Electronic Application Form Specification
Draft version 0.10

12 July 2002

Status

This section describes the status of this document at the time of its publication. Other documents may supersede this document.

This is an internal draft for review by the *Telematic Implementation Group for electronic submission and ICH Implementation* (TIGes) and other concerned parties. It is a stand-alone document to ease its review. This document is still in its early stage, and may be updated or replaced by other documents at any time. It is inappropriate to use this working draft as reference material or to cite them as other than "work in progress". The latest version of this specification can be found on:
http://esubmission.eudra.org/ectd/application

Please send review comments to the chairman of the TIGes, Miguel Bley at the following E-mail address : miguel.bley@afssaps.sante.fr

Introduction

The *Electronic Common Technical Document* [eCTD] developed in the framework of the *International Conference on Harmonization* [ICH] specifies that Module 1 should contain region specific information. The content of Module 1 is described in the *EU Module 1 Specification* [MOD1]. Volumes 2B and 2C of the *Notice to Applicants* [NtA] describe administrative information for marketing authorisation of medicinal products by *European Competent Authorities* [ECA] that will be included in the Rules governing Medicinal Products in the European Community.

This document describes the administrative information contained in the Application Form document [FORM] in Volume 2B of the *Notice to Applicants* in XML format [XML] for first submission of an application for marketing authorisation of a medicinal product in the EU Module 1 of the eCTD.

This document should be read together with:
- Application Form in the Notice to Applicants [FORM]
- ICH eCTD Specification [eCTDSPEC]
- EU Module 1 Specification [MOD1]

Origin and Purpose

The decision of developing an electronic Application Form in XML format was taken by the TIGes. This group was set up by the *Telematic Steering Committee* (TSC) chaired by the European Commission in June 2000 as part of a new structure for the management of European IT projects in the pharmaceutical regulatory area and endorsed by the Pharmaceutical Committee. All concerned European Competent Authorities are represented and the group is chaired by France. It works in close collaboration with the European delegation of the ICH M2 Expert Working Group [M2] responsible for the ICH eCTD Specification.

The TIGes is responsible for the maintenance and evolution of this regional standard.

The purpose is to:

1. Provide a regional standard for the exchange of structured administrative information contained in Application Form in the Notice to Applicants for new applications of medicinal products between Industry and European Competent Authorities to be part of the EU Module 1 of the eCTD.

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

Concerned Parties

1) Pharmaceutical Industry [PHARMA] as defined in the Procedures for marketing authorisation in the Notice to Applicants.

2) European Competent Authorities :

    a. European Agency for the Evaluation of Medicinal Products [EMEA].

    b. EU Member States. Candidate countries for the accession to the European Union will also be concerned by this standard once they become Member States.

    c. Countries that are part of the European Economic Area [EEA] namely Norway, Iceland and Liechtenstein.

Rationale

A conceptual data model largely based on the European Pre-Standard ENV 12610 by the CEN-TC 251[CEN] was developed to describe the Application Form document. Definitions and concepts follow this Pre-Standard and the Notice to Applicants. A physical data model for the set up of a "buffer" database that allows for the creation and/or storage of the data contained in the XML instance of the submission was also developed. The application.dtd presented in this document was created from an object oriented representation of the physical data model.

Coding of some elements are based on existing dictionaries which are maintained by identified institutions (ISO, OMS, European Pharmacopoeia).

Documentation

This section is *informative* and it is not part of the specification.
The concept data model, the physical data model and the object oriented representation of the physical model are available with the specification as additional documentation [DOC]. The scripts for the creation of different databases of widespread use are also available in order to facilitate the automated implementation of the standard.

References

[eCTD]
http://www.ifpma.org/ichctd.html

[ICH]
http://www.ifpma.org/ich1.html

[MOD1]
http://esubmission.eudra.org/ectd

[NtA]
http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm

[ECA]
Notice to Applicants, Volume 2A, Chapter 1
http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm

[XML]
Extensible Markup Language (XML) 1.0 (Second Edition)
http://www.w3.org/TR/REC-xml.html

[FORM]
Notice to Applicants, Volume 2B
http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm

[eCTDSPEC]
http://www.ifpma.org/ichectd.html

[M2]
http://www.fda.gov/cder/m2/default.htm

[PHARMA]
Notice to Applicants, Volume 2A, Chapter 1
http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm

[EMEA]
http://www.emea.eu.int/

[EEA]
http://secretariat.efta.int/euroeco/

[DOC]
http://esubmission.eudra.org/ectd/application

[CEN]
www.centc251.org/Ginfo/scope_Tc251.htm

Annex A : Application Form DTD

```
<!--
PUBLIC "-//EU//DTD eCTD EU Application 0.73//EN"
SYSTEM "http://esubmission.eudra.org/ectd/eu-application.dtd"
In the eCTD File Organisation: "util/dtd/eu-application.dtd"

11 July 2002

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Notes:
This version of the dtd is based on the
Notice to Applicants, Volume 2B, Application Form, 18 June 2002

Future directions :
- This dtd will read the "envelope" as the "eu-index.dtd".
- xmlns should be used.

Meaning/value of the sufixes and prefixes:
 ?      : the element must appear 0 or 1 times
 *      : the element must appear 0 or more times
 +      : the element must appear 1 or more times

.................................................................
tradename or invented name, according to context

-->

<!-- Root element ==================================================== -->
<!ELEMENT applicationform (
  declaration
, application
, maaparticulars
, scientificadvice
, paediatric-program
, othermaa
)>

<!ATTLIST applicationform dtd-version CDATA #FIXED "0.73" >

<!-- administrative data ........................................... -->
<!ELEMENT declaration (
  medicinal-product-name
, strength-quantity
, strength-unit
, form-name
, substance-name
, applicant
, person-authorised
, signature
, name-person
, function-person
, place-signature
, date-signature
, ann-letter-communication
, ann-proof-payment
```

```
  )>

<!-- 1. TYPE OF APPLICATION ........................................ -->
<!-- 1.1. This application concerns -->
<!ELEMENT application (
  type-procedure
, orphan-drug-flag
, fundamental-change?
, directive
)>

<!ELEMENT type-procedure (
  mutualrecognitionprocedure
| centralisedprocedure
| nationalprocedure
)>

<!-- 1.1.1. Centralised Procedure ................................... -->
<!-- 5.3. attach copy of correspondence with European commission -->
<!ELEMENT centralisedprocedure (
  (cpr-partA | cpr-partB)
, rapporteur
, co-rapporteur
, contact-product-defects
, attach-copy-correspondence
)>

<!ELEMENT contact-product-defects (contact) >


<!-- 1.1.2. Mutual recognition Procedure ........................... -->
<!ELEMENT mutualrecognitionprocedure (
  reference-member-state
, date-first-authorisation
, mrp-marketing-authorisation-number
, ann-marketing-authorisation
, mrp-procedure-number
, mrp-userank
, country+
)>

<!-- 1.1.3. National Procedure ..................................... -->
<!ELEMENT nationalprocedure (
  national-application-number?
, country*
, othermaanational
)>

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

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

<!-- 1.2. Orphan Designation ======================================= -->
<!ELEMENT orphan-drug-flag (
  orphan-status
, orphan-condition-flag
)>

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

<!ELEMENT pending (orphan-designation-procnumber) >

<!ELEMENT granted (
  orphan-date-status
```

```
, orphan-benefit-flag
, orphan-number-register
, ann-orphan-decision
)>

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

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

<!ELEMENT orphan-condition-flag (
  orphan-eu-designation-number?
, orphan-similar-flag?
)>

<!-- ============================================================ -->
<!-- 1.3. Fundamental change to existing marketing authorisation -->

<!ELEMENT fundamental-change (
  fundamental-change-flag
, marketing-holder-name
, fullname-existing-product
, manumber-application-made

)>

<!ELEMENT fundamental-change-flag (
  lineextension
| notlineextension
)>

<!-- 1.3.1. Line Extension ........................................ -->
<!ELEMENT lineextension (
  line-extension-change-newform
, line-extension-change-substance
, line-extension-add-route
, line-extension-change-pharmacokinetics
, line-extension-diff-therapeutic
, line-extension-qual-notnew-substance
, line-extension-qual-other
)>


<!-- 1.3.2. Not Line Extension .................................... -->
<!ELEMENT notlineextension (
  nline-extension-add-substance
, nline-extension-del-substance
, nline-extension-qual-new-substance
, nline-extension-qual-other
)>

<!-- ............................................................. -->
<!-- 1.4. THIS APPLICATION IS SUBMITTED IN ACCORDANCE WITH -->
<!ELEMENT directive (
  complete
| bibliographical
| abridged
| fixedcombination
)>

<!ELEMENT abridged ( informedconsentapplication | firstlastparagraph ) >

<!ELEMENT informedconsentapplication (
  product-fullname
, holder
, rmp-ems+
, letter-consent-flag
)>


<!ELEMENT firstlastparagraph ( firstparagraph | lastparagraph )>


<!ELEMENT rmp-ems (marketing-authorisation-number, country-name)>
```

```
<!ELEMENT firstparagraph (
  genericapplication
, gaoriginalproduct
, gareferencemedicinalproduct
, rmp-ems+
, gabip
)>

<!ELEMENT genericapplication (
  product-fullname
, holder
)>

<!ELEMENT gaoriginalproduct (
  date-first-authorisation
, country-name
)>

<!ELEMENT gareferencemedicinalproduct (
  product-fullname
, holder
)>

<!ELEMENT gabip (
  product-fullname
, holder
, country-name
)>

<!ELEMENT lastparagraph (
  lporiginalproduct
, lprmp
, lprmp-ems+
, lpbioequivalence
, lpdifferentoriginalproduct
)>

<!ELEMENT lporiginalproduct (
  product-fullname
, holder
, date-first-authorisation
, country-name?
)>

<!ELEMENT lprmp (
  product-fullname
, holder
)>

<!ELEMENT lprmp-ems (
  marketing-authorisation-number
, country-name
)>

<!ELEMENT lpbioequivalence (
  product-fullname
, holder
, country-name?
)>

<!ELEMENT lpdifferentoriginalproduct (
  different-pharmaceutical-form
, different-strength
, different-route
, different-pharmacokinetic
, different-therapeutic-use
, other-difference
)>

<!-- ............................................................ -->
<!-- 2. MARKETING AUTHORISATION APPLICATION PARTICULARS -->
<!ELEMENT maaparticulars (
  medicinalproduct
, substance+
```

```
, atcclass+
, formfull
, substance-strength-pharma+
, route+
, typeofpack+
, legal-status
, dossier
, manufacturerbatchrelease+
, pharmaproductmanufacturer+
, manufactureractivesubstance+
, contractcompany+
, composition+
, substancepharmaproduct+
, gmo
)>

<!-- 2.1.1. Proposed .............................................. -->
<!ELEMENT medicinalproduct (
  medicinal-product-name
, national-name-flag
)>

<!-- 2.1.3. Pharmacotherapeutic group .............................. -->
<!ELEMENT atcclass (
  atc-code
, atc-version
, atc-name
, atc-pending
)>

<!-- 2,2,1, Strength and Pharmaceutical form ....................... -->
<!ELEMENT formfull (
 form-name
)>

<!ELEMENT substance-strength-pharma (
  substance-name
, strength-quantity
, strength-unit
)>

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

<!-- .............................................................. -->
<!-- 2.2.3.  Container, closure and administration device(s) -->
<!ELEMENT typeofpack (
  container
, closure
, administrationdevice*
, presentation+
)>

<!ELEMENT administrationdevice (
 device-name
)>


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

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

<!-- 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 notprescription (
  supply-flag
, promotion-healthcare-flag
)>

<!-- 2.4. Marketing ... -->
<!ELEMENT dossier (
  marketingholder
, personcomduringprocedure
, personcomafterauthorisation
, personforpharmacovigilance
, scientificservicemah
)>

<!ELEMENT marketingholder (
  contact
, ann-proof-establishment
)>

<!ELEMENT personcomduringprocedure (
  contact
, attach-letter-authorisation
)>

<!ELEMENT personcomafterauthorisation (
  contact
, attach-letter-authorisation
)>

<!ELEMENT personforpharmacovigilance (
  contact
, ann-cv-person
)>

<!ELEMENT scientificservicemah (
  contact
)>

<!-- 2.5. MANUFACTURERS -->
<!ELEMENT manufacturerbatchrelease (
  contact
, ann-copy-authorisation
, ann-justification
, manufacturing-aut-number
, contact-blood-vaccines
, contact-batchtesting-site+
)>

<!ELEMENT contact-blood-vaccines    (contact) >
<!ELEMENT contact-batchtesting-site (contact) >

<!-- ........................................................... -->
<!-- 2.5.2.  Manufacturer of the medicinal product and site of manufacture -->
<!ELEMENT pharmaproductmanufacturer (
  contact
, description-functions
, attach-flowchart
, (manufacturerineea | manufacturerouteea)
)>

<!ELEMENT manufacturerineea (
  manufacturing-aut-number-eea
, attach-manu-authorisation
, name-qualified-person?
)>

<!ELEMENT manufacturerouteea (
  attach-equimanuautho
, inspection-flag
```

```
, ann-inspection-site
, gmp-compliant-flag
)>

<!-- 2.5.3.  Manufacturer of the active substance -->
<!ELEMENT manufactureractivesubstance (
  substance-name
, contact
, (pheur-certificate | use-dmf)
)>


<!ELEMENT pheur-certificate (
  substance-name
, contact-name
, reference-number-certificate
, date-lastupdate-pheur
, ann-certificate-suitability
)>

<!ELEMENT use-dmf (
  substance-name
, contact-name
, reference-number-competent-aut
, date-submission
, date-lastupdate-dmf
, ann-letter-access
, ann-written-confirmation
, outcome
)>

<!-- 2.5.4. Contract ... -->
<!ELEMENT contractcompany (
  contact
, duty-performed
)>

<!-- 2.6.  Qualitative and Quantitative composition -->
<!ELEMENT composition (
  substance
, substance-indicator
, strength-quantity
, strength-unit
, reference-monograph-standard
, overage
, quantity-note
)>

<!-- 2.6.2. List ... -->
<!ELEMENT substancepharmaproduct (
  substance-name
, function-material
, material-origin-flag
, special-origin
, pheur-tse-flag
)>

<!-- 2.6.3. Does ... -->
<!ELEMENT gmo (
  gmo-flag
, council-flag
, ann-written-consent-gmo
)>

<!-- 3. SCIENTIFIC ADVICE ======================================== -->
<!ELEMENT scientificadvice (
  cpmp-scientific-advice?
, scientific-recommendation-flag+
)>

<!ELEMENT cpmp-scientific-advice (
  scientific-advice-date
, scientific-advice-reference
, ann-scientific-advice-cpmp
)>
```

```
<!ELEMENT scientific-recommendation-flag (
  country-name
, date-recommendation
)>

<!-- 4. PAEDIATRIC DEVELOPMENT PROGRAMME ============================ -->
<!ELEMENT paediatric-program (paediatric-relevant-section) >

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

<!ELEMENT othermaa (
  typeoftreatment
, dossiermultipleapplication*
)>

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

<!-- 5.2.  Marketing ... -->
<!-- and 5.4.  Marketing ... -->


<!ELEMENT typeoftreatment (
  ( product-authorised-in | product-authorised-outside )
, product-pending
, product-refused
, product-withdrawnbefore
, product-withdrawnafter
, product-suspendedauthority
)>


<!-- 5.3. -->
<!ELEMENT dossiermultipleapplication (
  name-other-product
, date-multiple-application
, applicant-for-multiple-application
)>


<!ELEMENT product-authorised-in (
  country-name
, date-notif
, tradename
, authorisation-number
, ann-marketing-authorisation
)>

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

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

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

<!ELEMENT product-withdrawnbefore (
  country-name
, date-notif
, tradename
, reason
)>

<!ELEMENT product-withdrawnafter (
  country-name
, date-notif
, authorisation-number
, reason
```

```
, tradename
)>

<!ELEMENT product-suspendedauthority (
  country-name
, date-notif
, reason
, tradename
)>

<!ELEMENT country (
 country-name
)>


<!-- =============================================================== -->
<!-- common -->

<!ELEMENT contact (
  contact-name
, company-name?
, address01
, address02?
, zipcode?
, town?
, country-name
, phone
, fax
, email
)>


<!-- Common element ================================================= -->
<!ELEMENT substance (
  substance-name
, salt-hydrate-form?
)>

<!-- Terminal elements ============================================= -->
<!ELEMENT special-origin            (#PCDATA) >
<!ATTLIST special-origin            special-origin          (
  animaltse
| otheranimal
| human
) #REQUIRED >

<!ELEMENT complete                  (#PCDATA)
>
<!ATTLIST complete                  complete                  ( newsubstance |
knownsubstance  ) #IMPLIED  >

<!ELEMENT supply-flag               (#PCDATA)
>
<!ATTLIST supply-flag               supply-flag               ( pharmacies | notpharmacies
) #REQUIRED >

<!ELEMENT outcome                   (#PCDATA)
>
<!ATTLIST outcome                   outcome                   ( positive | negative
) #REQUIRED >

<!ELEMENT mrp-userank               (#PCDATA)
>
<!ATTLIST mrp-userank               mrp-userank               ( first | repeated
) #REQUIRED >

<!ELEMENT promotion-healthcare-flag (#PCDATA)
>
<!ATTLIST promotion-healthcare-flag promotion-healthcare-flag ( healthcareonly |
generalpublic ) #REQUIRED >

<!ELEMENT substance-indicator       (#PCDATA)
>
<!ATTLIST substance-indicator       substance-indicator       ( AS | EX
) #REQUIRED >
```

```
<!ELEMENT function-material           (#PCDATA)
>
<!ATTLIST function-material         function-material        ( AS │ EX │ R
) #REQUIRED >

<!-- .................................................................. -->
<!ENTITY % extension-att "
( replacementsalt
│ replacementisomer
│ replacementbiological
│ otherchange
) #REQUIRED
">

<!ELEMENT line-extension-qual-notnew-substance (#PCDATA)
>
<!ATTLIST line-extension-qual-notnew-substance line-extension-qual-notnew-substance
%extension-att; >

<!ELEMENT nline-extension-qual-new-substance   (#PCDATA)
>
<!ATTLIST nline-extension-qual-new-substance   nline-extension-qual-new-substance
%extension-att; >

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

<!ELEMENT inspection-flag                       EMPTY         >
<!ATTLIST inspection-flag                       flag   %yesno; >

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

<!ELEMENT material-origin-flag                  EMPTY         >
<!ATTLIST material-origin-flag                  flag   %yesno; >

<!ELEMENT gmo-flag                              EMPTY         >
<!ATTLIST gmo-flag                              flag   %yesno; >

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

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

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

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

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

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


<!-- .................................................................. -->
<!-- YYYY-MM-DD -->
<!ELEMENT date-lastupdate-pheur                     (#PCDATA) >
<!ELEMENT date-submission                           (#PCDATA) >
<!ELEMENT date-lastupdate-dmf                       (#PCDATA) >
<!ELEMENT date-notif                                (#PCDATA) >
<!ELEMENT scientific-advice-date                    (#PCDATA) >
<!ELEMENT date-recommendation                       (#PCDATA) >
<!ELEMENT date-multiple-application                 (#PCDATA) >
<!ELEMENT orphan-date-status                        (#PCDATA) >
<!ELEMENT date-signature                            (#PCDATA) >
<!ELEMENT date-first-authorisation                  (#PCDATA) >

<!-- 6. ANNEXED DOCUMENTS ......................................... -->
<!ELEMENT ann-proof-payment                         (#PCDATA) >
<!ELEMENT letter-consent-flag                       (#PCDATA) >
<!ELEMENT ann-proof-establishment                   (#PCDATA) >
<!ELEMENT ann-letter-communication                  (#PCDATA) >
```

```
<!ELEMENT attach-letter-authorisation                   (#PCDATA) >
<!ELEMENT ann-cv-person                                 (#PCDATA) >
<!ELEMENT ann-copy-authorisation                        (#PCDATA) >
<!ELEMENT attach-manu-authorisation                     (#PCDATA) >
<!ELEMENT attach-equimanuautho                          (#PCDATA) >
<!ELEMENT ann-justification                             (#PCDATA) >
<!ELEMENT attach-flowchart                              (#PCDATA) >
<!ELEMENT ann-inspection-site                           (#PCDATA) >
<!ELEMENT ann-certificate-suitability                   (#PCDATA) >
<!ELEMENT ann-letter-access                             (#PCDATA) >
<!ELEMENT ann-written-confirmation                      (#PCDATA) >
<!ELEMENT ann-written-consent-gmo                       (#PCDATA) >
<!ELEMENT ann-scientific-advice-cpmp                    (#PCDATA) >
<!ELEMENT ann-marketing-authorisation                   (#PCDATA) >
<!ELEMENT attach-copy-correspondence                    (#PCDATA) >
<!ELEMENT list-mockup-flag                              (#PCDATA) >
<!ELEMENT ann-orphan-decision                           (#PCDATA) >
<!ELEMENT national-name-flag                            (#PCDATA) >


<!-- ............................................................... -->
<!ELEMENT fixedcombination                              (#PCDATA) >
<!ELEMENT bibliographical                               (#PCDATA) >
<!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 copy-authorisation                            (#PCDATA) >
<!ELEMENT therapeutic-implication-note                  (#PCDATA) >
<!ELEMENT tradename                                     (#PCDATA) >
<!ELEMENT authorisation-number                          (#PCDATA) >
<!ELEMENT reason                                        (#PCDATA) >
<!ELEMENT country-name                                  (#PCDATA) >
<!ELEMENT reference-member-state                        (#PCDATA) >
<!ELEMENT product-fullname                              (#PCDATA) >
<!ELEMENT holder                                        (#PCDATA) >
<!ELEMENT marketing-authorisation-number                (#PCDATA) >
<!ELEMENT different-pharmaceutical-form                 (#PCDATA) >
<!ELEMENT different-strength                            (#PCDATA) >
<!ELEMENT different-route                               (#PCDATA) >
<!ELEMENT different-pharmacokinetic                     (#PCDATA) >
<!ELEMENT different-therapeutic-use                     (#PCDATA) >
<!ELEMENT other-difference                              (#PCDATA) >
<!ELEMENT salt-hydrate-form                             (#PCDATA) >
<!ELEMENT atc-code                                      (#PCDATA) >
<!ELEMENT atc-version                                   (#PCDATA) >
<!ELEMENT atc-name                                      (#PCDATA) >
<!ELEMENT atc-pending                                   (#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-for-multiple-application            (#PCDATA) >
<!ELEMENT medicinal-product-name                        (#PCDATA) >
<!ELEMENT strength-quantity                             (#PCDATA) >
<!ELEMENT strength-unit                                 (#PCDATA) >
<!ELEMENT form-name                                     (#PCDATA) >
<!ELEMENT substance-name                                (#PCDATA) >
<!ELEMENT person-authorised                             (#PCDATA) >
<!ELEMENT signature                                     (#PCDATA) >
<!ELEMENT name-person                                   (#PCDATA) >
<!ELEMENT function-person                               (#PCDATA) >
<!ELEMENT place-signature                               (#PCDATA) >
```

```
<!ELEMENT applicant                                (#PCDATA) >
<!ELEMENT cpr-partA                                (#PCDATA) >
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