Title: Course of administrative procedure for determination of the maximum price and the amount and terms of reimbursement of a similar product – summary procedure

1. OBJECTIVE

To establish the process (course of administrative procedure) for the determination of the maximum price and the amount and terms of reimbursement of a similar product in compliance with the provision of Section 39g, paragraph 9 of the Act on Public Health Insurance.
An analogical procedure shall be applied also in case of maximum price reduction referred to under the provision of Section 39i, paragraph 4 of the Act on Public Health Insurance.

2. USERS

The Procedure shall be binding for the employees of the Price and Reimbursement Regulation Branch.

3. DEFINITION OF TERMS AND ABBREVIATIONS

ADM DTB – an employee of the VAS department in charge of entries into the information system (DMP), and the web service for CAU

ADM SECR – an assistant of the CAU Branch in charge of distribution of documents in SSL AA

ADM UNI – an assistant of the CAU Branch 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

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

IAP – individual administrative procedure with a timeline for the issuance of a decision stipulated by Section 39g, paragraph 2

COO – coordinator – an expert employee of STP responsible for process correctness, specified as the dossier owner

CBA – Department of Preparation of Complex Background Materials and Analyses

APC – Department of Administrative Procedure Coordination

MedP – medicinal product

MP – maximum price

MP+ACR – a joint procedure to determine the maximum price and amount and conditions of reimbursement

MoH – Ministry of Health of the Czech Republic

EiF – entry into force

FSMP – food for special medical purposes

CAU S –secretariat of the CAU Branch

APC S – secretariat of the Department of Administrative Procedure Coordination

STP S – secretariat of the Department of Selected Types of Administrative Procedures

SCAU – List of prices and reimbursements of medicinal products/foods for special medical purposes

AP – administrative procedure

SŘDLP – a system for administrative procedures – database of medicinal products

SSL AA – documentary service AthenA

NB –SÚKL's Notice Board

Institute – State Institute for Drug Control

CAU M –CAU Branch Manager
APC M – Administrative Procedure Coordination Department Manager
STP M – Selected Types of Administrative Procedures Department Manager
VAS – Department of Validations and Administrative Support
ACR – amounts and conditions of reimbursement
STP – Department of Selected Types of Administrative Procedures
CES – certified electronic signature
PHI Act – Act on Public Health Insurance

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 (Act on Pharmaceuticals), as amended.
Act No. 48/1997 Coll., on Public Health Insurance and Amendments to Some Related Acts, as amended (the "Public Health Insurance Act")
Act No. 634/2004 Coll., on Administrative Fees, as amended (hereinafter referred to as the Act on Administrative Fees)
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, as amended
Decree No. 376/2011 Coll., implementing some of the provisions of the Act on Public Health Insurance
Act No. 265/1991 Coll., of the Czech National Council, 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, as amended
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
Decree No 259/2012 Coll., on details regarding documentary service operation
Act No 372/2011 Coll., on Healthcare Services, as amended
Decree No 84/2008 Coll., on good pharmaceutical practice, detailed conditions of handling of pharmaceuticals in pharmacies, healthcare facilities and other operators and facilities dispensing medicinal products

Legal framework

Similar product definition – the provision of Section 39b, paragraph 4 of the Act on Public Health Insurance
Course of administrative procedure – the provision of Section 39g, paragraph 9 and Section 39g, paragraph 10 of the Act on Public Health Insurance

6. PROCEDURE

Title: Course of administrative procedure for determination of the maximum price and the amount and terms of reimbursement of a similar product – summary procedure

The course of the administrative procedure is outlined in the flow chart in Annex 2.

The procedure for expert assessment of compliance with the conditions for the determination of the maximum price and the amount and conditions of reimbursement of a similar product is outlined in Annex 1.

The Institute shall decide within the timeline of 30 days of the commencement of the administrative procedure as referred to under the provision of Section 39g, paragraph 10 of the Act on Public Health Insurance.

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

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

The assessment, annex to the notification on EiF and the CT for SCAU shall be in the excel format.

Activity	Specification	Conducted by	Document/aid/ system
1. Dossier take-over (timeline: within 48 hours of the submission of the application, if there are no shortcomings in the application)	Following the validation of the application pursuant to SP-CAU-032, the ADM VAL shall forward the dossier to the STP S in case the application is complete and without any errors. The STP S shall take over the dossier from VAS electronically via the SŘDLP and SSL AA applications. The hard-copy dossier shall be handed over to the ADM SECR for storage in the Reference Registry. If the application has not been forwarded within 48 hours of the submission of the application, the ADM VAL shall inform the COO by e-mail about this procedure. If the application contains shortcomings or the administrative fee has not been paid, the dossier shall be forwarded to the STP S only after the shortcoming is eliminated/fee paid. In such a case, the VAS shall send information on the suspension of the administrative procedure to the COO. *The assessment referred to by section 4 and Annex 1 hereto (Similar Product Assessment) shall be entered within 10 days of the commencement of the procedure regardless of the suspension of the procedure.*	ADM VAL STP S	SŘDLP SSL AA e-mail SP-CAU-032

2. Dossier allocation	The STP S shall forward the dossier to the COO in SSL AA. Concurrently, the dossier shall be forwarded via the SŘDLP application.	STP S	SŘDLP SSL AA
3. Authorisation for the processing of expert assessment	The COO shall inform the selected ASSR of the newly running procedure.	COO	e-mail
4. Data check and evaluation	The ASSR shall assess the forwarded documentation as to whether it contains the necessary data about the similar product corresponding to the particulars referred to under Section 39g, paragraph 9 of the PHI Act. The ASSR shall carry out the assessment as referred to by Annex 1 hereto (Similar Product Assessment). The ASSR shall enter the assessment into SŘDLP and thereafter shall enter the assessment signed with his/her CES into the dossier and shall inform the COO about the result of the assessment.	ASSR	SŘDLP SSL AA F-CAU-026-14
5. The issuance of END (timeline: no later than within 10 days of the commencement of the procedure)	The COO shall instruct the ADM UNI to check the status of marketing authorisation of the medicinal products and parties to the procedure. In the SŘDLP application, the COO shall complete the F-CAU-026-07 form – Notification of commencement, determination of END timeline for proposals of evidence (similar MedP) (hereinafter referred to as the "F-CAU-026-07 form") and shall determine the timeline for opinion on source materials for the decision (5 days). In case the procedure was suspended and resumed prior to the hand-over from VAS, only the F-CAU-026-04 form – Notification of completion of identification of source materials for decision (hereinafter referred to as the "F-CAU-026-04") shall be used. The COO shall hand over the document via the SŘDLP application to the STP M for signature. The STP M shall check the document	ASSR COO STP M ADM UNI	SŘDLP SSL AA e-mail F-CAU-026-07 F-CAU-026-04

	and either sign it or return it for reprocessing. After the STP M´s signature of the document, the COO shall enter the document into SSL AA and shall ensure its publication on the Institute´s Notice Board. Alternatives of further procedure are described in step 6.		
6 A. The application is complete, but the conditions set forth by Section 39g, paragraph 9 of the PHI Act have not been met	The COO shall prepare the F-CAU-026-07 form in SŘDLP as referred to under step 5, through which he/she shall inform the parties to the procedure about the possibility to agree on the stopping of the administrative procedure in compliance with the procedure outlined under the provision of Section 39g, paragraph 10 of the PHI Act. I. The applicant additionally meets the conditions referred to under Section 39g, paragraph 9 of the PHI Act: a) By day 19 of the administrative procedure, the COO shall inform the ASSR, who shall draft a second assessment in compliance with Annex 1 hereto (Similar Product Assessment) and, with an attached CES, shall enter it into SŘDLP and SSL AA. Thereafter he/she shall inform the COO of this fact by e-mail. The COO shall proceed as outlined in step 5 hereof, but instead of using the F-CAU-026-07 form shall use the F-CAU-026-04 form. Thereafter, the COO in cooperation with the ASSR shall draft the decision as per step 7 hereof, or, if the timeline for the issue of the decision expires, a fictitious decision shall apply. b) After Day 19	COO ASSR STP M ADM UNI	SŘDLP SSL AA F-CAU-026-02 F-CAU-026-04 F-CAU-026-07 F-CAU-026-08 F-CAU-026-12 F-CAU-026-14 F-CAU-026-16

	The COO in cooperation with the ASSR shall draft the decision as outlined in step 7 hereof. II. The applicant does not additionally meet the conditions referred to under Section 39g, paragraph 9 of the PHI Act: a) At least one party to the procedure agrees with the stopping within the determined timeline: The COO in cooperation with the ASSR shall draft a "decision to stop the administrative procedure", F-CAU-026-02, in compliance with Section 66, paragraph 1(h) of the Administrative Code and Section 39g, paragraph 10 of the PHI Act. The COO shall forward the drafted decision by e-mail to the STP M for review. The STP M shall check the decision and in case shortcomings are identified shall return it to the COO for reprocessing. Once the STP M approves of the decision, the COO shall instruct the ADM UNI to check the status of the marketing authorisation of the MedP and parties to the procedure and shall file the decision via SŘDLP for signature by the STP M. The STP M shall sign the document and the ADM UNI shall enter the document into SSL AA and shall arrange for its publication on the Institute´s Notice Board. On the day following the EiF of the decision to stop the procedure the Institute shall commence an IAP and thereafter procedure outlined under SP-CAU-003 shall apply and the F-CAU-026-12 commencement form shall be used.		

	b) Consent with the stopping of the procedure has not been obtained within the determined timeline: the COO in cooperation with the ASSR shall draft a "decision on rejection of the application", F-CAU-026-08 in compliance with Section 51, paragraph 3 of the Administrative Code, and thereafter the procedure outlined under step 7 hereof shall be followed.		
6 B. The application is complete and meets the conditions set forth by Section 39g, paragraph 9 of the PHI Act	The COO shall prepare the form in SŘDLP as referred to under step 5. Within the timeline for providing an opinion on source materials for decision (5 days): a) At least one of the parties expresses its disagreement with this procedure; then the ASSR shall re-assess whether the conditions set forth by Section 39f, paragraph 8 of the PHI Act have been met: 1) If he/she finds out that the conditions have been met, the COO shall issue a decision as per step 7 hereof within the timeline for its issuance, determining the maximum price and/or amount and conditions of reimbursement therein. 2) If he/she finds out that the conditions have not been met, he/she shall decline the application pursuant to Section 51, paragraph 3 of the Administrative Code, by analogy to the procedure outlined under 6A. II. b) hereof. In such a case, the AP may no longer be stopped	COO ASSR STP M	SŘDLP SSL AA F-CAU-026-07

	pursuant to Section 66, paragraph 1 (h) of the Administrative Code, as the failure to meet the particulars was not identified within 10 days of the commencement of the AP. b) None of the parties express their disagreement with this process; then the COO shall issue a decision as per step 7 hereof within the timeline for its issuance or this timeline will expire and a fictitiously issued decision shall apply.		
7. Decision/fictitious decision (no later than on Day 30 of the AP)	If the conditions for the issuance of the decision have been met, the COO in cooperation with the ASSR shall complete the decision form. Following finalisation, the COO shall forward the decision by e-mail to the STP M for review. Where the Institute does not issue a decision within 30 days of the commencement of the procedure, fictitious decision shall be employed and thereafter the procedure outlined under step 9 hereof shall be followed. The decision shall be issued in any case where the application is being declined.	COO ASSR	e-mail F-CAU-026-08 F-CAU-026-09
8. Signature of the decision and send-off of the decision to parties to the procedure (timeline: no later than on Day 30 of the commencement of the procedure)	The STP M shall check the decision and in case shortcomings are identified shall return it to the COO for reprocessing. After the STP M approves of the decision, the COO shall inform an ADM UNI employee who shall check the status of marketing authorisation of the medicinal products and the parties to the procedure. Thereafter, via SŘDLP, the COO shall draft a decision to be signed by the STP M. The STP M shall sign the decision and the COO shall enter the decision into SSL AA and shall arrange for its publication on the Institute's Notice Board no later than	COO STP M ADM UNI	SŘDLP SSL AA

	within day 30 of the AP.		
9. Announcement of the entry into force and its inclusion into the dossier (no sooner than on Day 31 of the commencement of the procedure)	In case of a fictitious decision, the COO, via SŘDLP, shall draft a "notification of fictitious EiF" together with an attachment to the notification of fictitious EiF, a "summary of data on determined maximum price and amount and conditions of reimbursement". Via SŘDLP, the COO shall forward the notification of EiF to the STP M for signature, the STP M shall sign the notification of EiF with his/her CES, the COO shall enter the signed notification of EiF into SSL AA. Thereafter, via SSL AA, the COO shall enter the attachment to the notification of EiF, and shall inform the STP M of such entry, the STP M shall sign it with his/her CES and the COO shall conclude the document.	COO STP M	SŘDLP SSL AA F-CAU-026-13 F-CAU-026-15
10. Reporting to the List and entry into force indication (timeline: as per the requirement of the ADM DTB, no later than on the 15th day of the month preceding the publication of the List)	The COO shall forward the information on the decision/fictitious decision to the ADM DTB, who shall process the information (enter the data into the information system) for the purposes of generation of the List of reimbursements of medicinal products and foods for special medical purposes. During the entry of data (implied by the decision) into the List, the procedure outlined under SP-CAU-023 shall be followed.	COO ADM DTB ASSR	e-mail SP-CAU-023
11. Dossier hand-over	The COO shall safeguard the hand-over of the dossier to the CAU S. In case of a fictitious decision, following the entry of the official record on fictitious EiF, the COO shall forward the dossier onto the archiv_CAU position.	ADM UNI COO CAU S	SSL AA
12. Delivered appeals	Delivered appeals shall be forwarded from the mail room to the APC S; the ADM SECR shall inform the APC M, who shall appoint the APC COO to whom the dossier shall be transferred and who shall process the appeal (authorised COO). The authorised COO shall inform	APC COO APC M ADM SECR	email SSL AA

	the STP ASSR and COO of the delivery of the appeal. Thereafter, the procedure outlined under SP-CAU-030 shall follow.		

Any documents published on the Notice Board shall bear not only a certified electronic signature, but also a timestamp.

7. ANNEXES

Annex 1: Similar Product Assessment
Annex 2: Flow Chart

SIMILAR PRODUCT ASSESSMENT

A similar product shall mean the concerned medicinal product in respect of which the application has been filed.

A model product shall mean a reimbursed medicinal product to which the concerned product is similar.

The Similar Product Assessment shall be conducted with a view to the effective enforceable values.

The Similar Product Assessment shall be always carried out with regard to the status at the time of issuance of the decision/fictitious decision date.

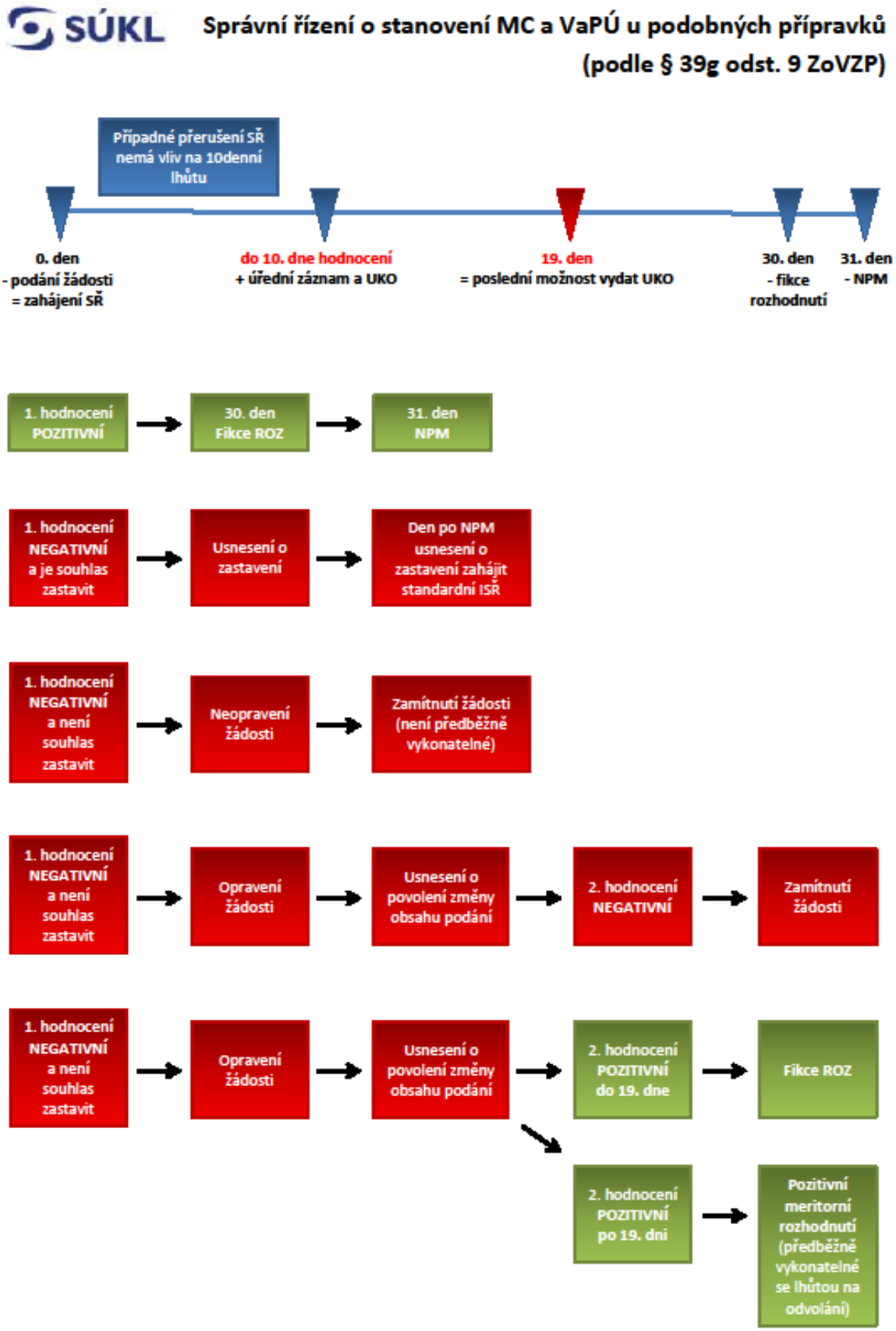
The Similar Product Assessment shall be conducted by the ASSR referring to chapter 6, step 4 hereof.

Assessed criterion	Specification
1. Identical active substance	The model and similar medicinal products have an identical active substance
2. Replaceability	Inclusion into the sale reference group/group of mutually replaceable medicinal products.
3. Identical indications	Comparison of indications as per SPCs. Where not all common indications have been identified, possible impact upon the assessment of replaceability and conditions of reimbursement as per steps 2 and 6.
4. Identical or similar pharmaceutical form	An assessment as to whether an identical or similar pharmaceutical form is concerned.
	The applicant does not need to assimilate to the "closest" pharmaceutical form, it is possible to assimilate to any similar pharmaceutical from.
	The Institute shall not change the closest model medicinal product from the applicant´s proposal as the Act mentions a similar pharmaceutical form rather than an identical one.
5. Reference group	Inclusion into the reference group as per Decree No 384/2007 Coll.
	The active substance has been included in a reference group: If the active substance has been newly included in a reference group in compliance with Decree No 384/2007 Coll., and no revision which would classify it in this manner has been completed to date, the medicinal product shall still be included in the reference group.
	The active substance has not been included in a reference group: If the reference group has not been newly included in the Decree, the similar medicinal product shall not be included in the reference group, even if the model product has been included in an old reference group.
6. Correct identification of the closest model product by the applicant	Use of the List of reimbursed medicinal products (selection within the scope of a group of therapeutically replaceable medicinal products, identical active substances and pharmaceutical forms)
	The closest model product shall be considered to be: - A product of identical strength and pack size. Where no such product exists, then: - A product of identical strength and different pack size. The closest possible pack size shall be decisive. Where 2 products meet the criteria, then the decisive product shall be the one with a smaller pack size. Where no such product exists, then: - A product of a different strength and identical/different pack size. The

	closest possible strength/pack size shall be decisive. Where 2 products meet the criteria, the decisive product shall be the one with the lower strength/smaller pack size.
	The Institute shall always select the proper model medicinal product with a view to the strength and size of the assessed similar medicinal product, regardless of what model product is proposed by the applicant, and the similar medicinal products shall be assessed in relation to the proper model medicinal product.
7. Is it the first similar medicinal product?	As referred to by the provision of Section 39b, paragraph 4 of the PHI Act
8. The tradability liability has been provided	The first similar product in a reference group – the liability is required in compliance with the provision of Section 15, paragraph 6(e) of the PHI Act.
	If it is the first similar medicinal product in the reference group and the liability has not been provided – negative assessment, conversion to an IAP is not possible, as without the liability it is not possible to determine the amount and conditions of reimbursement for the medicinal product. The liability may be provided during the course of the entire administrative procedure until the issue of the DEC.
9. Maximum price proposal	The proposal shall be identical to or lower than the maximum price of the model medicinal product. In case of an application submitted pursuant to the provision of Section 39a, paragraph 4 of the PHI Act (application for MP reduction), the currently effective enforceable price of the concerned medicinal product shall be compared to the newly proposed maximum price.
	Conversion to other sizes/strength: Applying the procedure outlined under Section 6 of Decree No 376/2011 Coll. The price of the model medicinal product shall be recalculated to the strength and pack size corresponding to the assessed medicinal product, arithmetically via the number of usual daily therapeutic doses (UDTD) in the pack. MAX ex-factory price (MAXCV) = $MAXCV_{model\ MedP}$/number of $UDTD_{model\ MedP}$*number of $UDTD_{similar\ MedP}$
10. Proposal of reimbursement per pack	The proposal shall be identical to or lower than the amount of reimbursement of the model medicinal product.
	<u>Conversion to other sizes:</u> Arithmetically from the closest pack size: Core reimbursement (JUHR) = $JUHR_{model\ MedP}$/number of $units_{model\ MedP}$*number of $units_{similar\ MedP}$ <u>Conversion to other strengths:</u> Using the procedure outlined by Sections 19-21 of Decree No 376/2011 Coll., the reimbursement of the model medicinal product shall be recalculated to the strength and pack size corresponding to the assessed medicinal product. If the result is identical (after the following point is taken into account, if applicable) to the applicant´s proposal, positive assessment may be issued. 1. The core basic reimbursement shall be calculated from the basic reimbursement if this has been determined pursuant to the old version of the Act effective until 30 November 2011. 2. Thereafter, reimbursement for the respective strength shall be calculated from the core basic reimbursement. 3. Thereafter, reimbursement per pack (JUHR) shall be calculated from this reimbursement.
11. Proposal of conditions of reimbursement	The proposed conditions may be identical or restricted compared to the conditions of the model medicinal product.
	Conditions of reimbursement which have not been described in effective

	legislation must not be applied, e.g. in cases where conditions of reimbursement as per legislation effective until 30 November 2011 apply to the model medicinal product.

FLOW CHART


SÚKL
Správní řízení o stanovení MC a VaPÚ u podobných přípravků
(podle § 39g odst. 9 ZoVZP)
Případné přerušení SŘ nemá vliv na 10denní lhůtu
0. den
- podání žádosti
= zahájení SŘ
do 10. dne hodnocení
+ úřední záznam a UKO
19. den
= poslední možnost vydat UKO
30. den
- fikce rozhodnutí
31. den
- NPM
1. hodnocení POZITIVNÍ
30. den Fikce ROZ
31. den NPM
1. hodnocení NEGATIVNÍ a je souhlas zastavit
Usnesení o zastavení
Den po NPM usnesení o zastavení zahájit standardní ISŘ
1. hodnocení NEGATIVNÍ a není souhlas zastavit
Neopravení žádosti
Zamítnutí žádosti (není předběžně vykonatelné)
1. hodnocení NEGATIVNÍ a není souhlas zastavit
Opravení žádosti
Usnesení o povolení změny obsahu podání
2. hodnocení NEGATIVNÍ
Zamítnutí žádosti
1. hodnocení NEGATIVNÍ a není souhlas zastavit
Opravení žádosti
Usnesení o povolení změny obsahu podání
2. hodnocení POZITIVNÍ do 19. dne
Fikce ROZ
2. hodnocení POZITIVNÍ po 19. dni
Pozitivní meritorní rozhodnutí (předběžně vykonatelné se lhůtou na odvolání)

Legend:

Administrative procedure for determination of maximum price and amounts and conditions of reimbursement for similar products (pursuant to Section 39g, paragraph 9 of the PHI Act)

	Potential suspension of AP does not affect the 10-day timeline				
Day 0 – submission of the application = AP commencement	By day 10 of the assessment + official record and END	Day 19 = the latest chance to issue END	Day 30 – fictitious decision	Day 31 - EiF	
1st assessment POSITIVE	Day 30 Fictitious DEC	Day 31 EiF			
1st decision NEGATIVE and agreement to stop	Decision to stop the procedure	Day after EiF of the decision to stop the procedure, standard IAP shall commence			
1st decision NEGATIVE and no agreement to stop	Non-amendment of the application	Application declined (not provisionally enforceable)			
1st decision NEGATIVE and no agreement to stop	Amendment of the application	Decision on permission to change the content of the submission	2nd assessment NEGATIVE	Application declined	
1st decision NEGATIVE and no agreement to stop	Amendment of the application	Decision on permission to change the content of the submission	2nd application POSITIVE By Day 19	Fictitious DEC	
			2nd application POSITIVE After Day 19	Positive substantive decision (provisionally enforceable with a timeline for appeals)	