Electronic Application Form: New Application

Specification

Version 2.1

March, 2007

Table of Content

Document Control

Change Record

Version	Date	Author(s)	Comments
0.1	February, 2003	Miguel Bley	Draft
0.2	May , 2003	Miguel Bley	Draft
0.3	June, 2003	Miguel Bley	Draft
0.4	November, 2003	Miguel Bley	Draft
0.5	November, 2003	Miguel Bley	Draft
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Reviewers

Version	Name	Organisation
0.1-0.2	Miguel Bley	Afssaps
0.3	Regulators	TIGes/Interlinking Group
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0.5	Regulators/Industry	TIGes/Interlinking/MRP Subgroup
0.6	Miguel Bley	Afssaps
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Distribution

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0.1-0.3	September, 2003	Regulators	TIGes
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2.01	March, 2007	Regulators/Industry	TIGes/Interlinking
2.1	March, 2007	Public	Notice to Applicants

Change Control

The changes to this document will be done according to the Change Control Process for European eCTD Standards described in a separate document (See [CCP] in the References).

Introduction

The Application Form in Volume 2B of the Notice to Applicants hereafter called the AF-New, describes administrative information of new applications for marketing authorisation of medicinal products in the European Community.

This document specifies the Electronic Application Form for New Applications compliant with Revision 6 of March 2005 of the Application Form hereafter called **eAF-New** that is part of EU Module 1 of the electronic Common Technical Document [eCTD] . The latest version of this specification can be found in the eCTD section, Volume 2B of the Notice to Applicants at: http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm

This document should be read together with:
- Application Form and User Guide in Notice to Applicants [FORM]
- ICH eCTD Specification [ICH]
- EU Module 1 Specification [M1SPEC]

Purpose

1. Provide a European standard for electronic exchange of structured administrative information contained in the AF-New for marketing authorisation application of medicinal products between Industry and European Regulatory Authorities.

2. Facilitate automated processing of this information by all concerned parties.

Concerned Parties

Pharmaceutical Industry [PHARMA] as defined in the Procedures for marketing authorisation in the Notice to Applicants.
 European Regulatory Authorities :
- European Medicines Agency [EMEA].
- Regulatory authorities [REG] in the European Economic Area [EEA] (EU Member States and Iceland, Liechtenstein and Norway).

File format

The acceptable file formats of documents that can be included in EU Module 1 of the eCTD are given in Table 1 of the EU Module 1 Specification [M1SPEC]. This document specifies the eAF-New in Extensible Markup Language [XML] format. Although the use of XML format is strongly recommended, regulatory authorities and applicants could agree on the use of other acceptable formats.

DTD

The Document Type Definition of the eAF-New is called **eu-application.dtd** (Appendix 2) and maps the complete information contained in the AF-New. It will be updated to be compliant with any new version of this document. The table in Appendix 1 gives a description of DTD elements related to the structure and content of the eAF-New with examples for each element. The following information has been given for each element in order to help the understanding of this specification :

Number
Each element has been numbered to ease its localisation

Section
Title or number of the corresponding section in the AF-New

Description
Transcription of the text in the AF-New that describes the element.

Element
Name of the a label that identifies either the structure or the content (data) of the eAF-New in the DTD.

Status
The DTD syntax can require that an element must be present in the document in order for the xml file to be valid. In this case the elements status is **Mandatory**. There could also be complementary information that would be required only if it is applicable. The xml file would still be valid if this information is not present in the document. In this case the element status is **Optional**. The status should be considered in its context or hierarchy in the structure.

Occurrence
In some cases the AF-New requests for information to be repeated in the document and the DTD syntax allows for elements to be repeated or to appear only one time. Thus the occurrence indicates one of two possibilities: the element appears **Only once** or **More** times.

Remarks
This information refers to different types of elements as follows:

- Data: This element type indicates that actual data should be typed in the eAF-New.

- End: This element type should be present in the eAF-New when the corresponding choice has been made. No actual data should be typed in the eAF-New.

- Link: This element type indicates that there is a link to a document that has been provided as one of the annexes to the eAF-New.

- List: This element type indicates that data should be chosen from a list included in the DTD for the element concerned. Data not included in the DTD would invalidate the eAF-New.

- Reference: This element type indicates the reference or ID given to the annexed document when the appropriate box in the eAF-New has been ticked.

- Standard term: Some data already exist as standard terms. Relevant reference dictionaries terminology should be used to type this data in the eAF-New.

- Structure: This element type indicates elements that define the hierarchical structure of the eAF-New and that contain other elements inside. No actual data should be typed in the eAF-New.

Examples
Examples of the content of the elements are given for guidance, either data as free text or listed data given by the DTD.

Business protocol

The exchange protocol is not described in this specification.

The eAF-New could be sent either within an eCTD or as a single document. The eAF-New must always be sent together with the eu-application.dtd (Appendix 2).

Paper submission of the dossier is still required in most countries of the European Community.

The eAF-New could be sent along with the paper submission during the transition from paper to electronic only submissions. When submitted as part of the eCTD, eAF-New should follow the conventions in the EU Module 1 Specification. When sent within an eCTD the eu-application.dtd must be placed in the location indicated in the EU Module 1 Specification [M1SPEC].

Media types to be used for submission of eAF-New are defined in M2 recommendations [M2]. Applicants could also send the eAF-New through available secure electronic means (e.g., E-mail, Eudralink).

For submission of the eAF-New applicants should ask individual regulatory authorities for guidance.

Annexed Documents

Annexed documents must be sent together with the eAF-New document. The file name for annexed documents must be annexaa where aa is one or two digit annex number that corresponds to the subsection number. Example : a document that goes in section 6.9 in AF-New should be named annex9.eee, where eee should be the most commonly used file extension to indicate the format.

When sent within an eCTD the annexed document must be placed in the location indicated in the EU Module 1 Specification [M1SPEC].

Creating the eAF-New

The eAF-New document in XML format should be compliant with the present specification. The way and tools used to create the eAF-New file are not part of this specification. However, any available program that creates, load or submit eAF-New could be used.

References

[CCP]
Notice to Applicants, Volume 2B, eCTD Section
http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm
[eCTD]
http://www.ich.org
[EEA]
http://secretariat.efta.int/euroeco/
[EMEA]
http://www.emea.eu.int/
[FORM]
Notice to Applicants, Volume 2B, CTD Section
http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm
[ICH]
http://www.ich.org
[M1SPEC]
http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm
[M2]
http://www.ich.org
[PHARMA]

Notice to Applicants, Volume 2A, Chapter 1, Section 2, Page 1.
http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm
[REG]
http://heads.medagencies.org/
[XML]
Extensible Markup Language (XML) 1.0 (Third Edition), 4 February 2004
http://www.w3.org/TR/2004/REC-xml-20040204/

Appendix 1 : DTD Elements Description Table

N	Section	Description	Element	Status	Occurrence	Remarks	Example
1	Root	APPLICATION FORM: ADMINISTRATIVE DATA	`applicationform`	Mandatory	Only once	Structure	`declaration and application and maa-particulars and scientific-advice and paediatric-program and other-maa and annexed-documents`
2	D&S	DECLARATION and SIGNATURE	`declaration`	Mandatory	Only once	Structure	`invented-name and strength-quantity and form-name and substance-name and applicant and person-authorised and signature and name-person and function-person and place-signature and date-signature and attach-letter-authorisation and attach-proof-payment`
3	D&S	Product (invented) name	`invented-name`	Mandatory	Only once	Data	`WONDERPIL`
4	D&S	Strength(s)	`strength-quantity`	Mandatory	More	Data	`10 mg`
5	D&S	Pharmaceutical form	`form-name`	Mandatory	Only once	Standard term	`film-coated tablet`
6	D&S	Active Substance(s)	`substance-name`	Mandatory	More	Data	`Iprubofen`
7	D&S	Applicant	`applicant`	Mandatory	Only once	Data	`Superlab Ltd.`
8	D&S	Person authorised for communication on behalf of the Applicant	`person-authorised`	Optional	Only once	Data	`M. Pierre DURAND`
9	D&S	Signature(s)	`signature`	Optional	Only once	End	`Empty`
10	D&S	Name of person signing on behalf of the applicant	`name-person`	Mandatory	Only once	Data	`Ms. Emma Brown`
11	D&S	Function	`function-person`	Mandatory	Only once	Data	`Head Regulatory Affairs`
12	D&S	Place of signature	`place-signature`	Mandatory	Only once	Data	`Brussels`
13	D&S	Date of signature	`date-signature`	Mandatory	Only once	Structure	`date`
14	D&S	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31`
15	D&S	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12`
16	D&S	yyyy	`year`	Mandatory	Only once	Data	`2003`
17	D&S	Letter of authorisation attached in annex 6.4	`attach-letter-authorisation`	Optional	Only once	Reference	`annex4`
18	D&S	Proof of payment attached in annex 6.1	`attach-proof-`	Optional	Only once	Reference	`annex1`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
			`payment`			e	
19	1.	TYPE OF APPLICATION	`application`	Mandatory	Only once	Structure	`type-procedure and orphan-designation and fundamental-change and directive`
20	1.1.	THIS APPLICATION CONCERNS:	`type-procedure`	Mandatory	Only once	List	`mutual-recognition-procedure, centralised-procedure, national-procedure`
21	1.1.1.	A CENTRALISED PROCEDURE	`centralised-procedure`	Mandatory	Only once	Structure	`mandatory-scope or optional-scope or generic-centralised and rapporteur and co-rapporteur and orphan-medicinal-product and consideratio-centralised and attach-copy-correspondence and contact-name`
22	1.1.1.	« Mandatory scope » (Article 3(1))	`mandatory-scope`	Mandatory	Only once	Structure	`annex1 or annex3 or annex4`
23	1.1.1.	Annex (1) (Biotech medicinal product)	`annex1`	Mandatory	Only once	End	`Empty`
24	1.1.1.	Annex (3) (New active substance for mandatory indications)	`annex3`	Mandatory	Only once	Structure	`date-acceptance`
25	1.1.1.	Annex (4) (Orphan designated medicinal product)	`annex4`	Mandatory	Only once	Structure	`date-acceptance`
26	1.1.1.	Date of acceptance by CHMP	`date-acceptance`	Mandatory	Only once	Structure	`date`
27	1.1.1.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11, 12,13,14,15,16,17,18,19,20,21,22, 23,24,25,26,27,28,29,30,31`
28	1.1.1.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11, 12`
29	1.1.1.	yyyy	`year`	Mandatory	Only once	Data	`2005`
30	1.1.1.	« Optional scope » (Article 3(2))	`optional-scope`	Mandatory	Only once	Structure	`annex32a or annex32b`
31	1.1.1.	Article 3(2)(a) (New active substance)	`annex32a`	Mandatory	Only once	Structure	`date-acceptance`
32	1.1.1.	Article 3(2)(b) (Significant innovation or interest of patients at Community level)	`annex32b`	Mandatory	Only once	Structure	`date-acceptance`
33	1.1.1.	Date of acceptance by CHMP	`date-acceptance`	Mandatory	Only once	Structure	`date`
34	1.1.1.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11, 12,13,14,15,16,17,18,19,20,21,22, 23,24,25,26,27,28,29,30,31`
35	1.1.1.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11, 12`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
36	1.1.1.	yyyy	`year`	Mandatory	Only once	Data	2005
37	1.1.1.	« Generic of a Centrally Authorised Medicinal Product » (Article 3(3))	`generic-centralised`	Mandatory	Only once	End	`Empty`
38	1.1.1.	Rapporteur:(Name of CPMP Member)	`rapporteur`	Mandatory	Only once	Data	`Prof. Peter Smith`
39	1.1.1.	Co-rapporteur:(Name of CPMP Member)	`co-rapporteur`	Mandatory	Only once	Data	`Dr. Samantha Jones`
40	1.2	ORPHAN MEDICINAL PRODUCT INFORMATION	`orphan-medicinal-product`	Mandatory	Only once	Structure	`orphan-designation and orphan-condition`
41	1.2.1.	HAS ORPHAN DESIGNATION BEEN APPLIED FOR THIS MEDICINAL PRODUCT ?	`orphan-designation`	Mandatory	Only once	Structure	`orphan-status and orphan-condition`
42	1.2.1.	NO ORPHAN DESIGNATION BEEN APPLIED FOR THIS MEDICINAL PRODUCT	`no-orphan-designation`	Mandatory	Only once	End	`Empty`
43	1.2.1.	Additional field	`orphan-status`	Mandatory	Only once	List	`no-orphan-designation, pending, granted, refused, withdrawn`
44	1.2.1.	Orphan Designation Procedure Number:	`orphan-designation-procnumber`	Mandatory	Only once	Data	`EU/H/1/09/148`
45	1.2.1.	Pending	`pending`	Mandatory	Only once	Structure	`orphan-designation-procnumber`
46	1.2.1.	Orphan Designation Granted	`granted`	Mandatory	Only once	Structure	`date-orphan-status and orphan-benefit and orphan-number-register and attach-orphan-decision`
47	1.2.1.	Date (yyyy-mm-dd) :	`date-orphan-status`	Mandatory	Only once	Structure	`date`
48	1.2.1.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11, 12,13,14,15,16,17,18,19,20,21,22, 23,24,25,26,27,28,29,30,31`
49	1.2.1.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11, 12`
50	1.2.1.	yyyy	`year`	Mandatory	Only once	Data	2003
51	1.2.1.	Based on the criterion of "significant benefit":	`orphan-benefit`	Mandatory	Only once	List	`yes, no`
52	1.2.1.	Number in the Community Register of Orphan Medicinal Products:	`orphan-number-register`	Mandatory	Only once	Data	`EMEA/COMP/1148/02`
53	1.2.1.	Attach copy of the Designation Decision (Annex 6.18)	`attach-orphan-decision`	Optional	Only once	Reference	`annex18`
54	1.2.1.	Orphan Designation Refused	`refused`	Mandatory	Only once	Structure	`date-orphan-status and orphan-`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
							`decision-refnumber`
55	1.2.1.	Date (yyyy-mm-dd) :	`date-orphan-status`	Mandatory	Only once	Structure	`date`
56	1.2.1.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12,13,14,15,16,17,18,19,20,21,22,` `23,24,25,26,27,28,29,30,31`
57	1.2.1.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
58	1.2.1.	yyyy	`year`	Mandatory	Only once	Data	`2003`
59	1.2.1.	Commission Decision Reference Number:	`orphan-decision-refnumber`	Mandatory	Only once	Data	`EU/5/00/001`
60	1.2.1.	Orphan Designation Withdrawn	`withdrawn`	Mandatory	Only once	Structure	`date`
61	1.2.1.	Date (yyyy-mm-dd) :	`date-orphan-status`	Mandatory	Only once	Structure	`date`
62	1.2.1.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12,13,14,15,16,17,18,19,20,21,22,` `23,24,25,26,27,28,29,30,31`
63	1.2.1.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
64	1.2.1.	yyyy	`year`	Mandatory	Only once	Data	`2003`
65	1.2.2.	Additional field	`orphan-condition`	Mandatory	Only once	Structure	`no-orphan-condition or orphan-eu-designation-number and orphan-similar`
66	1.2.2.	Has any medicinal product been designated as an Orphan medicinal product for the condition subject to this application?	`no-orphan-condition`	Mandatory	Only once	End	`Empty`
67	1.2.2.	Please specify the EU Orphan Designation Number(s):	`orphan-eu-designation-number`	Mandatory	More	Data	`EU/H/1/09/148`
68	1.2.2.	Is marketing authorisation granted in the EU?	`orphan-granted`	Mandatory	Only once	Structure	`no-orphan-granted or product-fullname and holder and marketing-authorisation-number and date-first-autorisation`
69	1.2.2.	No marketing authorisation granted in the EU	`no-orphan-granted`	Mandatory	Only once	End	`Empty`
70	1.2.2.	Name, strength, pharmaceutical form of the authorised product	`product-fullname`	Mandatory	Only once	Structure	`invented-name and strength-quantity and strength-unit and form-name`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
71	1.2.2.	Additional field	`invented-name`	Mandatory	Only once	Data	`WONDERPIL`
72	1.2.2.	Additional field	`strength-quantity`	Mandatory	Only once	Data	`10`
73	1.2.2.	Additional field	`strength-unit`	Mandatory	Only once	Data	`mg`
74	1.2.2.	Additional field	`form-name`	Mandatory	Only once	Standard term	`film-coated tablet`
75	1.2.2.	Name of the marketing authorisation holder	`holder`	Mandatory	Only once	Data	`Superlab Ltd.`
76	1.2.2.	Marketing authorisation number(s)	`marketing-authorisation-number`	Mandatory	More	Data	`NL19854`
77	1.2.2.	Date (yyyy-mm-dd) :	`date-first-authorisation`	Mandatory	Only once	Structure	`date`
78	1.2.2.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31`
79	1.2.2.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12`
80	1.2.2.	yyyy	`year`	Mandatory	Only once	Data	`2003`
81	1.2.2.	Is the medicinal product considered as "similar" as defined in Art.3	`orphan-similar`	Mandatory	Only once	List	`yes, no`
82	1.5.	CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED…	`consideration-centralised`	Optional	Only once	Structure	`conditional-approval or exceptional-circumstances and accelerated-review`
83	1.5.1.	Conditional Approval	`conditional-approval`	Mandatory	Only once	End	`Empty`
84	1.5.2	Exceptional Circumstances	`exceptional-circumstances`	Mandatory	Only once	End	`Empty`
85	1.5.3.	Accelerated Review	`accelerated-review`	Optional	Only once	Structure	`date-acceptance`
86	1.5.3.	Date of acceptance by CHMP	`date-acceptance`	Mandatory	Only once	Structure	`date`
87	1.5.3.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31`
88	1.5.3.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12`
89	1.5.3.	yyyy	`year`	Mandatory	Only once	Data	`2005`
90	5.3.	Attach copy of correspondence with the EC	`attach-copy-correspondence`	Optional	Only once	Reference	`annex16`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
91	2.4.1.	holder/person legally responsible for placing the product	`contact-name`	Mandatory	Only once	Data	`Dr. James O'Connor`
92	1.1.2.	A MUTUAL RECOGNITION PROCEDURE	`mutual-recognition-procedure`	Mandatory	Only once	Structure	`eu-member-state and date-first-authorisation and mrp-marketing-authorisation-number and mrp-procedure-number and mrp-first-use or mrp-repeat-use`
93	1.1.2.	Reference Member State:	`eu-member-state`	Mandatory	Only once	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL, NO,PL,PT,RO,SE,SI,SK,UK`
94	1.1.2.	Date of authorisation:	`date-first-authorisation`	Mandatory	Only once	Structure	`date`
95	1.1.2.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11, 12,13,14,15,16,17,18,19,20,21,22, 23,24,25,26,27,28,29,30,31`
96	1.1.2.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11, 12`
97	1.1.2.	yyyy	`year`	Mandatory	Only once	Data	`2003`
98	1.1.2.	Marketing authorisation number:	`mrp-marketing-authorisation-number`	Mandatory	Only once	Data	`NL23592`
99	1.1.2.	Procedure number:	`mrp-procedure-number`	Mandatory	Only once	Data	`FR/H/388/01`
100	1.1.2.	First use	`mrp-first-use`	Mandatory	Only once	Structure	`eu-member-state`
101	1.1.2.	Concerned Member State(s)	`eu-member-state`	Mandatory	More	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL, NO,PL,PT,RO,SE,SI,SK,UK`
102	1.1.2.	Proposed Common Renewal Date:	`date-proposed-common-renewal`	Mandatory	Only once	Structure	`date`
103	1.1.2.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11, 12,13,14,15,16,17,18,19,20,21,22, 23,24,25,26,27,28,29,30,31`
104	1.1.2.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11, 12`
105	1.1.2.	yyyy	`year`	Mandatory	Only once	Data	`2003`
106	1.1.2.	If a waiver or amendment of PSUR-cycle is applied for	`specify-waiver-amendment-psur?`	Optional	Only once	Data	`Specify`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
107	1.1.2.	Repeat Use 1st Wave	`mrp-repeat-use`	Optional	More	Structure	`eu-member-state`
108	1.1.2.	Concerned Member State(s)	`eu-member-state`	Mandatory	More	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,NO,PL,PT,RO,SE,SI,SK,UK`
109	1.1.2.	Agreed Common Renewal Date:	`date-agreed-common-renewal`	Mandatory	Only once	List	`date`
110	1.1.2.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31`
111	1.1.2.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12`
112	1.1.2.	yyyy	`year`	Mandatory	Only once	Data	`2003`
113	1.5.	CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED…	`consideration-requested`	Optional	Only once	Structure	`exceptional-circumstances or article101 or article105 or article74a`
114	1.5.2.	Exceptional Circumstances	`exceptional-circumstances`	Mandatory	Only once	End	`Empty`
115	1.5.4.	Article 10(1) of Directive 2001/83/EC	`article101`	Mandatory	Only once	End	`Empty`
116	1.5.5.	Article 10(5) of Directive 2001/83/EC	`article105`	Mandatory	Only once	End	`Empty`
117	1.5.6.	Article 74(a) of Directive 2001/83/EC	`article74a`	Mandatory	Only once	End	`Empty`
118	1.1.3.	A DECENTRALISED PROCEDURE	`decentralised-procedure`	Mandatory	Only once	Structure	`eu-member-state and procedure-number and first-use and specify-waiver-amendment-psur and consideration-requested`
119	1.1.3.	Reference Member State:	`eu-member-state`	Mandatory	Only once	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,NO,PL,PT,RO,SE,SI,SK,UK`
120	1.1.3.	Procedure number:	`procedure-number`	Mandatory	Only once	Data	`FR/H/388/01`
121	1.1.3.	First use	`first-use`	Mandatory	Only once	Structure	`eu-member-state`
122	1.1.3.	Concerned Member State(s)	`eu-member-state`	Mandatory	More	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,NO,PL,PT,RO,SE,SI,SK,UK`
123	1.1.3.	If a waiver or amendment of PSUR-cycle is applied for	`specify-waiver-amendment-psur`	Optional	Only once	Data	`Specify`
124	1.5.	CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED…	`consideration-requested`	Optional	Only once	Structure	`exceptional-circumstances or article101 or article105 or article74a`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
125	1.5.2.	Exceptional Circumstances	`exceptional-circumstances`	Mandatory	Only once	End	`Empty`
126	1.5.4.	Article 10(1) of Directive 2001/83/EC	`article101`	Mandatory	Only once	End	`Empty`
127	1.5.5.	Article 10(5) of Directive 2001/83/EC	`article105`	Mandatory	Only once	End	`Empty`
128	1.5.6.	Article 74(a) of Directive 2001/83/EC	`article74a`	Mandatory	Only once	End	`Empty`
129	1.1.4.	A NATIONAL PROCEDURE	`national-procedure`	Mandatory	Only once	Structure	`eu-member-state and national-application-number and specify-waiver-amendment-psur and consideration-requested and other-maa-national`
130	1.1.4.	Member State	`eu-member-state`	Optional	More	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL, NO,PL,PT,RO,SE,SI,SK,UK`
131	1.1.4.	If available, application number	`national-application-number`	Optional	Only once	Data	`RVG 12345`
132	1.1.4.	If a waiver or amendment of PSUR-cycle is applied for	`specify-waiver-amendment-psur?`	Optional	Only once	Data	`Specify`
133	1.5.	CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED…	`consideration-requested`	Optional	Only once	Structure	`exceptional-circumstances or article101 or article105 or article74a`
134	1.5.2.	Exceptional Circumstances	`exceptional-circumstances`	Mandatory	Only once	End	`Empty`
135	1.5.4.	Article 10(1) of Directive 2001/83/EC	`article101`	Mandatory	Only once	End	`Empty`
136	1.5.5.	Article 10(5) of Directive 2001/83/EC	`article105`	Mandatory	Only once	End	`Empty`
137	1.5.6.	Article 74(a) of Directive 2001/83/EC	`article74a`	Mandatory	Only once	End	`Empty`
138	5.1	FOR NATIONAL APPLICATIONS ONLY	`other-maa-national`	Mandatory	Only once	Structure	`application-pending-same-product and authorisation-granted-same-product and therapeutic-implication and state-authorisation`
139	5.1.1.	Is there another Member State(s) where an application for the same* product is pending?	`application-pending-same-product`	Mandatory	Only once	List	`yes, no`
140	5.1.2.	Is there another Member State(s) where an authorisation is granted for the same product?	`authorisation-granted-same-product`	Mandatory	Only once	List	`yes, no`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
141	5.1.2.	Are there any differences which have therapeutic implications between this application and the applications/authorisations for the same product in other Member States	`therapeutic-implication`	Optional	Only once	List	`yes, no`
142	5.1.	If yes, please elaborate:	`therapeutic-implication-note`	Mandatory	Only once	Data	`Explanation`
143	5.1.3.	Is there another Member State(s) where an authorisation was refused/ suspended/ revoked by competent authorities for the same* product?	`state-authorisation`	Optional	Only once	List	`yes, no`
144	1.3.	IS THIS AN APPLICATION FOR A CHANGE LEADING TO AN EXTENSION	`fundamental-change`	Mandatory	Only once	List	`specify-change and line-extension and holder and product-fullname and manumber-application-made`
145	1.3.	Please specify:	`specify-change`	Mandatory	Only once	Data	`Specify`
146	1.3.	The change to your existing marketing authorisation is considered to be a line extension.	`line-extension`	Mandatory	Only once	Structure	`line-extension-qual-notnew-substance and line-extension-bioavailability and line-extension-change-pharmacokinetics and line-extension-change-strength and line-extension-change-newform and line-extension-add-route`
147	1.3.	qualitative change in declared active substance not defined as a new active substance	`line-extension-qual-notnew-substance`	Optional	Only once	List	`line-extension-replacement-salt or line-extension-replacement-isomer or line-extension-replacement-biological or line-extension-new-ligand or line-extension-change-extraction`
148	1.3.	replacement by a different salt/ester, complex/derivative (same therapeutic moiety)	`line-extension-replacement-salt`	Mandatory	Only once	End	`Empty`
149	1.3.	replacement by a different isomer, mixture of isomers, of a mixture by an isolated isomer	`line-extension-replacement-isomer`	Mandatory	Only once	End	`Empty`
150	1.3.	replacement of a biological substance or product of biotechnology	`line-extension-replacement-biological`	Mandatory	Only once	End	`Empty`
151	1.3.	new ligand or coupling mechanism for a radiopharmaceutical	`line-extension-new-ligand`	Mandatory	Only once	End	`Empty`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
152	1.3.	change to the extraction solvent or the radio of herbal drug to herbal drug preparation	`line-extension-change-extraction`	Mandatory	Only once	End	`Empty`
153	1.3.	addition / change of indication in a different therapeutic area	`line-extension-bioavailability`	Optional	Only once	End	`Empty`
154	1.3.	change of pharmacokinetics (including different bioavailability)	`line-extension-change-pharmacokinetics`	Optional	Only once	End	`Empty`
155	1.3.	addition of a new strength / quantitative change to the active substance(s)	`line-extension-change-strength`	Optional	Only once	End	`Empty`
156	1.3.	change or addition of a new pharmaceutical form	`line-extension-change-newform`	Optional	Only once	End	`Empty`
157	1.3.	addition of a new route of administration	`line-extension-add-route`	Optional	Only once	End	`Empty`
158	1.3.	other change(s), please specify	`line-extension-other`	Mandatory	Only once	Data	`Explanation`
159	1.3.	Name of the marketing authorisation holder:	`holder`	Mandatory	Only once	Data	`Superlab Ltd.`
160	1.3.	Name, strength, pharmaceutical form of the existing product:	`product-fullname`	Mandatory	Only once	Structure	`invented-name and strength-quantity and strength-unit and form-name`
161	1.3.	Additional field	`invented-name`	Mandatory	Only once	Data	`WONDERPIL`
162	1.3.	Additional field	`strength-quantity`	Mandatory	Only once	Data	`10`
163	1.3.	Additional field	`strength-unit`	Mandatory	Only once	Data	`mg`
164	1.3.	Additional field	`form-name`	Mandatory	Only once	Standard term	`film-coated tablet`
165	1.3.	Marketing authorisation number(s):	`manumber-application-made`	Mandatory	More	Data	`RVG 13752`
166	1.4.	THIS APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC	`directive`	Mandatory	Only once	List	`complete or generic or hybrid or similar-biological or well-established-use or fixed-combination or informed-consent or traditional-use-registration`
167	1.4.1.	Article 8.3 application	`complete`	Mandatory	Only once	List	`new-substance, known-substance`
168	1.4.2.	Article 10(1) generic application	`generic`	Mandatory	Only once	Structure	`reference-authorised-eea and reference-medicinal-product and bioequivalence-study`
169	1.4.2.	Reference medicinal product authorised for not less than 6/10 years in EEA	`reference-authorised-eea`	Mandatory	Only once	Structure	`product-fullname and holder and date-first-autorisation and eu-`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
							`member-state`
170	1.4.2.	Product name, strength, pharmaceutical form:	`product-fullname`	Mandatory	Only once	Structure	`invented-name and strength-quantity and strength-unit and form-name`
171	1.4.2.	Additional field	`invented-name`	Mandatory	Only once	Data	`WONDERPIL`
172	1.4.2.	Additional field	`strength-quantity`	Mandatory	Only once	Data	`10`
173	1.4.2.	Additional field	`strength-unit`	Mandatory	Only once	Data	`mg`
174	1.4.2.	Additional field	`form-name`	Mandatory	Only once	Standard term	`film-coated tablet`
175	1.4.2.	Marketing authorisation holder:	`holder`	Mandatory	Only once	Data	`InventorLab Co.`
176	1.4.2.	Marketing authorisation number(s):	`marketing-authorisation-number`	Mandatory	More	Data	`NL12356`
177	1.4.2.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31`
178	1.4.2.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12`
179	1.4.2.	yyyy	`year`	Mandatory	Only once	Data	`2003`
180	1.4.2.	Member State (EEA)/Community:	`eu-member-state`	Optional	More	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,NO,PL,PT,RO,SE,SI,SK,UK`
181	1.4.2.	Reference medicinal product where the application is made:	`reference-medicinal-product`	Optional	More	Structure	`product-fullname and holder and marketing-authorisation-number`
182	1.4.2.	Product name, strength, pharmaceutical form:	`product-fullname`	Mandatory	Only once	Structure	`invented-name and strength-quantity and strength-unit and form-name`
183	1.4.2.	Additional field	`invented-name`	Mandatory	Only once	Data	`WONDERPIL`
184	1.4.2.	Additional field	`strength-quantity`	Mandatory	Only once	Data	`10`
185	1.4.2.	Additional field	`strength-unit`	Mandatory	Only once	Data	`mg`
186	1.4.2.	Additional field	`form-name`	Mandatory	Only once	Standard term	`film-coated tablet`
187	1.4.2.	Marketing authorisation holder:	`holder`	Mandatory	Only once	Data	`InventorLab Co.`
188	1.4.2.	Marketing authorisation number(s):	`marketing-authorisation-number`	Mandatory	More	Data	`NL12356`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
189	1.4.2.	Medicinal Product used for bioequivalence study	bioequivalence-study	Optional	More	Structure	product-fullname and holder and eu-member-state
190	1.4.2.	Product name, strength, pharmaceutical form :	product-fullname	Mandatory	Only once	Structure	invented-name and strength-quantity and strength-unit and form-name
191	1.4.2.	Aditional Field	invented-name	Mandatory	Only once	Data	ORIGINPIL
192	1.4.2.	Aditional Field	strength-quantity	Mandatory	Only once	Data	10
193	1.4.2.	Aditional Field	strength-unit	Mandatory	Only once	Data	mg
194	1.4.2.	Aditional Field	form-name	Mandatory	Only once	Standard term	film-coated tablet
195	1.4.2.	Member State of source:	eu-member-state	Mandatory	Only once	List	AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL, NO,PL,PT,RO,SE,SI,SK,UK
196	1.4.3.	Article 10(3) hybrid application	hybrid	Mandatory	Only once	Structure	reference-authorised-eea and reference-medicinal-product and bioequivalence-study and different-original-product
197	1.4.3.	Reference medicinal product authorised for not less than 6/10 years in EEA	reference-authorised-eea	Mandatory	Only once	Structure	product-fullname and holder and date-first-autorisation and eu-member-state
198	1.4.3.	Product name, strength, pharmaceutical form:	product-fullname	Mandatory	Only once	Structure	invented-name and strength-quantity and strength-unit and form-name
199	1.4.3.	Additional field	invented-name	Mandatory	Only once	Data	WONDERPIL
200	1.4.3.	Additional field	strength-quantity	Mandatory	Only once	Data	10
201	1.4.3.	Additional field	strength-unit	Mandatory	Only once	Data	mg
202	1.4.3.	Additional field	form-name	Mandatory	Only once	Standard term	film-coated tablet
203	1.4.3.	Marketing authorisation holder:	holder	Mandatory	Only once	Data	InventorLab Co.
204	1.4.3.	Marketing authorisation number(s):	marketing-authorisation-number	Mandatory	More	Data	NL12356
205	1.4.3.	dd	day	Mandatory	Only once	List	01,02,03,04,05,06,07,08,09,10,11, 12,13,14,15,16,17,18,19,20,21,22, 23,24,25,26,27,28,29,30,31
206	1.4.3.	mm	month	Mandatory	Only once	List	01,02,03,04,05,06,07,08,09,10,11, 12

N	Section	Description	Element	Status	Occurrence	Remarks	Example
207	1.4.3.	yyyy	`year`	Mandatory	Only once	Data	2003

208	1.4.3.	Member State (EEA)/Community:	`eu-member-state`	Optional	More	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,`
							`FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,`
							`NO,PL,PT,RO,SE,SI,SK,UK`

209	1.4.3.	Reference medicinal product where the application is made:	`reference-medicinal-product`	Optional	More	Structure	`product-fullname and holder and` `marketing-authorisation-number`

210	1.4.3.	Product name, strength, pharmaceutical form:	`product-fullname`	Mandatory	Only once	Structure	`invented-name and strength-`
							`quantity and strength-unit and`
							`form-name`

211	1.4.3.	Additional field	`invented-name`	Mandatory	Only once	Data	`WONDERPIL`
212	1.4.3.	Additional field	`strength-quantity`	Mandatory	Only once	Data	`10`
213	1.4.3.	Additional field	`strength-unit`	Mandatory	Only once	Data	`mg`
214	1.4.3.	Additional field	`form-name`	Mandatory	Only once	Standard term	`film-coated tablet`
215	1.4.3.	Marketing authorisation holder:	`holder`	Mandatory	Only once	Data	`InventorLab Co.`
216	1.4.3.	Marketing authorisation number(s):	`marketing-authorisation-number`	Mandatory	More	Data	`NL12356`
217	1.4.3.	Medicinal Product used for bioequivalence study	`bioequivalence-study`	Optional	More	Structure	`product-fullname and holder and` `eu-member-state`

218	1.4.3.	Product name, strength, pharmaceutical form :	`product-fullname`	Mandatory	Only once	Structure	`invented-name and strength-`
							`quantity and strength-unit and`
							`form-name`

219	1.4.3.	Aditional Field	`invented-name`	Mandatory	Only once	Data	`ORIGINPIL`
220	1.4.3.	Aditional Field	`strength-quantity`	Mandatory	Only once	Data	`10`
221	1.4.3.	Aditional Field	`strength-unit`	Mandatory	Only once	Data	`mg`
222	1.4.3.	Aditional Field	`form-name`	Mandatory	Only once	Standard term	`film-coated tablet`

223	1.4.3.	Member State of source:	`eu-member-state`	Mandatory	Only once	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,`
							`FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,`
							`NO,PL,PT,RO,SE,SI,SK,UK`

224	1.4.3.	Difference(s) compared to the original product:	`different-original-product`	Mandatory	Only once	Structure	`different-active-substance and`
							`different-therapeutic-use and`
							`different-pharmaceutical-form and`
							`different-strength and different-`
							`route and different-`
							`bioequivalence`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
225	1.4.3.	changes in the active substance(s)	`different-active-substance`	Optional	Only once	End	`Empty`
226	1.4.3.	change in therapeutic indications	`different-therapeutic-use`	Optional	Only once	End	`Empty`
227	1.4.3.	change in pharmaceutical form	`different-pharmaceutical-form`	Optional	Only once	End	`Empty`
228	1.4.3.	change in strength	`different-strength`	Optional	Only once	End	`Empty`
229	1.4.3.	change in route of administration	`different-route`	Optional	Only once	End	`Empty`
230	1.4.3.	bioequivalence cannot be demonstrated	`different-bioequivalence`	Optional	Only once	End	`Empty`
231	1.4.4.	Article 10(4) similar biological application	`similar-biological`	Mandatory	Only once	Structure	`reference-authorised-eea and reference-medicinal-product and bioequivalence-study`
232	1.4.4.	Reference medicinal product authorised for not less than 6/10 years in EEA	`reference-authorised-eea`	Mandatory	Only once	Structure	`product-fullname and holder and date-first-autorisation and eu-member-state`
233	1.4.4.	Product name, strength, pharmaceutical form:	`product-fullname`	Mandatory	Only once	Structure	`invented-name and strength-quantity and strength-unit and form-name`
234	1.4.4.	Additional field	`invented-name`	Mandatory	Only once	Data	`WONDERPIL`
235	1.4.4.	Additional field	`strength-quantity`	Mandatory	Only once	Data	`10`
236	1.4.4.	Additional field	`strength-unit`	Mandatory	Only once	Data	`mg`
237	1.4.4.	Additional field	`form-name`	Mandatory	Only once	Standard term	`film-coated tablet`
238	1.4.4.	Marketing authorisation holder:	`holder`	Mandatory	Only once	Data	`InventorLab Co.`
239	1.4.4.	Marketing authorisation number(s):	`marketing-authorisation-number`	Mandatory	More	Data	`NL12356`
240	1.4.4.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11, 12,13,14,15,16,17,18,19,20,21,22, 23,24,25,26,27,28,29,30,31`
241	1.4.4.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11, 12`
242	1.4.4.	yyyy	`year`	Mandatory	Only once	Data	`2003`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
243	1.4.4.	Member State (EEA)/Community:	`eu-member-state`	Optional	More	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL, NO,PL,PT,RO,SE,SI,SK,UK`
244	1.4.4.	Reference medicinal product where the application is made:	`reference-medicinal-product`	Optional	More	Structure	`product-fullname and holder and marketing-authorisation-number`
245	1.4.4.	Product name, strength, pharmaceutical form:	`product-fullname`	Mandatory	Only once	Structure	`invented-name and strength-quantity and strength-unit and form-name`
246	1.4.4.	Additional field	`invented-name`	Mandatory	Only once	Data	`WONDERPIL`
247	1.4.4.	Additional field	`strength-quantity`	Mandatory	Only once	Data	`10`
248	1.4.4.	Additional field	`strength-unit`	Mandatory	Only once	Data	`mg`
249	1.4.4.	Additional field	`form-name`	Mandatory	Only once	Standard term	`film-coated tablet`
250	1.4.4.	Marketing authorisation holder:	`holder`	Mandatory	Only once	Data	`InventorLab Co.`
251	1.4.4.	Marketing authorisation number(s):	`marketing-authorisation-number`	Mandatory	More	Data	`NL12356`
252	1.4.4.	Medicinal Product used for bioequivalence study	`bioequivalence-study`	Optional	More	Structure	`product-fullname and holder and eu-member-state`
253	1.4.4.	Product name, strength, pharmaceutical form :	`product-fullname`	Mandatory	Only once	Structure	`invented-name and strength-quantity and strength-unit and form-name`
254	1.4.4.	Aditional Field	`invented-name`	Mandatory	Only once	Data	`ORIGINPIL`
255	1.4.4.	Aditional Field	`strength-quantity`	Mandatory	Only once	Data	`10`
256	1.4.4.	Aditional Field	`strength-unit`	Mandatory	Only once	Data	`mg`
257	1.4.4.	Aditional Field	`form-name`	Mandatory	Only once	Standard term	`film-coated tablet`
258	1.4.4.	Member State of source:	`eu-member-state`	Mandatory	Only once	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL, NO,PL,PT,RO,SE,SI,SK,UK`
259	1.4.5.	Article 10a well-established use application	`well-established-use`	Mandatory	Only once	End	`Empty`
260	1.4.6.	Article 10b fixed combination application	`fixed-combination`	Mandatory	Only once	End	`Empty`
261	1.4.7.	Article 10c informed consent application	`informed-consent`	Mandatory	Only once	Structure	`product-fullname and holder and marketing-authorisation-number and attach-letter-consent`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
262	1.4.7.	Product name, strength, pharmaceutical form:	`product-fullname`	Mandatory	Only once	Structure	`invented-name and strength-quantity and strength-unit and form-name`
263	1.4.7.	Additional field	`invented-name`	Mandatory	Only once	Data	`WONDERPIL`
264	1.4.7.	Additional field	`strength-quantity`	Mandatory	Only once	Data	`10`
265	1.4.7.	Additional field	`strength-unit`	Mandatory	Only once	Data	`mg`
266	1.4.7.	Additional field	`form-name`	Mandatory	Only once	Standard term	`film-coated tablet`
267	1.4.7.	Marketing authorisation holder:	`holder`	Mandatory	Only once	Data	`InventorLab Co.`
268	1.4.7.	Marketing authorisation number(s):	`marketing-authorisation-number`	Mandatory	More	Data	`NL12356`
269	1.4.7.	Attach letter of consent from holder of the authorised product	`attach-letter-consent`	Optional	Only once	Reference	`annex2`
270	1.4.8.	Article 16a Traditional use registration for herbal medicinal product	`traditional-use-registration`	Mandatory	Only once	End	`Empty`
271	2.	MARKETING AUTHORISATION APPLICATION PARTICULARS	`maa-particulars`	Mandatory	Only once	Structure	`names-atccode and strength-form-route and legal-status and dossier and manufacturers and qualitative-quantitative-composition`
272	2.1.	Name(s) and ATC code	`names-atccode`	Mandatory	Only once	Structure	`medicinal-product and active-substance and atc-class`
273	2.1.1.	Additional field	`medicinal-product`	Mandatory	Only once	Structure	`invented-name and attach-invented-name`
274	2.1.1.	Proposed (invented) name	`invented-name`	Mandatory	Only once	Data	`WONDERPIL`
275	2.1.1.	If different (invented) names in different Member States are proposed in a mutual recognition procedure, these should be listed in Annex 6.19	`attach-invented-name`	Optional	Only once	Reference	`annex19`
276	2.1.2.	Name of the active substance(s):	`active-substance`	Mandatory	More	Data	`Iprubofen`
277	2.1.3.	Pharmacotherapeutic group (Please use current ATC code):	`atc-class`	Mandatory	More	Structure	`atc-code and atc-version and atc-name and atc-pending`
278	2.1.3.	ATC Code:	`atc-code`	Mandatory	Only once	Standard term	`M01AE01`
279	2.1.3.	Group:	`atc-name`	Mandatory	Only once	Data	`Antiinflamatory and antirheumatic products, non steroids`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
280	2.1.3.	Additional field	`atc-version`	Optional	Only once	Data	`Version of ATC list`
281	2.1.3.	Please indicate if the application for the ATC Code is still pending:	`atc-pending`	Mandatory	Only once	List	`yes, no`
282	2.2.	Strength, pharmaceutical form, route of administration, container and pack sizes	`strength-form-route`	Mandatory	Only once	Structure	`form-name and substance-strength and routes and types-of-pack`
283	2.2.1.	Pharmaceutical form:	`form-name`	Mandatory	Only once	Standard term	`film-coated tablet`
284	2.2.1.	Additional field	`substance-strength`	Mandatory	More	Structure	`substance-name and strength-quantity and strength-unit`
285	2.2.1.	Active substance(s)	`substance-name`	Mandatory	More	Data	`Iprubofen`
286	2.2.1.	Strength(s)	`strength-quantity`	Mandatory	More	Data	`10`
287	2.2.1.	Additional field	`strength-unit`	Mandatory	More	Data	`mg`
288	2.2.2.	Additional field	`routes`	Mandatory	Only once	Structure	`route-name`
289	2.2.2.	Route(s) of administration (use current list of standard terms - European Pharmacopoeia)	`route-name`	Mandatory	More	Standard term	`oral`
290	2.2.3.	Container, container material, closure, administration device(s) including description of material (s) from which it is constructed. (use current list of standard terms - European Pharmacopoeia)	`types-of-pack`	Mandatory	Only once	Structure	`type-of-pack and attach-list-mockup`
291	2.2.3.	Additional field	`type-of-pack`	Mandatory	More	Structure	`container and container-material and closure and closure-material and device-name and device-material and presentation`
292	2.2.3.	Container	`container`	Mandatory	Only once	Standard term	`blister`
293	2.2.3.	Additional field	`container-material`	Mandatory	Only once	Data	`PVC/Aluminium`
294	2.2.3.	closure	`closure`	Optional	Only once	Data	`stopper`
295	2.2.3.	Additional field	`closure-material`	Optional	Only once	Data	`rubber`
296	2.2.3.	administration device(s)	`device-name`	Optional	More	Data	`spoon`
297	2.2.3.	Additional field	`device-material`	Optional	More	Data	`polypropylene`
298	2.2.3.	For each type of pack give:	`presentation`	Mandatory	Only once	Structure	`pack-size and life-shelf and life-open and life-reconstituted and storage-shelf and storage-shelf-open`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
299	2.2.3.1.	Package size(s):	`pack-size`	Mandatory	Only once	Data	`12,24,48 tablets per box`
300	2.2.3.2.	Proposed shelf life:	`life-shelf`	Mandatory	Only once	Data	`36 months`
301	2.2.3.3.	Proposed shelf life (after first opening container):	`life-open`	Optional	Only once	Data	`Not applicable`
302	2.2.3.4.	Proposed shelf life (after reconstitution or dilution):	`life-reconstituted`	Optional	Only once	Data	`Not applicable`
303	2.2.3.5.	Proposed storage conditions:	`storage-shelf`	Mandatory	Only once	Data	`Store below 25°C`
304	2.2.3.6.	Proposed storage conditions after first opening:	`storage-shelf-open`	Optional	Only once	Data	`Not applicable`
305	2.2.3.	Attach list of Mock-ups or Samples/specimens sent with the application, as appropriate (Annex 6.17).	`attach-list-mockup`	Optional	Only once	Reference	`annex17`
306	2.3.	Legal status	`legal-status`	Mandatory	Only once	List	`prescription, non-prescription`
307	2.3.1.	For products subject to medical prescription:	`prescription`	Mandatory	Only once	Structure	`product-prescription-renew and product-prescription-not-renew and product-special-prescription and product-restricted-prescription`
308	2.3.2.	product on prescription which may be renewed (if applicable)	`product-prescription-renew`	Optional	Only once	End	`Empty`
309	2.3.2.	product on prescription which may not be renewed (if applicable)	`product-prescription-not-renew`	Optional	Only once	End	`Empty`
310	2.3.2.	product on special prescription	`product-special-prescription`	Optional	Only once	End	`Empty`
311	2.3.2.	product on restricted prescription	`product-restricted-prescription`	Optional	Only once	End	`Empty`
312	2.3.1.	Supply for products not subject to medical prescription	`non-prescription`	Mandatory	Only once	Structure	`supply and promotion-healthcare`
313	2.3.3.	Supply for products not subject to medical prescription	`supply`	Mandatory	Only once	List	`pharmacies, not-pharmacies`
314	2.3.4.	Promotion for products not subject to medical prescription	`promotion-healthcare`	Mandatory	Only once	List	`healthcare-only, general-public`
315	2.4.	Marketing authorisation holder / Contact persons / Company	`dossier`	Mandatory	Only once	Structure	`marketing-holder and person-com-during-procedure and person-com-`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
							`after-authorisation and person-pharmacovigilance and scientific-service-mah`
316	2.4.1.	Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the Community / each MS:	`marketing-holder`	Mandatory	More	Data	`Superlab Ltd.`
317	2.4.1.	(Company) Name:	`company-name`	Mandatory	Only once	Data	`Superlab Ltd.`
318	2.4.1.	Additional field	`contact`	Mandatory	Only once	Structure	`address01 and address02 and zipcode and town and country and phone and fax and email`
319	2.4.1.	Address:	`address01`	Optional	Only once	Data	`Inventorshouse`
320	2.4.1.	Additional field	`address02`	Optional	Only once	Data	`7, Lemontreestreet`
321	2.4.1.	Additional field	`zipcode`	Optional	Only once	Data	`ZW5 8ML`
322	2.4.1.	Additional field	`town`	Optional	Only once	Data	`London`
323	2.4.1.	Country:	`country`	Mandatory	Only once	Data	`UK`
324	2.4.1.	Telephone:	`phone`	Mandatory	Only once	Data	`44 20 81820431`
325	2.4.1.	Telefax:	`fax`	Optional	Only once	Data	`44 20 81856432`
326	2.4.1.	E-Mail:	`email`	Optional	Only once	Data	`inventor@chello.nl`
327	2.4.1.	Attach proof of establishment of the applicant in the EEA (Annex 6.3)	`attach-proof-establishment`	Optional	Only once	Reference	`annex3`
328	2.4.2.	Person/company authorised for communication on behalf of the applicant during the procedure in the Community /each MS:	`person-com-during-procedure`	Mandatory	More	Structure	`contact-name and company-name and contact and attach-letter-authorisation`
329	2.4.2.	Name:	`contact-name`	Mandatory	Only once	Data	`Dr P..Black`
330	2.4.2.	Company name:	`company-name`	Mandatory	Only once	Data	`Superlab Ltd.`
331	2.4.2.	Additional field	`contact`	Mandatory	Only once	Structure	`address01 and address02 and zipcode and town and country and phone and fax and email`
332	2.4.2.	Address:	`address01`	Optional	Only once	Data	`Inventorshouse`
333	2.4.2.	Additional field	`address02`	Optional	Only once	Data	`7, Lemontreestreet`
334	2.4.2.	Additional field	`zipcode`	Optional	Only once	Data	`ZW5 8ML`
335	2.4.2.	Additional field	`town`	Optional	Only once	Data	`London`
336	2.4.2.	Country:	`country`	Mandatory	Only once	Data	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
							`NO,PL,PT,RO,SE,SI,SK,UK`
337	2.4.2.	Telephone:	`phone`	Mandatory	Only once	Data	`44 20 81820543`
338	2.4.2.	Telefax:	`fax`	Optional	Only once	Data	`44 20 81856433`
339	2.4.2.	E-Mail:	`email`	Optional	Only once	Data	`black.inventor@chello.uk`
340	2.4.2.	If different to 2.4.1 above, Attach letter of authorisation (Annex 6.4)	`attach-letter-authorisation`	Optional	Only once	Reference	`annex4`
341	2.4.3.	Person/Company authorised for communication between the marketing authorisation holder and the competent authorities after authorisation if different from 2.4.2 in the Community/each MS:	`person-com-after-authorisation`	Mandatory	More	Structure	`contact-name and company-name and contact and attach-letter-authorisation`
342	2.4.3.	Name:	`contact-name`	Mandatory	Only once	Data	`Dr. A. White`
343	2.4.3.	Company name:	`company-name`	Mandatory	Only once	Data	`Drugcompetence`
344	2.4.3.	Additional field	`contact`	Mandatory	Only once	Structure	`address01 and address02 and zipcode and town and country and phone and fax and email`
345	2.4.3.	Address:	`address01`	Optional	Only once	Data	`Old Brigde`
346	2.4.3.	Additional field	`address02`	Optional	Only once	Data	`5, Bird Lane`
347	2.4.3.	Additional field	`zipcode`	Optional	Only once	Data	`KL6 4PQ`
348	2.4.3.	Additional field	`town`	Optional	Only once	Data	`London`
349	2.4.3.	Country:	`country`	Mandatory	Only once	Data	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL, NO,PL,PT,RO,SE,SI,SK,UK`
350	2.4.3.	Telephone:	`phone`	Mandatory	Only once	Data	`44 20 51530311`
351	2.4.3.	Telefax:	`fax`	Optional	Only once	Data	`44 20 5153765`
352	2.4.3.	E-Mail:	`email`	Optional	Only once	Data	`a.white@drugcpt.uk`
353	2.4.3.	If different to 2.4.1 above, Attach letter of authorisation (Annex 6.4)	`attach-letter-authorisation`	Optional	Only once	Reference	`annex4`
354	2.4.4.	Qualified person in the EEA for Pharmacovigilance	`person-pharmacovigilance`	Mandatory	More	Structure	`contact-name and company-name and contact and attach-cv-person`
355	2.4.4.	Name:	`contact-name`	Mandatory	Only once	Data	`Dr. M. Watson`
356	2.4.4.	Company name:	`company-name`	Mandatory	Only once	Data	`Superlab Sister ltd`
357	2.4.4.	Additional field	`contact`	Mandatory	Only once	Structure	`address01 and address02 and zipcode and town and country and phone and fax and email`
358	2.4.4.	Address:	`address01`	Optional	Only once	Data	`Eagle Centre`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
359	2.4.4.	Additional field	`address02`	Optional	Only once	Data	`Eagle Terrace 2`
360	2.4.4.	Additional field	`zipcode`	Optional	Only once	Data	`01446Z`
361	2.4.4.	Additional field	`town`	Optional	Only once	Data	`Dublin`

362	2.4.4.	Country:	`country`	Mandatory	Only once	Data	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,`
							`FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,`
							`NO,PL,PT,RO,SE,SI,SK,UK`

363	2.4.4.	Telephone:	`phone`	Mandatory	Only once	Data	`35327875082`
364	2.4.4.	Telefax:	`fax`	Optional	Only once	Data	`35327575065`
365	2.4.4.	E-Mail:	`email`	Optional	Only once	Data	`m.watson.@lab.ie`
366	2.4.4.	Attach C.V. of qualified person (Annex 6.5)	`attach-cv-person`	Optional	Only once	Reference	`annex5`
367	2.4.5.	Scientific service of the MAH in the EEA	`scientific-service-mah`	Mandatory	More	Structure	`contact-name and company-name and` `contact`
368	2.4.5.	Name of contact person:	`contact-name`	Mandatory	Only once	Data	`Mrs N. Yellow`
369	2.4.5.	Company name:	`company-name`	Mandatory	Only once	Data	`Superlab Ltd.`

370	2.4.5.	Additional field	`contact`	Mandatory	Only once	Structure	`address01 and address02 and`
							`zipcode and town and country and`
							`phone and fax and email`

371	2.4.5.	Address:	`address01`	Optional	Only once	Data	`Inventorshouse`
372	2.4.5.	Additional field	`address02`	Optional	Only once	Data	`7, Lemontree`
373	2.4.5.	Additional field	`zipcode`	Optional	Only once	Data	`G4 NA7`
374	2.4.5.	Additional field	`town`	Optional	Only once	Data	`ZW5 8ML`

375	2.4.5.	Country:	`country`	Mandatory	Only once	Data	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,`
							`FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,`
							`NO,PL,PT,RO,SE,SI,SK,UK`

376	2.4.5.	Telephone:	`phone`	Mandatory	Only once	Data	`44 20 818 50673`
377	2.4.5.	Telefax:	`fax`	Optional	Only once	Data	`44 20 81850675`
378	2.4.5.	E-Mail:	`email`	Optional	Only once	Data	`N. Yellow.inventor@chello.uk`

379	2.5.	Manufacturers	`manufacturers`	Mandatory	Only once	Structure	`manufacturers-batch-release and`
							`pharma-product-manufacturers and`
							`manufacturers-active-substance`
							`and contract-company`

380	2.5.1.	Additional field	`manufacturers-batch-release`	Mandatory	Only once	Structure	`manufacturer-batch-release and`
							`contact-blood-vaccines and`
							`contact-batch-testing-site`

381	2.5.1.	Authorised manufacturer(s) (or importer)	`manufacturer-`	Mandatory	More	Structure	`company-name and contact and`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
		responsible for batch release in the EEA	`batch-release`				`manufacturing-aut-number and attach-manu-authorisation and attach-justification`
382	2.5.1.	Name of Company:	`company-name`	Mandatory	Only once	Data	`Superstorage`
383	2.5.1.	Additional field	`contact`	Mandatory	Only once	Structure	`address01 and address02 and zipcode and town and country and phone and fax and email`
384	2.5.1.	Address:	`address01`	Optional	Only once	Data	`26 Bld Saint Remy`
385	2.5.1.	Additional field	`address02`	Optional	Only once	Data	`55, Old Bailey`
386	2.5.1.	Additional field	`zipcode`	Optional	Only once	Data	`932100`
387	2.5.1.	Additional field	`town`	Optional	Only once	Data	`Paris`
388	2.5.1.	Country:	`country`	Mandatory	Only once	Data	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL, NO,PL,PT,RO,SE,SI,SK,UK`
389	2.5.1.	Telephone:	`phone`	Mandatory	Only once	Data	`33 1 66963276`
390	2.5.1.	Telefax:	`fax`	Optional	Only once	Data	`33 1 66961265`
391	2.5.1.	E-Mail:	`email`	Optional	Only once	Data	`superstorage@kpn.fr`
392	2.5.1.	Manufacturing Authorisation number:	`manufacturing-aut-number`	Mandatory	Only once	Data	`FR/I/6538/98`
393	2.5.1.	Attach copy of manufacturing authorisation(s) (Annex 6.6)	`attach-manu-authorisation`	Optional	Only once	Reference	`annex6`
394	2.5.1.	Attach justification if more than one manufacturer responsible for batch release is proposed (Annex 6.7)	`attach-justification`	Optional	Only once	Reference	`annex7`
395	2.5.1.	For Blood Products and Vaccines :	`contact-blood-vaccines`	Optional	Only once	Structure	`contact-name and contact`
396	2.5.1.	Name:	`contact-name`	Mandatory	Only once	Data	`M. A Belamy`
397	2.5.1.	Additional field	`contact`	Mandatory	Only once	Structure	`address01 and address02 and zipcode and town and country and phone and fax and email`
398	2.5.1.	Address:	`address01`	Optional	Only once	Data	`Rond point`
399	2.5.1.	Additional field	`address02`	Optional	Only once	Data	`11, Linden Str.`
400	2.5.1.	Additional field	`zipcode`	Optional	Only once	Data	`NW123`
401	2.5.1.	Additional field	`town`	Optional	Only once	Data	`Big Town`
402	2.5.1.	Country:	`country`	Mandatory	Only once	Data	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
							`NO,PL,PT,RO,SE,SI,SK,UK`
403	2.5.1.	Telephone:	`phone`	Mandatory	Only once	Data	`12 3 4567890`
404	2.5.1.	Telefax:	`fax`	Optional	Only once	Data	`12 3 4567899`
405	2.5.1.	E-Mail:	`email`	Optional	Only once	Data	`bel@amy.com`
406	2.5.1.1.	Contact person in the EEA for product defects and recalls:	`contact-product-defects`	Mandatory	Only once	Structure	`contact-name and contact`
407	2.5.1.1.	Name:	`contact-name`	Mandatory	Only once	Data	`Miss Elisabeth Spencer, PhD`
408	2.5.1.1.	Additional field	`contact`	Mandatory	Only once	Structure	`address01 and address02 and zipcode and town and country and phone and fax and email`
409	2.5.1.1.	Address:	`address01`	Optional	Only once	Data	`13, Boulevard Raspail`
410	2.5.1.1.	Additional field	`address02`	Optional	Only once	Data	`La Grand Arche`
411	2.5.1.1.	Additional field	`zipcode`	Optional	Only once	Data	`B-4598`
412	2.5.1.1.	Additional field	`town`	Optional	Only once	Data	`Brussels`
413	2.5.1.1.	Country:	`country`	Mandatory	Only once	Data	`BE`
414	2.5.1.1.	24H contact telephone number:	`phone`	Mandatory	Only once	Data	`00 32 2 999 000`
415	2.5.1.1.	Telefax:	`fax`	Optional	Only once	Data	`00 32 2 999 001`
416	2.5.1.1.	E-mail:	`email`	Optional	Only once	Data	`elisabeth.spencer@superlab.com`
417	2.5.1.2.	Site(s) in EEA or in countries with MRA/PECA in operation,where batch control/testing takes place (if different from 2.5.1):	`contact-batch-testing-site`	Optional	More	Structure	`company-name and contact`
418	2.5.1.2.	Name of the Company:	`company-name`	Mandatory	Only once	Data	`Pioneer Ltd`
419	2.5.1.2	Additional field	`contact`	Mandatory	Only once	Structure	`address01 and address02 and zipcode and town and country and phone and fax and email`
420	2.5.1.2.	Brief description of control test carried out by the laboratory(ies) concerned:	`description-control-test`	Mandatory	Only once	Data	`Analysis of tablets`
421	2.5.1.3	Address:	`address01`	Optional	Only once	Data	`Icevalley`
422	2.5.1.2.	Additional field	`address02`	Optional	Only once	Data	`7, Prince Rpertstreet`
423	2.5.1.4	Additional field	`zipcode`	Optional	Only once	Data	`2500 PP`
424	2.5.1.2.	Additional field	`town`	Optional	Only once	Data	`Toronto`
425	2.5.1.5	Country:	`country`	Mandatory	Only once	Data	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL, NO,PL,PT,RO,SE,SI,SK,UK`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
426	2.5.1.2.	Telephone:	`phone`	Mandatory	Only once	Data	`28 12 56987`
427	2.5.1.6	Telefax:	`fax`	Optional	Only once	Data	`28 12 56887`
428	2.5.1.2.	E-Mail:	`email`	Optional	Only once	Data	`pioneer@chi.com`
429	2.5.2.	Additional field	`pharma-product-manufacturers`	Mandatory	Only once	Structure	`pharma-product-manufacturer`
430	2.5.2.	Manufacturer(s) of the medicinal product and site(s) of manufacture:	`pharma-product-manufacturer`	Mandatory	More	Structure	`contact-name and company-name and contact and description-functions and attach-flowchart and manufacturer-ineea or manufacturer-outeea`
431	2.5.2.	Name:	`contact-name`	Mandatory	Only once	Data	`Green company`
432	2.5.2.	Company name:	`company-name`	Mandatory	Only once	Data	`trading as Green Ltd`
433	2.5.2.	Additional field	`contact`	Mandatory	Only once	Structure	`address01 and address02 and zipcode and town and country and phone and fax and email`
434	2.5.2.	Address:	`address01`	Optional	Only once	Data	`Industry Parc`
435	2.5.2.	Additional field	`address02`	Optional	Only once	Data	`1, Industry Lane`
436	2.5.2.	Additional field	`zipcode`	Optional	Only once	Data	`18500`
437	2.5.2.	Additional field	`town`	Optional	Only once	Data	`New Delhi`
438	2.5.2.	Country:	`country`	Mandatory	Only once	Data	`ISO Country Code`
439	2.5.2.	Telephone:	`phone`	Mandatory	Only once	Data	`983 3 6368123`
440	2.5.2.	Telefax:	`fax`	Optional	Only once	Data	`983 3 63681 24`
441	2.5.2.	E-Mail:	`email`	Optional	Only once	Data	`green@comp.in`
442	2.5.2.	Brief description of functions performed by manufacturer of dosage form/assembler, etc.:	`description-functions`	Mandatory	Only once	Data	`tabletting`
443	2.5.2.	Attach flow-chart indicating the sequence of the different sites involved in the manufacturing process (Annex 6.8)	`attach-flowchart`	Optional	Only once	Reference	`annex8`
444	2.5.2.	If the manufacturing site is in the EEA,	`manufacturer-ineea`	Mandatory	Only once	Structure	`manufacturing-aut-number-eea and attach-manu-authorisation and name-qualified-person`
445	2.5.2.	Manufacturing authorisation number	`manufacturing-aut-number-eea`	Mandatory	Only once	Data	`P.442, Ml/6549/1`
446	2.5.2.	Attach manufacturing authorisations (Annex 6.6)	`attach-manu-authorisation`	Optional	Only once	Reference	`annex6`
447	2.5.2.	Name of qualified person:	`name-qualified-`	Optional	Only once	Data	`Dr. P. Whitecoat`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
			`person`				
448	2.5.2.	If the manufacturing site is outside the EEA,	`manufacturer-outeea`	Mandatory	Only once	Structure	`attach-manu-authorisation and inspection`
449	2.5.2.	Where MRA/PECA is in operation, attach equivalent of manufacturing authorisation (Annex 6.6)	`attach-manu-authorisation`	Optional	Only once	Reference	`annex6`
450	2.5.2.	Additional field	`inspection`	Mandatory	Only once	Structure	`no-inspection-authority or attach-inspection-site and gmp-compliant`
451	2.5.2.	Has the site been inspected for GMP Compliance by an EEA authority NO	`no-inspection-authority`	Mandatory	Only once	End	`Empty`
452	2.5.2.	If yes, provide in Annex 6.9 for each site a statement from the competent authority which carried out the inspection	`attach-inspection-site`	Optional	Only once	Reference	`annex9`
453	2.5.2.	If yes, outcome of the inspection GMP compliant	`gmp-compliant`	Mandatory	Only once	List	`yes, no`
454	2.5.2.	Has the site been inspected for GMP Compliance by any other authority?	`no-inspection-authority`	Mandatory	Only once	Structure	`no-inspection-authority or attach-inspection-site`
455	2.5.2.	site has not been inspected by any other authority	`no-inspection`	Mandatory	Only once	End	`Empty`
456	2.5.2.	If yes, please provide summary information in Annex 6.9	`attach-inspection-site`	Optional	Only once	Reference	`annex9`
457	2.5.3.	Additional field	`manufacturers-active-substance`	Mandatory	Only once	Structure	`manufacturer-active-substance`
458	2.5.3.	Manufacturer(s) of the active substance(s):	`manufacturer-active-substance`	Mandatory	More	Structure	`substance-name and contact-name and contact and description-manufacturing and attach-flowchart and attach-declaration-qualified-person and pheur-certificate or use-dmf or certificate-vamf or no-pheur-dmf and eea-inspection`
459	2.5.3.	Substance:	`substance-name`	Mandatory	Only once	Data	`Iprubofen`
460	2.5.3.	Name:	`contact-name`	Mandatory	Only once	Data	`Superlab`
461	2.5.3.	Additional field	`contact`	Mandatory	Only once	Structure	`address01 and address02 and zipcode and town and country and phone and fax and email`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
462	2.5.3.	Address:	`address01`	Optional	Only once	Data	`Industry Parc`
463	2.5.3.	Additional field	`address02`	Optional	Only once	Data	`Production street`
464	2.5.3.	Additional field	`zipcode`	Optional	Only once	Data	`KZ 14500`
465	2.5.3.	Additional field	`town`	Optional	Only once	Data	`Tokyo`
466	2.5.3.	Country:	`country`	Mandatory	Only once	Data	`ISO Country Code`
467	2.5.3.	Telephone:	`phone`	Mandatory	Only once	Data	`60 3 456783`
468	2.5.3.	Telefax:	`fax`	Optional	Only once	Data	`60 3 456978`
469	2.5.3.	E-Mail:	`email`	Optional	Only once	Data	`super@kpn.com`
470	2.5.3.	Brief description of manufacturing steps performed by manufacturing site	`description-manufacturing`	Mandatory	Only once	Data	`synthesis`
471	2.5.3.	Attach flow-chart indicating the sequence and activities of the different sites	`attach-flowchart`	Optional	Only once	Reference	`annex8`
472	2.5.3.	For each active substance, attach a declaration from the Qualified Person	`attach-declaration-qualified-person`	Optional	Only once	Reference	`annex22`
473	2.5.3.	If a Ph.Eur. Certificate of suitability has been issued for the active substance(s)	`pheur-certificate`	Mandatory	Only once	Structure	`substance-name and company-name and reference-number-certificate and date-last-update-pheur and attach-letter-access`
474	2.5.3.	substance:	`substance-name`	Mandatory	Only once	Data	`Iprubofen`
475	2.5.3.	name of the manufacturer:	`company-name`	Mandatory	Only once	Data	`Superlab`
476	2.5.3.	reference number:	`reference-number-certificate`	Mandatory	Only once	Data	`Cos 76/2001`
477	2.5.3.	date of last update (yyyy-mm-dd):	`date-last-update-pheur`	Mandatory	Only once	Structure	`date`
478	2.5.3.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31`
479	2.5.3.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12`
480	2.5.3.	yyyy	`year`	Mandatory	Only once	Data	`2003`
481	2.5.3.	Provide copy in Annex 6.10	`attach-letter-access`	Optional	Only once	Reference	`annex10`
482	2.5.3.	If a European Drug Master File is to be used for the active substance(s) reference/original	`use-dmf`	Mandatory	Only once	Structure	`substance-name and company-name andreference-number-competent-aut and date-submission and date-`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
							`last-update-dmf and attach-letter-access and attach-written-confirmation`
483	2.5.3.	substance:	`substance-name`	Mandatory	Only once	Data	`Iprubofen`
484	2.5.3.	name of the manufacturer:	`company-name`	Mandatory	Only once	Data	`Superlab`
485	2.5.3.	reference number for EMEA / competent authority:	`reference-number-competent-aut`	Mandatory	Only once	Data	`E/12345`
486	2.5.3.	date of submission (yyyy-mm-dd):	`date-submission`	Mandatory	Only once	Structure	`date`
487	2.5.3.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31`
488	2.5.3.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12`
489	2.5.3.	yyyy	`year`	Mandatory	Only once	Data	`2003`
490	2.5.3.	date of last update (yyyy-mm-dd):	`date-last-update-dmf`	Optional	Only once	Structure	`date`
491	2.5.3.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31`
492	2.5.3.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12`
493	2.5.3.	yyyy	`year`	Mandatory	Only once	Data	`2003`
494	2.5.3.	attach letter of access for Community/Member State authorities where the application is made (Annex 6.10)	`attach-letter-access`	Optional	Only once	Reference	`annex10`
495	2.5.3.	attach copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications (Annex 6.11)	`attach-written-confirmation`	Optional	Only once	Reference	`annex11`
496	2.5.3.	If an EMEA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted	`certificate-vamf`	Mandatory	Only once	Structure	`substance-name, certificate-holder, reference-number-certificate, date-submission, date-last-update-vamf, attach-certificate-vamf`
497	2.5.3.	substance name:	`substance-name`	Mandatory	Only once	Data	`Iprubofen`
498	2.5.3.	name of the VAMF Certificate Holder/	`certificate-`	Mandatory	Only once	Data	`Superlab`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
		VAMF Applicant:	`holder`				
499	2.5.3.	reference number of Application/ Certificate:	`reference-number-certificate`	Mandatory	Only once	Data	`EMEA/XX/001`
500	2.5.3.	date of submission (if pending) (*yyyy-mm-dd*):	`date-submission`	Optional	Only once	Structure	`date`
501	2.5.3.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12,13,14,15,16,17,18,19,20,21,22,` `23,24,25,26,27,28,29,30,31`
502	2.5.3.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
503	2.5.3.	yyyy	`year`	Mandatory	Only once	Data	`2003`
504	2.5.3.	date of approval or last update (if approved) (*yyyy-mm-dd*):	`date-last-update-vamf`	Optional	Only once	Structure	`date`
505	2.5.3.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12,13,14,15,16,17,18,19,20,21,22,` `23,24,25,26,27,28,29,30,31`
506	2.5.3.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
507	2.5.3.	yyyy	`year`	Mandatory	Only once	Data	`2003`
508	2.5.3.	Provide copy in Annex 6.20	`attach-certificate-vamf`	Optional	Only once	Reference	`annex20`
509	2.5.3.	No Ph.Eur. Certificate of suitability been issued and no European Drug Master File to be used-Additional field	`no-pheur-dmf`	Mandatory	Only once	End	`Empty`
510	2.5.3.	Additional field	`eea-inspection`	Optional	Only once	Structure	`attach-inspection-site and` `inspection-outcome`
511	2.5.3.	The following information should be provided in Annex 6.9 for each site	`attach-inspection-site`	Optional	Only once	Reference	`annex9`
512	2.5.3.	outcome:	`inspection-outcome`	Mandatory	Only once	List	`positive, negative`
513	2.5.4.	Contract companies used for clinical trial(s) on bioavailability or bioequivalence	`contract-company`	Mandatory	Only once	Structure	`title-study and protocol-code and` `eudract-number and contact-name` `and contact and duty-performed`
514	2.5.4.	Title of the study	`title-study`	Mandatory	Only once	Data	`The Efficacy and Safety of` `Iprubofen as First Line Treatment` `for Migraine`
515	2.5.4.	Protocol code	`protocol-code`	Mandatory	Only once	Data	`CV031-176`
516	2.5.4.	EudraCT-Number	`eudract-number`	Mandatory	Only once	Data	`2004-999999-99`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
517	2.5.4.	Name:	contact-name	Mandatory	Only once	Data	Farmosearch
518	2.5.4.	Additional field	contact	Mandatory	Only once	Structure	address01 and address02 and zipcode and town and country and phone and fax and email
519	2.5.4.	Address:	address01	Optional	Only once	Data	Villa Cathrina
520	2.5.4.	Additional field	address02	Optional	Only once	Data	Allée philippe II
521	2.5.4.	Additional field	zipcode	Optional	Only once	Data	L-2130
522	2.5.4.	Additional field	town	Optional	Only once	Data	Luxembourg
523	2.5.4.	Country:	country	Mandatory	Only once	Data	ISO Country Code
524	2.5.4.	Telephone:	phone	Mandatory	Only once	Data	352 478 44 93
525	2.5.4.	Telefax:	fax	Optional	Only once	Data	352 478 44 89
526	2.5.4.	E-Mail:	email	Optional	Only once	Data	farmasearch@kpn. Lu
527	2.5.4.	Duty performed according to contract:	duty-performed	Mandatory	Only once	Data	bioavailability study
528	2.6.	Qualitative and quantitative composition	qualitative-quantitative-composition	Mandatory	Only once	Structure	composition and materials and gmo
529	2.6.1.	Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s):	composition	Mandatory	More	Structure	quantity-note and substance-info and excipient-info
530	2.6.1.	A note should be given as to which quantity the composition refers (e.g. 1 capsule)	quantity-note	Optional	Only once	Data	1 tablet
531	2.6.1.	List the active substance(s) separately from the excipient(s): active substance(s)	substance-info	Mandatory	More	Structure	substance-name and strength-quantity and strength-unit and reference-monograph-standard and overage
532	2.6.1.	Name of active substance(s)	substance-name	Mandatory	Only once	Data	Iprubofen
533	2.6.1.	Quantity	strength-quantity	Mandatory	Only once	Data	400
534	2.6.1.	Additional field	strength-unit	Mandatory	Only once	Data	mg
535	2.6.1.	Reference/Monograph standard	reference-monograph-standard	Mandatory	Only once	Data	Ph. Eur
536	2.6.1.	active substance(s) details of any overages :	overage	Optional	Only once	Data	0,05
537	2.6.1.	List the active substance(s) separately from the excipient(s): excipient(s)	excipient-info	Optional	More	Structure	excipient-name and strength-quantity and strength-unit and reference-monograph-standard and overage

N	Section	Description	Element	Status	Occurrence	Remarks	Example
538	2.6.1.	Name of excipient(s)	`excipient-name`	Mandatory	Only once	Data	`lactose`
539	2.6.1.	Quantity	`strength-quantity`	Mandatory	Only once	Data	`100`
540	2.6.1.	Additional field	`strength-unit`	Mandatory	Only once	Data	`mg`
541	2.6.1.	Reference/Monograph standard	`reference-monograph-standard`	Mandatory	Only once	Data	`Ph. Eur`
542	2.6.1.	excipient(s) details of any overages :	`overage`	Optional	Only once	Data	`0,05`
543	2.6.2.	List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product?	`materials`	Mandatory	Only once	Structure	`no-materials or material and attach-certificates-suitability`
544	2.6.2.	NONE	`no-materials`	Mandatory	Only once	End	`Empty`
545	2.6.2.	Additional field	`material`	Mandatory	More	Structure	`material-name and material-function and material-origin`
546	2.6.2.	Name	`material-name`	Mandatory	Only once	Data	`magnesium stearate`
547	2.6.2.	Function	`material-function`	Mandatory	Only once	List	`AS, EX, R`
548	2.6.2.	Additional field	`material-origin`	Mandatory	Only once	Structure	`animal-tse and cert-suitability or other-animal or human`
549	2.6.2.	Animal origin susceptible to TSE	`animal-tse`	Mandatory	Only once	End	`Empty`
550	2.6.2.	Certificate of suitability for TSE	`cert-suitability`	Optional	Only once	Data	`TSE 196/2001`
551	2.6.2.	State Number	`state-number`	Mandatory	Only once	Data	`sheep`
552	2.6.2.	Other animal origin	`other-animal`	Mandatory	Only once	End	`Empty`
553	2.6.2.	Human origin	`human`	Mandatory	Only once	End	`Empty`
554	2.6.2.	If a Ph. Eur. Certificate of Suitability for TSE is available attach it in Annex 6.12	`attach-certificates-suitability`	Optional	Only once	Reference	`annex12`
555	2.6.3.	If an EMEA certificate for a Plasma Master File (PMF) issued or submitted	`plasma-master-files`	Mandatory	Only once	Structure	`no-plasma-master-files or plasma-master-file and attach-certificate-pmf`
556	2.6.3.	no	`no-plasma-master-files`	Mandatory	Only once	End	`Empty`
557	2.6.3.	Additional field	`plasma-master-file`	Mandatory	Only once	Structure	`substance-name and material-function and certificate-holder and reference-number-certificate and date-submission and date-last-update-pmf`
558	2.6.3.	Substance referring to PMF:	`substance-name`	Mandatory	Only once	Data	`name`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
559	2.6.3.	function	`material-function`	Mandatory	Only once	List	`AS, EX, R`
560	2.6.3.	name of the PMF Certificate Holder/ PMF Applicant:	`certificate-holder`	Mandatory	Only once	Data	`Superlab`
561	2.6.3.	reference number of Application/ Certificate:	`reference-number-certificate`	Mandatory	Only once	Data	`EMEA/XX/001`
562	2.6.3.	date of submission (if pending) (*yyyy-mm-dd*):	`date-submission`	Optional	Only once	Structure	`date`

563	2.6.3.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,`
							`12,13,14,15,16,17,18,19,20,21,22,`
							`23,24,25,26,27,28,29,30,31`

564	2.6.3.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
565	2.6.3.	yyyy	`year`	Mandatory	Only once	Data	`2003`
566	2.6.3.	date of approval or last update (if approved) (*yyyy-mm-dd*):	`date-last-update-pmf`	Optional	Only once	Structure	`date`

567	2.6.3.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,`
							`12,13,14,15,16,17,18,19,20,21,22,`
							`23,24,25,26,27,28,29,30,31`

568	2.6.3.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
569	2.6.3.	yyyy	`year`	Mandatory	Only once	Data	`2003`
570	2.6.3.	Provide copy in Annex 6.21+C391	`attach-certificate-pmf`	Optional	Only once	Reference	`annex21`
571	2.6.4.	Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs)?	`gmo`	Mandatory	Only once	Structure	`no-gmo or council and attach-written-consent-gmo`
572	2.6.4.	No	`no-gmo`	Mandatory	Only once	End	`Empty`
573	2.6.4.	If yes, does the product comply with Council Directive 90/220/EEC ?	`council`	Mandatory	Only once	List	`yes, no`
574	2.6.4.	If yes, attach a copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes (Annex 6.13)	`attach-written-consent-gmo`	Optional	Only once	Reference	`annex13`
575	3.	SCIENTIFIC ADVICE	`scientific-advice`	Mandatory	Only once	Structure	`cpmp-scientific-advice and scientific-recommendations`
576	3.1.	Was there formal scientific advice given by the CPMP for this medicinal product ?	`cpmp-scientific-advice`	Mandatory	Only once	Structure	`no-scientific-advice or date-scientific-advice and scientific-advice-reference and attach-`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
							`scientific-advice-cpmp`
577	3.1.	No	`no-scientific-advice`	Mandatory	Only once	End	`Empty`
578	3.1.	If yes, Date (yyyy-mm-dd):	`date-scientific-advice`	Mandatory	Only once	Structure	`date`
579	3.1.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31`
580	3.1.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12`
581	3.1.	yyyy	`year`	Mandatory	Only once	Data	`2003`
582	3.1.	If yes, reference of the scientific letter:	`scientific-advice-reference`	Mandatory	Only once	Data	`EMEA/H/245/02`
583	3.1.	If yes, attach copy of the scientific letter (Annex 6.14)	`attach-scientific-advice-cpmp`	Optional	Only once	Reference	`annex14`
584	3.2.	Was there scientific recommendation(s) given by Member State(s) for this medicinal product?	`scientific-recommendations`	Mandatory	Only once	List	`no-scientific-recommendation,scientific-recommendation`
585	3.2.	No	`no-scientific-recommendation`	Mandatory	Only once	End	`Empty`
586	3.2.	Yes	`scientific-recommendation`	Mandatory	More	Structure	`eu-member-state and date-recommendation`
587	3.2.	Member State(s):	`eu-member-state`	Mandatory	Only once	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,NO,PL,PT,RO,SE,SI,SK,UK`
588	3.2.	Date(s) (yyyy-mm-dd):	`date-recommendation`	Mandatory	Only once	Structure	`date`
589	3.2.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31`
590	3.2.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12`
591	3.2.	yyyy	`year`	Mandatory	Only once	Data	`2003`
592	4.	PAEDIATRIC DEVELOPMENT PROGRAM	`paediatric-program`	Mandatory	Only once	List	`no-paediatric-program,paediatric-relevant-section`
593	4.1.	There is no paediatric development	`no-paediatric-`	Mandatory	Only once	End	`Empty`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
		programme for this medicinal product	`program`				
594	4.1.	If yes, please indicate the relevant section(s) in the dossier if included:	`paediatric-relevant-section`	Mandatory	More	Data	`4.2`
595	5.	OTHER MARKETING AUTHORISATION APPLICATIONS	`other-maa`	Mandatory	Only once	Structure	`same-product-eea and dossier-multiple-application and same-product-non-eea`
596	5.2.	Marketing authorisation applications for the same product in the EEA	`same-product-eea`	Mandatory	Only once	Structure	`product-authorised-in and product-pending-in and product-refused-in and product-withdrawn-before-in and product-withdrawn-after-in and product-suspended-authority-in`
597	5.2.	Authorised	`product-authorised-in`	Optional	More	Structure	`eu-member-state and date-notif and tradename and authorisation-number and attach-marketing-authorisation`
598	5.2.	Country:	`eu-member-state`	Mandatory	Only once	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,NO,PL,PT,RO,SE,SI,SK,UK`
599	5.2.	date of authorisation yyyy-mm-dd):	`date-notif`	Mandatory	Only once	Structure	`date`
600	5.2.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31`
601	5.2.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12`
602	5.2.	yyyy	`year`	Mandatory	Only once	Data	`2003`
603	5.2.	invented name:	`tradename`	Mandatory	Only once	Data	`The Pil`
604	5.2.	authorisation number:	`authorisation-number`	Mandatory	Only once	Data	`NL 00001`
605	5.2.	Attach marketing authorisation (Annex 6.15)	`attach-marketing-authorisation`	Optional	Only once	Reference	`annex15`
606	5.2.	Pending	`product-pending-in`	Optional	More	Structure	`eu-member-state and date-notif`
607	5.2.	Country:	`eu-member-state`	Mandatory	Only once	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,NO,PL,PT,RO,SE,SI,SK,UK`
608	5.2.	date of submission (yyyy-mm-dd):	`date-notif`	Mandatory	Only once	Structure	`date`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
609	5.2.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12,13,14,15,16,17,18,19,20,21,22,` `23,24,25,26,27,28,29,30,31`
610	5.2.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
611	5.2.	yyyy	`year`	Mandatory	Only once	Data	`2003`
612	5.2.	Refused	`product-refused-in`	Optional	More	Structure	`country`
613	5.2.	Country:	`eu-member-state`	Mandatory	Only once	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,` `FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,` `NO,PL,PT,RO,SE,SI,SK,UK`
614	5.2.	date of refusal (yyyy-mm-dd):	`date-notif`	Mandatory	Only once	Structure	`date`
615	5.2.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12,13,14,15,16,17,18,19,20,21,22,` `23,24,25,26,27,28,29,30,31`
616	5.2.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
617	5.2.	yyyy	`year`	Mandatory	Only once	Data	`2003`
618	5.2.	Withdrawn (by applicant before authorisation)	`product-withdrawn-before-in`	Optional	More	Structure	`eu-member-state and date-notif` `and tradename and reason`
619	5.2.	Country:	`eu-member-state`	Mandatory	Only once	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,` `FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,` `NO,PL,PT,RO,SE,SI,SK,UK`
620	5.2.	date of withdrawal (yyyy-mm-dd):	`date-notif`	Mandatory	Only once	Structure	`date`
621	5.2.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12,13,14,15,16,17,18,19,20,21,22,` `23,24,25,26,27,28,29,30,31`
622	5.2.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
623	5.2.	yyyy	`year`	Mandatory	Only once	Data	`2003`
624	5.2.	invented name:	`tradename`	Mandatory	Only once	Data	`Smartex`
625	5.2.	reason for withdrawal:	`reason`	Mandatory	Only once	Data	`safety concerns`
626	5.2.	Withdrawn (by applicant after authorisation)	`product-withdrawn-after-in`	Optional	More	Structure	`eu-member-state and date-notif` `and authorisation-number and` `reason and tradename`
627	5.2.	Country:	`eu-member-state`	Mandatory	Only once	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
							`FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,` `NO,PL,PT,RO,SE,SI,SK,UK`
628	5.2.	Date of withdrawal (yyyy-mm-dd):	`date-notif`	Mandatory	Only once	Structure	`date`
629	5.2.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12,13,14,15,16,17,18,19,20,21,22,` `23,24,25,26,27,28,29,30,31`
630	5.2.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
631	5.2.	yyyy	`year`	Mandatory	Only once	Data	`2003`
632	5.2.	authorisation number:	`authorisation-` `number`	Mandatory	Only once	Data	`RVG 02346`
633	5.2.	reason for withdrawal:	`reason`	Mandatory	Only once	Data	`commercial`
634	5.2.	invented name:	`tradename`	Mandatory	Only once	Data	`Stasterk`
635	5.2.	Suspended/revoked (by competent authority)	`product-` `suspended-` `authority-in`	Optional	More	Structure	`eu-member-state and date-notif` `and reason and tradename`
636	5.2.	Country:	`eu-member-state`	Mandatory	Only once	List	`AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,` `FR,HU,IS,IE,IT,LI,LU,LT,LV,MT,NL,` `NO,PL,PT,RO,SE,SI,SK,UK`
637	5.2.	Date of suspension/revocation (yyyy-mm-dd):	`date-notif`	Mandatory	Only once	Structure	`date`
638	5.2.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12,13,14,15,16,17,18,19,20,21,22,` `23,24,25,26,27,28,29,30,31`
639	5.2.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
640	5.2.	yyyy	`year`	Mandatory	Only once	Data	`2003`
641	5.2.	reason for suspension/revocation:	`reason`	Mandatory	Only once	Data	`safety concerns`
642	5.2.	invented name:	`tradename`	Mandatory	Only once	Data	`Brusco`
643	5.3.	For multiple applications of the same medicinal product:	`dossier-multiple-` `application`	Optional	More	Structure	`name-other-product and date-` `multiple-application and` `applicant-multiple-application`
644	5.3.	Name of the other product(s):	`name-other-` `product`	Mandatory	Only once	Data	`Duplex pil`
645	5.3.	Date of application(s) (yyyy-mm-dd):	`date-multiple-` `application`	Mandatory	Only once	Structure	`date`
646	5.3.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12,13,14,15,16,17,18,19,20,21,22,`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
							`23,24,25,26,27,28,29,30,31`
647	5.3.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
648	5.3.	yyyy	`year`	Mandatory	Only once	Data	`2003`

649	5.3.	Applicant(s):	`applicant-`
			`multiple-`
			`application`
				Mandatory	Only once	Data	`Superlab2`

650	5.4.	Marketing authorisation applications for the same product outside the EEA	`same-product-non-` `eea`	Mandatory	Only once	Structure	`product-authorised-out` and `product-pending-out` and `product-refused-out` and `product-withdrawn-before-out` and `product-withdrawn-after-out` and `product-suspended-authority-out`
651	5.4.	Authorised	`product-` `authorised-out`	Optional	More	Structure	`country` and `date-notif` and `tradename`
652	5.4.	Country:	`country`	Mandatory	Only once	Data	`ISO Country Code`
653	5.4.	date of authorisation yyyy-mm-dd):	`date-notif`	Mandatory	Only once	Structure	`date`

654	5.4.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,`
							`12,13,14,15,16,17,18,19,20,21,22,`
							`23,24,25,26,27,28,29,30,31`

655	5.4.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
656	5.4.	yyyy	`year`	Mandatory	Only once	Data	`2003`
657	5.4.	invented name:	`tradename`	Mandatory	Only once	Data	`Brusca`
658	5.4.	Pending	`product-pending-` `out`	Optional	More	Structure	`country` and `date-notif`
659	5.4.	Country:	`country`	Mandatory	Only once	Data	`ISO Country Code`
660	5.4.	date of submission (yyyy-mm-dd):	`date-notif`	Mandatory	Only once	Structure	`date`

661	5.4.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,`
							`12,13,14,15,16,17,18,19,20,21,22,`
							`23,24,25,26,27,28,29,30,31`

662	5.4.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,` `12`
663	5.4.	yyyy	`year`	Mandatory	Only once	Data	`2003`
664	5.4.	Refused	`product-refused-` `out`	Optional	More	Structure	`country` and `date-notif`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
665	5.4.	Country:	country	Mandatory	Only once	Data	ISO Country Code
666	5.4.	date of refusal (yyyy-mm-dd):	date-notif	Mandatory	Only once	Structure	date
667	5.4.	dd	day	Mandatory	Only once	List	01,02,03,04,05,06,07,08,09,10,11, 12,13,14,15,16,17,18,19,20,21,22, 23,24,25,26,27,28,29,30,31
668	5.4.	mm	month	Mandatory	Only once	List	01,02,03,04,05,06,07,08,09,10,11, 12
669	5.4.	yyyy	year	Mandatory	Only once	Data	2003
670	5.4.	Withdrawn (by applicant before authorisation)	product-withdrawn-before-out	Optional	More	Structure	country and date-notif and tradename and reason
671	5.4.	Country:	country	Mandatory	Only once	Data	ISO Country Code
672	5.4.	date of withdrawal (yyyy-mm-dd):	date-notif	Mandatory	Only once	Structure	date
673	5.4.	dd	day	Mandatory	Only once	List	01,02,03,04,05,06,07,08,09,10,11, 12,13,14,15,16,17,18,19,20,21,22, 23,24,25,26,27,28,29,30,31
674	5.4.	mm	month	Mandatory	Only once	List	01,02,03,04,05,06,07,08,09,10,11, 12
675	5.4.	yyyy	year	Mandatory	Only once	Data	2003
676	5.4.	Invented name:	tradename	Mandatory	Only once	Data	Brusci
677	5.4.	reason for withdrawal:	reason	Mandatory	Only once	Data	commercial
678	5.4.	Withdrawn (by applicant after authorisation)	product-withdrawn-after-out	Optional	More	Structure	country and date-notif and authorisation-number and reason and tradename
679	5.4.	Country:	country	Mandatory	Only once	Data	ISO Country Code
680	5.4.	date of withdrawal (yyyy-mm-dd):	date-notif	Mandatory	Only once	Structure	date
681	5.4.	dd	day	Mandatory	Only once	List	01,02,03,04,05,06,07,08,09,10,11, 12,13,14,15,16,17,18,19,20,21,22, 23,24,25,26,27,28,29,30,31
682	5.4.	mm	month	Mandatory	Only once	List	01,02,03,04,05,06,07,08,09,10,11, 12
683	5.4.	yyyy	year	Mandatory	Only once	Data	2003
684	5.4.	authorisation number:	authorisation-number	Mandatory	Only once	Data	XPR 78659
685	5.4.	reason for withdrawal:	reason	Mandatory	Only once	Data	side effects
686	5.4.	Invented name:	tradename	Mandatory	Only once	Data	Brasco

N	Section	Description	Element	Status	Occurrence	Remarks	Example
687	5.4.	Suspended/revoked (by competent authority)	`product-suspended-authority-out`	Optional	More	Structure	`country and date-notif and reason and tradename`
688	5.4.	Country:	`country`	Mandatory	Only once	Data	`ISO Country Code`
689	5.4.	date of suspension/revocation (yyyy-mm-dd):	`date-notif`	Mandatory	Only once	Structure	`date`
690	5.4.	dd	`day`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31`
691	5.4.	mm	`month`	Mandatory	Only once	List	`01,02,03,04,05,06,07,08,09,10,11,12`
692	5.4.	yyyy	`year`	Mandatory	Only once	Data	`2003`
693	5.4.	reason for suspension/revocation:	`reason`	Mandatory	Only once	Data	`side effects`
694	5.4.	trade name:	`tradename`	Mandatory	Only once	Data	`Brasci`
695	6.	ANNEXED DOCUMENTS (WHERE APPROPRIATE)	`annexed-documents`	Mandatory	Only once	Structure	`ann-proof-payment and ann-letter-consent and ann-proof-establishment and ann-letter-authorisation and ann-cv-person and ann-manu-authorisation and ann-justification and ann-flowchart and ann-inspection-site and ann-letter-access and ann-written-confirmation and ann-certificates-suitability and ann-written-consent-gmo and ann-scientific-advice-cpmp and ann-marketing-authorisation and ann-copy-correspondence and ann-list-mockup and ann-orphan-decision and ann-invented-name and ann-certificate-vamf and ann-certificate-pmf`
696	6.1.	Proof of payment	`ann-proof-payment`	Optional	More	Link	`annex-name.pdf`
697	6.2.	Informed consent letter of marketing authorisation holder of authorised medicinal product.	`ann-letter-consent`	Optional	More	Link	`annex-name.pdf`
698	6.3.	Proof of establishment of the applicant in the EEA.	`ann-proof-establishment`	Optional	More	Link	`annex-name.pdf`

N	Section	Description	Element	Status	Occurrence	Remarks	Example
699	6.4.	Letter of authorisation for communication on behalf of the applicant/MAH	`ann-letter-authorisation`	Optional	More	Link	`annex-name.pdf`
700	6.5.	Curriculum Vitae of the Qualified Person for Pharmacovigilance	`ann-cv-person`	Optional	More	Link	`annex-name.pdf`
701	6.6.	Manufacturing Authorisation required under article 40 of Directive 2001/83/EC (or equivalent, outside of the EEA where MRA/PECA is in operation)	`ann-manu-authorisation`	Optional	More	Link	`annex-name.pdf`
702	6.7.	Justification for more than one manufacturer responsible for batch release in the EEA	`ann-justification`	Optional	More	Link	`annex-name.pdf`
703	6.8.	Flow-chart indicating the different sites involved in the manufacturing process of the medicinal product	`ann-flowchart`	Optional	More	Link	`annex-name.pdf`
704	6.9.	Statement from the competent authority which carried out the inspection of the manufacturing site(s)	`ann-inspection-site`	Optional	More	Link	`annex-name.pdf`
705	6.10.	Letter(s) of access to Drug Master File(s) or copy of Ph. Eur. Certificate(s) of suitability	`ann-letter-access`	Optional	More	Link	`annex-name.pdf`
706	6.11.	Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications	`ann-written-confirmation`	Optional	More	Link	`annex-name.pdf`
707	6.12.	Ph. Eur. Certificate(s) of suitability for TSE	`ann-certificates-suitability`	Optional	More	Link	`annex-name.pdf`
708	6.13.	Written consent(s) of the competent authorities regarding GMO release in the environment.	`ann-written-consent-gmo`	Optional	More	Link	`annex-name.pdf`
709	6.14.	Scientific Advice given by CPMP	`ann-scientific-advice-cpmp`	Optional	More	Link	`annex-name.pdf`
710	6.15.	Copy of Marketing Authorization(s)	`ann-marketing-authorisation`	Optional	More	Link	`annex-name.pdf`
711	6.16.	Correspondence with European Commission regarding multiple applications.	`ann-copy-correspondence`	Optional	More	Link	`annex-name.pdf`
712	6.17.	List of Mock-ups or Samples/specimens sent with the application, as appropriate	`ann-list-mockup`	Optional	More	Link	`annex-name.pdf`
713	6.18.	Copy of the Orphan Designation Decision.	`ann-orphan-decision`	Optional	More	Link	`annex-name.pdf`

	Section	Description	Element	Status	Occurrence	Remarks	Example
714	6.19.	List of proposed (invented) names and marketing authorisation holders in the concerned member states	`ann-invented-name`	Optional	More	Link	`annex-name.pdf`
715	6.20.	Copy of EMEA certificate for a Vaccine Antigen Master File (VAMF)	`ann-certificate-vamf`	Optional	More	Link	`annex-name.pdf`
716	6.21.	Copy of EMEA certificate for a Plasma Master File (PMF)	`ann-certificate-pmf`	Optional	More	Link	`annex-name.pdf`
717	6.22.	For each active substance, attach a declaration from the Qualified Person	`attach-declaration-qualified-person`	Optional	More	Link	`annex-name.pdf`

Appendix 2 : eu-application.dtd

```
<!--
PUBLIC "-//EU//DTD eCTD EU Application 2.1//EN"
In the eCTD File Organisation: "util/dtd/eu-application.dtd"

19 February 2007

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Acknowledgement:
Bertrand SENE, Afssaps

Based on the Notice to Applicants, Volume 2B, Application Form, Revision 8,
FEBRUARY 2007
-->

<!-- Root element ================================================== -->
<!ELEMENT eu-application:applicationform (
  declaration
, application
, maa-particulars
, scientific-advice
, paediatric-program
, other-maa
, annexed-documents
)>

<!ATTLIST eu-application:applicationform dtd-version CDATA #FIXED "2.1"
  xmlns:eu-application CDATA #FIXED "http://pharmacos.eudra.org/eu-
application"
  xmlns:xlink          CDATA #FIXED "http://www.w3c.org/1999/xlink" >

<!-- administrative data ......................................... -->
<!ELEMENT declaration (
  invented-name
, strength-quantity+
, form-name
, substance-name+
, applicant
```

```
, person-authorised?
, signature?
, name-person
, function-person
, place-signature
, date-signature
, attach-letter-authorisation?
, attach-proof-payment?
)>

<!-- ================================================================= -->
<!-- 1. TYPE OF APPLICATION -->

<!-- 1.1. This application concerns -->
<!ELEMENT application (
  type-procedure
, fundamental-change?
, directive
)>

<!ELEMENT type-procedure (
  centralised-procedure
| mutual-recognition-procedure
| decentralised-procedure
| national-procedure
)>

<!-- 1.1.1. Centralised Procedure .................................... -->
<!-- 1.2. Orphan medicinal product information ===================== -->
<!-- 5.3. attach copy of correspondence with European commission -->
<!-- 2.4.1 Contact person at this address marketing holder -->
<!ELEMENT centralised-procedure (
( mandatory-scope | optional-scope | generic-centralised )
, rapporteur
, co-rapporteur
, orphan-medicinal-product
, consideration-centralised?
, attach-copy-correspondence?
, contact-name
)>

<!ELEMENT mandatory-scope (
  annex1
| ((annex3 | annex4), date-acceptance)
)>

<!ELEMENT optional-scope (
  ( annex32a | annex32b )
 , date-acceptance
)>

<!-- New legislation: for all Procedures ............................ -->
<!ELEMENT contact-product-defects (
  contact-name
, contact
)>

<!-- Member states ................................................. -->
<!ELEMENT eu-member-state EMPTY>
<!ATTLIST eu-member-state state (
    AT
```

```
      | BE
      | BG
      | CY
      | CZ
      | DE
      | DK
      | EE
      | EL
      | ES
      | FI
      | FR
      | HU
      | IE
      | IS
      | IT
      | LI
      | LT
      | LU
      | LV
      | MT
      | NL
      | NO
      | PL
      | PT
      | RO
      | SE
      | SI
      | SK
      | UK
) #REQUIRED>

<!-- 1.1.2. Mutual recognition Procedure ........................... -->
<!ELEMENT mutual-recognition-procedure (
  eu-member-state
, date-first-authorisation
, mrp-marketing-authorisation-number
, mrp-procedure-number
, mrp-first-use
, mrp-repeat-use*
, consideration-requested?
)>

<!-- First use .. Concerned Member State(s) ........................ -->
<!ELEMENT mrp-first-use (
  eu-member-state+
, date-proposed-common-renewal?
, specify-waiver-amendment-psur?
)>

<!-- Repeat Use 1st Wave .. Concerned Member State(s) ............... -->
<!ELEMENT mrp-repeat-use (
  eu-member-state+
, date-agreed-common-renewal
)>

<!-- 1.1.3. Decentralised Procedure ........................... -->
<!ELEMENT decentralised-procedure (
  eu-member-state
, procedure-number
, first-use
, specify-waiver-amendment-psur?
```

```
, consideration-requested?
)>

<!ELEMENT first-use (
  eu-member-state+
)>

<!-- 1.1.4. National Procedure ..................................... -->
<!-- 5.1 Other MAA National -->
<!ELEMENT national-procedure (
  eu-member-state
, national-application-number?
, specify-waiver-amendment-psur?
, consideration-requested?
, other-maa-national
)>

<!-- 5.1. For national ... -->
<!ELEMENT other-maa-national (
  application-pending-same-product
, authorisation-granted-same-product
, therapeutic-implication?
, state-authorisation
)>

<!ELEMENT therapeutic-implication (therapeutic-implication-note) >

<!-- 1.2. Orphan medicinal product information ===================== -->
<!-- 1.2.1 Has Orphan designation been applied  ..................... -->

<!ELEMENT orphan-medicinal-product (
  orphan-designation
, orphan-condition
)>

<!ELEMENT orphan-designation (
   no-orphan-designation
|  orphan-status
)>

<!ELEMENT orphan-status (
   orphan-designation-procnumber
, ( pending
   | granted
   | refused
   | withdrawn
  )
)>

<!ELEMENT granted (
  date-orphan-status
, orphan-benefit
, orphan-number-register
, attach-orphan-decision?
)>

<!ELEMENT refused (
  date-orphan-status
, orphan-decision-refnumber
)>
```

```
<!ELEMENT withdrawn (date-orphan-status) >

<!-- 1.2.2 Information relating to Orphan market exclusively........ -->
<!ELEMENT orphan-condition (
  no-orphan-condition
| (orphan-eu-designation-number+
    , orphan-granted)
)>

<!-- Has any of the designated Orphan medicinal products been granted -->
<!ELEMENT orphan-granted (
  no-orphan-granted
| (product-fullname
    , holder
    , marketing-authorisation-number+
    , date-first-authorisation
    , orphan-similar)
)>

<!-- 1.5 Consideration of this application is also requested under the
following....... -->
<!-- centralised procedure only..... -->
<!ELEMENT consideration-centralised (
 ( conditional-approval | exceptional-circumstances )
 ,  accelerated-review?
)>

<!-- 1.5 Mutual recognition, Decentralised, National procedures only..... -
-->
<!ELEMENT consideration-requested (
    exceptional-circumstances
  | article101
  | article105
  | article74a
)>

<!ELEMENT accelerated-review (
  date-acceptance
)>

<!-- ================================================================= -->
<!-- 1.3. Is this an application for a change to existing marketing
authorisation -->
<!ELEMENT fundamental-change (
  specify-change
, line-extension
, holder
, product-fullname
, manumber-application-made+
)>

<!ELEMENT product-fullname (
  invented-name
, strength-quantity
, strength-unit
, form-name
)>

<!-- 1.3. Extension ........................................ -->
<!ELEMENT line-extension (
  line-extension-qual-notnew-substance?
```

```
, line-extension-bioavailability?
, line-extension-change-pharmacokinetics?
, line-extension-change-strength?
, line-extension-change-newform?
, line-extension-add-route?
)>

<!ELEMENT line-extension-qual-notnew-substance (
     line-extension-replacement-salt
   | line-extension-replacement-isomer
   | line-extension-replacement-biological
   | line-extension-new-ligand
   | line-extension-change-extraction
)>

<!-- .......................................................... -->
<!-- 1.4. THIS APPLICATION IS SUBMITTED IN ACCORDANCE WITH -->
<!ELEMENT directive (
    complete
  | generic
  | hybrid
  | similar-biological
  | well-established-use
  | fixed-combination
  | informed-consent
  | traditional-use-registration
)>

<!-- 1.4.2. Article 10(1) generic application -->
<!ELEMENT generic (
  reference-authorised-eea
, reference-medicinal-product*
, bioequivalence-study*
)>

<!-- 1.4.3. Article 10(3) hybrid application -->
<!ELEMENT hybrid (
  reference-authorised-eea
, reference-medicinal-product*
, bioequivalence-study*
, different-original-product
)>

<!-- 1.4.4. Article 10(4) similar biological application -->
<!ELEMENT similar-biological (
  reference-authorised-eea
, reference-medicinal-product*
, bioequivalence-study*
)>

<!-- 1.4.5. Article 10a well-established application -->
<!-- 1.4.6. fixed combinaison application -->
<!-- 1.4.8. Traditional use registration -->
<!-- 1.4.7. Authorised product in the Community/Member State -->
<!ELEMENT informed-consent (
  product-fullname
, holder
, marketing-authorisation-number+
, attach-letter-consent?
)>
```

```
<!--  Reference medicinal product which is or has been authorised for not
less than 6/10 years -->
<!ELEMENT reference-authorised-eea (
  product-fullname
, holder
, date-first-authorisation
, eu-member-state
)>

<!-- Reference medicinal product marketed in the Community/Member State -->
<!ELEMENT reference-medicinal-product (
  product-fullname
, holder
, marketing-authorisation-number+
)>

<!-- Medicinal Product used for bioequivalence study (where applicable) -->
<!ELEMENT bioequivalence-study (
  product-fullname
, holder
, eu-member-state
)>

<!-- differences compared to the original product -->
<!ELEMENT different-original-product (
  different-active-substance?
, different-therapeutic-use?
, different-pharmaceutical-form?
, different-strength?
, different-route?
, different-bioequivalence?
)>

<!-- ================================================================ -->
<!--2. MARKETING AUTHORISATION APPLICATION PARTICULARS -->

<!ELEMENT maa-particulars (
  names-atccode
, strength-form-route
, legal-status
, dossier
, manufacturers
, qualitative-quantitative-composition
)>

<!-- 2.1 -->
<!ELEMENT names-atccode (
  medicinal-product
, active-substance+
, atc-class+
)>

<!-- 2.1.1. Proposed ........................................... -->
<!ELEMENT medicinal-product (
  invented-name
, attach-invented-name?
)>

<!-- 2.1.3. Pharmacotherapeutic group .............................. -->
<!ELEMENT atc-class (
  atc-code
```

```
, atc-version?
, atc-name
, atc-pending
)>


<!-- 2.2. -->
<!ELEMENT strength-form-route (
  form-name
, substance-strength+
, routes
, types-of-pack
)>


<!-- 2.2.1. Strength and Pharmaceutical form ....................... -->
<!ELEMENT substance-strength (
  substance-name
, strength-quantity
, strength-unit
)>


<!-- 2.2.2. Route(s) of administration ............................ -->
<!ELEMENT routes (route-name+) >


<!-- ............................................................. -->
<!-- 2.2.3.  Container, closure and administration device(s) -->
<!ELEMENT types-of-pack (
  type-of-pack+
, attach-list-mockup?
)>


<!ELEMENT type-of-pack (
  container
, container-material
, (closure
    , closure-material)?
, (device-name
    , device-material)*
, presentation
)>


<!ELEMENT presentation (
  pack-size
, life-shelf
, life-open?
, life-reconstituted?
, storage-shelf
, storage-shelf-open?
)>

<!-- 2.3. legal status ........................................... -->
<!-- 2.3.1.   -->
<!ELEMENT legal-status (prescription | non-prescription)>

<!-- 2.3.2.  For products subject to medical prescriptions -->
<!ELEMENT prescription (
  product-prescription-renew?
, product-prescription-not-renew?
, product-special-prescription?
, product-restricted-prescription?
)>
```

```
<!-- 2.3.3.  Supply for products not subject to medical prescription -->
<!ELEMENT non-prescription (
  supply
, promotion-healthcare
)>

<!-- 2.4. Marketing ... -->
<!ELEMENT dossier (
  marketing-holder+
, person-com-during-procedure+
, person-com-after-authorisation+
, person-pharmacovigilance+
, scientific-service-mah+
)>

<!-- 2.4.1. -->
<!ELEMENT marketing-holder (
  company-name
, contact
, attach-proof-establishment?
)>

<!-- 2.4.2. -->
<!ELEMENT person-com-during-procedure (
  contact-name
, company-name
, contact
, attach-letter-authorisation?
)>

<!-- 2.4.3. -->
<!ELEMENT person-com-after-authorisation (
  contact-name
, company-name
, contact
, attach-letter-authorisation?
)>

<!-- 2.4.4. -->
<!ELEMENT person-pharmacovigilance (
  contact-name
, company-name
, contact
, attach-cv-person?
)>

<!-- 2.4.5. -->
<!ELEMENT scientific-service-mah (
  contact-name
, company-name
, contact
)>

<!-- 2.5. MANUFACTURERS -->
<!ELEMENT manufacturers (
  manufacturers-batch-release,
  pharma-product-manufacturers,
  manufacturers-active-substance,
  contract-company*
)>
```

```
<!-- 2.5.1. -->
<!-- 2.5.1.1. Contact person in EEA for product defects (all procedures
now) -->
<!ELEMENT manufacturers-batch-release (
  manufacturer-batch-release+
, contact-blood-vaccines?
, contact-product-defects
, contact-batch-testing-site*
)>

<!ELEMENT manufacturer-batch-release (
  company-name
, contact
, manufacturing-aut-number
, attach-manu-authorisation?
, attach-justification?
)>

<!ELEMENT contact-blood-vaccines    (
  contact-name
, contact
)>

<!ELEMENT contact-batch-testing-site (
  company-name
, contact
, description-control-test
)>

<!-- ......................................................... -->
<!-- 2.5.2.  Manufacturer of the medicinal product and site of manufacture
-->
<!ELEMENT pharma-product-manufacturers (pharma-product-manufacturer+) >

<!ELEMENT pharma-product-manufacturer (
  contact-name
, company-name
, contact
, description-functions
, attach-flowchart?
, (manufacturer-ineea | manufacturer-outeea)
)>

<!-- the Manufacturer site is in EEA -->
<!ELEMENT manufacturer-ineea (
  manufacturing-aut-number-eea
, attach-manu-authorisation?
, name-qualified-person?
)>

<!-- the Manufacturer site is outside the EEA -->
<!ELEMENT manufacturer-outeea (
  attach-manu-authorisation?
, inspection
)>

<!-- has the site been inspected by an EEA authority -->
<!ELEMENT inspection (
    no-inspection-authority
  | (attach-inspection-site?
      , gmp-compliant)
```

```
)>

<!-- has the site been inspected by any other authority -->
<!ELEMENT no-inspection-authority (
    no-inspection
  | (attach-inspection-site?
     , gmp-compliant)
)>

<!-- 2.5.3.  Manufacturer of the active substance -->
<!ELEMENT manufacturers-active-substance (manufacturer-active-substance+) >

<!-- only the final manufacturer (not broker not supplier) -->
<!ELEMENT manufacturer-active-substance (
  substance-name
, contact-name
, contact
, description-manufacturing
, attach-flowchart?
, attach-declaration-qualified-person?
, (pheur-certificate | use-dmf | certificate-vamf | no-pheur-dmf)
, eea-inspection?
)>

<!-- Ph. European Certificate of suitability -->
<!ELEMENT pheur-certificate (
  substance-name
, company-name
, reference-number-certificate
, date-last-update-pheur
, attach-letter-access?
)>

<!-- European Drug Master File -->
<!ELEMENT use-dmf (
  substance-name
, company-name
, reference-number-competent-aut
, date-submission
, date-last-update-dmf?
, attach-letter-access?
, attach-written-confirmation?
)>

<!-- Certificate for a Vaccine Antigen Master File -->
<!ELEMENT certificate-vamf (
  substance-name
, certificate-holder
, reference-number-certificate
, date-submission?
, date-last-update-vamf?
, attach-certificate-vamf?
)>

<!-- inspection active ingredient manufacturer -->
<!ELEMENT eea-inspection (
  attach-inspection-site
, inspection-outcome
)>

<!-- 2.5.4. Contract companies used for bioavailability ... -->
```

```
<!ELEMENT contract-company (
  title-study
, protocol-code
, eudract-number
, contact-name
, contact
, duty-performed
)>

<!-- 2.6.  Qualitative and Quantitative composition -->
<!ELEMENT qualitative-quantitative-composition (
  composition+
, materials
, plasma-master-files
, gmo
)>

<!ELEMENT composition (
  quantity-note?
, substance-info+
, excipient-info*
)>

<!ELEMENT substance-info (
  substance-name
, strength-quantity
, strength-unit
, reference-monograph-standard
, overage?
)>

<!ELEMENT excipient-info (
  excipient-name
, strength-quantity
, strength-unit
, reference-monograph-standard
, overage?
)>

<!-- 2.6.2. List of materials -->
<!ELEMENT materials (
  no-materials
| (material+
    , attach-certificates-suitability?)
)>

<!ELEMENT material (
  material-name
, material-function
, material-origin
)>

<!ELEMENT material-origin (
  ((animal-tse, cert-suitability?)
| other-animal | human)
)>

<!ELEMENT cert-suitability (
 state-number
)>
```

```
<!-- 2.6.3. Is a certificate for Plasma Master File (PMF) issued -->
<!ELEMENT plasma-master-files (
  no-plasma-master-files
| (plasma-master-file+
    , attach-certificate-pmf?)
)>

<!ELEMENT plasma-master-file (
  substance-name
, material-function
, certificate-holder
, reference-number-certificate
, date-submission?
, date-last-update-pmf?
)>

<!-- 2.6.4. Does the medicinal product contain or consist of GMOs ... -->
<!ELEMENT gmo (
  no-gmo
| (council
    , attach-written-consent-gmo?)
)>

<!-- ================================================================= -->
<!-- 3. SCIENTIFIC ADVICE -->

<!ELEMENT scientific-advice (
  chmp-scientific-advice
, scientific-recommendations
)>

<!ELEMENT chmp-scientific-advice (
  no-scientific-advice
| (date-scientific-advice
    , scientific-advice-reference
    , attach-scientific-advice-chmp?)
)>

<!ELEMENT scientific-recommendations (
  no-scientific-recommendation
| scientific-recommendation+
)>

<!ELEMENT scientific-recommendation (
  eu-member-state
, date-recommendation
)>

<!-- ================================================================= -->
<!-- 4. PAEDIATRIC DEVELOPMENT PROGRAM  -->

<!ELEMENT paediatric-program (
  no-paediatric-program
| paediatric-relevant-section+
)>

<!-- ================================================================= -->
<!-- 5. OTHER MARKETING AUTHORISATION APPLICATIONS -->

<!ELEMENT other-maa (
  same-product-eea
```

```
, dossier-multiple-application*
, same-product-non-eea
)>


<!-- 5.1. (see 1.1.3. -->

<!-- 5.2.  Marketing authorisation applications for the same product in the
EEA -->
<!ELEMENT same-product-eea (
  product-authorised-in*
, product-pending-in*
, product-refused-in*
, product-withdrawn-before-in*
, product-withdrawn-after-in*
, product-suspended-authority-in*
)>


<!ELEMENT product-authorised-in (
  eu-member-state
, date-notif
, tradename
, authorisation-number
, attach-marketing-authorisation?
)>


<!ELEMENT product-pending-in (
  eu-member-state
, date-notif
)>


<!ELEMENT product-refused-in (
  eu-member-state
, date-notif
)>


<!ELEMENT product-withdrawn-before-in (
  eu-member-state
, date-notif
, tradename
, reason
)>


<!ELEMENT product-withdrawn-after-in (
  eu-member-state
, date-notif
, authorisation-number
, reason
, tradename
)>


<!ELEMENT product-suspended-authority-in (
  eu-member-state
, date-notif
, reason
, tradename
)>


<!-- 5.3. For multiple applications of the same medicinal product -->
<!ELEMENT dossier-multiple-application (
  name-other-product
, date-multiple-application
```

```
, applicant-multiple-application
)>

<!-- 5.4.  Marketing authorisation applications for the same product
outside the EEA... -->
<!ELEMENT same-product-non-eea (
  product-authorised-out*
, product-pending-out*
, product-refused-out*
, product-withdrawn-before-out*
, product-withdrawn-after-out*
, product-suspended-authority-out*
)>

<!ELEMENT product-authorised-out (
  country
, date-notif
, tradename
)>

<!ELEMENT product-pending-out (
  country
, date-notif
)>

<!ELEMENT product-refused-out (
  country
, date-notif
)>

<!ELEMENT product-withdrawn-before-out (
  country
, date-notif
, tradename
, reason
)>

<!ELEMENT product-withdrawn-after-out (
  country
, date-notif
, authorisation-number
, reason
, tradename
)>

<!ELEMENT product-suspended-authority-out (
  country
, date-notif
, reason
, tradename
)>

<!-- 6. ANNEXED DOCUMENTS -->
<!ELEMENT annexed-documents (
  ann-proof-payment*
, ann-letter-consent*
, ann-proof-establishment*
, ann-letter-authorisation*
, ann-cv-person*
, ann-manu-authorisation*
, ann-justification*
```

```
, ann-flowchart*
, ann-inspection-site*
, ann-letter-access*
, ann-written-confirmation*
, ann-certificates-suitability*
, ann-written-consent-gmo*
, ann-scientific-advice-chmp*
, ann-marketing-authorisation*
, ann-copy-correspondence*
, ann-list-mockup*
, ann-orphan-decision*
, ann-invented-name*
, ann-certificate-vamf*
, ann-certificate-pmf*
, ann-declaration-qualified-person*
)>

<!-- ================================================================ -->
<!-- Common element -->
<!ELEMENT contact (
  address01?
, address02?
, zipcode?
, town?
, country
, phone
, fax?
, email?
)>

<!-- ............................................................. -->
<!-- Terminal elements -->
<!ELEMENT complete                                    EMPTY >
<!ATTLIST complete                                    constituent (
  new-substance
| known-substance
) #REQUIRED  >

<!ELEMENT supply                                      EMPTY >
<!ATTLIST supply                                      pharmacies  (
  pharmacies
| not-pharmacies
) #REQUIRED >

<!ELEMENT inspection-outcome                          EMPTY >
<!ATTLIST inspection-outcome                          outcome     (
  positive
| negative
) #REQUIRED >

<!ELEMENT promotion-healthcare                        EMPTY >
<!ATTLIST promotion-healthcare                        promotion   (
  healthcare-only
| general-public
) #REQUIRED >

<!ELEMENT material-function                           EMPTY >
<!ATTLIST material-function                           function    (
  AS
| EX
| R
```

```
) #REQUIRED >

<!-- ......................................................... -->
<!ENTITY % yesno " flag ( yes | no ) #REQUIRED ">

<!ELEMENT gmp-compliant                             EMPTY   >
<!ATTLIST gmp-compliant                             %yesno; >

<!ELEMENT council                                   EMPTY   >
<!ATTLIST council                                   %yesno; >

<!ELEMENT application-pending-same-product          EMPTY   >
<!ATTLIST application-pending-same-product          %yesno; >

<!ELEMENT authorisation-granted-same-product        EMPTY   >
<!ATTLIST authorisation-granted-same-product        %yesno; >

<!ELEMENT state-authorisation                       EMPTY   >
<!ATTLIST state-authorisation                       %yesno; >

<!ELEMENT orphan-benefit                            EMPTY   >
<!ATTLIST orphan-benefit                            %yesno; >

<!ELEMENT orphan-similar                            EMPTY   >
<!ATTLIST orphan-similar                            %yesno; >

<!ELEMENT atc-pending                               EMPTY   >
<!ATTLIST atc-pending                               %yesno; >


<!-- ......................................................... -->
<!-- YYYY-MM-DD -->
<!ENTITY % att-date "
year CDATA                                          #REQUIRED
month (01|02|03|04|05|06|07|08|09|10|11|12)         #REQUIRED
day (01|02|03|04|05|06|07|08|09|10|11|12|13|14|15|
        16|17|18|19|20|21|22|23|24|25|26|27|28|29|30|31) #REQUIRED">

<!ELEMENT date-last-update-pheur                    EMPTY     >
<!ATTLIST date-last-update-pheur                    %att-date; >

<!ELEMENT date-submission                           EMPTY     >
<!ATTLIST date-submission                           %att-date; >

<!ELEMENT date-last-update-dmf                      EMPTY     >
<!ATTLIST date-last-update-dmf                      %att-date; >

<!ELEMENT date-last-update-vamf                     EMPTY     >
<!ATTLIST date-last-update-vamf                     %att-date; >

<!ELEMENT date-last-update-pmf                      EMPTY     >
<!ATTLIST date-last-update-pmf                      %att-date; >

<!ELEMENT date-notif                                EMPTY     >
<!ATTLIST date-notif                                %att-date; >

<!ELEMENT date-scientific-advice                    EMPTY     >
<!ATTLIST date-scientific-advice                    %att-date; >

<!ELEMENT date-recommendation                       EMPTY     >
<!ATTLIST date-recommendation                       %att-date; >
```

```
<!ELEMENT date-multiple-application                    EMPTY      >
<!ATTLIST date-multiple-application                    %att-date; >

<!ELEMENT date-orphan-status                           EMPTY      >
<!ATTLIST date-orphan-status                           %att-date; >

<!ELEMENT date-signature                               EMPTY      >
<!ATTLIST date-signature                               %att-date; >

<!ELEMENT date-first-authorisation                     EMPTY      >
<!ATTLIST date-first-authorisation                     %att-date; >

<!ELEMENT date-acceptance                              EMPTY      >
<!ATTLIST date-acceptance                              %att-date; >

<!ELEMENT date-proposed-common-renewal                 EMPTY      >
<!ATTLIST date-proposed-common-renewal                 %att-date; >

<!ELEMENT date-agreed-common-renewal                   EMPTY      >
<!ATTLIST date-agreed-common-renewal                   %att-date; >


<!-- ..................................................................... -->
<!ELEMENT description-functions                 (#PCDATA) >
<!ELEMENT manufacturing-aut-number-eea          (#PCDATA) >
<!ELEMENT name-qualified-person                 (#PCDATA) >
<!ELEMENT reference-number-certificate          (#PCDATA) >
<!ELEMENT reference-number-competent-aut        (#PCDATA) >
<!ELEMENT duty-performed                        (#PCDATA) >
<!ELEMENT reference-monograph-standard          (#PCDATA) >
<!ELEMENT overage                               (#PCDATA) >
<!ELEMENT quantity-note                         (#PCDATA) >
<!ELEMENT therapeutic-implication-note          (#PCDATA) >
<!ELEMENT tradename                             (#PCDATA) >
<!ELEMENT authorisation-number                  (#PCDATA) >
<!ELEMENT reason                                (#PCDATA) >
<!ELEMENT country                               (#PCDATA) >
<!ELEMENT holder                                (#PCDATA) >
<!ELEMENT marketing-authorisation-number        (#PCDATA) >
<!ELEMENT atc-code                              (#PCDATA) >
<!ELEMENT atc-version                           (#PCDATA) >
<!ELEMENT atc-name                              (#PCDATA) >
<!ELEMENT route-name                            (#PCDATA) >
<!ELEMENT contact-name                          (#PCDATA) >
<!ELEMENT address01                             (#PCDATA) >
<!ELEMENT address02                             (#PCDATA) >
<!ELEMENT zipcode                               (#PCDATA) >
<!ELEMENT town                                  (#PCDATA) >
<!ELEMENT phone                                 (#PCDATA) >
<!ELEMENT fax                                   (#PCDATA) >
<!ELEMENT email                                 (#PCDATA) >
<!ELEMENT company-name                          (#PCDATA) >
<!ELEMENT scientific-advice-reference           (#PCDATA) >
<!ELEMENT paediatric-relevant-section           (#PCDATA) >
<!ELEMENT name-other-product                    (#PCDATA) >
<!ELEMENT applicant-multiple-application        (#PCDATA) >
<!ELEMENT invented-name                         (#PCDATA) >
<!ELEMENT strength-quantity                     (#PCDATA) >
<!ELEMENT strength-unit                         (#PCDATA) >
<!ELEMENT form-name                             (#PCDATA) >
<!ELEMENT substance-name                        (#PCDATA) >
```

```
<!ELEMENT person-authorised                            (#PCDATA) >
<!ELEMENT name-person                                  (#PCDATA) >
<!ELEMENT function-person                              (#PCDATA) >
<!ELEMENT place-signature                              (#PCDATA) >
<!ELEMENT applicant                                    (#PCDATA) >
<!ELEMENT rapporteur                                   (#PCDATA) >
<!ELEMENT co-rapporteur                                (#PCDATA) >
<!ELEMENT mrp-marketing-authorisation-number           (#PCDATA) >
<!ELEMENT mrp-procedure-number                         (#PCDATA) >
<!ELEMENT national-application-number                  (#PCDATA) >
<!ELEMENT orphan-designation-procnumber                (#PCDATA) >
<!ELEMENT orphan-number-register                       (#PCDATA) >
<!ELEMENT orphan-decision-refnumber                    (#PCDATA) >
<!ELEMENT orphan-eu-designation-number                 (#PCDATA) >
<!ELEMENT manumber-application-made                    (#PCDATA) >
<!ELEMENT container                                    (#PCDATA) >
<!ELEMENT closure                                      (#PCDATA) >
<!ELEMENT device-name                                  (#PCDATA) >
<!ELEMENT pack-size                                    (#PCDATA) >
<!ELEMENT life-shelf                                   (#PCDATA) >
<!ELEMENT life-open                                    (#PCDATA) >
<!ELEMENT life-reconstituted                           (#PCDATA) >
<!ELEMENT storage-shelf                                (#PCDATA) >
<!ELEMENT storage-shelf-open                           (#PCDATA) >
<!ELEMENT manufacturing-aut-number                     (#PCDATA) >
<!ELEMENT active-substance                             (#PCDATA) >
<!ELEMENT container-material                            (#PCDATA) >
<!ELEMENT closure-material                             (#PCDATA) >
<!ELEMENT device-material                              (#PCDATA) >
<!ELEMENT excipient-name                               (#PCDATA) >
<!ELEMENT material-name                                (#PCDATA) >
<!ELEMENT state-number                                 (#PCDATA) >
<!ELEMENT description-control-test                      (#PCDATA) >
<!ELEMENT description-manufacturing                     (#PCDATA) >
<!ELEMENT certificate-holder                           (#PCDATA) >
<!ELEMENT specify-waiver-amendment-psur                (#PCDATA) >
<!ELEMENT title-study                                  (#PCDATA) >
<!ELEMENT protocol-code                                (#PCDATA) >
<!ELEMENT eudract-number                               (#PCDATA) >
<!ELEMENT specify-change                               (#PCDATA) >
<!ELEMENT procedure-number                             (#PCDATA) >

<!-- .......................................................... -->
<!ELEMENT fixed-combination                            EMPTY >
<!ELEMENT well-established-use                          EMPTY >
<!ELEMENT traditional-use-registration                 EMPTY >
<!ELEMENT signature                                    EMPTY >
<!ELEMENT line-extension-change-newform                EMPTY >
<!ELEMENT line-extension-change-strength               EMPTY >
<!ELEMENT line-extension-add-route                     EMPTY >
<!ELEMENT line-extension-change-pharmacokinetics       EMPTY >
<!ELEMENT line-extension-bioavailability               EMPTY >
<!ELEMENT product-prescription-renew                   EMPTY >
<!ELEMENT product-prescription-not-renew               EMPTY >
<!ELEMENT product-special-prescription                 EMPTY >
<!ELEMENT product-restricted-prescription              EMPTY >
<!ELEMENT different-pharmaceutical-form                EMPTY >
<!ELEMENT different-strength                            EMPTY >
<!ELEMENT different-route                               EMPTY >
<!ELEMENT different-therapeutic-use                     EMPTY >
<!ELEMENT no-orphan-designation                         EMPTY >
```

```
<!ELEMENT no-orphan-condition                          EMPTY >
<!ELEMENT no-orphan-granted                            EMPTY >
<!ELEMENT no-plasma-master-files                       EMPTY >
<!ELEMENT line-extension-replacement-salt              EMPTY >
<!ELEMENT line-extension-replacement-isomer            EMPTY >
<!ELEMENT line-extension-replacement-biological        EMPTY >
<!ELEMENT no-gmo                                       EMPTY >
<!ELEMENT no-inspection                                EMPTY >
<!ELEMENT no-materials                                 EMPTY >
<!ELEMENT no-scientific-advice                         EMPTY >
<!ELEMENT no-scientific-recommendation                 EMPTY >
<!ELEMENT no-paediatric-program                        EMPTY >
<!ELEMENT no-pheur-dmf                                 EMPTY >
<!ELEMENT animal-tse                                   EMPTY >
<!ELEMENT other-animal                                 EMPTY >
<!ELEMENT human                                        EMPTY >
<!ELEMENT pending                                      EMPTY >
<!ELEMENT annex1                                       EMPTY >
<!ELEMENT annex3                                       EMPTY >
<!ELEMENT annex4                                       EMPTY >
<!ELEMENT annex32a                                     EMPTY >
<!ELEMENT annex32b                                     EMPTY >
<!ELEMENT generic-centralised                          EMPTY >
<!ELEMENT line-extension-new-ligand                    EMPTY >
<!ELEMENT line-extension-change-extraction             EMPTY >
<!ELEMENT different-active-substance                   EMPTY >
<!ELEMENT different-bioequivalence                     EMPTY >
<!ELEMENT conditional-approval                         EMPTY >
<!ELEMENT exceptional-circumstances                    EMPTY >
<!ELEMENT article101                                   EMPTY >
<!ELEMENT article105                                   EMPTY >
<!ELEMENT article74a                                   EMPTY >


<!-- ================================================================ -->
<!-- 6. ANNEXED DOCUMENTS -->
<!-- depending on context annexed document is prefixed by ann or attach -->

<!--  Link elements -->
<!ENTITY % xlink '
  xmlns:xlink  CDATA                      #FIXED
"http://www.w3c.org/1999/xlink"
  xlink:type   CDATA                      #FIXED "simple"
  xlink:role   CDATA                      #IMPLIED
  xlink:href   CDATA                      #REQUIRED
  xlink:title  CDATA                      #IMPLIED
  xlink:show (new | replace | embed | other | none) #IMPLIED
  xlink:actuate (onLoad | onRequest | other | none) #IMPLIED
  id           ID                         #REQUIRED ' >

<!-- 6.1. -->
<!ELEMENT ann-proof-payment                  EMPTY   >
<!ATTLIST ann-proof-payment                  %xlink; >


<!-- 6.2. -->
<!ELEMENT ann-letter-consent                 EMPTY   >
<!ATTLIST ann-letter-consent                 %xlink; >


<!-- 6.3. -->
<!ELEMENT ann-proof-establishment            EMPTY   >
<!ATTLIST ann-proof-establishment            %xlink; >
```

```
<!-- 6.4. -->
<!ELEMENT ann-letter-authorisation                    EMPTY   >
<!ATTLIST ann-letter-authorisation                    %xlink; >


<!-- 6.5. -->
<!ELEMENT ann-cv-person                               EMPTY   >
<!ATTLIST ann-cv-person                               %xlink; >


<!-- 6.6. -->
<!ELEMENT ann-manu-authorisation                      EMPTY   >
<!ATTLIST ann-manu-authorisation                      %xlink; >


<!-- 6.7. -->
<!ELEMENT ann-justification                           EMPTY   >
<!ATTLIST ann-justification                           %xlink; >


<!-- 6.8. -->
<!ELEMENT ann-flowchart                               EMPTY   >
<!ATTLIST ann-flowchart                               %xlink; >


<!-- 6.9. -->
<!ELEMENT ann-inspection-site                         EMPTY   >
<!ATTLIST ann-inspection-site                         %xlink; >


<!-- 6.10. -->
<!ELEMENT ann-letter-access                           EMPTY   >
<!ATTLIST ann-letter-access                           %xlink; >


<!-- 6.11. -->
<!ELEMENT ann-written-confirmation                    EMPTY   >
<!ATTLIST ann-written-confirmation                    %xlink; >


<!-- 6.12. -->
<!ELEMENT ann-certificates-suitability                EMPTY   >
<!ATTLIST ann-certificates-suitability                %xlink; >


<!-- 6.13. -->
<!ELEMENT ann-written-consent-gmo                     EMPTY   >
<!ATTLIST ann-written-consent-gmo                     %xlink; >


<!-- 6.14. -->
<!ELEMENT ann-scientific-advice-chmp                  EMPTY   >
<!ATTLIST ann-scientific-advice-chmp                  %xlink; >


<!-- 6.15. -->
<!ELEMENT ann-marketing-authorisation                 EMPTY   >
<!ATTLIST ann-marketing-authorisation                 %xlink; >


<!-- 6.16. -->
<!ELEMENT ann-copy-correspondence                     EMPTY   >
<!ATTLIST ann-copy-correspondence                     %xlink; >


<!-- 6.17. -->
<!ELEMENT ann-list-mockup                             EMPTY   >
<!ATTLIST ann-list-mockup                             %xlink; >


<!-- 6.18. -->
<!ELEMENT ann-orphan-decision                         EMPTY   >
<!ATTLIST ann-orphan-decision                         %xlink; >


<!-- 6.19. -->
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<!ELEMENT ann-invented-name                         EMPTY   >
<!ATTLIST ann-invented-name                         %xlink; >


<!-- 6.20. -->
<!ELEMENT ann-certificate-vamf                      EMPTY   >
<!ATTLIST ann-certificate-vamf                      %xlink; >


<!-- 6.21. -->
<!ELEMENT ann-certificate-pmf                       EMPTY   >
<!ATTLIST ann-certificate-pmf                       %xlink; >


<!-- 6.22. -->
<!ELEMENT ann-declaration-qualified-person          EMPTY   >
<!ATTLIST ann-declaration-qualified-person          %xlink; >


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<!ELEMENT attach-proof-establishment                EMPTY      >
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<!ELEMENT attach-letter-authorisation               EMPTY      >
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<!ELEMENT attach-marketing-authorisation            EMPTY      >
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<!ELEMENT attach-copy-correspondence                  EMPTY     >
<!ATTLIST attach-copy-correspondence                  %att-refs; >

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<!ELEMENT attach-declaration-qualified-person         EMPTY     >
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