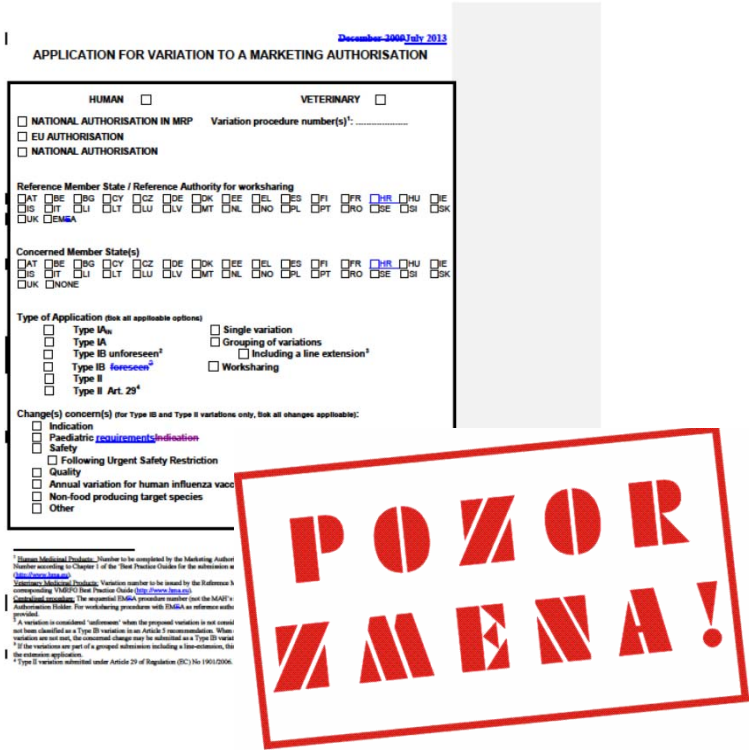
ŽÁDOST O ZMĚNU REGISTRACE

Bc. Tereza Havelková
Oddělení administrativní podpory

OSNOVA:

- Nový formulář žádosti a požadavky na formát dokumentace
- První strana žádosti – druh registrace a změny
- Typ změny a datum implementace
- Strana z klasifikačního pokynu
- Příklady
- Odkazy

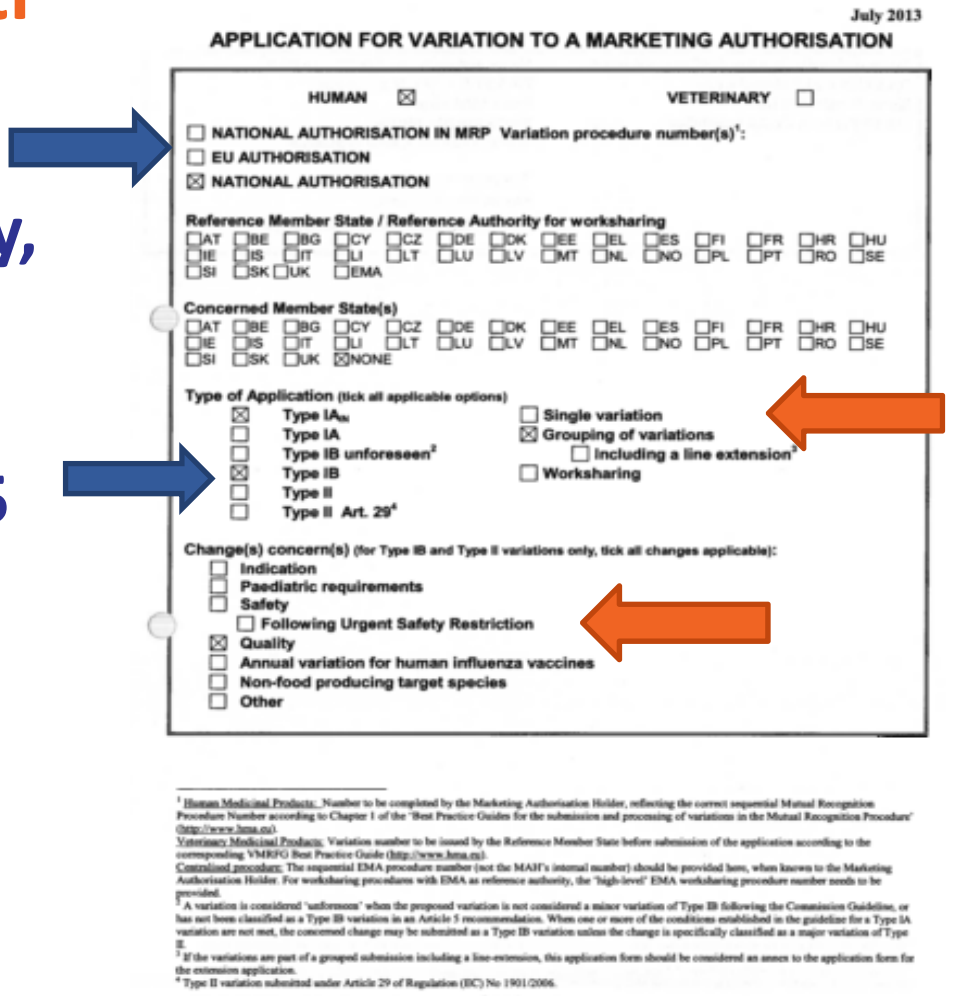
Žádost o změnu – nová AF a formát dokumentace:



- Od 1.1.2014 SÚKL akceptuje předkládanou dokumentaci pouze ve formátu eCTD a NeeS
- http://www.sukl.cz/leciva/v-jakem-formatu-ma-byt-od-novely-registracni-vyhlasky?highlightWords=ectd

Úvodní strana žádosti

Jako unforeseen se označují pouze IB změny, jejichž klasifikace není určena pokynem ani doporučením k Article 5



July 2013

APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION

HUMAN ☒ VETERINARY ☐

☐ NATIONAL AUTHORISATION IN MRP Variation procedure number(s)[1]:
☐ EU AUTHORISATION
☒ NATIONAL AUTHORISATION

Reference Member State / Reference Authority for worksharing
☐AT ☐BE ☐BG ☐CY ☐CZ ☐DE ☐DK ☐EE ☐EL ☐ES ☐FI ☐FR ☐HR ☐HU
☐IE ☐IS ☐IT ☐LI ☐LT ☐LU ☐LV ☐MT ☐NL ☐NO ☐PL ☐PT ☐RO ☐SE
☐SI ☐SK ☐UK ☐EMA

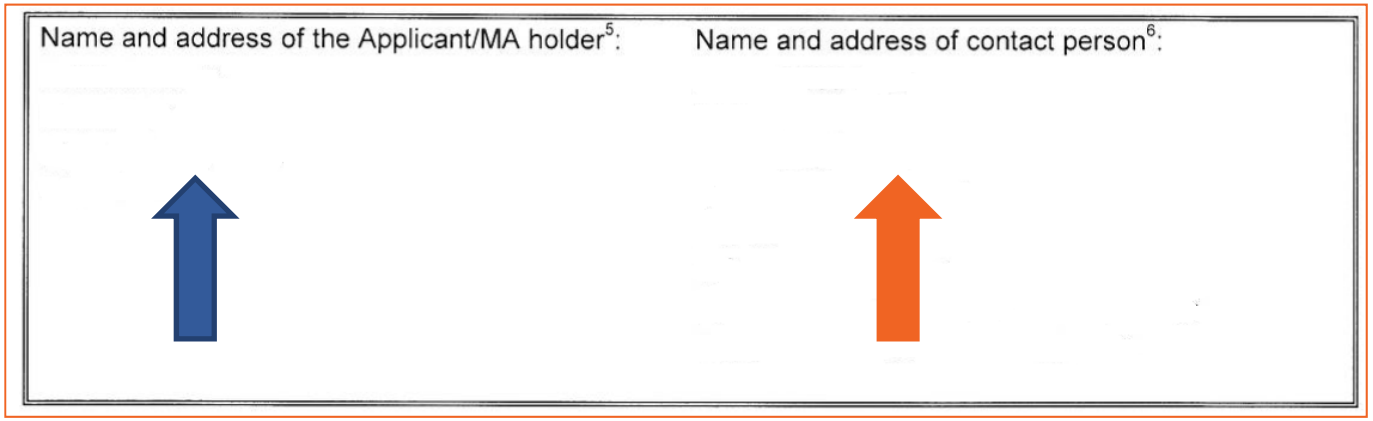
Concerned Member State(s)
☐AT ☐BE ☐BG ☐CY ☐CZ ☐DE ☐DK ☐EE ☐EL ☐ES ☐FI ☐FR ☐HR ☐HU
☐IE ☐IS ☐IT ☐LI ☐LT ☐LU ☐LV ☐MT ☐NL ☐NO ☐PL ☐PT ☐RO ☐SE
☐SI ☐SK ☐UK ☒NONE

Type of Application (tick all applicable options)
☒ Type IA$_{MI}$
☐ Type IA
☐ Type IB unforeseen[2]
☒ Type IB
☐ Type II
☐ Type II Art. 29[4]
☐ Single variation
☒ Grouping of variations
☐ Including a line extension[3]
☐ Worksharing

Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable):
☐ Indication
☐ Paediatric requirements
☐ Safety
☐ Following Urgent Safety Restriction
☒ Quality
☐ Annual variation for human influenza vaccines
☐ Non-food producing target species
☐ Other

[1] Human Medicinal Products: Number to be completed by the Marketing Authorisation Holder, reflecting the correct sequential Mutual Recognition Procedure Number according to Chapter 1 of the "Best Practice Guides for the submission and processing of variations in the Mutual Recognition Procedure" (http://www.hma.eu).
Veterinary Medicinal Products: Variation number to be issued by the Reference Member State before submission of the application according to the corresponding VMRFG Best Practice Guide (http://www.hma.eu).
Centralised procedure: The sequential EMA procedure number (not the MAH's internal number) should be provided here, when known to the Marketing Authorisation Holder. For worksharing procedures with EMA as reference authority, the "high-level" EMA worksharing procedure number needs to be provided.
[2] A variation is considered "unforeseen" when the proposed variation is not considered a minor variation of Type IB following the Commission Guideline, or has not been classified as a Type IB variation in an Article 5 recommendation. When one or more of the conditions established in the guideline for a Type IA variation are not met, the concerned change may be submitted as a Type IB variation unless the change is specifically classified as a major variation of Type II.
[3] If the variations are part of a grouped submission including a line-extension, this application form should be considered an annex to the application form for the extension application.
[4] Type II variation submitted under Article 29 of Regulation (EC) No 1901/2006.

MAH a kontaktní osoba



- Kromě MAH by měla být v žádosti uvedena i kontaktní osoba s platným pověřením
- Osoba s platným pověřením by měla jednat i v případě doplňování či opravy již podané dokumentace

Klasifikace a typ změny:

TYPE(S) of CHANGE(S)

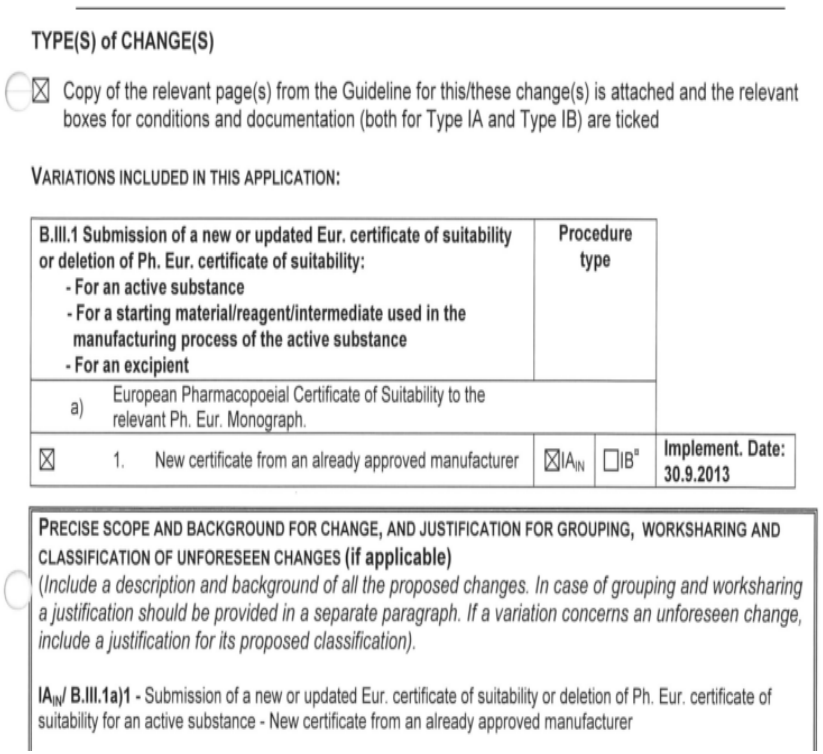
☒ Copy of the relevant page(s) from the Guideline for this/these change(s) is attached and the relevant boxes for conditions and documentation (both for Type IA and Type IB) are ticked

VARIATIONS INCLUDED IN THIS APPLICATION:

C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006		Procedure type	
☐ a)	Implementation of wording agreed by the competent authority	☐IA_{IN}	☐IB^{a}
☐ b)	Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH	II	
☒ z)	Other variation	☐IA ☒IB ☐II	☒ Art 5 Implement. Date:

- Důležité vyznačit jak klasifikaci, tak i typ změny
- V případě klasifikace podle Article 5 zaškrtnout příslušné políčko

Datum implementace u IA/IAin:



TYPE(S) of CHANGE(S)

☒ Copy of the relevant page(s) from the Guideline for this/these change(s) is attached and the relevant boxes for conditions and documentation (both for Type IA and Type IB) are ticked

VARIATIONS INCLUDED IN THIS APPLICATION:

B.III.1 Submission of a new or updated Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: - For an active substance - For a starting material/reagent/intermediate used in the manufacturing process of the active substance - For an excipient				Procedure type
a)	European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph.			
☒	1. New certificate from an already approved manufacturer	☒ IA_{IN}	☐ IB*	Implement. Date: 30.9.2013

PRECISE SCOPE AND BACKGROUND FOR CHANGE, AND JUSTIFICATION FOR GROUPING, WORKSHARING AND CLASSIFICATION OF UNFORESEEN CHANGES **(if applicable)**

(Include a description and background of all the proposed changes. In case of grouping and worksharing a justification should be provided in a separate paragraph. If a variation concerns an unforeseen change, include a justification for its proposed classification).

IA_{IN}/ B.III.1a)1 - Submission of a new or updated Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability for an active substance - New certificate from an already approved manufacturer

- Datum implementace ve formátu dd/mm/rrrr
- IA: podání změn do 1 roku od implementace (pokud podání později → IB)
- IAin: podání změny neprodleně od implementace (cca do 14 dní) – **od 1.1.2014 bude vyžadováno (pokud podání později → IB**)
- V případě groupingu do popisu změny též odůvodnění pro grouping

Datum implementace u IB a II:

The following amended product information proposals are provided in the relevant sections of the EU-CTD format or NTA volume 6B format, where applicable:

Declaration of the Applicant:
I hereby submit a notification/application for the above Marketing Authorisation(s) to be varied in accordance with the proposals given above. I declare that (*Please tick the appropriate declarations*):

- ☒ There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel);
- ☒ Where applicable, all conditions as set for the variation(s) concerned are fulfilled;
- ☒ For type IA notifications: the required documents as specified for the changes concerned have been submitted;
- ☒ Where applicable, national fees have been paid;
- ☐ This notification/application has been submitted simultaneously in RMS and all CMSs *(for products within the Mutual Recognition Procedure and worksharing)* or both to EMA and (Co-) Rapporteur *(for products within the Centralised Procedure) or, in case of worksharing involving the EMA, to the relevant National Competent Authorities and/or RMS/CMS (as applicable) and the EMA;*
- ☐ For worksharing or grouped variations affecting more than one MA: the MAs concerned belong to the same MAH.

Change(s) will be implemented from[14]: ☒ Next production run/next printing
☐ Date: _____

- Next production run/next printing

- Date: Upon approval
- Date: 11.12.2013

- Date: within 6 months after approval

Druhy textů:

- Pokud se změna projeví v textech, měly by být vyznačeny

The following amended product information proposals are provided in the relevant sections of the EU-CTD format or NTA volume 6B format, where applicable:

- ☒ Summary of Product Characteristics
- ☐ Manufacturing Authorisation Holder responsible for batch release and conditions of the Marketing Authorisation[10]
- ☐ Labelling
- ☒ Package leaflet
- ☐ Mock-ups[11]
- ☐ Specimens[11]

Strana z klasifikačního pokynu:

- Měla by být přiložena ke každé změně, nejlépe jako součást žádosti
- Viditelně vyznačit relevantní podmínky a dokumentaci

A.7 Deletion of manufacturing sites (including for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier).	Conditions to be fulfilled	Documentation to be supplied	Procedure type
	1, 2	1, 2	IA
Conditions			
☒1. There should at least remain one site/manufacturer, as previously authorised, performing the same function as the one(s) concerned by the deletion.			
☒2. The deletion should not be due to critical deficiencies concerning manufacturing.			
Documentation			
☒1. The variation application form should clearly outline the "present" and "proposed" manufacturers as listed in section 2.5 of the (Part IA) application form.			
☒2. Amendment of the relevant section(s) of the dossier (presented in the EU-CTD format or NTA volume 6B format for veterinary products, as appropriate), including revised product information as appropriate.			

Příklady

Grouping:

- Pokud žádost obsahuje několik změn stejné klasifikace, mělo by to být na žádosti jasně vyznačené

3x

B.III.1 Submission of a new or updated Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: - For an active substance - For a starting material/reagent/intermediate used in the manufacturing process of the active substance - For an excipient			Procedure type		
a)	European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph.				
☐	1.	New certificate from an already approved manufacturer	☐IA_{IN}	☐IB*	Implement. Date:
☒*	2.	Updated certificate from an already approved manufacturer	☒IA	☐IB*	Implement. Date: 31.03.2013

1x

B.I.d.1 Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier			Procedure type		
a)	Re-test period/storage period				
☐	1.	Reduction	☐IA	☐ IB*	Implement. Date:
☐	2.	Extension of the retest period based on extrapolation of stability data not in accordance with ICH/VICH guidelines*	II		
☐	3.	Extension of storage period of a biological/ immunological active substance not in accordance with an approved stability protocol	II		
☒	4.	Extension or introduction of a re-test period/storage period supported by real time data	IB		

PRECISE SCOPE AND BACKGROUND FOR CHANGE, AND JUSTIFICATION FOR GROUPING, WORKSHARING AND CLASSIFICATION OF UNFORESEEN CHANGES (if applicable)

(Include a description and background of all the proposed changes. In case of grouping and worksharing a justification should be provided in a separate paragraph. If a variation concerns an unforeseen change, include a justification for its proposed classification)

Submission of new CEPs for the active substances prednisolone, estradiol benzoate and salicylic acid.

- Submission of an updated Ph. Eur. Certificate of Suitability from the already approved manufacturer [redacted]
- According to the new documentation from the manufacturer of the active substance [redacted] we want to extend the re-test period of 60 months supported by real time data
- Submission of an updated Ph. Eur. Certificate of Suitability from the already approved manufacturer [redacted] Even though the CEP mentions a new company [redacted] as manufacturer, this is only an administrative change and the manufacturer remains the same
- Submission of an updated Ph. Eur. Certificate of Suitability from the already approved manufacturer [redacted] Also the address of [redacted] has changed

Justification for the grouping:

Article 7(2)(a) of the Variations Regulation sets out the possibility for a MAH to group several type-IA or -IA_{IN} variations under a single notification to the same relevant authority, or to group them with other types of variation.

Grouping II:

- Jedna změna pro více registračních čísel – stejná klasifikace i totožná změna (obsah)

- Změna B.II.b.1 a) pro 2 LP:
- LP 1:

přidání místa výroby „XXX“ 

- LP 2:

přidání místa výroby „YYY“ 

- → nutné podat pro každý LP zvlášť

Typ změny:

- Je důležité vyznačit i typ změny, nejen klasifikaci

VARIATIONS INCLUDED IN THIS APPLICATION:

Change no. 1:

		B.III.1 Submission of a new or updated Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: - For an active substance - For a starting material/reagent/intermediate used in the manufacturing process of the active substance - For an excipient	Procedure type		
	a)	European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph.			
☒	1.	New certificate from an already approved manufacturer	☐IA_{IN}	☐IB*	**Implement. Date:** October 15, 2013
☐	2.	Updated certificate from an already approved manufacturer	☐IA	☐IB*	Implement. Date:
☐	3.	New certificate from a new manufacturer (replacement or addition)	☐IA_{IN}	☐IB*	Implement. Date:
☐	4.	Deletion of certificates (in case multiple certificates exist per material)	☐IA	☐IB*	
☐	5.	New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free	IB		
	b)	European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient			
☐	1.	New certificate for an active substance from a new or an already approved manufacturer	☐IA_{IN}	☐IB*	Implement. Date:
☐	2.	New certificate for a starting material/reagent/ intermediate/or excipient from a new or an already approved manufacturer	☐IA	☐IB*	Implement. Date:
☐	3.	Updated certificate from an already approved manufacturer	☐IA	☐IB*	Implement. Date:
☐	4.	Deletion of certificates (in case multiple certificates exist per material)	☐IA	☐IB*	
☐	5.	New/updated certificate from an already-approved/new manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agents is required	II		
☐	z)	Other variation	☐IA ☐IB ☐II		☐ Art 5 Implement. Date:

* If one of the conditions is not met and the change is not specifically listed as Type II.

Typ změny:

- Je nutné vyplnit typ změny výše, v tabulce s požadavky na dokumentaci není místo k vyplnění některých údajů

TYPE(S) of CHANGE(S)

☐ Copy of the relevant page(s) from the Guideline for this/these change(s) is attached and the relevant boxes for conditions and documentation (both for Type IA and Type IB) are ticked

VARIATIONS INCLUDED IN THIS APPLICATION:

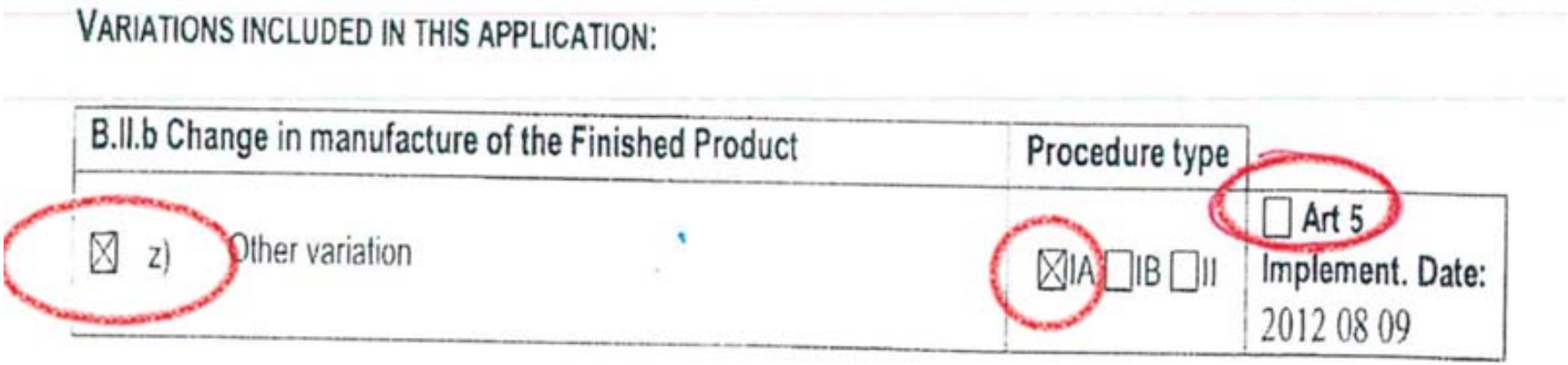
Number and title of variation, as per the classification guideline	Procedure type
☒ a) Specific variation applied for, as per the classification guideline	type

*(**Select and include** in this section the applicable variation(s) from the list presented at the end of this application form template (see detailed instructions provided with the list). The above example and the list of variations at the end of the form should subsequently be deleted from the completed form to be submitted).*

B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product	Conditions to be fulfilled	Documentation to be supplied	Procedure type
☐ a) Secondary packaging site	1, 2	1,3, 8	IAIN
☐ b) Primary packaging site	1, 2, 3, 4, 5	1, 2, 3, 4, 8, 9	IAIN
☐ c) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes			II
☐ d) Site which requires an initial or product specific inspection			II
☒ e) Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products		1, 2, 3, 4, 5, 6, 7, 8, 9	IB
☐ f) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/		1, 2, 3, 4, 5, 6, 7, 8	IB

Klasifikace podle Article 5:

- Změny IA se klasifikují jako „z“ pouze na základě Article 5



VARIATIONS INCLUDED IN THIS APPLICATION:

B.II.b Change in manufacture of the Finished Product	Procedure type	
☒ z) Other variation	☒IA ☐IB ☐II	☐ Art 5 Implement. Date: 2012 08 09

Nesplnění podmínky pro určenou klasifikaci:

- **Pokud jedna z podmínek pro změnu IA není splněna (včetně pozdějšího podání), klasifikuje se defaultně jako změna IB (foreseen)**

- change in the batch size (including batch size ranges) of the finished product - B.II.b.4.a, this is a minor type IA variation, but as one of the conditions is not met we are classifying it as Type IB (foreseen.)

Chybně:

B.II.b.4 Change in the batch size (including batch size ranges) of the finished product	Procedure type	
☒ z) Other variation	☐IA ☒IB ☐II	☐ Art 5 Implement. Date:

Správně:

B.II.b.4 Change in the batch size (including batch size ranges) of the finished product	Procedure type	
☒ a) Up to 10-fold compared to the originally approved batch size	☐IA ☒IB ☐II	☐ Art 5 Implement. Date:

Doporučení klasifikace – certifikát shody nového výrobce:

Certifikát shody nového výrobce obsahuje schválenou dobu reatestace:

VARIATIONS INCLUDED IN THIS APPLICATION:

B.III.1 Submission of a new or updated Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: - For an active substance - For a starting material/reagent/intermediate used in the manufacturing process of the active substance - For an excipient				Procedure type	
a)	European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph.				
☒	3.	New certificate from a new manufacturer (replacement or addition)	☒IA$_{IN}$	☐IB[a]	Implement. Date: 13.02.2013

[a] If one of the conditions is not met and the change is not specifically listed as Type II.

Certifikát shody nového výrobce neobsahuje schválenou dobu reatestace:

Grouping IA/B.III.1. a) 3 + IB/B.I.d.1 a) 4

B.I.d.1 Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier			Procedure type		
a)	Re-test period/storage period				
☐	1.	Reduction	☐IA	☐IB[a]	Implement. Date:
☐	2.	Extension of the retest period based on extrapolation of stability data not in accordance with ICH/VICH guidelines*	II		
☐	3.	Extension of storage period of a biological/ immunological active substance not in accordance with an approved stability protocol	II		
☒	4.	Extension or introduction of a re-test period/storage period supported by real time data	IB		

[a] If one of the conditions is not met and the change is not specifically listed as Type II.

Nebo podání IB/B.II.1 a) 3

Doporučení klasifikace – změna ve výrobním procesu pro tablety s prodlouženým uvolňováním

Změna ve výrobním procesu pro lékovou formu tablety s prodlouženým uvolňováním:

Pokud není splněna podmínka pro změnu typu IA, změna se podává jako typ IB, pokud není výslovně uvedena jako změna typu II (typ II uveden v pokynu, doporučení Art.5, změna má podstatný vliv na kvalitu, účinnost nebo bezpečnost přípravku)

VARIATIONS INCLUDED IN THIS APPLICATION:

B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product		Procedure type	
☒ a)	Minor change in the manufacturing process	☐IA ☒IB*	Implement. Date:
☐ b)	Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	II	
☐ c)	The product is a biological/immunological medicinal product and the change requires an assessment of comparability	II	
☐ d)	Introduction of a non-standard terminal sterilisation method	II	
☐ e)	Introduction or increase in the overage that is used for the active substance	II	
☐ f)	Minor change in the manufacturing process of an aqueous oral suspension	IB	
☐ z)	Other variation	☐IA ☐IB ☐II	☐ Art 5 Implement. Date:

* If one of the conditions is not met and the change is not specifically listed as Type II.

B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product	Conditions to be fulfilled	Documentation to be supplied	Procedure type
● a) Minor change in the manufacturing process	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7, 8	IA

Conditions		
✓	1.	No change in qualitative and quantitative impurity profile or in physico-chemical properties.
	2.	Either the change relates to an immediate release solid oral dosage form / oral solution and the medicinal product concerned is not a biological /immunological or herbal medicinal product; or the change relates to process parameter(s) that, in the context of a previous assessment, have been considered to have no impact on the quality of the finished product (regardless of the type of product and/or dosage form).
✓	3.	The manufacturing principle including the single manufacturing steps remain the same, e.g. processing intermediates and there are no changes to any manufacturing solvent used in the process.
✓	4	The currently registered process has to be controlled by relevant in-process controls and no changes (widening or deletion of limits) are required to these controls.
✓	5.	The specifications of the finished product or intermediates are unchanged.
✓	6.	The new process must lead to an identical product regarding all aspects of quality, safety and efficacy.
✓	7.	Relevant stability studies in accordance with the relevant guidelines have been started with at least one pilot scale or industrial scale batch and at least three months stability data are at the disposal of the applicant. Assurance is given that these studies will be finalised and that the data will be provided immediately to the competent authorities if outside specifications or potentially outside specifications at the end of the approved shelf life (with proposed action).

Doporučení klasifikace – změna místa výroby

Přidání/nahrazení místa výroby bulku, primárního balení/plnění a sekundárního balení u sterilního léčivého přípravku.

VARIATIONS INCLUDED IN THIS APPLICATION:

B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product		Procedure type		
☐ a)	Secondary packaging site	☐IA_{IN}	☐IB*	Implement. Date:
☒ b)	Primary packaging site	☒IA_{IN}	☐IB*	Implement. Date: 18.10.2013
☐ c)	Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products or for pharmaceutical forms manufactured by complex manufacturing processes	II		
☐ d)	Site which requires an initial or product specific inspection	II		
☐ e)	Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	IB		
☐ f)	Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for steri medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products	IB		
☐ z)	Other variation	☐IA ☐IB ☐II		☐ Art 5 Implement. Date:

B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product		Procedure type		
☐ a)	Secondary packaging site	☐IA_{IN}	☐IB*	Implement. Date:
☐ b)	Primary packaging site	☐IA_{IN}	☐IB*	Implement. Date:
☐ c)	Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products or for pharmaceutical forms manufactured by complex manufacturing processes	II		
☐ d)	Site which requires an initial or product specific inspection	II		
☐ e)	Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	IB		
☒ f)	Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for steri medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products	IB		OK ✓
☐ z)	Other variation	☐IA ☐IB ☐II		☐ Art 5 Implement. Date:

B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product		Procedure type		
☒ a)	Secondary packaging site	☒IA_{IN}	☐IB*	Implement. Date: 18.10.2013
☐ b)	Primary packaging site	☐IA_{IN}	☐IB*	Implement. Date:

OK ✓

- Změna primárního balení je obsažena ve změně B.II.B.1f)

Doporučení klasifikace – doba použitelnosti:

Zavedení doby použitelnosti přípravku po prvním otevření

- ✓ dosud v registrační dokumentaci neuvedeno
- ✓ předložení stabilitní studie (supported by real time data)

VARIATIONS INCLUDED IN THIS APPLICATION:

B.II.f.1 Change in the shelf-life or storage conditions of the finished product			Procedure type		
	a)	Reduction of the shelf life of the finished product			
☐	1.	As packaged for sale	☐IA$_{IN}$	☐IB*	Implement. Date:
☒	2.	After first opening	☒IA$_{IN}$	☐IB*	Implement. Date: 30.04.2014
☐	3.	After dilution or reconstitution	☐IA$_{IN}$	☐IB*	Implement. Date:
	b)	Extension of the shelf life of the finished product			
☐	1.	As packaged for sale (supported by real time data)	IB		
☒	2.	After first opening (supported by real time data)	IB		
☐	3.	After dilution or reconstitution (supported by real time data)	IB		
☐	4.	Extension of the shelf-life based on extrapolation of stability data not in accordance with ICH/VICH guidelines*	II		
☐	5.	Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol.	IB		
☐	c)	Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol	II		
☐	d)	Change in storage conditions of the finished product or the diluted/reconstituted product	IB		
☐	e)	Change to an approved stability protocol	☐IA	☐IB*	
☐	z)	Other variation	☐IA ☐IB ☐II		☐ Art 5 Implement. Date:

* If one of the conditions is not met and the change is not specifically listed as Type II.

Odkazy:

- Formulář žádosti
  http://ec.europa.eu/health/files/eudralex/vol-2/c/variation_form__201307_en.pdf
- Pokyny k vyplňování žádosti
  http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Variations/CMDh_133_2010_Rev6_2013_07_clean_a.pdf
- Pokyny EK
  http://ec.europa.eu/health/files/eudralex/vol-2/2013_05_16_c2804_en.pdf

Děkujeme za pozornost

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