Specification of Electronic Medicinal Product Documentation in eCTD Format for Bosnia and Herzegovina

— Instructions for Applicants —

Version 1.3 APPROVED

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1 Revision History

Version	Date	Name	Description
1.0	16.05.2025	Jelena Aničić	Initial version
1.1	16.06.2025	Jelena Aničić	Revised version incorporating stakeholders' comments.
1.2	16.07.2025	Jelena Aničić	The checksum for *ba-regional.xsl* on page 19 has been corrected.
1.3	04.12.2025	Jelena Aničić	Approval of the final version.

2 Introduction

This document sets out the specification for electronic medicinal product documentation in Bosnia and Herzegovina in the eCTD format.

The purpose of this specification is to enable the electronic submission of medicinal product documentation by industry to ALMBIH. The reverse process, from ALMBIH to industry, is not supported or provided for under this specification.

2.1 Glossary

Term	Description
ICH	**The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)** – an initiative involving regulatory authorities and the research-based pharmaceutical industry of the European Union, Japan and the United States, which addresses scientific and technical discussions on issues and procedures necessary to ensure the safety, quality and efficacy of medicinal products.
EU	European Union
CTD	**Common Technical Document (CTD)** – a medicinal product documentation format consisting of five modules. The standard was adopted by the ICH in 2000 and became mandatory in the EU and Japan in 2003.
Applicant	The marketing authorisation holder in Bosnia and Herzegovina (a legal entity representing a foreign manufacturer and having its registered office in Bosnia and Herzegovina) or a manufacturer established in Bosnia and Herzegovina who submits an application for a regulatory procedure and provides medicinal product information/documentation to the Agency.
eCTD	**Electronic Common Technical Document (eCTD)** – the electronic format of CTD documentation based on XML technology, enabling electronic submission of CTD documentation from the applicant to the regulatory authority.
Submission / Sequence	A set of documents or information submitted at one time by the applicant to the regulatory authority. The term designates each electronic transmission of documentation, whether partial or complete.
PDF	Portable Document Format - a document format used for the presentation of documents in a manner independent of software, hardware or operating system. The format is open and defined by ISO standard
XML	Extensible Markup Language
DTD	Document Type Definition

3 General

3.1 Electronic Medicinal Product Dossier

The electronic medicinal product dossier is submitted in the format accepted in the European Union: eCTD.

By its structure (directory and document arrangement), the eCTD format follows the ICH CTD guidelines, which define the structure of the medicinal product dossier regardless of its format or medium (paper or electronic).

The electronic format of CTD documentation adopted as the standard in ICH regions is eCTD. Further information on the architecture and requirements of the eCTD standard is available on the EMA website: https://esubmission.ema.europa.eu/ectd/index.html

3.2 Electronic Dossier in Bosnia and Herzegovina

NeeS and eCTD are the officially accepted electronic formats of medicinal product documentation received by ALMBIH.

3.3 eCTD Specification in Bosnia and Herzegovina

For eCTD submissions in Bosnia and Herzegovina, the following rules and validation criteria must be complied with:

- ICH guidelines (Electronic Common Technical Document Specification V3.2.2)
- Harmonised Technical Guidance for eCTD Submissions in the EU (Harmonised guidance eCTD - version 6.0.1)
- EU eCTD Module 1 specification (EU eCTD M1 Specification, version 3.1.1)
- EU Region eCTD Validation Criteria v8.2

4 Module 1

In accordance with the ICH CTD specification, CTD Module 1 contains region-specific administrative information and medicinal product data.

It should be noted that the documents submitted within Module 1 vary depending on the type of application, the stage of the procedure (e.g. initial submission, responses to questions, etc.) and the type of medicinal product (e.g. vaccines, herbal medicinal products, etc.); therefore, not all documents listed in the specification will generally be submitted.

Instructions and explanations regarding which documents are required for each type of submission are provided further in this document, as well as in the guidelines and regulations of ALMBIH governing the granting, variation and renewal of marketing authorisations for finished medicinal products.

Main folder naming: SZL number
Note: The SZL number must be obtained from the e-Portal from the SZL application corresponding to the submission. The SZL number is an internal reference assigned to each application prepared by applicants through the Agency's e-Portal.

4.1 Recommendations for File Naming

In addition to the mandatory rules for naming folders and files set out in the EU Module 1 specification, the following recommendations shall also be observed:

1. The cover letter shall be placed within the "**m1/eu/10-cover**" folder, as illustrated in the example below:
   m1/eu/10-cover/ba/
   ba-cover.pdf

2. Documents,
   a. Application form (requestform),
   b. Proof of payment of the fees for granting the marketing authorisation (proofpayment),
   c. Proof of payment of the administrative fee (admintax),

   should be placed within the "**m1/eu/12-form**" folder, in compliance with the file naming convention (cc-form-annex-var.pdf)), as illustrated in the example below. When naming these documents, the variable part of the file name (highlighted in red) shall use the recommended document names:

   m1/eu/12-form/ba/
   ba-form-annex-requestform.pdf
   ba-form-annex-proofpayment.pdf
   ba-form-annex-admintax.pdf

3. Documents**:**
    a. Written consent from the manufacturer or the documentation owner granting the right to use the Active Substance Master File for the purpose of granting a marketing authorisation (**dmfletter**),
    b. Certificate of the European Pharmacopoeia for the active substance – CEP (**cosas**),
    c. European Pharmacopoeia certificate on the safety of substances with regard to the transmission of transmissible spongiform encephalopathy (TSE/BSE Ph. Eur. certificate) (**coste**),
    d. Certificate of a Pharmaceutical Product (CPP) (**cpp**),
    e. Valid certificates of compliance with Good Manufacturing Practice (**gmpcert**),
    f. Manufacturing authorisations for all declared medicinal product manufacturing sites (**documanuf**),
    g. Schematic overview of all manufacturers, from the active substance to the finished medicinal product, indicating the manufacturing steps performed by each (**manufflowchart**),
    h. Statement from the finished medicinal product manufacturer confirming that it will be informed of any changes in the manufacture or quality of the active substance (**gmpconform**),
    i. Chronological list of approved variations and urgent safety restrictions in Bosnia and Herzegovina from the date of granting or last renewal of the marketing authorisation up to the date of submission of the renewal application (**varlist**),
    j. Copy of the approved or notified variation (**varproof**),

should be placed within the "**m1/eu/additional-data**" folder, in compliance with the file naming convention (cc-additionaldata-var.pdf), as illustrated in the example below. When naming these documents, the variable part of the file name (highlighted in red) shall use the recommended document name suffixes listed below:

m1/eu/additional-data/ba/

ba-additionaldata-dmfletter-var.pdf
ba-additionaldata-cosas-var.pdf
ba-additionaldata-coste-var.pdf
ba-additionaldata-cpp-var.pdf
ba-additionaldata-gmpcert-var.pdf
ba-additionaldata-documanuf-var.pdf
ba-additionaldata-manufflowchart-var.pdf
ba-additionaldata-gmpconform-var.pdf
ba-additionaldata-varlist-var.pdf
ba-additionaldata-varproof-var.pdf

5 Folder and File Structure for Modules 2–5

Modules 2–5 are fully aligned with the ICH guidelines for directory structure and file naming in the eCTD.

6 Working documents

For documents related to the legal status of the representative (*extract from the court register, representation agreement, decision of the Ministry of Foreign Trade and Economic Relations verifying the representation agreement, insurance policy, and documents related to responsible persons*), ALMBIH requires that they be submitted within the "Working documents" folder, under the subfolder "ba/legalnost_zastupnika". These files shall be named and placed in the "Working documents" folder as follows:

000N-workingdocuments					
	ba				
		legalnost_zastupnika			
				regentproof-var.pdf	Proof of registration of the applicant in the court register
				mindecission-var.pdf	Valid decision of the Ministry of Foreign Trade and Economic Relations of Bosnia and Herzegovina approving the representation agreement for the purpose of obtaining a marketing authorisation
				repcontr-var.pdf	Valid representation agreement of the foreign manufacturer
				inspolicy-var.pdf	Insurance policy covering the manufacturer's liability for potential damage caused to the user of the medicinal product, valid in the territory of Bosnia and Herzegovina
				respperappoint-var.pdf	Decision on the appointment of the person responsible for placing the medicinal product on the market
				resppercv-var.pdf	Curriculum vitae of the person responsible for placing the medicinal product on the market
				pvperappoint-var.pdf	Decision on the appointment of the person responsible for pharmacovigilance
				pvpercv-var.pdf	Curriculum vitae of the person responsible for pharmacovigilance
		smpc-pil30mgtablete.doc			*Example of other files*

For the documents *Summary of Product Characteristics, Package Leaflet and Mock-ups*, ALMBIH requires submission in an editable format (MS Word). Such files must not be included within the eCTD sequence but shall be submitted in a separate folder named "000N_workingdocuments", where 000N represents the eCTD sequence number to which the working documents relate.

In addition to the documents listed above, ALMBIH may request other documents from the applicant in an editable format. All such files shall be placed in the "Working documents" folder.

When naming files in the "Working documents" folder, the applicant shall follow the guidelines applicable to documentation within the eCTD structure (e.g. smpc-var.doc, pil-var.doc, etc.). The purpose and content of each file must be clearly identifiable from the file name.

If different SmPCs, PILs or mock-ups are included within the same dossier (for different pharmaceutical forms or different pack sizes), the documents must be named in such a way that the variable part of the file name clearly indicates the medicinal product to which the document relates.

Examples:
smpc-wonderpil30mgtablete.doc
pil-wonderpil30mgtablete.doc
lab-wonderpil30mgtablete3x10.doc
lab-wonderpil30mgtablete6x10.doc

7 Technical Validation of Documentation

Technical validation is the process of verifying the formal compliance of electronic medicinal product documentation in eCTD format in accordance with the rules and requirements of ALMBIH.

7.1 Criteria for Technical Validation of the BiH eCTD

The rules for technical validation are presented in the table below and are based on all applicable rules defined in the EU guidelines for eCTD validation published in:

- EU Region eCTD Validation Criteria v8.2

Differences in relation to the EU specification concern the definition of country codes (**additional country code for Bosnia and Herzegovina "ba"**), language codes **(additional language codes "sr" and "bs"**), and agency codes (**additional code for ALMBIH: BA-ALMBIH**).

All differences in the validation rules compared to the EU Region eCTD Validation Criteria v8.2 are listed in ***Appendix 2: Validation Rules Specific to the BiH eCTD Specification***.

The applicant shall obligatorily place the technical validation report for the sequence in the "000N-validationreport" folder, where 000N denotes the eCTD sequence number to which the report relates.

000N-validationreport		
	validation-report-var.format	*eCTD validation report* *The term format describes the file extension. Files in PDF, RTF, HTML and MHTML formats are permitted.* *For example:* *validation-report-toolname.pdf*

8 Application of eCTD in Regulatory Procedures in Bosnia and Herzegovina

8.1.1 *General information*

1. All procedures shall be conducted as national procedures.

2. The Agency is not part of an electronic signature system; this has been addressed through statements by the persons responsible for placing the medicinal product on the market, confirming the authenticity of the submitted data. The application, cover letter and proof of payment shall continue to be submitted in paper form.

3. Only one sequence shall be submitted per submission (i.e. a single sequence within one ZIP file).

4. Sequences shall be submitted consecutively, without skipping sequence numbers (0000, 0001, 0002, 0003, …).

5. At the point when the applicant transitions to eCTD, a "baseline submission" containing the complete dossier previously submitted in NeeS or any other format must first be submitted. In the envelope, the submission unit type shall be set to "reformat" and the submission type to "none". After submission of the baseline submission, it is no longer permitted to revert that dossier to the NeeS format.

6. Extensions of the EU eCTD schema should not be used.

7. In relation to the EU eCTD Module 1 specification, the following minimum changes are required for the BiH eCTD Module 1 specification:
   - In **Appendix 2.1: Destination Codes**, the following additional country code shall be supported:
     ba - Bosnia and Herzegovina (ISO-3166-1-alpha-2 code)
   - In **Appendix 2.2: Language Codes**, the following additional language codes shall be supported:
     - **bs - Bosnian (ISO 639-1 Code)**
     - **sr - Serbian (ISO 639-1 Code)**
   - In **Appendix 2.4: Agency Codes and Names**, the following additional agency code shall be supported:
     - **BA-ALMBIH - Agency for medicinal products and medical devices of Bosnia and Herzegovina**

8. The "**root folder**" (the folder containing the sequence folder) shall be defined as the "**Internal SZL application reference number" („Interna šifra SZL zahtjeva**").

8.1.2 Types of Medicinal Products

This guideline applies to medicinal products falling within the scope of ALMBIH, i.e. exclusively medicinal products for human use. This includes prescription and non-prescription medicinal products, innovative and generic medicinal products, and covers the following types of medicinal products: chemical medicinal products, small molecules, biotechnological, herbal and homeopathic medicinal products, vaccines, and medicinal products derived from blood and blood plasma.

8.1.3 Types of Procedures

ALMBIH will accept eCTD submissions for any type of application related to regulatory affairs, including initial marketing authorisation, renewal of marketing authorisation, variations, transfer or withdrawal/revocation of the marketing authorisation, PSUR and ASMF. Once an applicant has submitted eCTD documentation for a medicinal product, all subsequent submissions/applications for the same medicinal product must be submitted in eCTD format.

8.1.4 Exemptions

This guideline does not apply to electronic documentation submitted prior to the granting of a marketing authorisation, including scientific advice, clinical trial documentation, Paediatric Investigation Plan (PIP) submissions, and other documentation whose content does not form part of the CTD dossier. ALMBIH will not accept such documentation in eCTD format.

9 Submission of eCTD to ALMBIH

9.1 How to submit documentation in eCTD format?

Electronic medicinal product documentation shall be submitted via the e-Portal.

In addition to the verification of the application, the electronic medicinal product documentation is also subject to technical validation in accordance with BiH criteria.

Each applicant is required to perform technical validation of the documentation prior to submitting the submission to ALMBIH.

Antivirus scanning of the electronic medicinal product documentation prior to submission to ALMBIH is mandatory.

9.2 Contacts at ALMBIH

For all information related to eCTD BiH, please contact:

Name: mr ph. Jelena Aničić
E-mail address: j.anicic@almbih.gov.ba
Telephone number: +387 51 456 040
Office hours: 9:00–13:00

10 eCTD Implementation Plan at ALMBIH

Marketing authorisation holders are hereby informed of the timelines for the implementation of medicinal product documentation in eCTD format:

- As of **01 February 2026**, submission of medicinal product documentation in eCTD format will be mandatory with applications for the **granting of a marketing authorisation (initial registration).**
- For medicinal products already authorised, and for medicinal products for which an application for granting a marketing authorisation was submitted prior to **01 February 2026**, a transitional period will be provided during which both NeeS and eCTD formats will be accepted.
- **The transitional period will last until 31 January 2031 at the latest.**
- During the transitional period, marketing authorisation holders are required to prepare **consolidated medicinal product documentation in eCTD format (baseline) in order to transition from the NeeS format to the eCTD format**.
  This obligation must be fulfilled by **31 January 2031**, or **at the latest during the renewal procedure that is ongoing within the transitional period.**
- A pilot project for testing the submission of medicinal product documentation in eCTD format is planned for **2025**.
- The **pilot project** will be implemented with selected marketing authorisation holders in the period **August–October 2025**.
- During this period, user feedback (both internal and external) will be collected and submitted to the software provider for further system improvements. The updated version of the software is to be delivered to the Agency and put into operation no later than **January 2026**.

Appendix 1: Additional ISO Codes Compared to the EU eCTD Module 1

The following ISO codes are added to Appendix 2 of the EU eCTD Module 1 Specification (EU eCTD M1 Specification, version 3.1):

In Appendix 2.1: Destination Codes, the following additional country code is added:

Code	Destination	Comment
ba	Bosnia and Hecegovina	ISO-3166-1-alpha-2 code

In Appendix 2.2: Language Codes, the following additional language codes are added:

Code	Language	Comment
bs	Bosnian	ISO-639-1 code
sr	Serbian	ISO 639-1 code

In Appendix 2.4: Agency Codes and Names, the following additional agency code is added:

Country	Agency Code	Human/Vet	Agency Name
Bosnia and Hecegovina	BA-ALMBIH	H	Agency for medicinal products and medical devices of Bosnia and Herzegovina

Appendix 2: Validation Rules Specific to the BiH eCTD Specification

The table below contains all differences in the validation rules for the **BiH eCTD specification** compared to the **EU Region eCTD Validation Criteria v8.2** of June 2025. The rule numbers listed in the "*Number*" column correspond to the validation rule numbers in the EU Region eCTD Validation Criteria v8.2.

Number	Category	Validation Criterion	Type of check	Comments
3.1	EU M1 DTD	The specified filename is used.	P/F	File is named **ba-regional.dtd**
3.3	EU M1 DTD	A currently acceptable version of the DTD is used (checksum matches the published value)	P/F	For example, the checksum for the DTD for BA m1 v3.1 is **becaf0ff98f817421936c0c939168abf**
5.1	EU M1 envelope MOD file	The specified filename is used	P/F	File is named **ba-envelope.mod**
5.3	EU M1 envelope MOD file	The checksum for the eu-envelope.mod file used must match the published checksum for the eu-envelope.mod file associated with the DTD used for the sequence	P/F	For example, the checksum for ba-envelope.mod from BA eCTD Module 1 v3.1 is **3a827e43a9901877b002d98c0bd8361a**

6.1	EU M1 stylesheet	The specified filename is used	P/F	File is named **ba-regional.xsl**
6.3	EU M1 stylesheet	The checksum for the stylesheet used must match the published checksum for the stylesheet associated with the DTD used for the sequence	P/F	For example, the checksum for the stylesheet from BA eCTD Module 1 v3.1 is **40cb4728d5d0c98bb2a0642dee045f6e**
9.2	EU regional XML	The file is named correctly	P/F	File is named **ba-regional.xml**
9.5	EU regional XML	The reference to the DTD in ba-regional.xml is directed to the DTD provided in the util folder.	P/F	This is the BA Regional DTD in /XXXX/util/dtd, and tested for validity by rules 3.1-3.5. A valid reference means a URI - see http://www.w3.org/TR/xml/ and http://www.ietf.org/rfc/rfc3986.txt (version 2005 page 22, section 3.3)
9.6	EU regional XML	The reference to the stylesheet in ba-regional.xml is directed to the stylesheet provided in the util folder.	P/F	This is the stylesheet in /XXXX/util/style, and tested for validity by rules 6.1-6.3. A valid reference means a URI - see http://www.w3.org/TR/xml/ and http://www.ietf.org/rfc/rfc3986.txt (version 2005 page 22, section 3.3).

13.3	Sequence number	The sequence folder name matches the sequence number in each envelope in **ba-regional.xml**	P/F	

All of the above-mentioned differences are required due to changes in the names of the DTD, XML and XSL files for the purposes of the BiH specification. The location of the files within the folder structure remains identical to that of the EU specification. The table below shows the differences in file names between the EU and BiH eCTD specifications, as well as the checksum values for the files included in the BiH eCTD package.

File name in the EU specification	**File name in the BiH specification**	**File location within the sequence**	**MD5 checksum of the file**
eu-regional.xml	ba-regional.xml	m1/eu/	
eu-regional.dtd	ba-regional.dtd	util/dtd/	becaf0ff98f817421936c0c939168abf
eu-envelope.mod	ba-envelope.mod	util/dtd/	3a827e43a9901877b002d98c0bd8361a
eu-leaf.mod	eu-leaf.mod	util/dtd/	23b854174e61c68044b9f53c0009af95
eu-regional.xsl	ba-regional.xsl	util/style/	40cb4728d5d0c98bb2a0642dee045f6e

Appendix 3: XML Schemas for BA Module 1

ba-regional.dtd

```
<!--
PUBLIC "-//EU//DTD eCTD EU Backbone 3.1//EN"
In the eCTD File Organisation: "util/dtd/ba-regional.dtd"

This DTD file is derived from the ze.dtd, with the following
customizations:
-Line 51: Added the country code ba
-Line 52: Added the language codes bs and sr


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Meaning or value of the suffixes:
? : element must appear 0 or 1 time
* : element must appear 0 or more time
+ : element must appear 1 or more times
<none>: element must appear once and only once
-->
```

```
<!-- General declarations, external modules
references..................... -->
<!ENTITY % countries
"(at|ba|be|bg|common|cy|cz|de|dk|edqm|ee|el|es|ema|fi|fr|hr|hu|ie|is|
it|li|lt|lu|lv|mt|nl|no|pl|pt|ro|se|si|sk|uk|xi)">
<!ENTITY % languages
"(bg|bs|cs|da|de|el|en|es|et|fi|fr|ga|hr|hu|is|it|lt|lv|mt|nl|no|pl|p
t|ro|sk|sl|sr|sv)">

<!ENTITY % leaf-node "(( leaf | node-extension )*)">

<!ENTITY % envelope-module SYSTEM "ba-envelope.mod" >
%envelope-module;

<!ENTITY % leaf-module SYSTEM "eu-leaf.mod" >
%leaf-module;
<!ELEMENT specific (
%leaf-node;
)>
<!ATTLIST specific
country %countries; #REQUIRED
>
<!ELEMENT pi-doc (
%leaf-node;
)>
<!ATTLIST pi-doc
xml:lang %languages; #REQUIRED
type (spc|annex2|outer|interpack|impack|other|pl|combined) #REQUIRED
country %countries; #REQUIRED
>

<!-- Root element
..................................................... -->
<!ELEMENT eu:eu-backbone (
eu-envelope,
m1-eu
)>

<!ATTLIST eu:eu-backbone
xmlns:eu CDATA #FIXED "http://europa.eu.int"
xmlns:xlink CDATA #FIXED "http://www.w3c.org/1999/xlink"
xml:lang CDATA #IMPLIED
dtd-version CDATA #FIXED "3.1"
>

<!--
................................................................... -
->
<!ELEMENT m1-eu (
m1-0-cover,
m1-2-form?,
m1-3-pi?,
m1-4-expert?,
m1-5-specific?,
m1-6-environrisk?,
```

```
m1-7-orphan?,
m1-8-pharmacovigilance?,
m1-9-clinical-trials?,
m1-10-paediatrics?,
m1-responses?,
m1-additional-data?
)>

<!--
..... -
->
<!ELEMENT m1-0-cover (
specific+
)>

<!--
..... -
->
<!ELEMENT m1-2-form (
specific+
)>

<!--
..... -
->
<!ELEMENT m1-3-pi (
m1-3-1-spc-label-pl?,
m1-3-2-mockup?,
m1-3-3-specimen?,
m1-3-4-consultation?,
m1-3-5-approved?,
m1-3-6-braille?
)>

<!ELEMENT m1-3-1-spc-label-pl (
pi-doc+
)>
<!ELEMENT m1-3-2-mockup (
specific+
)>
<!ELEMENT m1-3-3-specimen (
specific+
)>
<!ELEMENT m1-3-4-consultation (
specific+
)>
<!ELEMENT m1-3-5-approved (
specific+
)>
<!ELEMENT m1-3-6-braille (
%leaf-node;
)>

<!--
..... -
->
```

```
<!ELEMENT m1-4-expert (
m1-4-1-quality?,
m1-4-2-non-clinical?,
m1-4-3-clinical?
)>

<!ELEMENT m1-4-1-quality %leaf-node;>
<!ELEMENT m1-4-2-non-clinical %leaf-node;>
<!ELEMENT m1-4-3-clinical %leaf-node;>

<!--
..................................................................... -
->
<!ELEMENT m1-5-specific (
m1-5-1-bibliographic?,
m1-5-2-generic-hybrid-bio-similar?,
m1-5-3-data-market-exclusivity?,
m1-5-4-exceptional-circumstances?,
m1-5-5-conditional-ma?
)>

<!ELEMENT m1-5-1-bibliographic %leaf-node;>
<!ELEMENT m1-5-2-generic-hybrid-bio-similar %leaf-node;>
<!ELEMENT m1-5-3-data-market-exclusivity %leaf-node;>
<!ELEMENT m1-5-4-exceptional-circumstances %leaf-node;>
<!ELEMENT m1-5-5-conditional-ma %leaf-node;>

<!--
..................................................................... -
->
<!ELEMENT m1-6-environrisk (
(m1-6-1-non-gmo | m1-6-2-gmo)?
)>
<!ELEMENT m1-6-1-non-gmo %leaf-node;>
<!ELEMENT m1-6-2-gmo %leaf-node;>

<!--
..................................................................... -
->
<!ELEMENT m1-7-orphan (
m1-7-1-similarity?,
m1-7-2-market-exclusivity?
)>
<!ELEMENT m1-7-1-similarity %leaf-node;>
<!ELEMENT m1-7-2-market-exclusivity %leaf-node;>

<!--
..................................................................... -
->
<!ELEMENT m1-8-pharmacovigilance (
m1-8-1-pharmacovigilance-system?,
m1-8-2-risk-management-system?
)>
<!ELEMENT m1-8-1-pharmacovigilance-system %leaf-node;>
<!ELEMENT m1-8-2-risk-management-system %leaf-node;>
```

```
<!--
..................................................................... -
->
<!ELEMENT m1-9-clinical-trials %leaf-node;>
<!--
..................................................................... -
->

<!ELEMENT m1-10-paediatrics %leaf-node;>

<!--
..................................................................... -
->
<!ELEMENT m1-responses (
specific+
)>

<!--
..................................................................... -
->
<!ELEMENT m1-additional-data (
specific+
)>
```

eu-envelope.mod

```
<!--
In the eCTD File Organisation: "util/dtd/ba-envelope.mod"

This MOD file is derived from the eu-envelope.mod, with the following
customizations:
-Line 95: Added the agency code BA-ALMBIH
-Line 109: Added the country code ba

Version 1.4
August 2009

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Version 2.0
February 2013

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Version 3.0
October 2015

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Version 3.0.1
May 2016

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Version 3.1
June 2024

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Version 3.1
July 2025

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<!-- ..................................................................... --
>
<!ELEMENT eu-envelope (
      envelope+
)>

<!ELEMENT envelope (
```

```
      identifier,
      submission,
      submission-unit,
      applicant,
      agency,
      procedure,
      invented-name+,
      inn*,
      sequence,
      related-sequence+,
      submission-description
)>

<!-- ..................................................................... --
>
<!ELEMENT identifier            ( #PCDATA )>
<!ELEMENT submission          ( number?, procedure-tracking )>
<!ELEMENT procedure-tracking  ( number+ )>
<!ELEMENT number        ( #PCDATA )>
<!ELEMENT submission-unit     EMPTY>
<!ELEMENT applicant           ( #PCDATA )>
<!ELEMENT agency        EMPTY>
<!ELEMENT procedure           EMPTY>
<!ELEMENT invented-name       ( #PCDATA )>
<!ELEMENT inn                   ( #PCDATA )>
<!ELEMENT sequence            ( #PCDATA )>
<!ELEMENT related-sequence    ( #PCDATA )>
<!ELEMENT submission-description ( #PCDATA )>

<!-- ..................................................................... --
>
<!ATTLIST submission
type (maa | var-type1a | var-type1ain | var-type1b | var-type2 | var-nat |
extension | rup | psur | psusa | rmp | renewal | pam-sob | pam-anx | pam-
mea | pam-leg | pam-sda | pam-capa | pam-p45 | pam-p46 | pam-paes | pam-rec
| pass107n | pass107q | asmf | pmf | referral-20 | referral-294 | referral-
29p | referral-30 | referral-31 | referral-35 | referral-5-3 | referral-
107i | referral-16c1c | referral-16c4 | annual-reassessment | usr | clin-
data-pub-rp | clin-data-pub-fv | paed-7-8-30 | paed-29 | paed-45 | paed-46
| article-58 | notification-61-3 | transfer-ma | lifting-suspension |
withdrawal | cep | article-18 | none) #REQUIRED
mode ( single | grouping | worksharing ) #IMPLIED
>

<!-- ..................................................................... --
>
<!ATTLIST submission-unit
type (initial | validation-response | response | additional-info | closing
| consolidating | corrigendum | reformat | re-examination ) #REQUIRED
>

<!-- ..................................................................... --
>
<!ATTLIST agency
code ( AT-BASG | BA-ALMBIH | BE-FAMHP | BG-BDA | CY-PHS | CZ-SUKL | DE-
BFARM | DE-PEI | DK-DKMA | EE-SAM | EL-EOF | ES-AEMPS | FI-FIMEA | FR-ANSM
```

```
| HR-HALMED | HU-OGYI | IE-HPRA | IS-IMCA | IT-AIFA | LI-LLV | LT-SMCA |
LU-MINSANT | LV-ZVA | MT-MEDAUTH | NL-MEB | NO-NOMA | PL-URPL | PT-INFARMED
| RO-ANMMD | SE-MPA | SI-JAZMP | SK-SIDC | UK-MHRA | EU-EMA | EU-EDQM )
#REQUIRED>

<!-- ..................................................................... --
>
<!ATTLIST procedure
 type (
   centralised
 | national
 | mutual-recognition
 | decentralised
 ) #REQUIRED
>

<!-- ..................................................................... --
>
<!ENTITY % env-countries
"(at|ba|be|bg|cy|cz|de|dk|edqm|ee|el|ema|es|fi|fr|hr|hu|ie|is|it|li|lt|lu|l
v|mt|nl|no|pl|pt|ro|se|si|sk|uk|xi)">

<!-- ..................................................................... --
>
<!ATTLIST envelope country %env-countries; #REQUIRED >

<!-- +++ -->
```

eu-leaf.mod

```
<!--
In the eCTD File Organisation: "util/dtd/eu-leaf.mod"

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Contributors:
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This is based on ich-ectd-3-2.dtd;

If the ich-ectd.dtd is modularized, this one could be replaced.
Hence, one is certain that the common and EU leaf are the same.
-->

<!-- ============================================================= -->
<!ELEMENT node-extension (title, (leaf | node-extension)+)>
<!ATTLIST node-extension
      ID ID #IMPLIED
      xml:lang CDATA #IMPLIED
>

<!-- ============================================================= -->
<!ENTITY % show-list " (new | replace | embed | other | none) ">
<!ENTITY % actuate-list " (onLoad | onRequest | other | none) ">
<!ENTITY % operation-list " (new | append | replace | delete) ">
<!ENTITY % leaf-element " (title, link-text?) ">
<!ENTITY % leaf-att '
 ID                  ID               #REQUIRED
 application-version CDATA            #IMPLIED
 version             CDATA            #IMPLIED
 font-library        CDATA            #IMPLIED
 operation           %operation-list;  #REQUIRED
 modified-file       CDATA            #IMPLIED
 checksum            CDATA            #REQUIRED
 checksum-type       CDATA            #REQUIRED
 keywords            CDATA            #IMPLIED
 xmlns:xlink         CDATA            #FIXED
"http://www.w3c.org/1999/xlink"
 xlink:type          CDATA            #FIXED    "simple"
 xlink:role          CDATA            #IMPLIED
 xlink:href          CDATA            #IMPLIED
 xlink:show          %show-list;      #IMPLIED
 xlink:actuate       %actuate-list;   #IMPLIED
 xml:lang            CDATA            #IMPLIED
 '>

<!ELEMENT leaf %leaf-element;>
<!ATTLIST leaf
      %leaf-att;
>
<!ELEMENT title (#PCDATA)>
```

```
<!ELEMENT link-text (#PCDATA | xref)*>

<!ELEMENT xref EMPTY>
<!ATTLIST xref
      ID ID #REQUIRED
      xmlns:xlink CDATA #FIXED "http://www.w3c.org/1999/xlink"
      xlink:type CDATA #FIXED "simple"
      xlink:role CDATA #IMPLIED
      xlink:title CDATA #REQUIRED
      xlink:href CDATA #REQUIRED
      xlink:show %show-list; #IMPLIED
      xlink:actuate %actuate-list; #IMPLIED
>

<!-- +++ -->
```