procedure, where the conditions for the determination of a fixed reimbursement referred to under the provision of Section 39c, paragraph 7 and 8 of the PHI Act have been met, the STP ASSR shall draft a protocol on ACR determination within the scope of the AR.</p>	CBA employee STP ASSR	Relevant forms of the F-CAU-001N and F-CAU-002N series SŘDLP e-mail
6. Assessment report drafting	<p>Once the timeline for the provision of evidence and submission of motions expires, the STP ASSR shall draft the AR, where the proposals and evidence provided by parties and, if applicable, by professional societies, are addressed by type and, if necessary, shall request cooperation from the CBA, APC or MTA department. He/she shall enter the determined MP/ACR in the AR.</p>	STP ASSR	F-CAU-003-04R SŘDLP e-mail

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p>The AR shall be forwarded to the STP M for review no later than on day 20/40 of the commencement of the procedure.</p> <p>Where a maximum price determination procedure is concerned and no motions referred to under the provision of Section 39g, paragraph 5 of the PHI Act have been filed, the protocol on MP determination shall serve as the AR.</p> <p>In the email sent by the STP ASSR to hand over the AR to the STP M for review, the STP ASSR shall inform whether the AR is subjected to reporting to CAU D or the DIR. If it is, the STP ASSR shall include a brief summary of the issues of the respective procedure in the e-mail message.</p>		
7. AR review by STP M	<p>The STP M shall review the AR. In case shortcomings are identified, the STP M shall return it to the STP ASSR for amendment or re-processing; thereafter, the STP ASSR shall re-send the amended AR to the STP M for review. The procedure shall be repeated until the STP M approves of the AR.</p> <p>In case the AR is subject to reporting, the STP M shall send an e-mail to the CAU D who shall safeguard the hand-over of the reporting to the DIR (repeated requests for opinion shall be also sent by the STP M to the CAU D).</p>	STP ASSR STP M	e-mail
8. Control of the status of MedP marketing authorisation and parties to the procedure	<p>The STP ASSR shall instruct the ADM UNI to review the status of the marketing authorisation of the medicinal product and parties to the procedure at least one day prior to the issue of the COMPL.</p> <p>The ADM UNI shall review the status of the MA codes of the medicinal products under which the administrative procedure was initiated, a review of their parallel codes, verification of the holder in case of centrally authorised products, a review of the holders (or importers/domestic manufacturers/SThP</p>	ADM UNI STP ASSR	SŘDLP e-mail

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p>submitters, where applicable) and of powers of attorney/authorisations. Where a shortcoming/non-compliance is identified, he/she shall contact the STP ASSR, who shall safeguard the elimination of the shortcoming/non-compliance. Where incorrect data about the holder or their authorised representative are identified in SŘDLP, the ADM UNI shall contact a responsible employee of the DDA/DLLA department who shall ensure that the situation is remedied.</p>		
9. Entry of evidence and assessment report in the dossier	<p>The STP ASSR shall enter the evidence collected by SÚKL into the document called "Evidence collected by SÚKL" in SSL AA.</p> <p>The STP ASSR shall file the AR in SŘDLP, selecting the "Assessment Report" option from the "Element Info" tab (no later than by day 40/120 of the commencement of the administrative procedure). Concurrently, he/she shall send an instruction to the ADM UNI to prepare the COMPL.</p>	STP ASSR ADM UNI	SSL AA SŘDLP
10. Notification of completion of source material identification	<p>In the SŘDLP application, the ADM UNI shall complete the COMPL form. The timeline for the provision of opinions on the source materials shall be 10 days of the delivery. The COMPL shall be handed over by the ADM UNI following STP ASSR review via SŘDLP for signature to the STP M and following signature, the ADM UNI shall arrange for its publication on the Institute's Notice Board, and, concurrently, shall conclude the documents with source materials/evidence and the AR.</p> <p>(No later than on day 40/120 of the commencement of the procedure.)</p> <p><i>Stage: Once the document is generated in the SŘDLP and published on the Institute's Notice Board (COMPL), the stage will be</i></p>	ADM UNI STP ASSR STP M	F-CAU-003-05R SŘDLP

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p><i>automatically changed to "Send DEC", the web will show "COMPL".</i></p> <p><i>Specification of products: the COMPL shall not specify parallelly imported products or parallel codes.</i></p> <p><i>The AR shall mention the parallelly imported products and parallel codes in a commentary only.</i></p> <p><i>The ADM UNI in cooperation with the STP ASSR shall, concurrently, record all of the data in so called "Specific part of the subject matter" in SŘDLP.</i></p> <p><i>The STP ASSR shall safeguard the assignment of the SRS subject matter to the administrative procedure in SŘDLP.</i></p>		
11. Objections on AR and their assessment	<p>Within the 10-day timeline of the date of delivery of the COMPL, the documents coming via SSL AA shall be forwarded from the mail-room to the STP S and therefrom distributed directly to the position of the concerned STP ASSR (step 4 refers).</p> <p>Where the document has been delivered by a party directly to the e-mail address of the STP ASSR or another employee, the STP ASSR shall be forthwith informed about this document and following control, he/she shall ask the ADM UNI to create a new external document in SSL AA and to file it in the respective dossier.</p> <p>Depending on the type of delivered opinions, the STP ASSR shall cooperate with the CBA, APC or MTA. Where new facts arise on the basis of which the procedure will change, step 6 shall follow. Otherwise step 12 shall follow.</p>	STP ASSR Employee of CBA, APC, MTA	SSL AA
12. Drafting of the decision	<p>Following the expiry of the timeline specified by the COMPL, the STP ASSR shall draft the decision. After finalisation, he/she shall forward it via e-mail to STP M for review.</p> <p>(No later than on day 60/150 of the commencement of the administrative procedure.)</p>	STP ASSR ADM UNI	F-CAU-003-02R F-CAU-003-03R

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

Filing of information about the method of MP/ACR determination	<p>When drafting the decision, the SŘDLP application shall be used. The ADM UNI in cooperation with the STP ASSR shall, concurrently, update any data in so called Specific part of the subject matter.</p> <p><i>Specification of products: within the scope of the decision, the parallel codes shall be mentioned both in the operative part of the decision and the rationale of the operative part for the "active" code. Parallely imported products shall be mentioned only in the rationale of the concerned operative part.</i></p>		SŘDLP e-mail
13. Review and signature of the decision	<p>The STP M shall review the decision, approve it or return it to the STP ASSR for re-processing.</p> <p>In case the DEC is subject to reporting to the CAU D or the DIR, the STP M shall send an e-mail also to the CAU D who shall safeguard the hand-over of the reporting to the DIR (repeated requests for opinion shall be also sent by the STP M to the CAU D).</p> <p>The STP ASSR shall instruct the ADM UNI to check the parties and products at least one day prior to the issue of the decision. The ADM UNI shall check the status of product SÚKL marketing authorisation codes, their parallel codes, holders and powers of attorney (see step 8).</p> <p>The STP M shall hand over the approved decision to the ADM UNI for filing in SŘDLP and for signature by STP M; following signature, the ADM UNI shall arrange for its entry in the dossier and publication on the Notice Board.</p>	STP ASSR STP M ADM UNI	e-mail SŘDLP SSL AA
14. Publication of decision	The ADM UNI shall publish the decision on the Institute's Notice Board (no later than on day 75/165 of the commencement of the administrative procedure) via SSL AA. Following publication, he/she shall arrange for and	ADM UNI	SŘDLP SSL AA

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	<p>check the change of stage in SŘDLP (possibly also on the following day). He/she shall save the Word version of the decision in the relevant file on the shared disk.</p> <p><i>Stage: Once the document is generated in SŘDLP and published on the Institute's Notice Board (Decision), the "Decision" option being selected from the "Element Info" tab, the stage will be automatically changed to "Awaiting EiF"; the website will display "DEC".</i></p>		
15. Reporting to SCAU/SCUP/SCAU_BEZ_UHRAD	<p>The STP ASSR shall forward the information about the decision to the ADM DTB, who shall process the information (enter the data into the information system) for the purposes of SCAU/SCUP generation.</p> <p>The entry of the data (arising from the decision) into SCAU/SCUP shall follow the procedure outlined in SP-CAU-023.</p> <p>The information on the decision regarding a product included in the SCAU_BEZ_UHRAD (no reimbursement list) shall be reported to the ADM DTB .</p> <p><u>Timeline:</u> as required by the ADM DTB, no later than within the 15th day of the month preceding the issuance of the List.</p>	STP ASSR ADM DTB	e-mail SP-CAU-023
16. Dossier hand-over to CAU S node in SSL AA	<p>Following the publication of the decision, the ADM UNI shall hand over the dossier to the CAU S position via SSL AA.</p>	ADM UNI CAU S	SSL AA
17. Delivery of appeal	<p>Delivered appeals shall be forwarded from the Institute's mail-room to the APC S; the ADM SECR shall inform the APC M, who shall appoint an authorised COO, who shall process the appeal. The authorised COO shall inform the STP ASSR on the delivery of the appeal.</p> <p>Thereafter, procedure outlined in SP-CAU-030 shall follow. In case no appeal has been delivered, step 18 of the procedure shall follow.</p> <p>In case the MoH, on the basis of an appeal, decides to revoke the decision</p>	ADM SECR COO APC M	SSL AA SP-CAU-030

Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes

	and to return the matter for new processing, following the return of the dossier the STP ASSR shall draft a resolution stipulating the timeline after the return from the MoH in the duration of 10 days of the date of delivery for providing an opinion and thereafter the relevant step of the procedure shall follow (3.2.).		F-CAU-003-21R
18. EiF indication	<p>After the expiry of the timeline for appeals or upon waiver of the right to file appeal by all parties to the procedure, the STP ASSR shall instruct the ADM DTB to indicate the EiF in the decision (shall attach the Word-format of the decision to the e-mail or provide the information that the decision has been generated in SŘDLP together with the information on the decision EiF). The ADM DTB shall indicate the EiF date in the decision, shall electronically sign it and enter in into the dossier in SSL AA.</p> <p><i>The stage will change to "DEC – EiF" and this information shall also appear on the website. Furthermore, where a ruling on the substance is concerned, after the entire decision becomes final, the ADM DTB shall indicate in the content in "Element Info" that a "final decision" is concerned. A document labelled in this manner shall be sent to DSD via AA to the website together with the information on the date of the EiF, which shall be completed by the ADM DTB in SŘDLP – in case of a partial EiF the information shall be indicated in the subjects only, in case of a complete decision EiF the current status shall always be changed in the subjects from pending to removed after entry into force, or in the Element Info in the option "basic data" on the AP.</i></p>	STP ASSR ADM DTB	e-mail SSL AA
19. Transfer and archival of the dossier	The ADM DTB shall transfer the dossier to the CAU archive position, and shall alert the STP ASSR and ADM SECR on the indication of the clause.	ADM DTB	SSL AA

STATE INSTITUTE FOR DRUG CONTROL	SP-CAU-003 - W	Version: 11 / Effective date: 05.11.2018 page 27 of 27
Title: Procedure for processing of an application for the determination/change of the maximum price and/or the amount and terms of reimbursement of a medicinal product / food for special medical purposes		

20. Filing the dossier in the Reference Registry	The ADM SECR shall file the dossier in the CAU Reference registry and shall indicate its location.	ADM SECR	Reference Registry
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Specifics of the procedure where applications of the determination of the amount and conditions of reimbursement for highly innovative medicinal products are concerned

The liabilities referred to under Section 39d, paragraph 3 of the PHI Act shall not be considered particulars of the application, and in case they fail to be delivered, a negative assessment report shall be subsequently issued.

In the determination of reimbursement, the Methodology for the determination of basic reimbursement specifically for highly innovative medicinal products shall be followed, if this procedure is outlined by the methodology; the reimbursement shall be always determined as *de novo* for 24 or 12 months, as per the provision of Section 39d, paragraph 2 of the PHI Act.

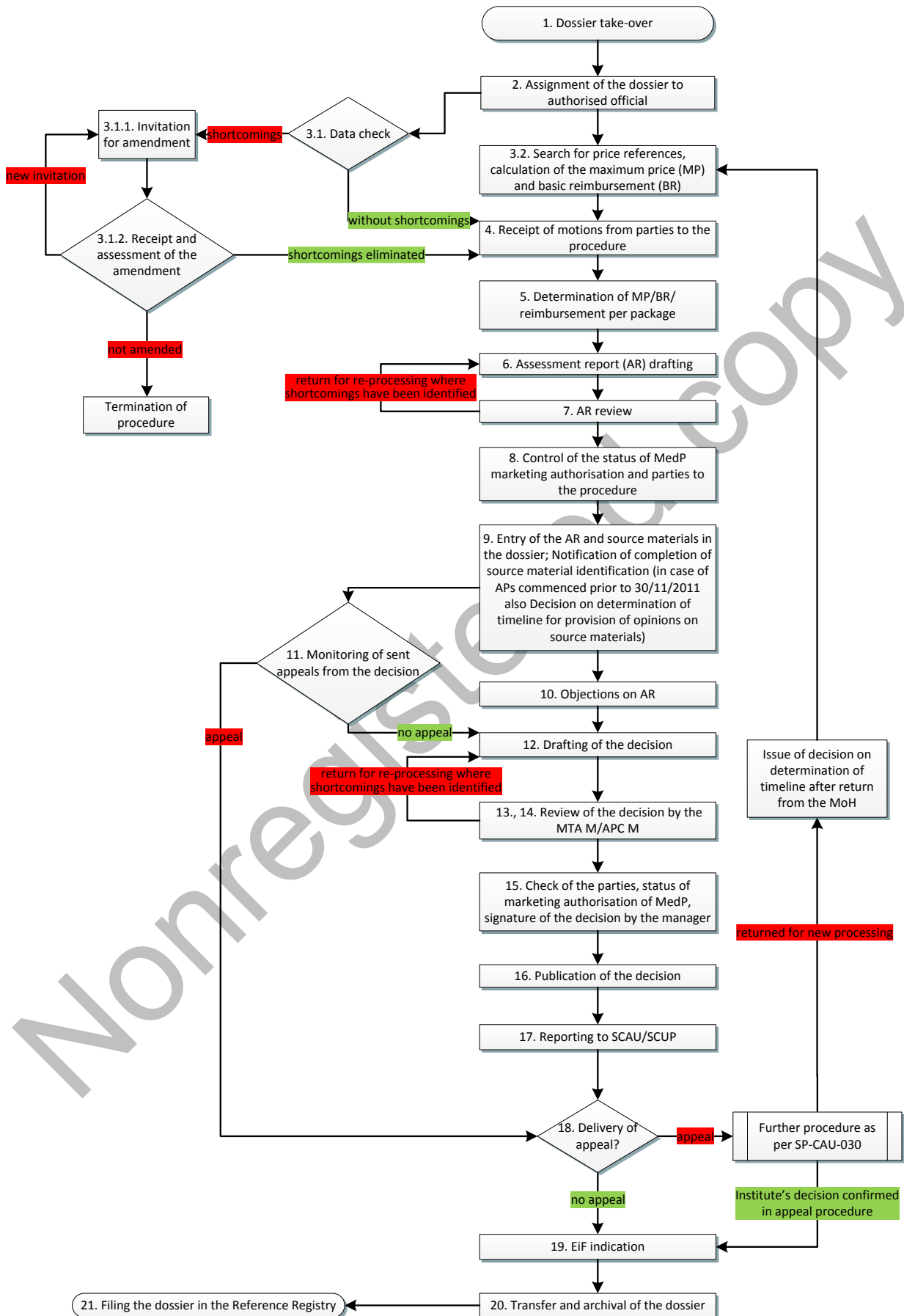
7. ANNEXES

Annex 1: Process map for the handling of applications for maximum price determination/change and/or the amount and conditions of reimbursement of a medicinal product for the APC department

Annex 2: Process map for the handling of applications for maximum price determination/change and/or the amount and conditions of reimbursement of a medicinal product for the STP department

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Process map for the handling of applications for maximum price determination/change and/or the amount and conditions of reimbursement of a medicinal product for the APC department



Process map for the handling of applications for maximum price determination/change and/or the amount and conditions of reimbursement of a medicinal product for the STP department

