

## Notice to Applicants Chapter 7 – General information

### Update AT

#### 6. NATIONAL PROCEDURE AFTER A COMMISSION DECISION ON A REFERRAL

<b>AUSTRIA</b>	<b>There is:</b>	<b>There should be:</b>
	Amended SPC, PL and labelling (highlighted version in hardcopy accompanying the application form and clean version sent to <a href="mailto:mrp-spc@ages.at">mrp-spc@ages.at</a> – format: word document)	Amended SmPC, PL and labelling (highlighted version in hardcopy accompanying the application form and clean version sent to <a href="mailto:mrp-spc@ages.at">mrp-spc@ages.at</a> – format: word document; subject should contain MRP number and ATC code!)

#### 7. LIST OF OFFICIAL JOURNALS

<b>AUSTRIA</b>	<b>There is:</b>	<b>There should be:</b>
	<a href="http://www.ages.at">www.ages.at</a>	<a href="http://www.basg.at">www.basg.at</a>

#### 8. ADDRESSES FOR DELIVERY OF THE DOSSIER AND SUBSEQUENT CORRESPONDENCE

**There should be:**

Federal Office for Safety in Health Care  
(Bundesamt für Sicherheit im Gesundheitswesen)  
Institut: LCM  
Schnirchgasse 9  
A-1030 Wien  
[www.basg.at](http://www.basg.at)

**New applications (AT = CMS/RMS/pure national):**

Preferably electronic submission [eCTD/Non eCTD electronical Submission (NeeS)].

	eCTD/NeeS	Paper only submission		
		Module 1	Module 2	Module 3-5
<b>AT=CMS</b>	e-submission & Cover Letter/Application Form (paper)	1	1	1
<b>AT=RMS/pure national</b>	e-submission & Cover Letter/Application Form (paper)	2	1	1

AT=CMS/RMS: During national phase MAH should send SmPC, PL and Labelling for Austria to [mrp-spc@ages.at](mailto:mrp-spc@ages.at) within 5 days. Subject should contain MRP Number and ATC Code.

**Variations and Renewals (AT = CMS/RMS/pure national):**

Preferably electronic submission [eCTD/Non eCTD electronic Submission (NeeS)].

	eCTD/NeeS	Paper only submission	
		Application Form	Documentation
<b>AT=CMS/RMS/pure national</b>	e-submission & Cover Letter/Application Form (paper)	2	1

AT=CMS/RMS (Type II and Renewal, grouped variation and worksharing): During national phase MAH should send SmPC, PL and Labelling for Austria to [mrp-spc@ages.at](mailto:mrp-spc@ages.at) within 5 days.

AT = pure national procedures, AT=CMS/RMS (Type IB): If variation causes changes in SPC, PIL or labelling MAH should send updated doc-files to [spc@ages.at](mailto:spc@ages.at) and [mrp-spc@ages.at](mailto:mrp-spc@ages.at). Subject should contain MRP number and ATC code.

**Written Responses (AT = CMS/RMS/pure national):**

Preferably electronic submission [eCTD/Non eCTD electronic Submission (NeeS)].

	eCTD/NeeS	Paper only submission	
		Cover Letter	Documentation
<b>AT=CMS/RMS/pure national</b>	Cover Letter	1	1

AT = CMS/RMS: Only in urgent cases send an e-mail (up to 2MB) to [responses@ages.at](mailto:responses@ages.at).

**Labelling CDs**

AT = CMS/RMS:

CDs always have to be labelled with the complete MRP/DCP-number, ATC-Code and name of the product.

AT = pure national procedures:

CDs should be labelled with the MA-number (when assigned), 6-digit product number

allocated by AGES PharmMed (when assigned) and name of the product. Further recommendations on electronic submission can be found on following website: [www.basg.at/arzneimittel/zulassung/elektronische-einreichung](http://www.basg.at/arzneimittel/zulassung/elektronische-einreichung).

## **9. ADDRESSES FOR RECEIPT OF FEES AND TERMS FOR PAYMENT**

**There should be:**

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#### **Published national rules**

Verordnung des Bundesamtes für Sicherheit im Gesundheitswesen über den Gebührentarif gemäß GESG

**Available** in Internet [www.basg.at/en/about-us/fees](http://www.basg.at/en/about-us/fees)

#### **Fees payable to:**

Bank Austria-Creditanstalt  
Konto Nummer: 50670 871 619  
BLZ: 12000  
IBAN: AT971200050670871619  
BIC/SWIFT: BKAUATWW

#### **Method of payment:**

An invoice will be sent upon receipt of the application.

**No payment of assessment fee should be made in advance.**

Please make sure that the whole amount of the invoice will be credited to our account net of any charges or transactions fees.

Cheques are not accepted.

## **10. 'BLUE-BOX' REQUIREMENTS**

**There should be:**

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#### *Additional labelling requirements*

#### **Price**

The price is not required and not wanted on the label.

#### **Reimbursement**

The reimbursement conditions are not required and not wanted on the label.

#### **Legal status**

The following are the specific requirements for the expression of the legal status in the boxed area:

- “rezept- und apothekenpflichtig”/”verschreibungspflichtig” = available only on prescription and only in pharmacies
- “apothekenpflichtig” = available only in pharmacies;
- If the supply is not restricted to pharmacies, this has to be declared appropriately.
- Radiopharmaceuticals: “Rezeptpflichtig. Abgabe nur an Inhaber einer Bewilligung für den Umgang mit radioaktiven Stoffen gemäß Strahlenschutzgesetz“ = available only on prescription for authorised personnel.

### Legal requirements for vaccines and blood products

- Vaccines and blood derivatives: „Charge staatlich freigegeben“ = Batch released by OMCL
- "Charge verkehrsfähig" for vaccines and blood derivatives that usually require official batch release but have been granted an exemption from this requirement.
- Inner label: The information given on the self adhesive label (see also "Additional requirements for Package Leaflet") is stated at the end of the inner labelling text in brackets: [Name of the product  
Ch.B.  
Verw. bis]

### Identification and authenticity


The EAN code is accepted on the label, but not required.

### Symbols or pictograms

A pictogram for medicines which cause tiredness:



“Achtung: Dieses Arzneimittel kann die Reaktionsfähigkeit und Verkehrstüchtigkeit beeinträchtigen.”

“Der Grüne Punkt”  or other recycling symbols are accepted on the label, but not required.

Radiopharmaceuticals  if applicable

### Additional requirements for Package Leaflet:

- MA-No.: “Z.Nr. ....” or other abbreviations
- For safety reasons additional information can be stated (eg. products containing substances with a high risk potential in case of an overdose, e.g. sedatives, opiates)
- Anti doping Note: if applicable only in the PL

"Die Anwendung des Arzneimittels [name of the product] kann bei Dopingkontrollen zu positiven Ergebnissen führen".

In case of misuse of the medicinal product for doping purposes the corresponding risks should be stated.

Symbols or pictograms:

A pictogram for medicines which cause tiredness/vertigo:



“Achtung: Dieses Arzneimittel kann die Reaktionsfähigkeit und Verkehrstüchtigkeit beeinträchtigen.”

**Legal requirements for vaccines and blood products**

For Blood derivatives or vaccines: in order to allow traceability from patient back to biological starting material (e.g. blood donation), the Austrian legislation requires attachment of a self-adhesive label – stating the name, expiry date and batch number – to each primary package of blood derivatives or vaccines for human use.

“Jede Verabreichung soll mittels beigefügter Selbstklebeetikette in der Krankengeschichte oder Impfpass dokumentiert werden.“ (“Each application should be documented in patient history or vaccination document using the self-adhesive label attached.”)