Legend

AMZV	Medicinal products authorisations ordinance
CHM	Complementary and herbal medicines
Doc OK	Documentation OK, formal aspects (milestone)
Eval. I / II	Evaluation phase I / II
Fast-track	Fast-track authorisation procedure
HUM	Human medicine
LoQ	List of Questions
MP	Medicinal product
MUMS	Minor Use / Minor Species
MP	Medicinal product
NA	New application
New API	New active pharmaceutical ingredient
Official dec	Official decision
Prelim. dec.	Preliminary decision (legal hearing)
TCM	Traditional Chinese medicine
VAM	Medicinal products ordinance
VAZV	Ordinance on the simplified authorisation and authorisation of medicinal products, notification procedure
VET	Veterinary medicine
	products, notification procedure

Unless stated otherwise, the time limits apply to applications for human, veterinary and complementary and herbal medicines!

Meetings

Scientific Advice Meeting and Presubmission Meeting

Examination of the meeting request by Swissmedic	Usually within 2 to 4 weeks of receipt of the meeting request
Meeting date	Usually within 4 to 8 weeks of receipt of the meeting request
Examination by Swissmedic of the minutes submitted by the applicant	Usually within 2 weeks of receipt of the minutes

Clarification Meeting

Submission of the meeting request	Within 2 weeks of receipt of the List of Questions
Examination of the meeting request by Swissmedic	Usually within 1 to 2 weeks of receipt of the meeting request
Meeting date	Usually within 3 to 6 weeks of receipt of the meeting request
Examination by Swissmedic of the minutes submitted by the applicant	Usually within 2 weeks of receipt of the minutes

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Requests

Time limit categories / application types	Swissmedic: formal control	Firm: correction of doc if formal objection	Swissmedic: Eval. I	Firm: Answer to LoQ	Swissmedic: Eval II	Firm: Answer to prelim. dec	Swissmedic: eval. answer to prelim. dec	Total Applicant time	Total Swissmedic time
Clarification re. application for fast-track	5	30	25	n.a.	n.a.	30	20 - 90[1]	30	50 - 120[1]
Clarification re. application for MUMS Status	30	60	30	n.a.	n.a.	90	30	150	90
Clarification re. Application for Orphan Drug status	30	120	90	90	60	90	30	300	210

[1] Depending on the respective review workload and the volume of the submitted documentation, a time limit of 20–90 CD is required for reviewing the statement in response to the preliminary decision.

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First authorisations and major variations

Time limit categories / application types	Swissmedic: formal control	Firm: correction of doc if formal objection	Swissmedic: Eval. I	Firm: Answer to LoQ	Swissmedic: Eval II	Firm: Answer to prelim. dec[2]	Swissmedic: eval. answer to prelim. dec	Total Applicant time	Total Swissmedic time
New applications	30	120	120	90	90	90	90	300	330
NA new API MP in accordance with Art. 12, para. 4, VAZV / Biosimilars									
NA Parallel import									
NA CHM: with/without indication, reduced dossier, master dossier, firm base dossier, TCM quality doc.									
With prior notification: NA new API and additional indications	10	10	100	90	90	90	64	190	264
NA Cough sweets (without LoQ)	30	120	90	n.a.	n.a.	90	90	210	210
Major variations	30	120	120	90	90	90	90	300	330
Major variations in accordance with Annex 9 AMZV									
Major variation manufacturing process API for MP , in acc. with Art. 12, para. 4, VAZV									
NA Authorisation with time limit	5	120	65	90	50	90	20	300	140
Fast-track authorisation procedure	5	120	65	90	50	90	20	300	140
Fast-track for NA new API / known API (incl. MP in acc. with Art. 12, para. 4, VAZV) / Biosimilars									
Fast-track for major variations in accordance with Annex 9, AMZV, fast-track									
NA Co-marketing	30	120	30	30	30	30	30	180	120
Evaluation of fulfilment of conditions (stated in official decision)	30	120	120	90	90	90	90	300	330
CHM product notification (incl. extensions)	30	120	210	n.a.	n.a.	90	90	210	330
NA VET. notification procedure	30	60	60	n.a.	n.a.	60	30	120	120

[2] During the pilot phase of the "Optimisation of labelling phases" package of measures (Swissmedic Journal 07/2017), a maximum time limit of 60 CD will apply to new applications and major variations for the evaluation phase of "Replying to a preliminary decision". Applications to extend the time limits may be submitted.

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Variations

Time limit categories / application types	Swissmedic: formal control	Firm: correction of doc if formal objection	Swissmedic: Eval. I	Firm: Answer to LoQ	Swissmedic: Eval II	Firm: Answer to prelim. dec	Swissmedic: eval. answer to prelim. dec	Total Applicant time	Total Swissmedic time
Variations requiring approval	30	120	120	60	60	90	60	270	270
Variations requiring approval with scientific assessment in accordance with Annex 7, Sect. 2 AMZV* (except for safety-relevant variations)									
Other variations with scientific assessment: change to dispensing category									
Variation CHM: firm basis dossier, reduced dossier, master dossier, adjustment of HAS list									
Other variations without scientific evaluation: discontinuation of distrib. dosage strength number (formerly sequence), discontinuation of target species, change of details on container / packaging elements, changes to cough sweets notification procedure, change of co-marketing authorisation to own authorisation (with/without doc.)	30	120	60	n.a.	n.a.	90	60	210	150
* For list of quality variations requiring approval see form *Quality variations requiring approval*									
Safety-relevant change to product information	5	10	35	n.a.	n.a.	30	20	30	60
Variation, notification procedure	n.a.	n.a.	30	n.a.	n.a.	n.a.	n.a.	0	30
Variation requiring notification in accordance with Annex 8, AMZV									
Notification procedure authorisation sample pack									

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Extension, renewal of authorisation and discontinuation of product

Time limit categories / application types	Swissmedic: formal control (doc OK, formal objection)	Firm: correction of doc if formal objection	Swissmedic: Eval. I (LoQ)	Firm: Answer to LoQ	Swissmedic: Eval II (prelim. dec.)	Firm: Answer to prelim. dec	Swissmedic: eval. answer to prelim. dec (official dec.)	Total Applicant time	Total Swissmedic time
Extension of authorisation	30	10	60	n.a.	n.a.	30	60	40	150
Extension of authorisation with time limit	10	10	25	n.a.	n.a.	10	15	20	50
Renewal of authorisation	30	120	60	n.a.	n.a.	90	60	210	150
Discontinuation of authorisation for product	10	10	20	n.a.	n.a.	10	20	20	50
Notification in accordance with Art. 8a, VAM (No marketing / interruption to distribution)	n.a.	n.a.	30	n.a.	n.a.	n.a.	n.a.	0	30

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Change history

At least the latest version change is visible: the numbering may therefore not begin with version 01

Version	Valid and binding as of:	Modified without version change	Description, comments (by author)	Author's initials
07	**01.10.17**		• **Various applications without LoQ: Swissmedic review time limits now presented in Rev I instead of Rev II** • **NA for temporary authorisation: Harmonisation of time limit patterns with "Fast-track authorisation procedure"** • **FTP application, new reference in footnote: "Depending on the respective review workload and the volume of the submitted documentation, a time limit of 20–90 CD is required for reviewing the statement in response to the preliminary decision."** • **First authorisations and major variations, new reference in footnote: "During the pilot phase of the "Optimisation of labelling phases" package of measures (Swissmedic Journal 07/2017), a time limit of 60 CD applies to new applications and major variations for the review phase for a "Reply to a preliminary decision".** • **Other applications: Minimal (5 CD) redistribution of time limits for the Swissmedic review phases with unchanged or reduced Swissmedic total time.**	**dts**
		10.07.17	Converting the Directory in Word 2013	tsj
06	**18.09.14**		**The Directory Time limits for authorisation applications has been adapted as a result of the modification of the information sheet "Explanations regarding fast-track authorisation procedure".**	**er, apk**

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