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

DAT – Data Support Department

PEA – Pharmaco-Economic Analysis team

ASSR – assessor (expert employee of MTA) – a person responsible for expert and content correctness

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 which contains data for SCAU

COO – administrative procedure coordinator (a APC employee) – a person responsible for process 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

PS – professional society

DSD – Documentary Service Department

FSMP – food for special medical purposes

DLLA – Department of Legal and Legislative Activities

DEC - decision

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 dcumentary service AthenA
AP – administrative procedure
SŘDLP – an application for the conduct of administrative procedures
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 doesn´t contain references to internal regulations and 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
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).

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 (within 48 hrs). The dossier shall be handed over from VAS to the APC S also with unsupported payment of the administrative fee (to be tracked and safeguarded by the ADM VAL).	APC S VAS ADM VAL	SŘDLP SSL AA
2. ASSR and COO appointment	The ADM SECR shall hand over the information about the dossier to the MTA M and APC M, who shall appoint the ASSR and COO (both informed). The ADM SECR shall forward the dossier to the appointed COO.	ADM SECR MTA M APC M	SŘDLP SSL AA e-mail
3.1. Data check	The COO shall assess the provided	COO	

	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.		
3.1.1. Invitation for amendment	Depending on the nature of the matter, the COO shall draft an invitation for amendment (an expert rationale, where applicable, shall be drafted by the ASSR and checked by the MTA M), and 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 decision. Once the amending information is delivered, step 3.1.2. of the procedure shall follow.	COO (ASSR-MTA M) APC M	F-CAU-003-20 F-CAU-003-21 F-CAU-003-32 F-CAU-003-33 F-CAU-003-37 F-CAU-003-38 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 the ADM UNI shall draft a notice on resumed administrative procedure and shall hand it over to the APC M for signature. The ADM UNI shall enter the signed document into the dossier and shall publish it on the Institute´s notice board. 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	COO ASSR ADM UNI APC M	F-CAU-003-03 F-CAU-003-22 F-CAU-003-34 F-CAU-003-39 SŘDLP SSL AA F-CAU-003-14

	eliminated from the application, the COO shall issue a decision terminating the administrative procedure and shall publish this fact on the Institute´s Notice Board.		
3.2. Search for price references, calculation of the maximum price and amount of reimbursement	Upon being informed that a file has been allocated thereto, 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 (external price reference, MP), cc COO. 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. The search shall be completed within 21 days of the commencement of the administrative procedure. 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 him/her 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.	ASSR CBA employee COO	SP-CAU-001 SP-CAU-002 SP-CAU-010 SP-CAU-020 F-CAU-001-04 F-CAU-001-04N F-CAU-002-01N F-CAU-002-14N e-mail SŘDLP
4. Receipt of motions from parties to the procedure	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.	A mail-room employee ADM SECR APC S ADM UNI COO ASSR MTA M APC M	SSL AA SŘDLP e-mail

	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 request the ADM UNI to create a new external document in the SSL AA and to enter it in the respective file, and shall inform the ASSR by means of a copy. If the content of the documents 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. 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. A request for an expert opinion by a professional society shall be signed and sent by the MTA M, cc ASSR and COO. The professional society shall send its opinion to the MTA M, assessor and coordinator, the COO shall enter it in the dossier.		F-CAU-003-25/N
5. Determination of maximum price/basic reimbursement/rei	A CBA employee appointed to draft the MP/ACR determination, shall draft a protocol on the MP/ACR determination in compliance with effective	CBA employee	Relevant forms of the F-CAU-001 and F-CAU-002 series

mbursement per package	methodologies. 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.		SŘDLP e-mail
6. Assessment report drafting	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 and, if necessary, shall request cooperation from the CBA and/or PEA departments. They shall enter the determined MP/ACR in the AR. The ASSR shall forward the completed AR by e-mail to the MTA M for review.	ASSR COO MTA M	F-CAU-003-04/N e-mail
7. AR review	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, and sends it to the APC M, cc ASSR and COO. Following the AR approval, the ASSR shall complete the source materials which are to be filed in the dossier and shall inform the COO. 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 MTA M COO ASSR	e-mail

	APC M issues his/her approval of the AR.		
8. Control of the status of MedP marketing authorisation and parties to the procedure	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 END. 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. Where a shortcoming/non-compliance is identified, they 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 DAT/DLLA department who shall ensure that the situation is remedied.	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 to file them in the dossier and to prepare a notification of completion of source material identification in SŘDLP. By means of a decision 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	COO ADM UNI APC M	F-CAU-003-05 F-CAU-003-10N SŘDLP SSL AA e-mail

	on source materials shall be established. Appeal from this decision 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. The evidence which requires signature shall be signed by the COO in SSL AA. 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 and the prepared AR for signature. 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 shall sign the AR in SŘDLP. Following review, the Notification of completion of source material identification 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 (Notification of completion of source material identification), the stage will be automatically changed to "Send DEC", the web will show "END" (completed).* *Specification of products: the Notification of completion of source material identification shall not specify parallelly imported products or parallel codes.*		

	The AR shall mention the parallelly imported products and parallel codes in a commentary only. *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.* *The COO shall safeguard the assignment of the SRS subject matter to the administrative procedure in SŘDLP.*		
10. Objections on AR	Within the 10-day timeline of the date of delivery of the Notification of completion of source material identification, 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. 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 ask the ADM UNI to create a new external document in SSL AA and to file it in the respective dossier and shall inform the ASSR by means of a copy. The procedure shall continue with step 12.	COO ADM UNI ADM SECR	SSL AA e-mail
11. Monitoring of sent appeals	Has an appeal from the decision mentioned in the Notification of completion of source material identification been delivered within 15 days of the delivery? If it has, step 18 shall continue. Appeal from the decision shall have no suspensory effect.	COO	SSL AA
12. Drafting of the decision	Following the expiry of the timeline specified by the Notification of completion of source material identification, or by Section 39g, paragraph 5 of the PHI Act, the COO	COO ASSR Employee of CBA/PEA ADM UNI	F-CAU-003-06/N F-CAU-003-24 F-CAU-003-36/N F-CAU-003-41

	shall draft the decision /the ASSR shall draft a new AR; depending on the type of delivered opinions, cooperation with the ASSR or a CBA and/or PEA employee shall be carried out. 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. 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. 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). *Specification of products: within the scope of the decision, the parallel codes shall be mentioned both in the Decision and the rationale of the statement of the "active" code. Parallelly imported products shall be mentioned only in the rationale of the concerned statement.*		SŘDLP e-mail
13. Review of the decision by the MTA M	Following finalisation, the COO shall forward the draft decision to the MTA M for review, cc ASSR. The e-mail shall contain a brief summary of the issues within the AP. The review shall be completed and in	MTA M ASSR COO	e-mail

	case shortcomings are identified, the MTA M shall return the draft to the ASSR and COO for amendment or re-processing; thereafter the COO shall send the amendment back to MTA M for review. The procedure shall be repeated until the approval of the decision by the MTA M, whereupon the MTA M shall send the approved decision to the APC M, cc ASSR and COO.		
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.	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 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. The e-mail shall be sent cc COO ASSR. *Specification of products: within the scope of the decision, the parallel codes shall be mentioned in the statement of the "active" code. Parallelly imported products shall be mentioned only in the rationale of the concerned statement.*	APC M COO ADM UNI	SSL AA SŘDLP e-mail

16. 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 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. *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).*	ADM UNI	SSL AA SŘDLP
17. Reporting to SCAU/SCUP	Once the decision is published, the dossier shall stay at the COO position. Concurrently with the publication of the 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. The procedure outlined in SP-CAU-023 shall apply to the entry of data (implied by the decision) into SCAU/SCUP. Timeline: as required by the ADM DTB, no later than within the 15th day of the month preceding the issuance of the SCAU.	COO ADM DTB	SSL AA SŘDLP e-mail SP-CAU-023
18. Delivery of appeal	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	COO APC S ADM SECR	SSL AA SP-CAU-030

	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. 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 decision 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-003-50
19. EiF indication	The COO shall monitor the timelines for the entry into force of the decision and shall inform the ASSR. After the expiry of the timeline for appeals or upon waiver of the right to file appeal by all parties to the procedure, the COO 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 was 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. *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*	COO ADM DTB	SŘDLP SSL AA e-mail SP-CAU-030 SP-CAU-023

	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. Where a MTA dossier is concerned, the aforementioned activities shall be carried out by the ASSR rather than the COO.		
20. Transfer and archival of the dossier	The ADM DTB shall inform the COO who shall transfer the dossier to the CAU archive position, and shall alert the COO, ASSR a ADM SECR of the indication of the clause.	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

ALTERNATIVE B (STP)

Activity	Specification	Performed by	Document/ Aid/ SŘDLP
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 (within 48 hrs). 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 SRDLP
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	Depending on the nature of the matter, the STP ASSR shall draft an invitation for elimination of shortcomings 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 is being sent, the administrative procedure shall be suspended by decision. Once the amending information is delivered, step 3.1.2. of the procedure shall follow.	STP ASSR STP M	F-CAU-003-20 F-CAU-003-21 F-CAU-003-32 F-CAU-003-33 F-CAU-003-37 F-CAU-003-38 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 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 on the Institute´s Notice Board.	STP ASSR ADM UNI STP M	F-CAU-003-03 F-CAU-003-22 F-CAU-003-34 F-CAU-003-39 SŘDLP SSL AA

	If the amendment does not contain the necessary data, the STP 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 STP ASSR shall issue a decision terminating the administrative procedure and shall publish this fact on the Institute´s Notice Board.		F-CAU-003-14
3.2. Search for price references, calculation of the maximum price and amount of reimbursement	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. 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. The search shall be completed within 21 days of the commencement of the administrative procedure. An appointed CBA employee shall hand over the form with retrieved 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. 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.	STP ASSR CBA employee	SP-CAU-001 SP-CAU-002 SP-CAU-010 SP-CAU-020 F-CAU-001-04 F-CAU-001-04N F-CAU-002-01N F-CAU-002-14N e-mail SŘDLP
4. Receipt of motions from parties to the procedure	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 to the S STP via the ADM SECR and thereafter distributed to the position of the concerned STP ASSR. The STP ASSR, having reviewed the document, shall	A mail-room employee ADM SECR ADM UNI STP S STP ASSR COO STP M	SSL AA SŘDLP e-mail

	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. 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 file. If the content of the documents is labelled as a business secret, prior to the conclusion of the document the STP ASSR shall ask the ADM UNI to arrange for this information to be hidden. 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 STP M shall arrange for its publication following signature. A request for an opinion by a professional society shall be processed by the STP ASSR, and sent via e-mail by the STP M (cc STP ASSR and MTA M), 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.		F-CAU-003-25/N
5. Determination of maximum price/basic reimbursement/reimbursement per package	A CBA employee appointed to draft the MP/ACR determination shall draft a protocol on the MP/ACR determination in compliance with effective methodologies. 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	CBA employee STP ASSR	Relevant forms of the F-CAU-001 and F-CAU-002 series SŘDLP e-mail

	him/her about the entry of those source materials by e-mail. 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 AR.		
6. Assessment report drafting	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 and, if necessary, shall request cooperation from the CBA, APC or MTA department. He/she shall enter the determined MP/ACR in the AR. The AR shall be forwarded to the STP M for review no later than on day 20/40 of the commencement of the procedure. 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.	STP ASSR	F-CAU-003-04/N SŘDLP e-mail
7. AR review by STP M	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.	STP ASSR STP M	e-mail
8. Control of the status of MedP marketing authorisation and parties to the procedure	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 END (completion). 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 submitters, where applicable) and of powers of attorney/authorisations.	ADM UNI STP ASSR	SŘDLP e-mail

	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 is identified in SŘDLP, the ADM UNI shall contact a responsible employee of the DAT/DLLA department who shall ensure that the situation is remedied.		
9. Entry of evidence and assessment report in the dossier	The STP ASSR shall enter the evidence collected by SÚKL into the document called "Evidence collected by SÚKL" in SSL AA. 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 notification of completion of identification of source materials for the decision.	STP ASSR ADM UNI	SSL AA SŘDLP
10. Notification of completion of source material identification	In the SŘDLP application, the ADM UNI shall complete the Notification of completion of identification of source materials for decision form. The timeline for the provision of opinions on the source materials shall be 10 days of the delivery. The Notification of completion of source material identification shall be handed over by the ADM UNI following 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 (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 (Notification of completion of source material identification), the stage will be automatically changed to "Send DEC", the web will show "END" (completed).* *Specification of products: the Notification of completion of source material*	ADM UNI STP ASSR STP M	F-CAU-003-05 F-CAU-003-10N SŘDLP

	identification shall not specify parallelly imported products or parallel codes. *The AR shall mention the parallelly imported products and parallel codes in a commentary only.* *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".* *The STP ASSR shall safeguard the assignment of the SRS subject matter to the administrative procedure in SŘDLP.*		
11. Objections on AR and their assessment	Within the 10-day timeline of the date of delivery of the Notification of completion of source material identification, the documents coming via SSL AA shall be forwarded via the ADM SEC to the STP S and therefrom distributed directly to the position of the concerned STP ASSR (step 4 refers). 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, shall ask the ADM UNI to create a new external document in SSL AA and to file it in the respective dossier. Depending on the type of delivered opinions, he/she 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.	STP ASSR ADM SECR Employee of CBA, APC, MTA	SSL AA
12. Drafting of the decision Filing of information about the method of MP/ACR determination	Following the expiry of the timeline specified by the Notification of completion of source material identification the STP ASSR shall draft the decision. After finalisation, he/she shall forward it via e-mail to STP M for review. (No later than on day 60/150 of the commencement of the administrative procedure). 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.	STP ASSR ADM UNI	F-CAU-003-06/N F-CAU-003-24 F-CAU-003-36/N F-CAU-003-41 SŘDLP e-mail

	Specification of products: within the scope of the decision, the parallel codes shall be mentioned both in the Decision and the rationale of the statement of the "active" code. Parallelly imported products shall be mentioned only in the rationale of the concerned statement.		
13. Review and signature of the decision	The STP M shall review the decision, approve it or return it to the STP ASSR for re-processing. 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). 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.	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 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. *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".*	ADM UNI	SŘDLP SSL AA
15. Reporting to SCAU/SCUP/SCAU_BEZ_UHRAD	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. The entry of the data (arising from the decision) into SCAU/SCUP shall follow the procedure outlined in SP-CAU-023. The information on the decision	STP ASSR ADM DTB DAT employee	e-mail SP-CAU-023

	regarding a product included in the SCAU_BEZ_UHRAD (no reimbursement list) shall be reported to a DAT employee. Timeline: as required by the ADM DTB, no later than within the 15th day of the month preceding the issuance of the SCAU list.		
16. Dossier hand-over to CAU S node in SSL AA	Following the publication of the decision, the ADM UNI shall hand over the dossier to the CAU S position via SSL AA.	ADM UNI CAU S	SSL AA
17. Delivery of appeal	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. Thereafter, procedure outlined in SP-CAU-030 shall follow. In case no appeal has been delivered, step 18 of the procedure shall follow. 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 STP ASSR shall draft a decision 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.).	ADM SECR COO APC M	SSL AA SP-CAU-030 F-CAU-003-50
18. EiF indication	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. *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*	STP ASSR ADM DTB	e-mail SSL AA

	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 remove after entry into force, or in the Element Info in the option "basic data" on the AP.		
19. Transfer and archival of the dossier	Following the entry of the decision with an identified EiF, the DTB employee shall forward the dossier to the CAU archive. The ADM DTB shall transfer the dossier to the CAU archive position, and shall alert the ASSR and ADM SECR on the indication of the clause.	ADM DTB	SSL AA
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

Specifics of the procedure where applications of the determination of the amount and conditions of reimbursement for highly innovative medicinal products are concerned

The particulars of the application shall constitute of the liabilities referred to under the provision of Section 39d, paragraph 3 of the PHI Act.

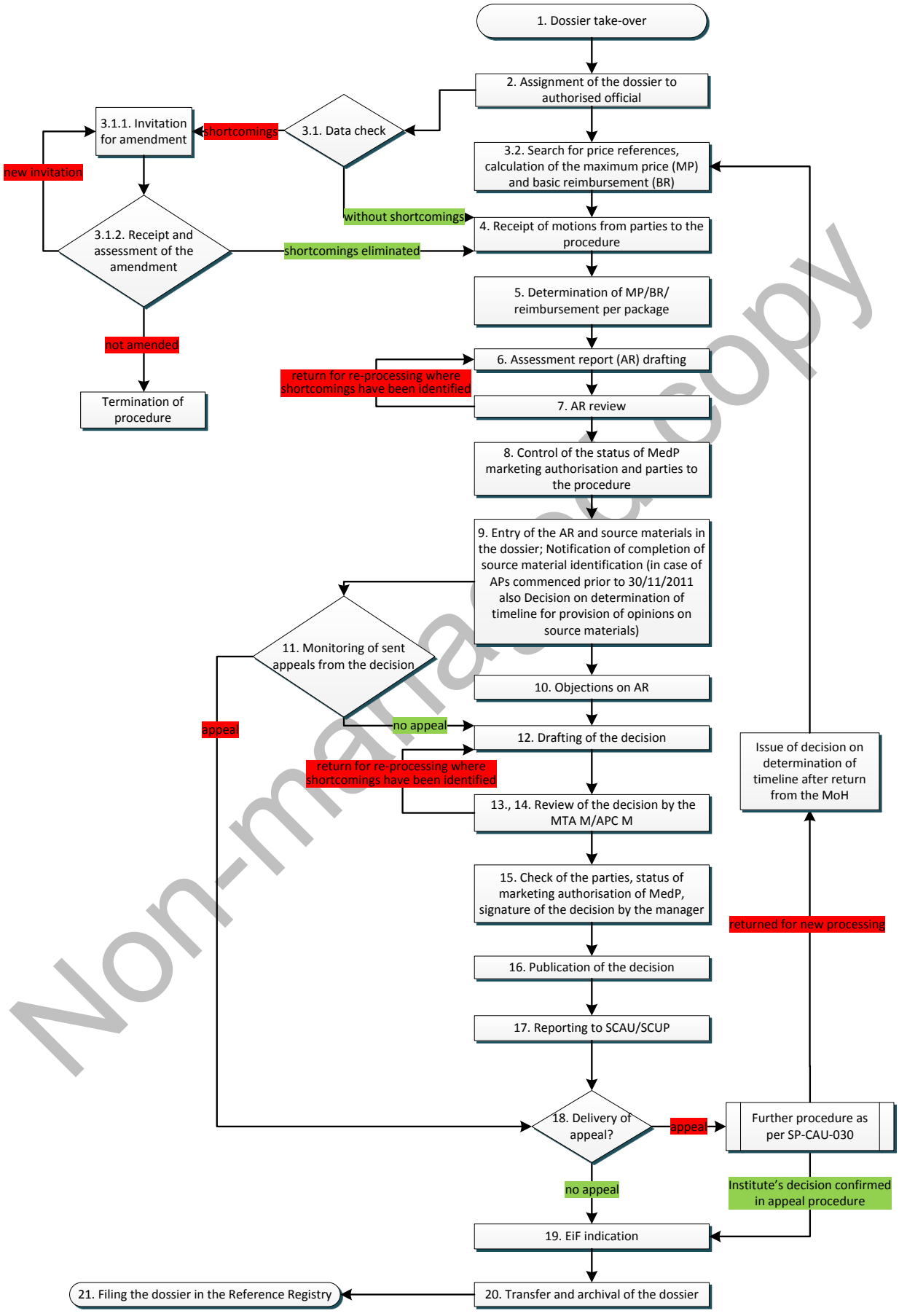
In the determination of reimbursement, the Methodology for the determination of basic reimbursement specifically for highly innovative medicinal products shall be followed, if this procedure is outlined by the methodology; the reimbursement shall be always determined as *de novo* for 24 or 12 months,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

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