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

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## 1. OBJECTIVE

Establish the procedure for determination/change of the maximum ex-factory price and the amount and terms of reimbursement of medicinal products/foods for special medical purposes.

## 2. USERS

The procedure is binding on the employees of the Price and Payment Regulation Section.

## 3. DEFINITION OF TERMS AND ABBREVIATIONS

PR	Department for determination of maximum ex-factory prices
UR	Department for determination of the amount and terms of reimbursement
SA	Department of statistics and analyses
LD	Legal Department
MP	Medicinal product
FSMP	Food for special medicinal purpose
AAFS	AthenA filing service
APMPD	Administrative procedure – Medicinal Products Database
AP	Administrative procedure
ER	Evaluation report
DEC	Decision
RAP	Administrative procedure initiated by virtue of office (review)
IAP	Individual administrative procedure initiated on the participant's request
CAU	Price and reimbursement regulation
UDTD	Usual daily therapeutic dose
VCR	External price reference
MC/MPC	Maximum ex-factory price
LF	Coming into force
Coordinator	Person responsible for the correctness of the procedure
ADM	Administrative support, person responsible for formal correctness
Evaluator	Person responsible for expert and content correctness
DTB employee	Person responsible for the takeover of the electronic file from the VAL, ensures the recording in the internal information system (MPD)

**Coordinator** – an employee supporting a correct course of the procedure and implementation of individual procedural steps. In cooperation with the head of the department and the Evaluator, the Coordinator assigns tasks to the ADM and is responsible for the time schedule and deadlines of the administrative procedure.

After the type and complexity of the procedure has been assessed by the Evaluator, the Coordinator follows the deadlines within the administrative procedure, ascertains when calls and requests for position are to be sent and completes complex forms.

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The Coordinator leads some of the administrative procedures, in such a case he/she is also the document owner; expert documentation for evaluation is ensured by the Evaluator.

If a given administrative procedure does not require the Coordinator's support, the tasks of the Coordinator are assumed by the Evaluator.

**ADM – an employee** responsible for formal correctness of the administrative procedure, use of up-to-date data (participants in the procedure, product codes, etc.) and up-to-date forms, completion of assigned tasks – a task is considered to have been completed upon change of phase in APMPD and upon checking of the change on the following day. He/she follows the instructions of the Coordinator and Evaluator. He/she is authorized to complete simple forms and prepares them to be signed.

**Evaluator (specialist)** – an employee responsible for completeness, correctness and expert processing of all materials necessary for a smooth course of the AP assigned to him/her, including the Evaluation Report and the Decision.

Within the evaluation, the Evaluator either prepares materials for the determination of reimbursement or asks the employee responsible for the preparation of pricing documentation to submit such materials.

If the procedure does not require the assistance of a Coordinator, the Evaluator is also responsible for the management of the procedure, which he/she carries out with the support of the administrative employees.

The Evaluator responsible for the given procedure prepares the documents necessary for determination of the maximum price or the amount of reimbursement or assigns the preparation of the documentation to another employee.

**Official** - any person who takes part in the course of the procedure or preparation of documents relevant to any decision taken within the procedure. The name of the person responsible for each act within the administrative procedure is always stated under the performed act or in association with the act in the AA FS and APMPD application. The person leading the administrative procedure is stated in the AA FS and APMPD as the file owner.

**Authorized Official** – a person performing acts in the competence of an administrative authority authorized to do so by the internal regulations of the administrative authority or appointed by the head of the administrative authority. The authorized official in the procedures relevant to prices and reimbursements is the head of the department or other superior head according to S-001 Approval Rule.

#### 4. RELATED INTERNAL REGULATIONS

SP-CAU-001	Methodology for determination of the maximum ex-factory price of a medicinal product /food for special medical purposes
SP-CAU-002	Methodology for determination of the basic reimbursement of the reference group/ active substance and fully reimbursed medicinal product
SP-CAU-010	Methodology for the conversion of the ascertained price to the reference price
SP-CAU-020	Fixed reimbursement
SP-CAU-021	Methodology for determination of reimbursement of combined products
SP-UST-013	Appeal against a decision issued by the State Institute for Drug Control
F-CAU-001-01	Determination of the maximum price of a medicinal product/food for special medical purposes in accordance with the provisions of Section § 39a(2)(a).
F-CAU-001-02	Determination of the maximum price of a medicinal product/food for special medical purposes in accordance with the provisions of Section § 39a(2)(b).
F-CAU-001-03	Determination of the maximum price of a medicinal product/food for special medical purposes in accordance with the provisions of Section § 39a(2)(c).
F-CAU-001-04	Calculation of the maximum ex-factory price
F-CAU-001-06	Comparable products

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F-CAU-002-01	External price reference – comparison of ex-factory prices in the EU countries
F-CAU-002-02	Medicinal products available in the CR
F-CAU-002-03	Determination of the basic reimbursement of a reference group according to Section 39c(2)(a)
F-CAU-002-04	Determination of the basic reimbursement of a reference group according to Section 39c(2)(b)
F-CAU-002-05	Determination of the basic reimbursement of an active substance according to Section 39c(4) and (2)(a)
F-CAU-002-06	Determination of basic reimbursement of an active substance according to Section 39c(4) and (2)(b)
F-CAU-002-07	Determination of another reimbursement
F-CAU-002-11	List of reference sources
F-CAU-002-12	Evaluation of the procedure according to Section 13
F-CAU-002-13	Savings estimation
F-CAU-003-01	Call to eliminate defects in the application for determination of the amount and terms of reimbursement (defect of the application)
F-CAU-003-02	Call to eliminate defects in the application for determination of the amount and terms of reimbursement (missing elements of the application)
F-CAU-003-03	Notice of continuation of an administrative procedure on determination of the amount and terms of reimbursement
F-CAU-003-04	Evaluation report
F-CAU-003-05	Notice of termination of the preparation of documentation relevant to the decision on the determination of the amount and terms of reimbursement
F-CAU-003-06	Decision on the determination of the amount and terms of reimbursement – upon request
F-CAU-003-12	Resolution on the joinder of an administrative procedure on the determination of the amount and terms of reimbursement and an administrative procedure on the determination of the maximum price of the same medicinal product
F-CAU-003-13	Extension of the time period stipulated by Section 39g(5) of Act No. 48/1997 Coll. for submitting motions for evidence and other motions by the participants in the procedure on the MC, AaTR
F-CAU-003-14	Discontinuance of the administrative procedure on the setting of the level and conditions of reimbursement upon request – the applicant failed to complete the application
F-CAU-003-20	Call to eliminate a shortcoming of the application for a change of the MC and AaTR
F-CAU-003-21	Call to eliminate a defect in the application for a change of the MC and AaTR
F-CAU-003-22	Notice of continuation of an administrative procedure on a change of the MC and AaTR
F-CAU-003-23	Notice of termination of the preparation of documents relevant to the decision on a change of the MC and AaTR
F-CAU-003-24	Decision on a change of MC and AaTR upon request
F-CAU-003-25	Call for cooperation in determination of the AaTR upon request
F-CAU-003-26	Extension of the time limit for providing a position - determination/change of the AaTR, MC
F-CAU-003-27	Refusal to extend the time limit for providing a position on the determination/change of AaTR, MC
F-CAU-003-28	Resolution on the refusal to extend the time limit under Section 39g(5) – determination of the AaTR, MC
F-CAU-003-29	Discontinuance of the application for determination of the AaTR – lack of grounds
F-CAU-003-30	Discontinuance of the application for determination/change of the MC, AaTR –

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	withdrawal
F-CAU-003-31	Discontinuance under Section 88(2), Section 66(1)(a)
F-CAU-003-32	Call to eliminate shortcomings of the application for determination of the MC+AaTR
F-CAU-003-33	Call to eliminate defects in the application for determination of the MC+AaTR
F-CAU-003-34	Notice of continuation of the administrative procedure on determination of the MC+AaTR
F-CAU-003-35	Notice of termination of the preparation of documents relevant to the decision on determination of the MC+AaTR (amount and terms of reimbursement)
F-CAU-003-36	Decision on the determination of MC+ AaTR upon request
F-CAU-003-37	Call to eliminate shortcomings of the application for a change of the AaTR (missing elements in the application)
F-CAU-003-38	Call to eliminate shortcomings of the application for a change of the AaTR (defects of the application)
F-CAU-003-39	Notice of continuation of the administrative procedure on a change of the AaTR
F-CAU-003-40	Notice of termination of the preparation of documents relevant to the decision on a change of the AaTR upon request
F-CAU-003-41	Decision on a change of the AaTR upon request
F-CAU-003-42	Suspension upon request – change of the MC
F-CAU-003-43	Notice of continuation of the administrative procedure after suspension upon request - determination/change of the MC
F-CAU-003-44	Public notice – loss of legal force
F-CAU-003-45	Price certificate
F-CAU-003-46	Decision under Section 87 of the Rules of Administrative Procedure
F-CAU-003-47	Rectifying Resolution – rectification of the reasoning
F-CAU-003-48	Rectifying Resolution – rectification of the ruling
F-CAU-003-49	Extension of the period of suspension of the administrative procedure upon request – determination/change of the MC
F-CAU-003-50	Resolution on the determination of the time limit for providing the opinion after returning the procedure to the Ministry of Health
F-CAU-003-51	Resolution on the permission to change the content of the application
F-CAU-003-52	Resolution on the dismissal of a change of the content of the application
F-CAU-003-53	Letter of request
F-CAU-003-54	Call to eliminate defects of the application – determination of the maximum price of the Ministry of Health
F-CAU-003-55	Call for cooperation - MC/AaTR upon request (generic)
F-CAU-003-56	Resolution on the extension of the time limit for the elimination of defects of an application for maximum ex-factory price
F-CAU-003-57	Committal of notification to a participant
F-CAU-003-58	Committal to the Health Ministry
F-CAU-003-59	Committal – resolution
F-CAU-003-60	Call to eliminate shortcomings of the application for a permission to change the content of the filing
F-CAU-003-61	Notification of an incorrect indication of the legal force
F-CAU-020-01	Determination of reimbursement based on previous legislation
F-CAU-020-02	Determination of fixed reimbursement according to a revision administrative procedure
F-CAU-020-03	Determination of a fixed reimbursement according to an individual administrative procedure

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F-CAU-020-04	Determination of fixed reimbursement according to previous legislation
F-105	Position – internal review
PN-CAU-001	CAU reference registry
SP-CAU-023	Procedure for the creation of the list of reimbursed HVLP FSMP
S-001	Approval rule
S-005	File processing and shredding rules

## 5. RELATED GENERALLY APPLICABLE LEGAL REGULATIONS, NORMS 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 (“Administrative Fees Act”)  
 Regulation No. 384/2007 Coll., on the list of reference groups, as amended  
 Regulation No. 385/2007 Coll., on determination of the list of active substances designated for support or supplementary treatment  
 Regulation No. 92/2008 Coll., on the creation of the list of reference countries, the manner of evaluation of the amount, terms and form of reimbursement of medicinal products and foods for special medical purposes and the elements of the application, as amended  
 Regulation No. 376/2011 Coll., implementing some of the provisions of the Act on Public Health Insurance  
 Act No. 261/2007 Coll., on stabilization of public budgets, part forty-eight, amending Act No. 265/1991 on the competence of Czech authorities concerning prices  
 Act No. 265/1991 Coll., on the competence of Czech authorities concerning prices, as amended  
 Act No. 526/1990 Coll., on prices, as amended  
 Act No. 362/2009 Coll., amending some acts related to the proposal of the Act on the State Budget of the Czech Republic for 2010  
 Act No. 76/2011 Coll., on temporary reduction of prices and reimbursements of medicinal products  
 Price Decision of the Health Ministry of 20.12.2007, setting the terms of price regulation of medicinal products and foods for specific medical purposes  
 Price Decision of the Health Ministry 1/2010-FAR, which stipulates the list of ATC groups of medicinal products and foods for special medical purposes – regulation of the ex-factory price as amended  
 Price Regulation of Health Ministry 2/2009/FAR of 20 March 2009 on the regulation of price of medicinal products and foods for special medical purposes, as amended

## 6. PROCEDURE

The procedure for processing of applications for the determination of the maximum price and the amount and terms of reimbursement of medicinal products/FSMP is described in the table and the development diagram – Annex 1. Throughout the procedure, the participants may apply for an extension of the time limit for submitting their position and may inspect the file (as indicated in the graph).

The person stated in the AA FS and APDMP as the file owner is primarily responsible for the file.

Activity	Description	Performed by	Document/ tool/ APMPD
1. Assumption of file	The CAU receives the file physically	CAU secretariat	APMPD

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	from the VAL and the DTB employees electronically through the APDMP AP and AAFS after it has been checked for completeness (within 48 hours for both types of procedure). The file is forwarded from VAL to the CAU secretariat even if it does not bear a certificate of payment of the administrative fee (to be verified and ensured by the CAU secretariat)	DTB employees VAL employee	AAFS
2. Distribution of file	Prague: The CAU secretariat hands the hard copy of the file in the AAFS over to the UR Head, who appoints the Evaluator Brno: The CAU secretariat hands the file through the AAFS over to the SA secretariat.	CAU secretariat SA secretariat UR Head	
3. Assignment to Coordinator	Within one day, the Head returns the distributed files to the UR secretariat, the secretariat hands the hard copy of the file over to the UR Evaluator through the AAFS. At the same time, the secretariat forwards the file through the APMPD application. Brno: The SA secretariat hands the file over to the Evaluator through the AAFS and sets up the Evaluator in the APMPD. The SA Evaluator receives the file electronically, the paper files of the SA Evaluator are kept with the ADM.	UR Head UR secretariat SA secretariat	APMPD AAFS
4. Distribution of file	The Evaluator sets up the rights to handle the file in the AAFS and APMPD for the ADM and other employees where applicable. Immediately after having received the file, the Evaluator enters in the table the search for price references relevant to the administrative procedure and informs the appointed SA Evaluator (procedure on AaTR) and PR Evaluator (procedure on MC+AaTR). The search must be completed within 21 days following the commencement of the administrative procedure. In a AaTR procedure where the amount of reimbursement is set according to the	Evaluator	APMPD AAFS

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	fixed reimbursement and there is no request for setting of an increased reimbursement (IR) above the amount of the fixed IR, the instruction to search for price references is not given.		
5. Identical products	The Evaluator assigns to the ADM employee a request to investigate the existence of identical products. If they exist, the following steps will apply to all identical products.	Evaluator, ADM	DLP
6. Data check	The Evaluator checks the received documentation for completeness. If it contains all the necessary data, the procedure continues with step 9. If some of the data are not available, the procedure continues with step 7.	Evaluator	
7. Call to supplement file	According to the nature of the matter, the Coordinator prepares a call to eliminate defects of the application or a call to supplement information (the reasoning is to be prepared by the Evaluator) and hands it over to the UR/SA Head for inspection and signing. The call will be published at the Institute's official notice board. If the application has any defects, the administrative procedure is suspended. After receiving the supplement information, the procedure continues with step 8.	Evaluator, Coordinator UR/SA Head	F-CAU-003-01 F-CAU-003-02 F-CAU-003-20 F-CAU-003-21 F-CAU-003-32 F-CAU-003-33 F-CAU-003-37 F-CAU-003-38
8. Acceptance and evaluation of supplement	The Evaluator evaluates the received supplementary documentation. If the supplement contains the necessary data, the Coordinator in cooperation with the ADM prepares a resolution on the continuation of the administrative procedure and submits it to the UR/SA Head for signature. The ADM employee incorporates the signed document in the file and publishes it on the Institute's official notice board. If the supplement does not include the necessary data, the Evaluator in	Evaluator , Coordinator ADM, UR/SA Head	F-CAU-003-03 F-CAU-003-22 F-CAU-003-34 F-CAU-003-39  F-CAU-003-01 F-CAU-003-02 F-CAU-003-14

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	cooperation with the Coordinator prepares a repeated call to supplement information within a time limit that is to be published on the Institute's official notice board, or, if the defects have not been eliminated, the procedure is discontinued and the notice of discontinuance is published on the Institute's bulletin board.		
9. Acceptance of motions from participants	<p>Motions of the participants in the procedure are accepted continuously from the day of commencement of the administrative procedure (day 1) – this is ensured by the Evaluator, who incorporates such motions in the file and incorporates them or comments on them in the Evaluation Report. Where the participants' motions require a consultation, the Evaluator may request the opinion of the employee who prepares the determination of reimbursement/price.</p> <p>One of the motions that can be filed by the participants in the proceedings is the request to extend the time period stipulated by Section § 39g(5) of Act No. 48/1997 Coll. for submitting proposals of evidence and other motions.</p> <p>If the Evaluator, upon consultation with the UR/SA Head, decides to satisfy the request, the Coordinator prepares a Resolution on the extension of the time limit to file proposals of evidence and other motions within the administrative procedure. If the Evaluator decides to dismiss the request, the Coordinator prepares a Resolution on a dismissal of an extension of the time limit. The Resolution will be posted on the Institute's official notice board.</p>	Filing office, CAU secretariat, ADM, Evaluator, Coordinator UR/SA Head	<p>F-CAU-002-02</p> <p>F-CAU-003-13</p> <p>F-CAU-003-28</p> <p>AAFS APMPD</p>
10. Drafting of the Evaluation Report proposal/calculation of reimbursement	The Evaluator drafts the Evaluation Report and sends it via the APMPD to the employee who prepares the determination of the	Evaluator	F-CAU-003-04 e-mail/APMPD



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	reimbursement/price (day 20 / day 40 following the commencement of the procedure).		
11.Determination of the basic reimbursement / reimbursement for package	After an inspection, the employee responsible for determination of the reimbursement/price calculates the reimbursement according to the applicable methodologies, or calculates the basic reimbursement for a group of interchangeable products. The employee responsible for the determination of the maximum price calculates the maximum price. The relevant documentation is submitted to the Evaluator via the APMPD application.	Employee responsible for determination of reimbursement,	F-CAU-001-01 F-CAU-001-02 F-CAU-001-03 F-CAU-001-04 F-CAU-002-01 F-CAU-002-02 F-CAU-002-03 F-CAU-002-04 F-CAU-002-04 F-CAU-002-05 F-CAU-002-06 F-CAU-002-07 APMPD
12. Evaluation Report finalization	The Evaluator finishes the Evaluation Report and submits it to the UR/SA Head for inspection and final review.  Where the reimbursement of a product is stipulated based on a fixed reimbursement, the Evaluator creates a template of the Evaluation Report, which is then approved by the UR/SA Head. This template is then provided to the ADM employee to fill in the required data from the application and to finally calculate the reimbursement per package. In this case, the final report is revised by the Evaluator.	Evaluator, UR/SA Head	F-CAU-003-04 e-mail
13.Incorporating of the Evaluation Report in the file	The Evaluator signs the revised Evaluation Report and incorporates it in the file (no later than on day 39/ 119) using the APMPD application. He/she also prepares all other relevant documents and evidence and incorporates them in the file or instructs the ADM employee to incorporate them in the file. After incorporating the evidence, the Evaluator examines the file. Then he/she asks the ADM employee to prepare the Notice of termination of gathering of the	Evaluator	F-CAU-003-04 AAFS APMPD

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	documentation relevant to the decision.		
14. Preparing the Notice of termination of collection of materials relevant to the decision	The ADM employee fills in the form Notice of termination of collection of materials relevant to the decision in the APMPD application. The time limit to provide an opinion on the materials is 10 days. Before sending the Notice, the ADM employee again checks the participants in the procedure and identical products.	ADM	F-CAU-003-05 F-CAU-003-23 F-CAU-003-35 F-CAU-003-40  APMPD DLP
15. Examination of the Notice of collection of gathering of documentation relevant to the decision	The Evaluator examines the Notice of termination of gathering of materials relevant to the decision and forwards it to the UR/SA head for signature via the APMPD application. A Notice prepared by the Evaluator is forwarded directly to the Head for signature. The signed Notice is incorporated in the file by the ADM.	Evaluator	F-CAU-003-05 F-CAU-003-23 F-CAU-003-35 F-CAU-003-40
16. Submitting the Notice to the UR head for signature and its incorporation in the file	After checking, the ADM employee forwards the document to the UR/SA Head for signature and subsequently incorporates the signed document in the file.	ADM, UR/SA Head	F-CAU-003-05 F-CAU-003-23 F-CAU-003-35 F-CAU-003-40  APMPD
17. Publishing of the Notice	The ADM employee publishes the Notice on the Institute's official notice board (no later on day 40 / day 120 following the commencement of the procedure). After the publishing, he/she provides for a change of phase in the APMPD and checks that this change has been made (this can be done on the next day).	ADM	F-CAU-003-05 F-CAU-003-23 F-CAU-003-35 F-CAU-003-40  APMPD
18. Extension of the time limit	If a participant applies for an extension of the time limit to provide its comments on the documentation relevant to the decision, the Evaluator may extend this time limit upon consultation with the UR/SA head (provided that this does not affect the purpose of the procedure or equality of the participants) or dismiss the extension of the time limit for providing an opinion by a resolution that	Coordinator ADM, UR/SA Head	F-CAU-003-26  F-CAU-003-27

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	is then published on the Institute's official notice board.		
19. Appeal delivery monitoring	If an appeal against the resolution stated in the Notice is delivered within 15 days following the service, the procedure continues with step 21. If no appeal has been filed, go to step 22.	Evaluator/ Coordinator	AAFS
20. Processing of an appeal	<p>If the appeal has been delivered on time and contains all the required elements, (to be confirmed by the LD), the Evaluator prepares a Position on the appeal or prepares a proposal of an internal review (within the time limit stipulated by the LD) and forwards it to the UR/SA Head, who revises the Position and forwards it to the CAU Head.</p> <p>The CAU Head revises the position on the appeal or the motion to proceed according to Section 87 of the Rules of Administrative Procedure (internal review), makes any additions necessary and forwards it to the LD.</p> <p>The appeal does not have a suspensory effect and the procedure continues without interruption with step 22.</p> <p>If the Health Ministry issues a decision in respect of an appeal against the Resolution stated in the Notice</p> <p>a) The Health Ministry has no objections and the procedure continues without being interrupted.</p> <p>b) If the Health Ministry has any objections, it states them in its decision and decides to which phase the procedure should be returned.</p>	LD employee	SP-UST-013
21. Drafting of a Decision	<p>The Notice is considered as delivered on the 5<sup>th</sup> day following its posting.</p> <p>On the 20<sup>th</sup> day following the sending of the Notice, the Evaluator prepares a draft of the Decision, including the reactions to any objections (no later than by day 60 / 150 following the commencement of the procedure).</p>	Evaluator, Employee responsible for determination of reimbursement /price ADM	F-CAU-003-06 F-CAU-003-24 F-CAU-003-36 F-CAU-003-41  APMPD

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	<p>When there are objections against the determination of reimbursement/price or when it is necessary to make a new calculation of the reimbursement/price stated in the decision, the Evaluator asks the employee responsible for the determination of reimbursement/price for cooperation.</p> <p>If the reimbursement has been determined according to the fixed reimbursement and there are no objections against the course of the procedure, the evaluator may ask the ADM employee to prepare a decision in the APMPD. Such decision shall be revised by the Evaluator before its sending for signature.</p>		
22. Review of the delivery of supplementary information	<p>In the case that further supplementary information has been ascertained from the participants in the proceedings which could not have been submitted within 15 days following the commencement of the procedure, the Evaluator add this information in the file and the procedure is returned to step 13. The Evaluator prepares a new version of the Evaluation Report and the ADM employee prepares for issuance a new Notice on the termination of gathering of materials.</p> <p>If any of the participants submits after the expiration of the 15-day period any information that was already available before its expiration, the Evaluator will not accept such materials and will address the submitted motions in the Decision.</p> <p>If the applicant withdraws the application before the issuance of a Decision, the procedure is discontinued. The Resolution on discontinuation of the procedure is published on the Institute's</p>	Evaluator, ADM	<p>F-CAU-003-05 F-CAU-003-23 F-CAU-003-35 F-CAU-003-40</p> <p>F-CAU-003-30</p>

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	official notice board.		
23. Revision of the Decision	The decision is revised by the UR/SA Head, and the CAU Head, where applicable.	Evaluator, UR/SA Head, CAU	F-CAU-003-06 F-CAU-003-24 F-CAU-003-36 F-CAU-003-41
26. Finalization of the Decision	The Evaluator finishes the Decision, the ADM employee checks the participants in the procedure and identical products once more. The Evaluator subsequently forwards the Decision by e-mail to the UR/SA Head for signature.	Evaluator ADM	F-CAU-003-06 F-CAU-003-24 F-CAU-003-36 F-CAU-003-41
27. Signing of the Decision	The UR/SA Head checks the Decision and signs it or returns it to the Evaluator for amendments. The ADM employee enters the signed Decision in the APMPD and in the file in AAFS.	UR/SA Head, Evaluator ADM	F-CAU-003-06 F-CAU-003-24 F-CAU-003-36 F-CAU-003-41  APMPD AAFS
28. Publishing of the Decision	The ADM employee posts the decision on the Institute's official notice board (no later than on day 75 / 165 following the commencement of the procedure). After its posting, he/she provides for and checks the change of phase in the APMPD (this can be done on the next day).	Employee of administrative support to the UR	F-CAU-003-06 F-CAU-003-24 F-CAU-003-36 F-CAU-003-41  APMPD
29. Forwarding of the file to the CAU node in the AAFS	After publishing the Decision, the Evaluator forwards the file to the UR/SA node. An employee of the UR/SA secretariat forwards the file to the node of the CAU secretariat, the CAU secretariat follows the documents of the file delivered via the AAFS.	Evaluator ADM secretariat	AAFS
30. Evaluation of legal force	The delivery of an appeal against the Decision is monitored (the appeal is delivered from the filing office to the legal department, the LD provides this information via e-mail and enters it in the appeal table in the share Public folder). If the appeal has been delivered in time and contains the necessary elements (to be confirmed by the LD), the procedure continues with step 30. Otherwise the LD informs the Evaluator who follows further instructions of the LD. If the appeal is not	Evaluator, filing office, Head and employees of the LD, ADM	SP-UST-013 PN-CAU-002

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	delivered in the stipulated time limit, the procedure continues with step 35.		
31. Position on the appeal	The Evaluator drafts a position on the appeal or a proposal for an internal review (within the time limit stipulated by the LD) and consults the procedure with the Head of UR/SA. The Evaluator forwards the information on the appeal in accordance with step 36.	Evaluator, UR/SA Head	e-mail
32. Revision of the Position	The UR/SA Head revises the Position on the appeal (or the proposal for an internal review), makes any necessary amendments and submits it to the CAU Head for approval. The CAU Head confirms the approval of the Position to the Evaluator via e-mail. Subsequently, the Evaluator forwards the Position to the LD via the APMPD application. In the case that the CAU/UR/SA Head does not approve the Position, it is returned to the Evaluator for amendments.	CAU Head UR/SA Head Evaluator	APMPD e-mail
33. Decision on the appeal	<p>The LD decides whether the requests of the appellant are to be fully satisfied, in which case the procedure continues with step 33, and returns the file to the CAU secretariat, which subsequently forwards it to the Coordinator. If the appellant's requests cannot be satisfied, a position is prepared and handed over by SÚKL to the Health Ministry (MH). After the delivery of the final and conclusive decision of the MH, the procedure continues with step 34.</p> <p>If the applicant has withdrawn the application before the file is forwarded to the MH, the procedure is discontinued and this fact is published on the Institute's official notice board.</p>	V-LD	<p>Call by LD AAFS</p> <p>F-CAU-003-31</p>
34. Internal Review	If the Evaluator, the UR/SA Head and	Evaluator, UR/SA	F-105

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	<p>the legal department evaluate the possibility to use an internal review as appropriate, then:</p> <ol style="list-style-type: none"> <li>In the case that the original Decision is cancelled, the procedure is returned to step 9.</li> <li>In the case that the original Decision is amended, the procedure is returned to step 22.</li> <li>If nobody files an appeal against the result of the internal review, the procedure continues with step 35.</li> </ol>	Head, CAU Head, LD	
35. Acceptance of the MH Decision	If the MH has confirmed the Institute's Decision, the procedure continues with step 35. Otherwise the procedure goes back to step 9 and the file is forwarded from the CAU secretariat to the Evaluator.	PRO, CAU Head, UR Head, Evaluator	
36. Handover of the file and indication of legal force	The Evaluator in cooperation with the Coordinator follows the dates of legal force of the Decision. If the Decision can become final and conclusive after the expiration of the respective time period, the Evaluator instructs the DTB employees to enter the date of legal force of the Decision electronically, the DTB employees incorporate the Decision with the date of legal force in the file in the AAFS via the APMPD application. The DTB employee ensures a change of phase in the APMPD and subsequently checks that the change has been performed.	UR secretariat, DTB employee Evaluator Coordinator	F-CAU-003-06 F-CAU-003-24 F-CAU-003-36 F-CAU-003-41 AAFS SP-CAU-023,
37. Forwarding of information on the appeal and entering of data in the MPD	The Evaluator in cooperation with the Coordinator forwards the information that an appeal has been filed or that the Decision has taken legal force to the DTB employees according to SP-CAU-023, who process the given information (enter the respective data in the	UR secretariat ADM Evaluator Coordinator	E-mail, Signed table in the MPD

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	information system) in order to incorporate it in the List of reimbursed MP/FSMP. Procedures initiated after 1 December 2011: If an appeal has been filed within the procedure, the Evaluator forwards this information to the DTB employees. Such decision is stated in the list as a preliminarily effective decision that can be enforced upon expiration of the time limit for appeal.		
38. Closing of the file	The CAU secretariat prepares the file to be entered in the reference registry and transfers it to the archive status in the AAFS.	ADM secretariat	AAFS, reference registry
39. Archiving of the file in the reference registry	The ADM employee archives the paper version of the file in the CAU reference registry, stating its location.	ADM	AAFS, reference registry SP-CAU-023,

The Evaluator proceeds in the same manner also when the Institute receives an application for determination of the maximum price of a medicinal product /FSMP and the procedure on the determination of the amount and terms of reimbursement of the same medicinal product/FSMP is already under way.

Where the Evaluator ascertains in the course of the procedure that the application has become groundless, he/she discontinues the procedure using the F-CAU-003-29 form.

F-CAU-003-25 Call to cooperation – provision of information – can be applied in any phase of the procedure.

All documents posted on the official notice board bear a guaranteed electronic signature and a date stamp.

### **Specific terms of applications for determination of the amount and terms of reimbursement of a highly innovative medicinal product.**

The obligatory elements of the application are stipulated in Section 39d (3) of the Public Health Insurance Act.

The determination of the reimbursement is subject to the Methodology for determination of basic reimbursement specifically for highly innovative medicinal products, if the methodology defines such procedure, the reimbursement is always determined *de novo* for 24 or 12 months according to the provisions of Section 39d (2) of the Public Health Insurance Act.

## **7. ANNEXES**

Annex 1: Procedural map for processing of an application for determination of the maximum ex-factory price or reimbursement of a medicinal product/FSMP

Překlad:

Participants may inspect file throughout the procedure.

1. Assumption of file



2. Distribution of file
3. Allocation to coordinator
4. Distribution of file
5. Identical codes
6. Verification of data
7. Removal of application defects requested
- YES - Call to remedy defects
- NO - Call to supplement application
8. Is documentation complete? - NO - AP suspended
9. Evaluation report compiled (day 20/40)
10. Examination of the evaluation report
11. Price benchmark provision
- Motions received from applicants
12. Motions received from applicants
13. Final version of the evaluation report
14. Evaluation report included in file (31/119)
15. Resolution on termination of document collection
16. Examination of the Notice on termination of document collection
17. Notice delivered to the CR/UR manager for signature and included in file
18. Notice notified to parties (day 40/120)
19. Time limit extension
20. Was resolution appealed within 15 days of delivery? - YES -
21. Appeal addressed by PRO
- NO
22. Draft decision compiled (day 60/150)
23. Additional information ascertained?
- NO
24. Opposing views to the decision compiled
25. Final draft of decision
26. Decision signed
27. Decision notified to parties (day 75/165)
28. File delivered to CAU node
29. Was decision appealed within 15 days of delivery?
- YES
30. Position to appeal compiled
31. Position examined
32. Did the Institute afford the appeal?
- YES
33. Internal review
- 33a. Original decision cancelled
- 33b. Original decision changed
- 33c. No objections
- NO
34. Did Ministry uphold Institute's decision?
35. File delivered and effective marked thereon
36. Appeal information delivered, data input in DLP
37. File closed
38. File archived in reference registry



