



MRP/DCP Tracking Table Description

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Document Control

Change Record

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Reviewers

Version	Name	Organisation
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Distribution

Version	Name	Organisation

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Introduction

This document describes the usage of the Tracking Table XML format to be used in the context of Mutual Recognition and Decentralised Procedures, under the Module 1 of the electronic Common Technical Document (eCTD) for the European Union ("EU").

This document should be read together with the ICH eCTD Specification and the EU Module 1 Specification to prepare a valid eCTD submission in the EU. The latest version of the ICH eCTD Specification can be found at: <http://estri.ich.org/ectd>. The latest version of the EU Module 1 Specifications can be found at: <http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm>.

Purpose of the Tracking Table

The purpose of the XML Tracking Table standard is to record the eCTD sequences that have been submitted from the Applicant to the Regulator. The information recorded identifies the Reference Member State and the Concerned Member States. Each submission is characterised with a description, the receiving agencies and the submission period (month and year).

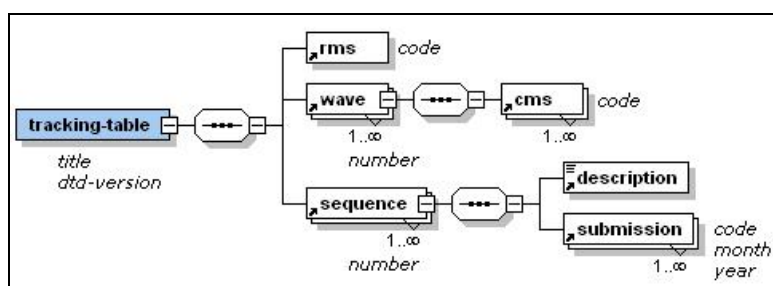
The XML Tracking Table intends to record the following information:

Sequence	Submission Description	RMS	Wave 1			Wave 2			Wave...
		RMS	CMS 1	CMS 2	CMS...	CMS x	CMS y	CMS...	CMS...
1234	Description of the Submission	Date	Date	Date	...	Date	Date
...									

The XML Tracking Table standard stores the tabular information in three zones:

- the RMS zone, where the Reference Member State is identified
- the Wave zone, where the waves are listed, and for each wave, the participating Concerned Member States
- the Sequence zone, where the sequences are listed, and for each sequence, the submission made to different agencies (RMS and/or CMSs) with identification of the submission period (month and year)

The information model of the XML Tracking Table displays in the figure below. Elements display within a square, attributes display in *italic*.



Location within the EU Module 1

The XML Tracking Table file should be named "tracking.xml" and be located in the Cover Letter folder (i.e. m1/eu/10-cover) within a "common" folder. Additional information on the usage of the EU M1 can be found in the EU Module 1 Specifications.

The DTD of the Tracking Table needs to be provided within the folder m1/eu/util/dtd and the style-sheet within the folder m1/eu/util/style of the EU Module 1.

Appendix 1: Tracking Table Element Description

The “tracking-table” element is the root element of the Tracking Table. This element may contain elements as described in the table below.

The three first columns describe the hierarchy between elements. Attributes are identified with the prefix “@”. For instance, the root element “tracking-table” contains 2 attributes (dtd-version and title) and 3 sub-elements (rms, wave and sequence). Similarly, the element “sequence” contains 1 attribute (number) and 2 sub-elements (description and submission).

Elements @attributes			Description/Instructions	Example	Constraint	Occurrence
tracking-table			Root element of the Tracking Table.	N/A	Mandatory	Unique
@dtd-version			The version of the Tracking Table DTD (value fixed by the standard).	0.1	Mandatory	Unique
@title			The title attached to the Tracking Table.	MRP Tracking Table	Mandatory	Unique
	rms		The entry for the Reference Member State. The element remains empty, as the value is identified with the code attribute (see below).	N/A	Mandatory	Unique
	@code		The identification of the Reference Member State, using the Destination Code listed in Appendix 2.	DE	Mandatory	Unique
	wave		The entry for the different waves that may belong to the Mutual Recognition or Decentralised Procedures	N/A	Mandatory	Repeatable
	@number		The identification of the wave, with a number, starting with 1.	1	Mandatory	Unique
		cms	The entry for the Concerned Member States implicated in that wave. The element remains empty, as the value is identified with the code attribute (see below).	N/A	Mandatory	Repeatable
		@code	The identification of the Concerned Member State, using the Destination Code listed in Appendix 2.	AT	Mandatory	Unique
	sequence		The entry for the different sequences that may belong to the Mutual Recognition or Decentralised Procedures.	N/A	Mandatory	Repeatable
	@number		The identification of the sequence, with a number, starting with 0000.	0002	Mandatory	Unique

Elements @attributes			Description/Instructions	Example	Constraint	Occurrence
		description	The description of the sequence.	Day 106 Responses to Questions	Mandatory	Unique
		submission	The entry for the different submissions that may belong to the sequence, per NCA. The element remains empty, as the value is identified with the code attribute (see below).	N/A	Mandatory	Repeatable
		@code	The identification of the NCA that has received the submission, either as RMS or CMS, using the Destination Code listed in Appendix 2.	N/A	Mandatory	Unique
		@month	The month of the submission, using the English literal value in 3 letters	Dec	Mandatory	Unique
		@year	The year of the submission, using 4 digits	2008	Mandatory	Unique

Appendix 2: Destination Codes

In most cases the destination code is an ISO-3166-1 code usually called “country code” or “CC” in this specification.

Code	Destination	Comment
AT	Austria	ISO-3166-1 code
BE	Belgium	ISO-3166-1 code
BG	Bulgaria	ISO-3166-1 code
CY	Cyprus	ISO-3166-1 code
CZ	Czech Republic	ISO-3166-1 code
DE	Germany	ISO-3166-1 code
DK	Denmark	ISO-3166-1 code
EE	Estonia	ISO-3166-1 code
EL	Greece	This is not an ISO code, but should be used as per guidance for application forms in the Notice to Applicants
ES	Spain	ISO-3166-1 code
FI	Finland	ISO-3166-1 code
FR	France	ISO-3166-1 code
HU	Hungary	ISO-3166-1 code
IE	Ireland	ISO-3166-1 code
IS	Iceland	ISO-3166-1 code
IT	Italy	ISO-3166-1 code
LI	Liechtenstein	ISO-3166-1 code
LT	Lithuania	ISO-3166-1 code
LU	Luxembourg	ISO-3166-1 code
LV	Latvia	ISO-3166-1 code
MT	Malta	ISO-3166-1 code
NL	Netherlands	ISO-3166-1 code
NO	Norway	ISO-3166-1 code
PL	Poland	ISO-3166-1 code
PT	Portugal	ISO-3166-1 code
RO	Romania	ISO-3166-1-code
SE	Sweden	ISO-3166-1 code
SI	Slovenia	ISO-3166-1 code
SK	Slovakia	ISO-3166-1 code
UK	United Kingdom	This is not an ISO country code, but should be used as per guidance for application forms in the Notice to Applicants

Appendix 3: Tracking Table Examples

This Tracking Table Description is accompanied by three examples. This Appendix provides instructions in the way to build a proper Tracking Table:

- Example 1, where all sequences are submitted to all RMS and CMSs in a single wave
- Example 2, where one sequence is submitted to a single NCA
- Example 3, where the usage of multiple waves is demonstrated

Instructions for Simple Tracking Table

For a simple Tracking Table, the following steps should be followed:

- Fill the title of the Tracking Table, e.g. "MRP Tracking Table"
- Identify the Reference Member State (in the example below, Germany)
- For the first wave, list the Concerned Member States (in the example below, Austria, Spain, France, Sweden and Slovak Republic)
- List the sequences starting with the most recent one, and for each sequence
 - Identify the number, using the 4-digit reference (e.g. 0003)
 - List the submissions for that sequence, and for each submission
 - Identify the receiving agency
 - Set the submission period (month and year)

```
<!DOCTYPE tracking-table SYSTEM "../../../util/dtd/tracking-table.dtd">
<?xml-stylesheet type="text/xsl" href="../../../util/style/tracking-table.xsl"?>
<tracking-table title="MRP Tracking Table">
  <rms code="DE"/>
  <wave number="1">
    <cms code="AT"/>
    <cms code="ES"/>
    <cms code="FR"/>
    <cms code="SE"/>
    <cms code="SK"/>
  </wave>
  <sequence number="0003">
    <description>Final agreed En product information</description>
    <submission code="DE" month="Jun" year="2008"/>
    <submission code="AT" month="Jun" year="2008"/>
    <submission code="ES" month="Jun" year="2008"/>
    <submission code="FR" month="Jun" year="2008"/>
    <submission code="SE" month="Jun" year="2008"/>
    <submission code="SK" month="Jun" year="2008"/>
  </sequence>
  <sequence number="0002">
    <description>Day 106 Responses to questions</description>
    <submission code="DE" month="May" year="2008"/>
    <submission code="AT" month="May" year="2008"/>
    <submission code="ES" month="May" year="2008"/>
    <submission code="FR" month="May" year="2008"/>
    <submission code="SE" month="May" year="2008"/>
    <submission code="SK" month="May" year="2008"/>
  </sequence>
  <sequence number="0001">
    <description>Validation update</description>
    <submission code="DE" month="Dec" year="2007"/>
    <submission code="AT" month="Dec" year="2007"/>
    <submission code="ES" month="Dec" year="2007"/>
    <submission code="FR" month="Dec" year="2007"/>
    <submission code="SE" month="Dec" year="2007"/>
    <submission code="SK" month="Dec" year="2007"/>
  </sequence>
  <sequence number="0000">
    <description>Initial MAA</description>
    <submission code="DE" month="Dec" year="2007"/>
  </sequence>
</tracking-table>
```

```

        <submission code="AT" month="Dec" year="2007"/>
        <submission code="ES" month="Dec" year="2007"/>
        <submission code="FR" month="Dec" year="2007"/>
        <submission code="SE" month="Dec" year="2007"/>
        <submission code="SK" month="Dec" year="2007"/>
    </sequence>
</tracking-table>

```

The example above displays through the Tracking Table style-sheet as follows:

MRP Tracking Table							
DTD Version 0.1							
Sequence	Submission Description	RMS	CMSs - Wave 1				
		DE	AT	ES	FR	SE	SK
0003	Final agreed En product information	Jun 2008	Jun 2008	Jun 2008	Jun 2008	Jun 2008	Jun 2008
0002	Day 106 Responses to questions	May 2008	May 2008	May 2008	May 2008	May 2008	May 2008
0001	Validation update	Dec 2007	Dec 2007	Dec 2007	Dec 2007	Dec 2007	Dec 2007
0000	Initial MAA	Dec 2007	Dec 2007	Dec 2007	Dec 2007	Dec 2007	Dec 2007

Instructions for Submission to Single NCA

In the case a sequence is submitted to a single NCA, a single submission needs to be provided with identification of the receiving agency, and the submission period. There is no need to provide any information about the NCAs that has not received the submission. The example below records a sequence submitted to the Spanish agency only.

```

<!DOCTYPE tracking-table SYSTEM "../util/dtd/tracking-table.dtd">
<?xml-stylesheet type="text/xsl" href="../util/style/tracking-table.xsl"?>
<tracking-table title="MRP Tracking Table">
    <rms code="DE"/>
    <wave number="1">
        <cms code="AT"/>
        <cms code="ES"/>
        <cms code="FR"/>
        <cms code="SE"/>
        <cms code="SK"/>
    </wave>
    <sequence number="0003">
        ...
    </sequence>
    <sequence number="0002">
        ...
    </sequence>
    <sequence number="0001">
        <description>Validation update (ES)</description>
        <submission code="ES" month="Dec" year="2007"/>
    </sequence>
    <sequence number="0000">
        ...
    </sequence>
</tracking-table>

```

The example above displays through the Tracking Table style-sheet as follows:

MRP Tracking Table							
DTD Version 0.1							
Sequence	Submission Description	RMS	CMSs - Wave 1				
		DE	AT	ES	FR	SE	SK
0003	Final agreed En product information	Jun 2008	Jun 2008	Jun 2008	Jun 2008	Jun 2008	Jun 2008
0002	Day 106 Responses to questions	May 2008	May 2008	May 2008	May 2008	May 2008	May 2008
0001	Validation update (ES)			Dec 2007			
0000	Initial MAA	Dec 2007	Dec 2007	Dec 2007	Dec 2007	Dec 2007	Dec 2007

Instructions for Multiple Waves

In the case of multiple waves, the element "**wave**" needs to be repeated so as to identify the Concerned Member States for each wave. Each wave needs to be identified by a number, starting with 1. The submissions are characterised with the receiving agency and submission period. There is no need to split the submissions per wave at that level, as waves have been determined at the top of the Tracking Table. . The example below identifies a second wave.

```
<!DOCTYPE tracking-table SYSTEM "../../../util/dtd/tracking-table.dtd">
<?xml-stylesheet type="text/xsl" href="../../../util/style/tracking-table.xsl"?>
<tracking-table title="MRP Tracking Table">
  <rms code="DE"/>
  <wave number="1">
    <cms code="AT"/>
    <cms code="ES"/>
    <cms code="FR"/>
    <cms code="SE"/>
    <cms code="SK"/>
  </wave>
  <wave number="2">
    <cms code="FI"/>
    <cms code="LV"/>
    <cms code="NL"/>
  </wave>
  <sequence number="0032">
    <description>Responses to Questions</description>
    <submission code="DE" month="Apr" year="2010"/>
    <submission code="AT" month="Apr" year="2010"/>
    <submission code="ES" month="Apr" year="2010"/>
    <submission code="FR" month="Apr" year="2010"/>
    <submission code="SE" month="Apr" year="2010"/>
    <submission code="SK" month="Apr" year="2010"/>
    <submission code="FI" month="Apr" year="2010"/>
    <submission code="LV" month="Apr" year="2010"/>
    <submission code="NL" month="Apr" year="2010"/>
  </sequence>
  <sequence number="0031">
    ...
  </sequence>
  <sequence number="0030">
    <description>Validation update (LV)</description>
    <submission code="LV" month="Feb" year="2010"/>
  </sequence>
  <sequence number="0029">
    <description>Country specific information (NL)</description>
    <submission code="NL" month="Jan" year="2010"/>
  </sequence>
  ...
  <sequence number="0026">
    <description>RUP initiation sequence</description>
    <submission code="DE" month="Dec" year="2009"/>
  </sequence>
</tracking-table>
```

```

        <submission code="FI" month="Jan" year="2010"/>
        <submission code="LV" month="Jan" year="2010"/>
        <submission code="NL" month="Jan" year="2010"/>
    </sequence>
    ...
</tracking-table>

```

The example above displays through the Tracking Table style-sheet as follows:

MRP Tracking Table										
DTD Version 0.1										
Sequence	Submission Description	RMS	CMSs - Wave 1					CMSs - Wave 2		
		DE	AT	ES	FR	SE	SK	FI	LV	NL
0032	Responses to Questions	Apr 2010	Apr 2010	Apr 2010	Apr 2010	Apr 2010	Apr 2010	Apr 2010	Apr 2010	Apr 2010
0031	Manufacturing change variation	Apr 2010	Apr 2010	Apr 2010	Apr 2010	Apr 2010	Apr 2010	Apr 2010	Apr 2010	Apr 2010
0030	Validation update (LV)								Feb 2010	
0029	Country specific information (NL)									Jan 2010
0028	Country specific information (LV)								Jan 2010	
0027	Country specific information (FI)							Jan 2010		
0026	RUP initiation sequence	Dec 2009						Jan 2010	Jan 2010	Jan 2010
0025	Responses to Questions - address change (FR)				Aug 2009					
0024	Variation - address change (FR)				Jul 2009					
0023	Responses to Questions	Jun 2009	Jun 2009	Jun 2009	Jun 2009	Jun 2009	Jun 2009	Jan 2010	Jan 2010	Jan 2010
0022	Manufacturing change variation	Mar 2009	Mar 2009	Mar 2009	Mar 2009	Mar 2009	Mar 2009	Jan 2010	Jan 2010	Jan 2010
0021	Amended product information (FR)				Nov 2008					
0020	Amended product information (DE)	Nov 2008								
0019	Translations of agreed EN product information (SK)						Nov 2008			

Appendix 4: DTD for Tracking Table

tracking-table.dtd

```
<!--
PUBLIC "-//EU//DTD MRP/DCP Tracking Table 0.1"
In the eCTD File Organisation: "m1/eu/util/dtd/tracking-table.dtd"

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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
-->

<!ELEMENT tracking-table (rms, wave+, sequence+)>
    <!ATTLIST tracking-table
        dtd-version    CDATA    #FIXED        "0.1"
        title           CDATA    #REQUIRED
    >

<!ELEMENT rms EMPTY>
    <!ATTLIST rms code CDATA #REQUIRED>

<!ELEMENT wave (cms+)>
    <!ATTLIST wave number CDATA #REQUIRED>

<!ELEMENT cms EMPTY>
    <!ATTLIST cms code CDATA #REQUIRED>

<!ELEMENT sequence (description, submission+)>
    <!ATTLIST sequence number CDATA #REQUIRED>

<!ELEMENT description (#PCDATA)>

<!ELEMENT submission EMPTY>
    <!ATTLIST submission
        code           CDATA    #REQUIRED
        month          CDATA    #REQUIRED
        year           CDATA    #REQUIRED
    >
```