EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 June 2014
EMA/140557/2012
Procedure Management & Business Support

Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004

Chapter 3.III: Practical Examples

Version 4.0

Date of coming into force: 16 June 2014

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Table of contents

This chapter provides practical examples illustrating how the data elements reflected in chapter 3.I and 3.II can be used.

3.III.1. Example: How to “insert” a centrally authorised medicinal product

For reference in this example, you are the marketing authorisation holder (MAH) for a centrally authorised medicinal product “Fusion 100 mg/ml powder and solvent for solution for injection”.

The Summary of Product Characteristics (SmPC) is as follows:

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Fusion 100 mg/ml powder and solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 112 mg zidovudine.

After reconstitution, each ml of solution contains 100 mg Zidovudine.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Fusion is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected patients.

4.2 Posology and method of administration

Fusion is only for subcutaneous injection.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Nucleoside and nucleotide reverse transcriptase inhibitors ATC code: J05AF01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder

Sodium carbonate

Mannitol

Solvent

Water for Injections

6.5 Nature and contents of container

Pack containing: 1 vial (of Powder) and 1.5 ml of Solvent

7. MARKETING AUTHORISATION HOLDER

MAHNEWX, 77 Westferry Circus

London E77 4HB United Kingdom

8. MARKETING AUTHORISATION NUMBER

EU/1/94/003/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06/06/1994

Date of renewal of the authorisation: 05/06/1999

10. DATE OF REVISION OF THE TEXT

07/02/2011

In addition, the following applies to the marketing authorisation:

Authorisation procedure: EU centralised procedure

Marketing Authorisation status: valid

Authorisation "country": European Union

EMA procedure number: EMEA/H/C/001234

Legal basis: Full application (Art 8(3) of Directive No 2001/83/EC) (1)

Medicinal product type: Other (7)

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Reference Section	**Ref. Code**	**Reference Name Data Element**	**M - Mandatory M* - Mandatory with conditions O - Optional**	**Example**
		Table 31. Authorised Product elements *M.AP Authorisedproduct*	**M**	
	@ AP..1	(@)operationtype	M (technical)	1 (= Insert)
	AP.1	localnumber	M* (technical)	34343434

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Section 7. Marketing Authorisation Holder	AP.4	mahcode	M (technical)	ORG5083
	@ AP.4..1	(@)resolutionmode	M (technical)	2
	AP.5	qppvcode	M (technical)	3577
	AP.6	mflcode	O	MFL282
	@ AP.6..1	(@)resolutionmode	M* (technical)	2
	AP.7	enquiryemail	M	mahnewx@info.org
	AP.8	enquiryphone	M	+44(0)20812345
	AP.9	senderlocalcode	O (technical)	123456789
	AP.10	infodateformat	O (technical)	
	AP.11	infodate	O	
	AP.14	comments	M*	
		Table 32. Authorised Product – Authorisation element ***AP.12 authorisation***	**M**	
	AP.12.1	authorisationcountrycode	M	EU
	AP.12.2	authorisationprocedure	M	1 (= EU authorisation procedures – centralised procedure)
	AP.12.3	authorisationstatus	M	1 (= Valid)
Section 8. Marketing Authorisatio	AP.12.4	authorisationnumber	M	EU/1/94/003/001

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
n Number				
Section 9. Date of first authorisation /renewal of the authorisation	AP.12.5	authorisationdate	M	19990605
	AP.12.6	authorisationdateformat	M (technical)	102 (corresponding to “CCYYMMDD”)
	AP.12.7	mrpnumber	M*	EMEA/H/C/001234
Section 8. Marketing Authorisation number	AP.12.8	eunumber	M*	EU/1/94/003/001
	AP.12.9	orphandrug	M	2 (= No)
	AP.12.10	intensivemonitoring	M	1 (= Yes)
	AP.12.11	Withdrawndateformat	M* (technical)	
	AP.12.12	Withdrawndate	M*	
	AP.12.13	legalbasis	M	1 (= Full Application (Article 8(3) of Directive No 2001/83/EC))
		Table 33. Authorisation – Medicinal Product Type elements *AP.12.MPT medicinalproducttype*		
	AP.12.MPT.1	producttypecode	M	7 (= Other)
Section 1.		**Table 34. Authorised Product –**	**M**	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Name of the medicinal product		**Presentation Name elements – *AP.13 presentationname***		
	AP.13.1	Productname	M	Fusion 100 mg/ml powder and solvent for solution for injection
	AP.13.2	Productshortname	M*	Fusion
	AP.13.3	Productgenericname	M*	
	AP.13.4	Productcompanyname	M*	
	AP.13.5	Productstrength	M*	100 mg/ml
	AP.13.6	Productform	M*	powder and solvent for solution for injection
Section 6.5 Nature and contents of container	AP.13.7	packagedesc	O	1 vial (of Powder) and 1.5 ml of Solvent
Section 2. Qualitative and quantitative composition		**Table 43. The Pharmaceutical Product – Active Ingredient element *PP.ACT activeingredient***	**M**	
	PP.ACT.1	substancecode	M (technical)	SUB00153MIG (= zidovudine)
	@ PP.ACT.1..1	(@)resolutionmode	M (technical)	2
	PP.ACT.2	concentrationtypecode	M	1 (= Equal)
	PP.ACT.3	lowamountnumervalue	M	100

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	PP.ACT.4	lowamountnumerprefix	M	Milli (1x10^-3)
	PP.ACT.5	lowamountnumerunit	M	Gram(s)
	PP.ACT.6	lowamountdenomvalue	M	1
	PP.ACT.7	lowamountdenomprefix	M	Milli (1x10^-3)
	PP.ACT.8	lowamountdenomunit	M	Litre
	PP.ACT.9	highamountnumervalue	M*	
	PP.ACT.10	highamountnumerprefix	M*	
	PP.ACT.11	highamountnumerunit	M*	
	PP.ACT.12	highamountdenomvalue	M*	
	PP.ACT.13	highamountdenomprefix	M*	
	PP.ACT.14	highamountdenomunit	M*	
		Table 35. Authorised product - Authorised Pharmaceutical Form elements ***AP.APF authpharmform***	**M**	
Section 3. Pharma-ceutical Form	AP.APF.1	authpharmformcode	M (technical)	PHF00190MIG (= Powder and solvent for solution for injection)
	@ AP.APF..1	resolutionmode	M (technical)	2
Section 3. Pharma-ceutical Form		**Table 41. The Pharmaceutical Product elements** ***AP.PP pharmaceuticalproduct***	**M**	
	PP.1	pharmformcode	M (technical)	PHF00231MIG (= solution for injection)
	@PP.1..1	(@)resolutionmode	M (technical)	2

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Section 4.2 Posology and method of admin-istration		**Table 42. The Pharmaceutical Product – Administration Route element *PP.AR adminroute***	**M**	
	PP.AR.1	adminroutecode	M (technical)	ADR00058MIG (= subcutaneous use)
	@ PP.AR.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. Pharmaceutical Product – Excipient Ingredient element *PP.EXC excipient***	**M***	
	PP.EXC.1	substancecode	M (technical)	SUB12580MIG (= Sodium carbonate)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. Pharmaceutical Product – Excipient Ingredient element *PP.EXC excipient***	**M***	
	PP.EXC.1	substancecode	M (technical)	SUB03087MIG (= Mannitol)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. Pharmaceutical Product – Excipient Ingredient element *PP.EXC excipient***	**M***	
	PP.EXC.1	substancecode	M (technical)	SUB12398MIG (= Water for injection)
	@	(@)resolutionmode	M (technical)	2

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	PP.EXC.1..1			
Section 4.1 Therapeutic indications		**Table 37. Authorised Product –Product Indication elements** ***AP.IND productindication***	**M**	
	AP.IND.1	meddraversion	M	17
	AP.IND.2	meddralevel	M	LLT (= Low Level Term)
	AP.IND.3	meddracode	M	10068341 (= HIV-1 infection)
Section 5.1 Pharmaco-dynamic properties		**Table 36. Authorised Product – ATC elements** ***AP.ATC productatc***	**M**	
	AP.ATC.1	atccode	M (technical)	J05AF01
	@ AP.ATC.1..1	(@)resolutionmode	M (technical)	2
		Table 5. Attachment elements ***ATT attachment***	**M**	
	@ ATT..1	(@)operationtype	M (technical)	The only value accepted is 1 (= Insert)
	ATT.1	localnumber	M* (technical)	121212
	ATT.2	filename	M (technical)	Fusion.doc
	ATT.3	filetype	M (technical)	2 (= DOC)
	ATT.4	attachmentname	M (technical)	Fusion SmPC
	ATT.5	attachmenttype	M (technical)	1 = Printed Product Information (PPI = SmPC)
	ATT.6	languagecode*	M (technical)	EN (= English)
	ATT.7	attachmentversion	M (technical)	1

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	ATT.8	attachmentversiondate	M (technical)	20110207
	ATT.9	versiondateformat	M (technical)	The value must be “102” for "CCYYMMDD”
		Table 40. The Authorised Product – Printed Product Information Attachment elements *AP.PPI ppiattachment*	**M**	
	AP.PPI.1	attachmentcode	M (technical)	5
	@ AP.PPI.1..1	(@)resolutionmode	M (technical)	1
	AP.PPI.2	validitydeclaration	M* (technical)	

* The language code is to be specified using the ISO 639-1 language codes

3.III.2. Example: How to “insert” a mutually recognised medicinal product

For reference in this example, you are the MAH for a mutually recognised medicinal product “ParaProfen® 200 mg/500 mg capsule et comprimé”.

The Summary of product characteristics (SmPC) is in French as follows:

1. DENOMINATION DU MEDICAMENT

ParaProfen® 200 mg/500 mg capsule et comprimé

2. COMPOSITION QUALITATIVE ET QUANTITATIVE

Chaque capsule contient 200 mg d’ibuprofène.

Chaque comprimé contient 500 mg de paracétamol.

Pour la liste complète des excipients, voir rubrique 6.1

3. FORME PHARMACEUTIQUE

Capsule

Comprimé

4. DONNEES CLINIQUES

4.1 Indications thérapeutiques

Traitement des céphalées, migraines et du mal de dos chez l’adulte et l’adolescent de plus de 15 ans.

4.2 Posologie et mode d'administration

Voie orale.

5. PROPRIETES PHARMACOLOGIQUES

5.1 Propriétés pharmacodynamiques

Code ATC: M01AE01 (Ibuprofen) et N02BE01 (paracétamol)

6. DONNEES PHARMACEUTIQUES

6.1 Liste des excipients

Capsule

croscarmellose sodique

cellulose microcristalline

Comprimé

Silice colloïdale anhydre

Stéarate de magnésium

6.5 Nature et contenu de l'emballage extérieur

Boîte de 12 capsules et 12 comprimés

7. TITULAIRE DE L'AUTORISATION DE MISE SUR LE MARCHE

MAHNEWY, 7 Cirque du soleil

20120 Paris

France

8. NUMERO(S) D'AUTORISATION DE MISE SUR LE MARCHE

7654321

9. DATE DE PREMIERE AUTORISATION / DE RENOUVELLEMENT DE L'AUTHORISATION

Date de première autorisation: 17 janvier 2011

10. DATE DE MISE À JOUR DU TEXTE

In addition, the following applies to your marketing authorisation:

Procédure d'autorisation: UE procédure de reconnaissance mutuelle

Statut de l'Autorisation de Mise sur le Marché: valide

Pays d'autorisation: France

Numéro MR: DE/H/0012/007

Base juridique: Application générique (Article 10(1) de la Directive No 2001/83/EC) (2)

Type de médicament: Autre (7)

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Reference Section	**Ref. Code**	**Reference Name Data Element**	**M - Mandatory M* - Mandatory with conditions O - Optional**	**Example**
		Table 31. Authorised Product elements *M.AP Authorisedproduct*	**M**	
	@ AP..1	(@)operationtype	M (technical)	1 (= Insert)
	AP.1	localnumber	M* (technical)	1234567

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Section 7. Marketing Authorisation Holder	AP.4	mahcode	M (technical)	ORG1234
	@ AP.4..1	(@)resolutionmode	M (technical)	2
	AP.5	qppvcode	M (technical)	3577
	AP.6	mflcode	O	
	@ AP.6..1	(@)resolutionmode	M* (technical)	
	AP.7	enquiryemail	M	mahnewy@info.org
	AP.8	enquiryphone	M	+33(0)191234567
	AP.9	senderlocalcode	O (technical)	
	AP.10	infodateformat	O (technical)	
	AP.11	infodate	O	
	AP.14	comments	M*	Medicinal product authorised for the treatment in children
		Table 32. Authorised Product – Authorisation element ***AP.12 authorisation***	**M**	
	AP.12.1	authorisationcountrycode	M	FR (The country code is to be specified using the ISO-3166)
	AP.12.2	authorisationprocedure	M	3 (= EU authorisation procedures – Mutual Recognition procedure)
	AP.12.3	authorisationstatus	M	1 (= Valid)
Section 8. Marketing	AP.12.4	authorisationnumber	M	7654321

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Authorisation number				
Section 9. Date of first authorisation/renewal of the authorisation	AP.12.5	authorisationdate	M	20110117
	AP.12.6	authorisationdateformat	M (technical)	102 (corresponding to “CCYYMMDD”)
	AP.12.7	mrpnumber	M*	DE/H/0012/007
	AP.12.8	eunumber	M*	
	AP.12.9	orphandrug	M	2 (= No)
	AP.12.10	intensivemonitoring	M	2 (= No)
	AP.12.11	withdrawndateformat	M* (technical)	
	AP.12.12	withdrawndate	M*	
	AP.12.13	legalbasis	M	2 (= Generic application (Article 10(1) of Directive No 2001/83/EC))
		Table 33. Authorisation – Medicinal Product Type elements *AP.12.MPT medicinalproducttype*		
	AP.12.MPT.1	producttypecode	M	7 (= Other)
Section 1. Name of the medicinal		**Table 34. Authorised Product – Presentation Name elements –**	**M**	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
product		***AP.13 presentationname***		
	AP.13.1	productname	M	ParaProfen® 200 mg/500 mg capsule et comprimé
	AP.13.2	productshortname	M*	ParaProfen
	AP.13.3	productgenericname	M*	
	AP.13.4	productcompanyname	M*	
	AP.13.5	productstrength	M*	200 mg/500 mg
	AP.13.6	productform	M*	capsule et comprimé
Section 6.5 Nature and contents of container	AP.13.7	packagedesc	O	Boîte de 12 capsules et 12 comprimés
Section 2. Qualitative and quantitative composition		**Table 43. The Pharmaceutical Product – Active Ingredient element *PP.ACT activeingredient***	**M**	
	PP.ACT.1	substancecode	M (technical)	SUB08098MIG (= Ibuprofène)
	@ PP.ACT.1..1	(@)resolutionmode	M (technical)	2
	PP.ACT.2	concentrationtypecode	M	1 (= Equal)
	PP.ACT.3	lowamountnumervalue	M	200
	PP.ACT.4	lowamountnumerprefix	M	Milli (1x10^-3)
	PP.ACT.5	lowamountnumerunit	M	Gram(s)
	PP.ACT.6	lowamountdenomvalue	M	1
	PP.ACT.7	lowamountdenomprefix	M	Single
	PP.ACT.8	lowamountdenomunit	M	Capsule
	PP.ACT.9	highamountnumervalue	M*	
	PP.ACT.10	highamountnumerprefix	M*	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	PP.ACT.11	highamountnumerunit	M*	
	PP.ACT.12	highamountdenomvalue	M*	
	PP.ACT.13	highamountdenomprefix	M*	
	PP.ACT.14	highamountdenomunit	M*	
		Table 35. Authorised product - Authorised Pharmaceutical Form elements ***AP.APF authpharmform***	**M**	
Section 3. Pharma-ceutical Form	AP.APF.1	authpharmformcode	M (technical)	PHF00005MIG (= Capsule)
	@ AP.APF..1	resolutionmode	M (technical)	2
Section 3. Pharma-ceutical Form		**Table 41. The Pharmaceutical Product elements** ***PP pharmaceuticalproduct***		
	PP.1	pharmformcode	M (technical)	PHF00005MIG (= Capsule)
	@PP.1..1	(@)resolutionmode	M (technical)	2
Section 4.2 Posology and method of admini-stration		**Table 42. The Pharmaceutical Product – Administration Route element** ***PP.AR adminroute***	**M**	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	PP.AR.1	adminroutecode	M (technical)	ADR00048MIG (= Oral use)
	@ PP.AR.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. Pharmaceutical Product – Excipient Ingredient element *PP.EXC excipient***	**M***	
	PP.EXC.1	substancecode	M (technical)	SUB11883MIG (= CROSCARMELLOSE SODIQUE)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. Pharmaceutical Product – Excipient Ingredient element *PP.EXC excipient***	**M***	
	PP.EXC.1	substancecode	M (technical)	SUB12635MIG (= CELLULOSE MICROCRISTALLINE)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 2. Qualitative and quantitative composition		**Table 43. The Pharmaceutical Product – Active Ingredient element *PP.ACT activeingredient***	**M**	
	PP.ACT.1	substancecode	M (technical)	SUB09611MIG (= Paracétamol)
	@ PP.ACT.1..1	(@)resolutionmode	M (technical)	2
	PP.ACT.2	concentrationtypecode	M	1 (= Equal)
	PP.ACT.3	lowamountnumervalue	M	500
	PP.ACT.4	lowamountnumerprefix	M	Milli (1x10^-3)
	PP.ACT.5	lowamountnumerunit	M	Gram(s)
	PP.ACT.6	lowamountdenomvalue	M	1

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	PP.ACT.7	lowamountdenomprefix	M	Single
	PP.ACT.8	lowamountdenomunit	M	Tablet
	PP.ACT.9	highamountnumervalue	M*	
	PP.ACT.10	highamountnumerprefix	M*	
	PP.ACT.11	highamountnumerunit	M*	
	PP.ACT.12	highamountdenomvalue	M*	
	PP.ACT.13	highamountdenomprefix	M*	
	PP.ACT.14	highamountdenomunit	M*	
		Table 35. Authorised product - Authorised Pharmaceutical Form elements *AP.APF authpharmform*	**M**	
Section 3. Pharma-ceutical Form	AP.APF.1	authpharmformcode	M (technical)	PHF00245MIG (= Comprimé)
	@ AP.APF..1	resolutionmode	M (technical)	2
Section 3. Pharma-ceutical Form		**Table 41. The Pharmaceutical Product elements *PP pharmaceuticalproduct***		
	PP.1	pharmformcode	M (technical)	PHF00245MIG (= Comprimé)
	@PP.1..1	(@)resolutionmode	M (technical)	2
Section 4.2		**Table 42. The**	**M**	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Posology and method of admini-stration		**Pharmaceutical Product – Administration Route element** ***PP.AR adminroute***		
	PP.AR.1	adminroutecode	M (technical)	ADR00048MIG (= Oral use)
	@ PP.AR.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. Pharmaceutical Product – Excipient Ingredient element** ***PP.EXC excipient***	**M***	
	PP.EXC.1	substancecode	M (technical)	SUB12277MIG (= Silice colloïdale anhydre)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. Pharmaceutical Product – Excipient Ingredient element** ***PP.EXC excipient***	**M***	
	PP.EXC.1	substancecode	M (technical)	SUB12527MIG (= Stéarate de magnésium)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 4.1 Therapeutic indications		**Table 37. Authorised Product –Product Indication elements** ***AP.IND productindication***	**M**	
	AP.IND.1	meddraversion	M	17
	AP.IND.2	meddralevel	M	LLT (= Low Level Term)
	AP.IND.3	meddracode	M	10019211 (= Headache)

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Section 4.1 Therapeutic indications		**Table 37. Authorised Product –Product Indication elements** ***AP.IND productindication***	**M**	
	AP.IND.1	meddraversion	M	17
	AP.IND.2	meddralevel	M	LLT (= Low Level Term)
	AP.IND.3	meddracode	M	10027599 (= Migraine)
Section 4.1 Therapeutic indications		**Table 37. Authorised Product –Product Indication elements** ***AP.IND productindication***	**M**	
	AP.IND.1	meddraversion	M	17
	AP.IND.2	meddralevel	M	LLT (= Low Level Term)
	AP.IND.3	meddracode	M	10003993 (= Backache)
5.1 Pharmaco-dynamic properties		**Table 36. Authorised Product – ATC elements** ***AP.ATC productatc***	**M**	
	AP.ATC.1	atccode	M (technical)	M01AE01
	@ AP.ATC.1..1	(@)resolutionmode	M (technical)	2
5.1 Pharmaco-dynamic properties		**Table 36. Authorised Product – ATC elements** ***AP.ATC productatc***	**M**	
	AP.ATC.1	atccode	M (technical)	N02BE01

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	@ AP.ATC.1..1	(@)resolutionmode	M (technical)	2
		Table 5. Attachment elements ***ATT attachment***	M	
	@ ATT..1	(@)operationtype	M (technical)	The only value accepted is 1 (= Insert)
	ATT.1	localnumber	M* (technical)	1234
	ATT.2	filename	M (technical)	ParaProfen.doc
	ATT.3	filetype	M (technical)	2 (= DOC)
	ATT.4	attachmentname	M (technical)	ParaProfen SmPC
	ATT.5	attachmenttype	M (technical)	1 = Printed Product Information (PPI = SmPC)
	ATT.6	languagecode*	M (technical)	FR (= French)**
	ATT.7	attachmentversion	M (technical)	1
	ATT.8	attachmentversiondate	M (technical)	20110120
	ATT.9	versiondateformat	M (technical)	The value must be “102” for "CCYYMMDD”
		Table 40. The Authorised Product – Printed Product Information Attachment elements ***AP.PPI ppiattachment***	**M**	
	AP.PPI.1	attachmentcode	M (technical)	3
	@ AP.PPI.1..1	(@)resolutionmode	M (technical)	1
	AP.PPI.2	validitydeclaration	M* (technical)	

* The language code is to be specified using the ISO 639-1 language code

** The common approved English text is also accepted. When the SmPC in the national language becomes available, it must be provided) in the context of the data maintenance, i.e. when the variations lead to changes as listed in section 2.2.3.1 Variations of marketing authorisation of chapter 3.II.

3.III.3. Example: How to “insert” a nationally authorised medicinal product (1)

For reference in this example, you are the MAH for a nationally authorised medicinal product “VACCINAL 10 microgram/strain suspension for injection Influenza vaccine (split virion, inactivated)”.

The Summary of product characteristics (SmPC) is as follows:

1. NAME OF THE MEDICINAL PRODUCT

VACCINAL 10 microgram/strain suspension for injection

Influenza vaccine (split virion, inactivated)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus surface antigens (haemagglutinin and neuraminidase) of the following strains*:

A/California/7/2009 (H1N1) – derived strain used NYMC X-179A	10 micrograms HA**
A/Perth/16/2009 (H3N2) – like strain used NYMC X-187	
derived from A/Victoria/210/2009	10 micrograms HA**
B/Brisbane/60/2008	10 micrograms HA**

per 0.1 ml dose.

* propagated in fertilised hens' eggs from healthy chicken flocks and adsorbed on aluminium phosphate adjuvant (100 to 200 micrograms of aluminium phosphate per 0.1 ml dose)

** haemagglutinin

This vaccine complies with the WHO recommendation (Northern hemisphere) and EU decision for the 2010/2011 season. For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylaxis of influenza

4.2 Posology and method of administration

Immunisation should be carried out by intramuscular or subcutaneous injection.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC Code: J07BB02

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride

Potassium dihydrogen phosphate

Water for injection

6.5 Nature and contents of container

0.1 ml of suspension in pre-filled syringe, pack size of 10 syringes.

7. MARKETING AUTHORISATION HOLDER

NEWMAHX, 77 Westferry Circus

London E77 4HB

United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 12345/0052

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07/06/2010

10. DATE OF REVISION OF THE TEXT

In addition, the following applies to your marketing authorisation:

Marketing authorisation status: Valid

Authorisation procedure: EU National procedure

Authorisation country: United Kingdom

Legal basis: Full application (Art 8(3) of Directive No 2001/83/EC) (1)

Medicinal product type: Other (7)

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Reference Section	**Ref. Code**	**Reference Name Data Element**	**M - Mandatory M* - Mandatory with conditions**	Example

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
			O - Optional	
		Table 31. Authorised Product elements ***M.AP Authorisedproduct***	**M**	
	@ AP..1	(@)operationtype	M (technical)	1 (= Insert)
	AP.1	localnumber	M* (technical)	1789
Section 7. Marketing Authorisation Holder	AP.4	mahcode	M (technical)	ORG5083
	@ AP.4..1	(@)resolutionmode	M (technical)	2
	AP.5	qppvcode	M (technical)	7735
	AP.6	mflcode	O	
	@ AP.6..1	(@)resolutionmode	M* (technical)	
	AP.7	enquiryemail	M	newmahx@info.org
	AP.8	enquiryphone	M	+44(0)20812345
	AP.9	senderlocalcode	O (technical)	789562
	AP.10	infodateformat	O (technical)	
	AP.11	infodate	O	
	AP.14	comments	M*	
		Table 32. Authorised Product – Authorisation element ***AP.12 authorisation***	**M**	
	AP.12.1	authorisationcountrycode	M	GB (The country code is to be specified using the ISO-3166)
	AP.12.2	authorisationprocedure	M	4 (= EU authorisation procedures – National

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
				procedure)
	AP.12.3	authorisationstatus	M	1 (= Valid)
Section 8. Marketing Authorisation number	AP.12.4	authorisationnumber	M	PL 12345/0052
Section 9. Date of first authorization /renewal of the authorisation	AP.12.5	authorisationdate	M	20100607
	AP.12.6	authorisationdateformat	M (technical)	102 (corresponding to “CCYYMMDD”)
	AP.12.7	mrpnumber	M*	
	AP.12.8	eunumber	M*	
	AP.12.9	orphandrug	M	2 (= No)
	AP.12.10	intensivemonitoring	M	2 (= No)
	AP.12.11	withdrawndateformat	M* (technical)	
	AP.12.12	withdrawndate	M*	
	AP.12.13	legalbasis	M	1 (= *Full application (Art 8(3) of Directive No 2001/83/EC)*)
		Table 33. Authorisation – Medicinal Product Type elements ***AP.12.MPT medicinalproducttype***		
	AP.12.MPT.1	producttypecode	M	7 (= Other)

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Section 1. Name of the medicinal product		**Table 34. Authorised Product – Presentation Name elements** ***AP.13 presentationname***	**M**	
	AP.13.1	productname	M	VACCINAL 10 microgram/strain suspension for injection Influenza vaccine (split virion, inactivated)
	AP.13.2	productshortname	M*	VACCINAL
	AP.13.3	productgenericname	M*	Influenza vaccine (split virion, inactivated)
	AP.13.4	productcompanyname	M*	
	AP.13.5	productstrength	M*	10 microgram/strain
	AP.13.6	productform	M*	suspension for injection
Section 6.5 Nature and contents of container	AP.13.7	packagedesc	O	0.1 ml of suspension in pre-filled syringe, pack size of 10 syringes
Section 2. Qualitative and quantitative composition		**Table 43. The Pharmaceutical Product – Active Ingredient element** ***PP.ACT activeingredient***	**M**	
	PP.ACT.1	substancecode	M (technical)	SUB31260 (= A/CALIFORNIA/7/2009(H1N1)-LIKE STRAIN (NYMC X-179A))
	@ PP.ACT.1..1	(@)resolutionmode	M (technical)	2
	PP.ACT.2	concentrationtypecode	M	1 (= Equal)

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	PP.ACT.3	lowamountnumervalue	M	10
	PP.ACT.4	lowamountnumerprefix	M	Micro (1x10^-6)
	PP.ACT.5	lowamountnumerunit	M	Gram(s) Haemagglutinin
	PP.ACT.6	lowamountdenomvalue	M	0.1
	PP.ACT.7	lowamountdenomprefix	M	Milli (1x10^-3)
	PP.ACT.8	lowamountdenomunit	M	Litre
	PP.ACT.9	highamountnumervalue	M*	
	PP.ACT.10	highamountnumerprefix	M*	
	PP.ACT.11	highamountnumerunit	M*	
	PP.ACT.12	highamountdenomvalue	M*	
	PP.ACT.13	highamountdenomprefix	M*	
	PP.ACT.14	highamountdenomunit	M*	
Section 2. Qualitative and quantitative composition		**Table 43. The Pharmaceutical Product – Active Ingredient element *PP.ACT activeingredient***	**M**	
	PP.ACT.1	substancecode	M (technical)	SUB31350 (= A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187))
	@ PP.ACT.1..1	(@)resolutionmode	M (technical)	2
	PP.ACT.2	concentrationtypecode	M	1 (= Equal)
	PP.ACT.3	lowamountnumervalue	M	10
	PP.ACT.4	lowamountnumerprefix	M	Micro (1x10^-6)
	PP.ACT.5	lowamountnumerunit	M	Gram(s) Haemagglutinin
	PP.ACT.6	lowamountdenomvalue	M	0.1

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	PP.ACT.7	lowamountdenomprefix	M	Milli (1x10^-3)
	PP.ACT.8	lowamountdenomunit	M	Litre
	PP.ACT.9	highamountnumervalue	M*	
	PP.ACT.10	highamountnumerprefix	M*	
	PP.ACT.11	highamountnumerunit	M*	
	PP.ACT.12	highamountdenomvalue	M*	
	PP.ACT.13	highamountdenomprefix	M*	
	PP.ACT.14	highamountdenomunit	M*	
Section 2. Qualitative and quantitative composition		**Table 43. The Pharmaceutical Product – Active Ingredient element *PP.ACT activeingredient***	**M**	
	PP.ACT.1	substancecode	M (technical)	SUB30542 (= B/BRISBANE/60/2008-LIKE VIRUS)
	@ PP.ACT.1..1	(@)resolutionmode	M* (technical)	2
	PP.ACT.2	concentrationtypecode	M	1 (= Equal)
	PP.ACT.3	lowamountnumervalue	M	10
	PP.ACT.4	lowamountnumerprefix	M	Micro (1x10^-6)
	PP.ACT.5	lowamountnumerunit	M	Gram(s) Haemagglutinin
	PP.ACT.6	lowamountdenomvalue	M	0.1
	PP.ACT.7	lowamountdenomprefix	M	Milli (1x10^-3)
	PP.ACT.8	lowamountdenomunit	M	Litre
	PP.ACT.9	highamountnumervalue	M*	
	PP.ACT.10	highamountnumerprefix	M*	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	PP.ACT.11	highamountnumerunit	M*	
	PP.ACT.12	highamountdenomvalue	M*	
	PP.ACT.13	highamountdenomprefix	M*	
	PP.ACT.14	highamountdenomunit	M*	
Section 2. Qualitative and quantitative composition		**Table 45. The Pharmaceutical Product – Adjuvant elements** ***PP.ADJ adjuvant***	**M***	
	PP.ADJ.1	substancecode	M (technical)	SUB12462MIG (= ALUMINIUM PHOSPHATE)
	@ PP.ADJ.1..1	(@) resolutionmode	M (technical)	2
	PP.ADJ.2	concentrationtypecode	M	2 (= Range)
	PP.ADJ.3	lowamountnumervalue	M	100
	PP.ADJ.4	lowamountnumerprefix	M	Micro (1x10^-6)
	PP.ADJ.5	lowamountnumerunit	M	Gram(s)
	PP.ADJ.6	lowamountdenomvalue	M	0.1
	PP.ADJ.7	lowamountdenomprefix	M	Milli (1x10^-3)
	PP.ADJ.8	lowamountdenomunit	M	Litre
	PP.ADJ.9	highamountnumervalue	M*	200
	PP.ADJ.10	highamountnumerprefix	M*	Micro (1x10^-6)
	PP.ADJ.11	highamountnumerunit	M*	Gram(s)
	PP.ADJ.12	highamountdenomvalue	M*	0.1
	PP.ADJ.13	highamountdenomprefix	M*	Milli (1x10^-3)
	PP.ADJ.14	highamountdenomunit	M*	Litre

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
		Table 35. Authorised product - Authorised Pharmaceutical Form elements ***AP.APF authpharmform***	**M**	
Section 3. Pharma-ceutical Form	AP.APF.1	authpharmformcode	M (technical)	PHF00243MIG (= SUSPENSION FOR INJECTION)
	@ AP.APF..1	resolutionmode	M (technical)	2
Section 3. Pharma-ceutical Form		**Table 41. The Pharmaceutical Product elements** ***AP.PP pharmaceuticalproduct***	**M**	
	PP.1	pharmformcode	M (technical)	PHF00243MIG (= SUSPENSION FOR INJECTION)
	@PP.1..1	(@)resolutionmode	M (technical)	2
Section 4.2 Posology and method of admini-stration		**Table 42. The Pharmaceutical Product – Administration Route element** ***PP.AR adminroute***	**M**	
	PP.AR.1	adminroutecode	M (technical)	ADR00030MIG (= INTRAMUSCULAR USE)
	@ PP.AR.1..1	(@)resolutionmode	M (technical)	2
Section 4.2 Posology and		**Table 42. The Pharmaceutical Product – Administration Route element**	**M**	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
method of admini-stration		***PP.AR adminroute***		
	PP.AR.1	adminroutecode	M (technical)	ADR00058MIG (= SUBCUTANEOUS USE)
	@ PP.AR.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. Pharmaceutical Product – Excipient Ingredient element *PP.EXC excipient***	**M***	
	PP.EXC.1	substancecode	M (technical)	SUB12581MIG (= SODIUM CHLORIDE)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. Pharmaceutical Product – Excipient Ingredient element *PP.EXC excipient***	**M***	
	PP.EXC.1	substancecode	M (technical)	SUB12233MIG (= POTASSIUM DIHYDROGEN PHOSPHATE)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. Pharmaceutical Product – Excipient Ingredient element *PP.EXC excipient***	**M***	
	PP.EXC.1	substancecode	M (technical)	SUB12398MIG (= WATER FOR INJECTION)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 4.1		**Table 37. Authorised Product –Product**	**M**	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Therapeutic indications		**Indication elements** ***AP.IND productindication***		
	AP.IND.1	meddraversion	M	17
	AP.IND.2	meddralevel	M	LLT (= Low Level Term)
	AP.IND.3	meddracode	M	10059430 (= Influenza immunization)
		Table 36. Authorised Product – ATC elements ***AP.ATC productatc***	**M**	
	AP.ATC.1	atccode	M (technical)	J07BB02
	@ AP.ATC.1..1	(@)resolutionmode	M (technical)	2
		Table 5. Attachment elements ***ATT attachment***	**M**	
	@ ATT..1	(@)operationtype	M (technical)	The only value accepted is 1 (= Insert)
	ATT.1	localnumber	M* (technical)	1456
	ATT.2	filename	M (technical)	Vaccinal.doc
	ATT.3	filetype	M (technical)	2 (= DOC)
	ATT.4	attachmentname	M (technical)	VACCINAL SmPC
	ATT.5	attachmenttype	M (technical)	1 = Printed Product Information (PPI = SmPC)
	ATT.6	languagecode*	M (technical)	EN (= English)
	ATT.7	attachmentversion	M (technical)	1
	ATT.8	attachmentversiondate	M (technical)	20110209
	ATT.9	versiondateformat	M (technical)	The value must be “102” for "CCYYMMDD”
		Table 40. The Authorised Product – Printed Product Information Attachment elements	**M**	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
		AP.PPI ppiattachment		
	AP.PPI.1	attachmentcode	M (technical)	4
	@ AP.PPI.1..1	(@)resolutionmode	M (technical)	1
	AP.PPI.2	validitydeclaration	M* (technical)	

* The language code is to be specified using the ISO 639-1 language codes

3.III.4. Example: How to “Update” a nationally authorised medicinal product following a variation procedure

For reference in this example, you are the MAH for the authorised herbal medicinal product “CoughingStop syrup” (new medicinal product name following a variation procedure).

The Summary of Product Characteristics (SmPC) is as follows:

1. NAME OF THE MEDICINAL PRODUCT

CoughingStop syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Althaea officinalis L., radix (marshmallow root) liquid extract corresponding to 2 – 6.5 g of herbal substance/100 ml.

3. PHARMACEUTICAL FORM

Syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic relief of cough

4.2 Posology and method of administration

For oral use

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose

Purified water

6.5 Nature and contents of container

Glass bottle 100 ml

7. MARKETING AUTHORISATION HOLDER

NEWMAHX, 77 Westferry Circus

London E77 4HB

United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 54321/0025

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06/06/2010

10. DATE OF REVISION OF THE TEXT

In addition, the following applies to your marketing authorisation:

Authorisation procedure: EU authorisation procedures - National Procedure

Marketing Authorisation status: valid

Authorisation country: United Kingdom

Legal basis: Well-established use application (Article 10a of Directive No 2001/83/EC) (5)

Medicinal product type: Authorised herbal medicinal product (2)

EVCODE: PRD123456

The name of the medicinal product stated in Section 1 of the SmPC has changed from "ALTHAEA OFFICINALIS Coughing syrup" to "CoughingStop syrup" following a variation procedure.

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Reference Section	**Ref. Code**	**Reference Name Data Element**	**M - Mandatory M* - Mandatory with conditions O - Optional**	**Example**
		Table 31. Authorised Product elements *M.AP Authorisedproduct*	**M**	
	@ AP..1	(@)operationtype	M (technical)	2 (= Update)
	AP.1	Localnumber	M* (technical)	
	AP.2	ev_code	M* (technical)	PRD123456
Section 7. Marketing Authorisation Holder	AP.4	Mahcode	M (technical)	ORG5083
	@ AP.4..1	(@)resolutionmode	M (technical)	2
	AP.5	Qppvcode	M (technical)	12345
	AP.6	Mflcode	O	
	@ AP.6..1	(@)resolutionmode	M*(technical)	
	AP.7	enquiryemail	M	newmahx@info.org
	AP.8	enquiryphone	M	+44(0)208512345

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	AP.9	senderlocalcode	O (technical)	
	AP.10	infodateformat	O (technical)	
	AP.11	infodate	O	
	AP.14	comments	M*	
		Table 32. Authorised Product – Authorisation element ***AP.12 authorisation***	**M**	
	AP.12.1	authorisationcountrycode	M	GB (The country code is to be specified using the ISO-3166)
	AP.12.2	authorisationprocedure	M	4 (= EU authorisation procedures - National Procedure)
	AP.12.3	authorisation status	M	1 (= Valid)
Section 8. Marketing Authorisation Number	AP.12.4	authorisationnumber	M	PL 54321/0025
Section 9. Date of first authorisation /renewal of the authorisation	AP.12.5	authorisationdate	M	20100606
	AP.12.6	authorisationdateformat	M (technical)	102 (corresponding to “CCYYMMDD”)
	AP.12.7	mrpnumber	M*	
	AP.12.8	eunumber	M*	
	AP.12.9	orphandrug	M	2 (= No)

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	AP.12.10	intensivemonitoring	M	2 (= No)
	AP.12.11	withdrawndateformat	M* (technical)	
	AP.12.12	withdrawndate	M*	
	AP.12.13	legalbasis	M	5 (= *Well-established use application (Article 10a of Directive No 2001/83/EC)*)
		Table 33. Authorisation – Medicinal Product Type elements *AP.12.MPT medicinalproducttype*		
	AP.12.MPT.1	producttypecode	M	2 (= Authorised herbal medicinal product)
Section 1. Name of the medicinal product		**Table 34. Authorised Product – Presentation Name elements *AP.13 presentationname***	**M**	
	AP.13.1	productname	M	CoughingStop Syrup
	AP.13.2	productshortname	M*	CoughingStop
	AP.13.3	productgenericname	M*	
	AP.13.4	productcompanyname	M*	
	AP.13.5	productstrength	M*	
	AP.13.6	productform	M*	Syrup
Section 6.5 Nature and contents of container	AP.13.7	packagedesc	O	Glass bottle 100 ml
Section 2. Qualitative		**Table 43. The Pharmaceutical Product – Active Ingredient element**	**M**	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
and quantitative composition		***PP.ACT activeingredient***		
	PP.ACT.1	substancecode	M (technical)	SUB33430 (= ALTHAEA OFFICINALIS L. RADIX)
	@ PP.ACT.1..1	(@)resolutionmode	M (technical)	2
	PP.ACT.2	concentrationtypecode	M	2 (= Range)
	PP.ACT.3	lowamountnumervalue	M	2
	PP.ACT.4	lowamountnumerprefix	M	Single
	PP.ACT.5	lowamountnumerunit	M	Gram(s)
	PP.ACT.6	lowamountdenomvalue	M	100
	PP.ACT.7	lowamountdenomprefix	M	Milli (1x10^-3)
	PP.ACT.8	lowamountdenomunit	M	Litre
	PP.ACT.9	highamountnumervalue	M*	6.5
	PP.ACT.10	highamountnumerprefix	M*	Single
	PP.ACT.11	highamountnumerunit	M*	Gram(s)
	PP.ACT.12	highamountdenomvalue	M*	100
	PP.ACT.13	highamountdenomprefix	M*	Milli (1x10^-3)
	PP.ACT.14	highamountdenomunit	M*	Litre
		Table 35. Authorised product - Authorised Pharmaceutical Form elements ***AP.APF authpharmform***	**M**	
Section 3. Pharma-ceutical	AP.APF.1	authpharmformcode	M (technical)	PHF00244MIG (= SYRUP)

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Form				
	@ AP.APF..1	resolutionmode	M (technical)	2
Section 3. Pharma-ceutical Form		**Table 41. The Pharmaceutical Product elements** ***AP.PP pharmaceuticalproduct***	**M**	
	PP.1	pharmformcode	M (technical)	PHF00244MIG (= SYRUP)
	@PP.1..1	(@)resolutionmode	M (technical)	2
Section 4.2 Posology and method of admini-stration		**Table 42. The Pharmaceutical Product – Administration Route element** ***PP.AR adminroute***	**M**	
	PP.AR.1	adminroutecode	M (technical)	ADR00048MIG (= oral use)
	@ PP.AR.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. Pharmaceutical Product – Excipient Ingredient element** ***PP.EXC excipient***	**M***	
	PP.EXC.1	substancecode	M (technical)	SUB12600MIG (= SUCROSE)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. Pharmaceutical Product – Excipient Ingredient element** ***PP.EXC excipient***	**M***	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	PP.EXC.1	substancecode	M (technical)	SUB49180 (= WATER, PURIFIED)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 4.1 Therapeutic indications		**Table 37. Authorised Product –Product Indication elements** ***AP.IND productindication***	**M**	
	AP.IND.1	meddraversion	M	17
	AP.IND.2	meddralevel	M	LLT (= Low Level Term)
	AP.IND.3	meddracode	M	10011232 (= Coughing)
Section 5.1 Pharmaco-dynamic properties		**Table 36. Authorised Product – ATC elements** ***AP.ATC productatc***	**M**	
	AP.ATC.1	atccode	M (technical)	NOTAPPLIC
	@ AP.ATC.1..1	(@)resolutionmode	M (technical)	2
		Table 5. Attachment elements ***ATT attachment***	M	
	@ ATT..1	(@)operationtype	M (technical)	The only value accepted is 1 (= Insert)
	ATT.1	localnumber	M* (technical)	1277
	ATT.2	filename	M (technical)	CoughingStop.doc
	ATT.3	filetype	M (technical)	2 (= DOC)
	ATT.4	attachmentname	M (technical)	CoughingStop SmPC
	ATT.5	attachmenttype	M (technical)	1 = Printed Product Information (PPI = SmPC)
	ATT.6	languagecode*	M (technical)	EN (= English)
	ATT.7	attachmentversion	M (technical)	2

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	ATT.8	attachmentversiondate	M (technical)	20140606
	ATT.9	versiondateformat	M (technical)	The value must be “102” for "CCYYMMDD”
		Table 40. The Authorised Product – Printed Product Information Attachment elements ***AP.PPI ppiattachment***	**M**	
	AP.PPI.1	attachmentcode	M (technical)	7
	@ AP.PPI.1..1	(@)resolutionmode	M (technical)	1
	AP.PPI.2	validitydeclaration	M* (technical)	

* The language code is to be specified using the ISO 639-1 language codes

3.III.5. Example: How to “invalidate” a medicinal product authorised for which the Marketing Authorisation has been transferred

For reference in this example, you are the MAH for the medicinal product “AMPIL Paediatric powder for oral suspension” for which the marketing authorisation has been transferred to another MAH.

The Summary of Product Characteristics (SmPC) is as follows:

1. NAME OF THE MEDICINAL PRODUCT

AMPIL Paediatric powder for oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Bottle contains ampicillin trihydrate equivalent to 10 g ampicillin.

After reconstitution, each 5 ml contains ampicillin trihydrate equivalent to 250 mg ampicillin.

3. PHARMACEUTICAL FORM

Powder for oral suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

AMPIL Paediatric powder for oral solution is indicated for the treatment of meningitis in children.

4.2 Posology and method of administration

For oral use

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: J01CA01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.5 Nature and contents of container

The powder for oral suspension is in a 250 ml glass bottle

7. MARKETING AUTHORISATION HOLDER

MAHNEWX, 77 Westferry Circus

London E77 4HB

United Kingdom

8. MARKETING AUTHORISATION NUMBER

EU/1/94/007/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07/07/1994

Date of renewal of the authorisation: 06/07/1999

10. DATE OF REVISION OF THE TEXT

In addition, the following applies to your marketing authorisation:

Authorisation procedure: EU centralised procedure

Marketing Authorisation status: Not valid- Superseded by Marketing Authorisation Transfer (11)

Authorisation country: European Union

EMA procedure number: EMEA/H/C/006789

Legal basis: Full application (Art 8(3) of Directive No 2001/83/EC) (1)

Medicinal product type: Other (7)

Date of transfer of the MA: 04/06/2014

EVCODE: PRD789123

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Reference Section	**Ref. Code**	**Reference Name Data Element**	**M - Mandatory M* - Mandatory with conditions O - Optional**	**Example**
		Table 31. Authorised Product elements *M.AP Authorisedproduct*	**M**	
	@ AP..1	(@)operationtype	M (technical)	6 (= Invalidate MA)
	AP.1	Localnumber	M* (technical)	
	AP.2	ev_code	M* (technical)	PRD789123
Section 7. Marketing Authorisation Holder	AP.4	mahcode	M (technical)	ORG5083
	@ AP.4..1	(@)resolutionmode	M (technical)	2
	AP.5	qppvcode	M (technical)	3577
	AP.6	mflcode	O	
	@ AP.6..1	(@)resolutionmode	M* (technical)	
	AP.7	enquiryemail	M	mahnewx@info.org

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	AP.8	enquiryphone	M	+44(0)20812345
	AP.9	senderlocalcode	O (technical)	
	AP.10	infodateformat	O (technical)	
	AP.11	infodate	O	
	AP.14	comments	M*	Medicinal product authorised for the treatment in children
		Table 32. Authorised Product – Authorisation element ***AP.12 authorisation***	**M**	
	AP.12.1	authorisationcountrycode	M	EU
	AP.12.2	authorisationprocedure	M	1 (= EU authorisation procedures – centralised procedure)
	AP.12.3	authorisationstatus	M	11 (= *Not valid - Superseded by Marketing Authorisation Transfer*)
Section 8. Marketing Authorisation Number	AP.12.4	authorisationnumber	M	EU/1/94/007/001
Section 9. Date of first authorisation /renewal of the authorisation	AP.12.5	authorisationdate	M	19990706
	AP.12.6	authorisationdateformat	M (technical)	102 (corresponding to “CCYYMMDD”)

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	AP.12.7	mrpnumber	M*	EMEA/H/C/006789
Section 8. Marketing Authorisation number	AP.12.8	eunumber	M*	EU/1/94/007/001
	AP.12.9	orphandrug	M	2 (= No)
	AP.12.10	intensivemonitoring	M	2 (= No)
	AP.12.11	Withdrawndateformat	M* (technical)	102 (corresponding to “CCYYMMDD”)
	AP.12.12	Withdrawndate	M*	20140604
	AP.12.13	legalbasis	M	1 (= Full application (Art 8(3) of Directive No 2001/83/EC))
		Table 33. Authorisation – Medicinal Product Type elements *AP.12.MPT medicinalproducttype*		
	AP.12.MPT.1	producttypecode	M	7 (= Other)
Section 1. Name of the medicinal product		**Table 34. Authorised Product – Presentation Name elements – *AP.13 presentationname***	**M**	
	AP.13.1	Productname	M	AMPIL Paediatric powder for oral suspension
	AP.13.2	Productshortname	M*	AMPIL Paediatric
	AP.13.3	Productgenericname	M*	
	AP.13.4	Productcompanyname	M*	
	AP.13.5	Productstrength	M*	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	AP.13.6	Productform	M*	powder for oral suspension
Section 6.5 Nature and contents of container	AP.13.7	packagedesc	O	250 ml glass bottle
Section 2. Qualitative and quantitative composition		**Table 43. The Pharmaceutical Product – Active Ingredient element *PP.ACT activeingredient***	**M**	
	PP.ACT.1	substancecode	M (technical)	SUB05487MIG (= AMPICILLIN)
	@ PP.ACT.1..1	(@)resolutionmode	M (technical)	2
	PP.ACT.2	concentrationtypecode	M	1 (= Equal)
	PP.ACT.3	lowamountnumervalue	M	250
	PP.ACT.4	lowamountnumerprefix	M	Milli (1x10^-3)
	PP.ACT.5	lowamountnumerunit	M	Gram(s)
	PP.ACT.6	lowamountdenomvalue	M	5
	PP.ACT.7	lowamountdenomprefix	M	Milli (1x10^-3)
	PP.ACT.8	lowamountdenomunit	M	Litre
	PP.ACT.9	highamountnumervalue	M*	
	PP.ACT.10	highamountnumerprefix	M*	
	PP.ACT.11	highamountnumerunit	M*	
	PP.ACT.12	highamountdenomvalue	M*	
	PP.ACT.13	highamountdenomprefix	M*	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	PP.ACT.14	highamountdenomunit	M*	
		Table 35. Authorised product - Authorised Pharmaceutical Form elements ***AP.APF authpharmform***	**M**	
Section 3. Pharma-ceutical Form	AP.APF.1	authpharmformcode	M (technical)	PHF00198MIG (= POWDER FOR ORAL SUSPENSION)
	@ AP.APF..1	resolutionmode	M (technical)	2
Section 3. Pharma-ceutical Form		**Table 41. The Pharmaceutical Product elements** ***AP.PP pharmaceuticalproduct***	**M**	
	PP.1	pharmformcode	M (technical)	PHF00170MIG (= ORAL SUSPENSION)
	@PP.1..1	(@)resolutionmode	M (technical)	2
Section 4.2 Posology and method of admini-stration		**Table 42. The Pharmaceutical Product – Administration Route element** ***PP.AR adminroute***	**M**	
	PP.AR.1	adminroutecode	M (technical)	ADR00048MIG (= ORAL USE)
	@ PP.AR.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of		**Table 44. Pharmaceutical Product – Excipient Ingredient element**	**M***	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
excipients		***PP.EXC excipient***		
	PP.EXC.1	substancecode	M (technical)	
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	
Section 4.1 Therapeutic indications		**Table 37. Authorised Product – Product Indication elements** ***AP.IND productindication***	**M**	
	AP.IND.1	meddraversion	M	17
	AP.IND.2	meddralevel	M	LLT (= Low Level Term)
	AP.IND.3	meddracode	M	10027199 (= Meningitis)
Section 5.1 Pharmaco-dynamic properties		**Table 36. Authorised Product – ATC element** ***AP.ATC productatc***	**M**	
	AP.ATC.1	atccode	M (technical)	J01CA01
	@ AP.ATC.1..1	(@)resolutionmode	M (technical)	2
		Table 5. Attachment elements ***ATT attachment***	**M**	
	@ ATT..1	(@)operationtype	M (technical)	The only value accepted is 1 (= Insert)
	ATT.1	localnumber	M* (technical)	3547854
	ATT.2	filename	M (technical)	Ampil.doc
	ATT.3	filetype	M (technical)	2 (= DOC)
	ATT.4	attachmentname	M (technical)	Ampil SmPC

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	ATT.5	attachmenttype	M (technical)	1 = Printed Product Information (PPI = SmPC)
	ATT.6	languagecode*	M (technical)	EN (= English)
	ATT.7	attachmentversion	M (technical)	1
	ATT.8	attachmentversiondate	M (technical)	19990701
	ATT.9	versiondateformat	M (technical)	The value must be “102” for "CCYYMMDD”
		Table 40. The Authorised Product – Printed Product Information Attachment elements *AP.PPI ppiattachment*	**M**	
	AP.PPI.1	attachmentcode	M (technical)	ATT123456
	@ AP.PPI.1..1	(@)resolutionmode	M (technical)	2
	AP.PPI.2	validitydeclaration	M* (technical)	1

* The language code is to be specified using the ISO 639-1

3.III.6. Example: How to “insert” information on a new Marketing Authorisation Holder (MAH)

New organisation information must be submitted in the XEVMPD via an XEVPRM with the operation type 'Insert (1)'.

The organisation information (i.e. MAH name and MAH address) refer to the legal entity of the medicinal product in a given country as indicated in section 7. Marketing Authorisation Holder of the SmPC:

NEWMAHX

99 Westferry Circus, Canary Wharf

London E99 4HB

United Kingdom

Email: info@newmahx.com

Tel: +44(0)3023456789

Fax: +44(0)3987654321

Additional Information

NEWMAHX does not have an SME status (i.e. micro, small or medium).

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Reference Section	**Ref. Code**	**Reference Name Data Element**	**M - Mandatory M* - Mandatory with conditions O - Optional**	**Example**
Section 7. Marketing		**Table 4. Organisation elements O organisation**	**M**	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Authorisation Holder				
	@ O..1	(@)operationtype	M (technical)	1 (= Insert)
	O.1	type_org	M (technical)	1 (= Marketing Authorisation Holder)
	O.2	name_org	M	NEWMAHX
	O.3	localnumber	M* (technical)	1999992332
	O.4	ev_code	M* (technical)	
	O.5	organisationsenderid	O (technical)	999999
	O.6	address	M	99 Westferry Circus, Canary Wharf
	O.7	city	M	London
	O.8	state	O	
	O.9	postcode	M	E99 4HB
	O.10	countrycode*	M	GB
	O.11	tel_number	O	(0)302345
	O.12	tel_extension	O	6789
	O.13	tel_countrycode	O	+44
	O.14	fax_number	O	(0)398765
	O.15	fax_extension	O	4321
	O.16	fax_countrycode	O	+44
	O.17	email	O	info@newmahx.com
	O.18	comments	M* (technical)	
	O.19	sme_status	M	1 (= N/A)
	O.20	Sme_number	O	

* The country code is to be specified using the ISO-3166 codes

3.III.7. Example: How to “insert” a Medicinal Product where the marketing authorisation has been transferred

For reference in this example, you are the new MAH for a centrally authorised medicinal product “Fusion 200 mg/ml powder and solvent for solution for injection”.

The Summary of Product Characteristics (SmPC) is as follows:

1. NAME OF THE MEDICINAL PRODUCT

Fusion 200 mg/ml powder and solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 224 mg zidovudine.

After reconstitution, each ml of solution contains 200 mg Zidovudine.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Fusion is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected patients.

4.2 Posology and method of administration

Fusion is only for subcutaneous injection.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Nucleoside and nucleotide reverse transcriptase inhibitors ATC code: J05AF01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder

Sodium carbonate

Mannitol

Solvent

Water for Injections

6.5 Nature and contents of container

Pack containing: 1 vial (of Powder) and 1.5 ml of Solvent. Not all pack sizes may be marketed.

7. MARKETING AUTHORISATION HOLDER

MAHNEWX, 77 Westferry Circus

London E77 4HB United Kingdom

8. MARKETING AUTHORISATION NUMBER

EU/1/94/003/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06/06/1994

Date of renewal of the authorisation: 05/06/1999

10. DATE OF REVISION OF THE TEXT

07/02/2011

In addition, the following applies to your marketing authorisation:

Authorisation procedure: EU centralised procedure

Marketing Authorisation status: Valid - Transferred Marketing Authorisation (9)

Authorisation country: European Union

EMA procedure number: EMEA/H/C/001212

Legal basis: Full application (Art 8(3) of Directive No 2001/83/EC) (1)

Medicinal product type: Other (7)

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
Reference Section	**Ref. Code**	**Reference Name Data Element**	**M - Mandatory M* - Mandatory with conditions O - Optional**	**Example**
		Table 31. Authorised Product elements *M.AP Authorisedproduct*	**M**	
	@ AP..1	(@)operationtype	M (technical)	1 (= Insert)
	AP.1	localnumber	M* (technical)	7889425
Section 7. Marketing Authorisation Holder	AP.4	mahcode	M (technical)	ORG5083

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	@ AP.4..1	(@)resolutionmode	M (technical)	2
	AP.5	qppvcode	M (technical)	3577
	AP.6	mflcode	O	MFL282
	@ AP.6..1	(@)resolutionmode	M* (technical)	2
	AP.7	enquiryemail	M	mahnewx@info.org
	AP.8	enquiryphone	M	+44(0)20812345
	AP.9	senderlocalcode	O (technical)	72264558
	AP.10	infodateformat	O (technical)	
	AP.11	infodate	O	
	AP.14	comments	M*	
		Table 32. Authorised Product – Authorisation element ***AP.12 authorisation***	**M**	
	AP.12.1	authorisationcountrycode	M	EU
	AP.12.2	authorisationprocedure	M	1 (= EU authorisation procedures – centralised procedure)
	AP.12.3	authorisationstatus	M	9 (= Valid - Transferred Marketing Authorisation)
Section 8. Marketing Authorisation Number	AP.12.4	authorisationnumber	M	EU/1/94/003/002
Section 9. Date of first	AP.12.5	authorisationdate	M	19990605

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
authorisation /renewal of the authorisation				
	AP.12.6	authorisationdateformat	M (technical)	102 (corresponding to “CCYYMMDD”)
	AP.12.7	mrpnumber	M*	EMEA/H/C/001212
Section 8. Marketing Authorisation number	AP.12.8	eunumber	M*	EU/1/94/003/002
	AP.12.9	orphandrug	M	2 (= No)
	AP.12.10	intensivemonitoring	M	2 (= No)
	AP.12.11	Withdrawndateformat	M* (technical)	
	AP.12.12	Withdrawndate	M*	
	AP.12.13	legalbasis	M	1 (= Full application (Art 8(3) of Directive No 2001/83/EC))
		Table 33. Authorisation – Medicinal Product Type elements *AP.12.MPT medicinalproducttype*		
	AP.12.MPT.1	producttypecode	M	7 (= Other)
Section 1. Name of the medicinal product		**Table 34. Authorised Product – Presentation Name elements – *AP.13 presentationname***	**M**	
	AP.13.1	Productname	M	Fusion 200 mg/ml powder and solvent for solution for

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
				injection
	AP.13.2	Productshortname	M*	Fusion
	AP.13.3	Productgenericname	M*	
	AP.13.4	Productcompanyname	M*	
	AP.13.5	Productstrength	M*	200 mg/ml
	AP.13.6	Productform	M*	powder and solvent for solution for injection
Section 6.5 Nature and contents of container	AP.13.7	packagedesc	O	1 vial (of Powder) and 1.5 ml of Solvent
Section 2. Qualitative and quantitative composition		**Table 43. The Pharmaceutical Product – Active Ingredient element** ***PP.ACT activeingredient***	**M**	
	PP.ACT.1	substancecode	M (technical)	SUB00153MIG (= zidovudine)
	@ PP.ACT.1..1	(@)resolutionmode	M (technical)	2
	PP.ACT.2	concentrationtypecode	M	1 (= Equal)
	PP.ACT.3	lowamountnumervalue	M	200
	PP.ACT.4	lowamountnumerprefix	M	Milli (1x10^-3)
	PP.ACT.5	lowamountnumerunit	M	Gram(s)
	PP.ACT.6	lowamountdenomvalue	M	1
	PP.ACT.7	lowamountdenomprefix	M	Milli (1x10^-3)

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
	PP.ACT.8	lowamountdenomunit	M	Litre
	PP.ACT.9	highamountnumervalue	M*	
	PP.ACT.10	highamountnumerprefix	M*	
	PP.ACT.11	highamountnumerunit	M*	
	PP.ACT.12	highamountdenomvalue	M*	
	PP.ACT.13	highamountdenomprefix	M*	
	PP.ACT.14	highamountdenomunit	M*	
		Table 35. Authorised product - Authorised Pharmaceutical Form elements ***AP.APF authpharmform***	**M**	
Section 3. Pharma-ceutical Form	AP.APF.1	authpharmformcode	M (technical)	PHF00190MIG (= Powder and solvent for solution for injection)
	@ AP.APF..1	resolutionmode	M (technical)	2
Section 3. Pharma-ceutical Form		**Table 41. The Pharmaceutical Product elements** ***AP.PP pharmaceuticalproduct***	**M**	
	PP.1	pharmformcode	M (technical)	PHF00231MIG (= solution for injection)
	@PP.1..1	(@)resolutionmode	M (technical)	2
Section 4.2 Posology and method of admin-		**Table 42. The Pharmaceutical Product – Administration Route element** ***PP.AR adminroute***	**M**	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
istration				
	PP.AR.1	adminroutecode	M (technical)	ADR00058MIG (= subcutaneous use)
	@ PP.AR.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. The Pharmaceutical product – Excipient Ingredient element** ***PP.EXC excipient***	**M***	
	PP.EXC.1	substancecode	M (technical)	SUB12580MIG (= Sodium carbonate)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. The Pharmaceutical product – Excipient element** ***PP.EXC excipient***	M*	
	PP.EXC.1	substancecode	M (technical)	SUB03087MIG (= Mannitol)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 6.1 List of excipients		**Table 44. The Pharmaceutical product – Excipient element** ***PP.EXC excipient***	**M***	
	PP.EXC.1	substancecodUnderstanding more about Eudravigilancee	M (technical)	SUB12398MIG (= Water for injection)
	@ PP.EXC.1..1	(@)resolutionmode	M (technical)	2
Section 4.1 Therapeutic		**Table 37. Authorised Product – Product Indication elements**	**M**	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
indications		***AP.IND productindication***		
	AP.IND.1	meddraversion	M	17
	AP.IND.2	meddralevel	M	LLT (= Low Level Term)
	AP.IND.3	meddracode	M	10068341 (= HIV-1 infection)
Section 5.1 Pharmaco-dynamic properties		**Table 36. Authorised Product – ATC elements** ***AP.ATC productatc***	**M**	
	AP.ATC.1	atccode	M (technical)	J05AF01
	@ AP.ATC.1..1	(@)resolutionmode	M (technical)	2
		Table 5. Attachment elements ***ATT attachment***	**M**	
	@ ATT..1	(@)operationtype	M (technical)	The only value accepted is 1 (= Insert)
	ATT.1	localnumber	M* (technical)	212121
	ATT.2	filename	M (technical)	Fusion.doc
	ATT.3	filetype	M (technical)	2 (= DOC)
	ATT.4	attachmentname	M (technical)	Fusion SmPC
	ATT.5	attachmenttype	M (technical)	1 = Printed Product Information (PPI = SmPC)
	ATT.6	languagecode*	M (technical)	EN (= English)
	ATT.7	attachmentversion	M (technical)	1
	ATT.8	attachmentversiondate	M (technical)	20110207
	ATT.9	versiondateformat	M (technical)	The value must be “102” for "CCYYMMDD”
		Table 40. The Authorised Product –	**M**	

SmPC Reference	Detailed Guidance – Chapter 3.I XEVPRM Technical Specifications		Detailed Guidance – Chapter 3.II XEVPRM User Guidance	
		Printed Product Information Attachment element *AP.PPI ppiattachment*		
	AP.PPI.1	attachmentcode	M (technical)	9
	@ AP.PPI.1..1	(@)resolutionmode	M (technical)	1
	AP.PPI.2	validitydeclaration	M* (technical)	

* The language code is to be specified using the ISO 639-1 language codes