EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PSUR Submissions in Single Assessment via EMA Gateway Webclient

Presenters of the Day, from EMA

Natasha Brown (ICT/Organiser)

Jaspreet Singh (ICT/Presenter)

Panel:

Kristiina Puusaari (EMA Business/S&E)

Brigitta Toth (EMA Business/PA-BUS)

Kelly Plueschke (EMA Business/PhV)

Antonios Yfantis (ICT Development)

Outline of Today's Webinar

- EU Single assessment of PSUR
- Legal basis and Requirements for PSUR submission / Introduction on EURD list
- What is the Gateway?
- Gateway Options
- Key features of Webclient & Gateway (AS2/AS3)
- Overview of Gateway Set-up
- Gateway Registration
- Using the Webclient
- Gateway Filenaming Conventions for PSURs in Single Assessment
- Technical validation Issues
- Key points during the Webclient Transmission
- How to Avoid Technical Problems
- Q & A Session

EU Single assessment of PSUR

- Objectives: harmonise and strengthen the safety and benefit-risk review of medicines across the EU; increase the shared use of resources between competent authorities; Assessment by the PRAC with CHMP involvement (for CAP and CAP/NAP) or CMDh (for NAP) in case of regulatory action
- Assessment leading to legally binding outcomes: maintenance, variation, suspension, revocation of the marketing authorisation
- Scope: Dir. Art. 107e to Art. 107g: "*All medicinal products containing the same active substance or the same combination of active substances authorised in more than one Member State for which a Union reference date and frequency of submission of PSURs has been established*"
  - ✓ Could include only centrally authorised products (CAP), mixed centrally authorised + nationally authorised products (CAP/NAP), only nationally authorised products (NAP)
- Note: procedure for substances contained in NAPs only is not implemented yet.
- Informal PSUR worksharing currently in place

What is the EURD list?

- EURD list: "List of European Union reference dates and frequency of submission of Periodic Safety Update Reports" - Legally binding since 1st April 2013 (1st publication on 1st Oct 2012)
- Legal basis: DIR Article 107c (paragraphs 4 and 7), and REG Article 26(g)
- Description: List of active substances and combinations of active substances for which PSUR shall be submitted as determined by the CHMP/CMDh after consultation of the PRAC.
- Objectives:
  - Support the single assessment procedure through the harmonisation of DLPs and frequency of submission of PSUR for products subject to different MA and authorised in several Member States
  - Periodicity defined on a risk-based approach: Optimisation of the management and assessment of PSUR for the same active substance
  - Increase of predictability in terms of PSUR submission
- Scope: substances/combinations subject to the **EU single assessment of PSUR** as defined in DIR Art 107e

Legal requirements for PSUR submission (1/4)

PSURs shall be submitted as follow:

- **According to the EU reference dates list**; or
- According to a condition of the MA; or
- According to DIR Art 107c (2) and REG Art 28(2): *Every 6 months during the first 2 years following the initial placing on the market, once a year for the following 2 years and at three-yearly intervals thereafter*
- PSURs also need to be submitted upon request from a Competent Authority DIR Art 107c (2)
- The EURD list **overrules** any conditions laid down in the MA of the products concerned and the standard submission schedule described above
- MAH to prepare a single PSUR for all its products containing the same active substance with information covering all authorised indications, routes of administration, dosage forms (unless specified differently in the EURD list)
- Generics (Dir art. 10(1)), well-established use medicinal products (Dir art. 10(a)), homeopathic medicinal products (Dir Art 14), traditional herbal medicinal products (Dir Art. 16a) exempted from submission of PSURs unless specified in EURD list/condition in MA/request by Competent Authority

Legal requirements for PSUR submission (2/4)

PSUR procedure type	Marketing Authorisation type of the products concerned	Addressees	Submission requirements	Reference document(s)	File name to be used when submitting to EMA
PSUR Assessment of substances contained in 1 or several centrally authorised product(s)	CAP	EMA	No change in the submission rules until further notice: eCTD format only via eSubmission Gateway or Web Client. Alternatively 1 DVD or CD-ROM with original signed cover letter is accepted.	Dossier requirements for Centrally Authorised Products (CAPs) http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500003980.pdf	File name for submissions via the Gateway or the Web Client: ESUBPXYZ_ESUBPROD_HC000999_Wonderpill_PSUR_0020.zip Submission Type (which is a mandatory field as per eCTD spec): PSUR
		CHMP, PRAC and CAT* Members + Alternates + * where relevant: CAT members, PRAC Independent Scientific experts and CHMP Co-Opted Members	*In case of submission to EMA via eSubmission Gateway or Web Client*: After the acknowledgement from EMA confirming the technical validation of the submission or the Validation Supplementary Information, send **one copy only** in eCTD format to the 'Dossier Delivery Address' of each National Competent Authority specifying the names of the relevant committee members (CHMP, PRAC, CAT - where relevant). *In case of CD/DVD submission to EMA*, send **one copy simultaneously** to the 'Dossier delivery address' of the Rapporteurs. After receipt of the EMA validation letter, send one copy only to all other members.	Dossier requirements for Centrally Authorised Products (CAPs) http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500003980.pdf	

Legal requirements for PSUR submission (3/4)

PSUR procedure type	Marketing Authorisation type of the products concerned	Addressees	Submission requirements	Reference document(s)	File name to be used when submitting to EMA
"**PSUSA**" PSUR single assessment of substances contained in centrally authorised product(s) **AND** nationally authorised products (including products authorised nationally in more than 1 Member States and through the mutual recognition and decentralised procedures)	CAP	EMA	eCTD format only via eSubmission Gateway or Web Client. Alternatively 1 DVD or CD-ROM with original signed cover letter is accepted.	EURD list cover note, section 5 http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/10/WC500133157.pdf	**See reference document in column E for more details on the file naming convention** File name for submissions via the Gateway or the Web Client: ESUBPXYZ_ESUBPROD_HCxxxxxx_Wonderpill_00000000_Substance_MAH_YYYYMM_psusa_00xx.zip Submission description field in the eCTD envelope for CAPs: substance, psusa/00000000/YYYYMM
	CAP	CHMP, PRAC Members + Alternates + where relevant: PRAC Independent Scientific experts and CHMP Co-Opted Members	*In case of submission to EMA via eSubmission Gateway or Web Client*: After the acknowledgement from EMA, confirming the technical validation of the submission or the Validation Supplementary Information, send **one copy only** in eCTD format to the 'Dossier Delivery Address' of each National Competent Authority specifying the names of the relevant committee members (CHMP, PRAC, CAT - where relevant). *In case of CD/DVD submission to EMA*, send **one copy simultaneously** to the 'Dossier delivery address' of the Rapporteurs. After receipt of the EMA validation letter, send one copy only to all other members.	Dossier requirements for Centrally Authorised Products (CAPs) http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500003980.pdf	

Legal requirements for PSUR submission (4/4)

PSUR procedure type	Marketing Authorisation type of the products concerned	Addressees	Submission requirements	Reference document(s)	File name to be used when submitting to EMA
"**PSUSA**" PSUR single assessment of substances contained in centrally authorised product(s) **AND** nationally authorised products (including products authorised nationally in more than 1 Member States and through the mutual recognition and decentralised procedures)	NAP	EMA	eCTD or NeeS format **only** via eSubmission Gateway or eSubmission Web Client.	EURD list cover note, section 5 http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/10/WC500133157.pdf	**Please refer to the reference document (see column E) for more details on the file naming convention** File name for submissions via the Gateway or the Web Client: ESUBPXYZ_ESUBPROD_00000000_substance_MAH_YYYYMM_psusa_00xx.zip Submission description field in the eCTD envelope for NAPs: MAH name, NAP Invented name
	NAP	CHMP, PRAC Members representing the Countries where the products are authorised + Alternates + PRAC rapporteur appointed for the procedure as identified in the EURD list Note: submission to the PRAC Independent Scientific experts and CHMP Co-Opted Members not required	1 submission package in accordance with the national requirements	National Competent Authorities (NCAs) and European Medicines Agency (EMA) requirements for submission of PSUR during the transitional period http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/05/WC500127656.pdf	

PSUR submission according to the EURD list

Rapporteur for single assessment proc. mixed CAPs + NAPs

Procedure Numbers for single assessment procedures of mixed CAP/NAP

List of Union reference dates and frequency of submission of periodic safety update reports (PSURs)

Related Information:

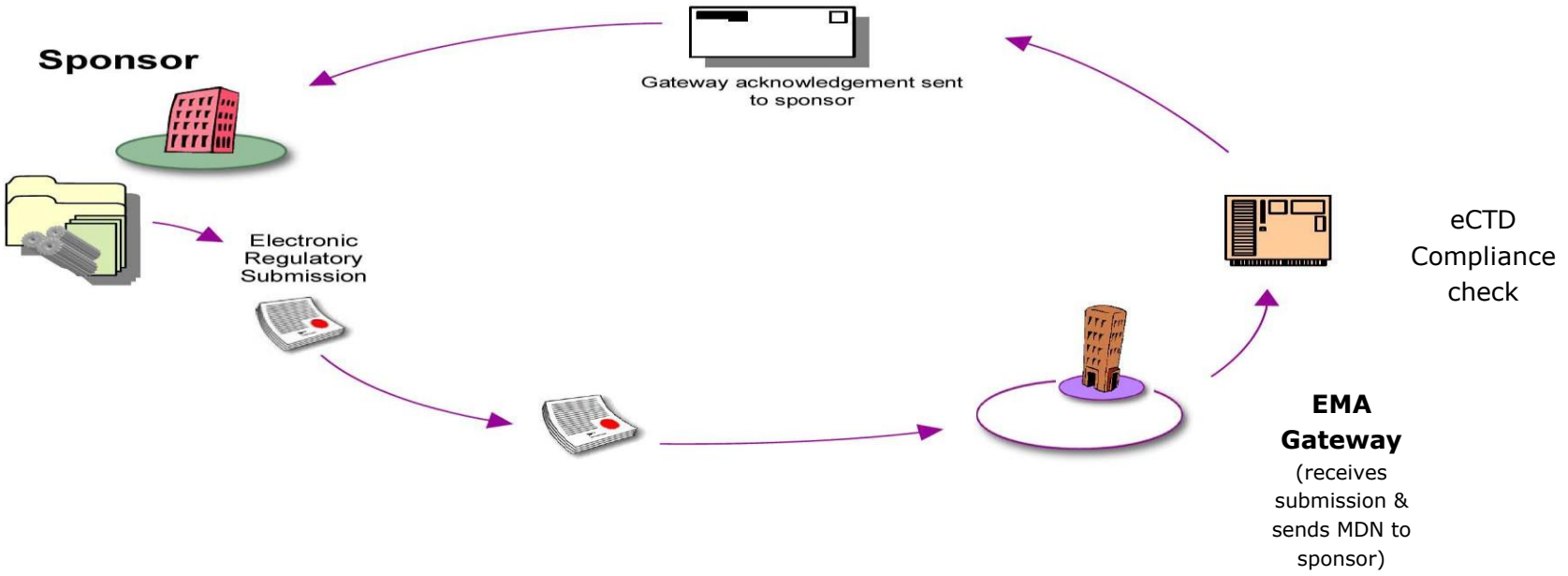
Introductory cover note to the List of European Union reference dates and frequency of submission of PSURs including requirements for PSURs submission	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/10/WC500133157.pdf
Requests for amendments of the EU reference dates list	http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2012/10/WC500133160.xls
The PSUR assessment procedure will start according to the Timetables published on EMA website following the Submission Dates indicated in	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/07/WC500129609.pdf

Active substances and combinations of active substances	European Union reference date (EURD) Not Available* = EURD not provided during the consultation phases	PSUR Submission Frequency	DLP	Submission date (According to the timelines defined in GVP Module VII, Section A)	Next DLP (For active substances or combination of active substances with a PSUR frequency of less than one year)	Next Submission date (According to the timelines defined in GVP Module VII, Section A - For active substances o	Are PSURs required for products referred to in Articles 10(1), 10a, 14, 16a of Directive 2001/83/EC as amended? Yes/No	Publication Date (in accordance with Article 107c(7) of Directive 2001/83/EC as amended)	Procedure number of the PSUR single assessment procedure for substances contained in both CAPs and NAPs	PRAC Rapporteur of the PSUR single assessment procedure for substances contained in both CAPs and NAPs
human hepatitis B immunoglobulin	02/06/1979	6 months	30/05/2013	08/08/2013	30/11/2013	08/02/2014	No	01/10/2012	PSUSA/00001631/201305	Brigitte Keller-Stanislawski (Germany)
human normal immunoglobulin	25/01/1985	1 year	31/05/2013	09/08/2013			No	31/01/2013	PSUSA/00001633/201305	Brigitte Keller-Stanislawski (Germany)
hydrochlorothiazide, irbesartan	15/10/1998	3 years	29/09/2013	28/12/2013			No	01/10/2012	PSUSA/00001653/201309	Dolores Montero Corominas (Spain)
hydrochlorothiazide, telmisartan / telmisartan	11/12/1998	1 year	11/04/2013	20/06/2013			Yes	01/10/2012	PSUSA/00002882/201304	Carmela Macchiarulo (Italy)
hydroxocobalamin	23/11/2007	1 year	23/11/2013	01/02/2014			No	01/10/2012	PSUSA/00001690/201311	Evelyne Falip (France)
leflunomide	10/09/1998	1 year	10/09/2013	19/11/2013			Yes	01/10/2012	PSUSA/00001837/201309	Sabine Straus (Netherlands)
levetiracetam	29/09/2000	1 year	30/11/2013	08/02/2014			Yes	01/10/2012	PSUSA/00001846/201311	Jean-Michel Dogné (Belgium)
measles, mumps, rubella, varicella vaccines (live)	26/07/2006	1 year	05/09/2013	14/11/2013			No	28/02/2013	PSUSA/00001936/201309	Brigitte Keller-Stanislawski (Germany)

http://www.emea.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000361.jsp&mid=WC0b01ac058066f910

What is the Gateway?

An Agency-wide solution and central transmission point for accepting secure electronic regulatory submissions over the Internet. The EMA eSubmission Gateway is a conduit, or "a route", along which submissions travel to reach their final destination. It does not open or review submissions; it automatically routes them to the relevant EMA Office.



eSubmissions Gateway Options

- EMA Gateway Web Client
  - Low cost option
  - Uses applet
  - EMA is using European Review System (EURS) to validate the eCTD Submissions
- Gateway to Gateway (AS2)
  - Applicability Statement 2 (AS2) and AS3 Gateway-to- Gateway
  - Requires an AS2 & AS3 compliant gateway software
  - EMA is using a product called Axway Synchrony Gateway Interchange (version 5.x) & EURS to validate the eCTD submissions.

EMA Gateway Webclient Facts

- EMA does not charge for the use of this solution.
- ONE Webclient account is allowed per applicant. A second account may be requested though please do provide a justification to esubregistration@ema.europa.eu
- Webclient uses Hypertext Transfer Protocol Secure (HTTPS) to ensure secure delivery of submissions over internet.
- Consultancy companies can register and send on behalf of Various Applicants.

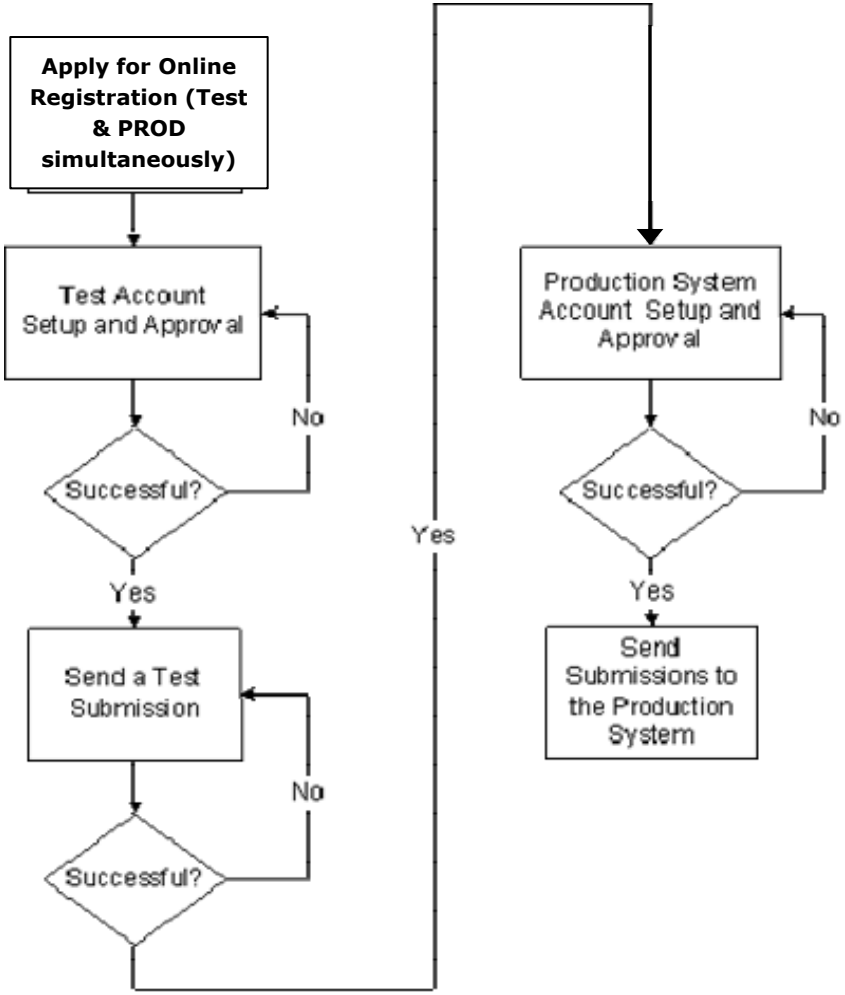
Feature comparison of WebClient and Gateway

Feature	Web Client	eSubmission Gateway
Removes the need for submitting CDs / DVDs to the EMA	✔	✔
Allows the technical possibility (after relevant registration) to connect to other EMA Gateway communities		✔
Allows eCTD submissions	✔	✔
Encrypts submissions upon receipt by EMA Gateway	✔	✔
Free solution	✔	
Suitable for consultancies / affiliate companies as well as Marketing Authorisation Holders	✔	✔
Provides automated message delivery notification (MDN)– Receipt	✔	✔
Provides confirmation of the submission's technical compliance	✔	✔
Compliant with ESTRI (Electronic Standards for the Transfer of Regulatory Information)		✔
Uses HTTPS (Hypertext Transfer Protocol Secure)	✔	
Accessible remotely via a website	✔	
Automated upload of submissions via custom development		✔
Suitable for transmitting multiple submissions*	✔	✔
Suitable for larger submission volumes		✔
Allows transmissions up to 15GB	✔	✔

Electronic Submissions Gateway Process – *What to do in order to use the gateway*

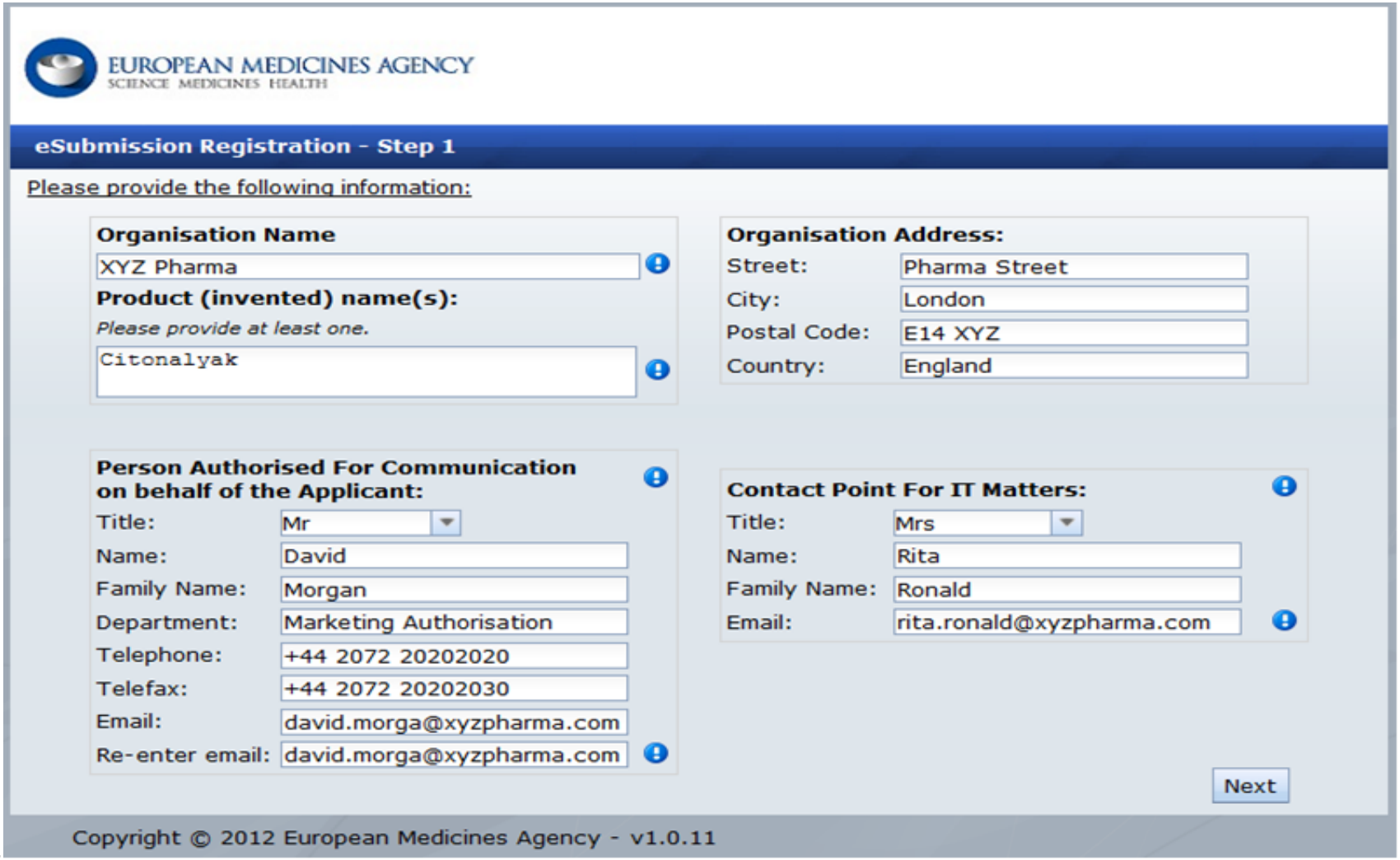
- Determine the preferred route i.e. AS2/GW or GW/Webclient
- To use the gateway webclient you need to ensure that online registration has been completed and account(s) have been activated.
- Understand and consult guidance documents on the eSubmission website http://esubmission.emea.europa.eu/esubmission.html
- File naming convention described in the guidance document is followed correctly when uploading zip files.

Overview of Gateway Set-up

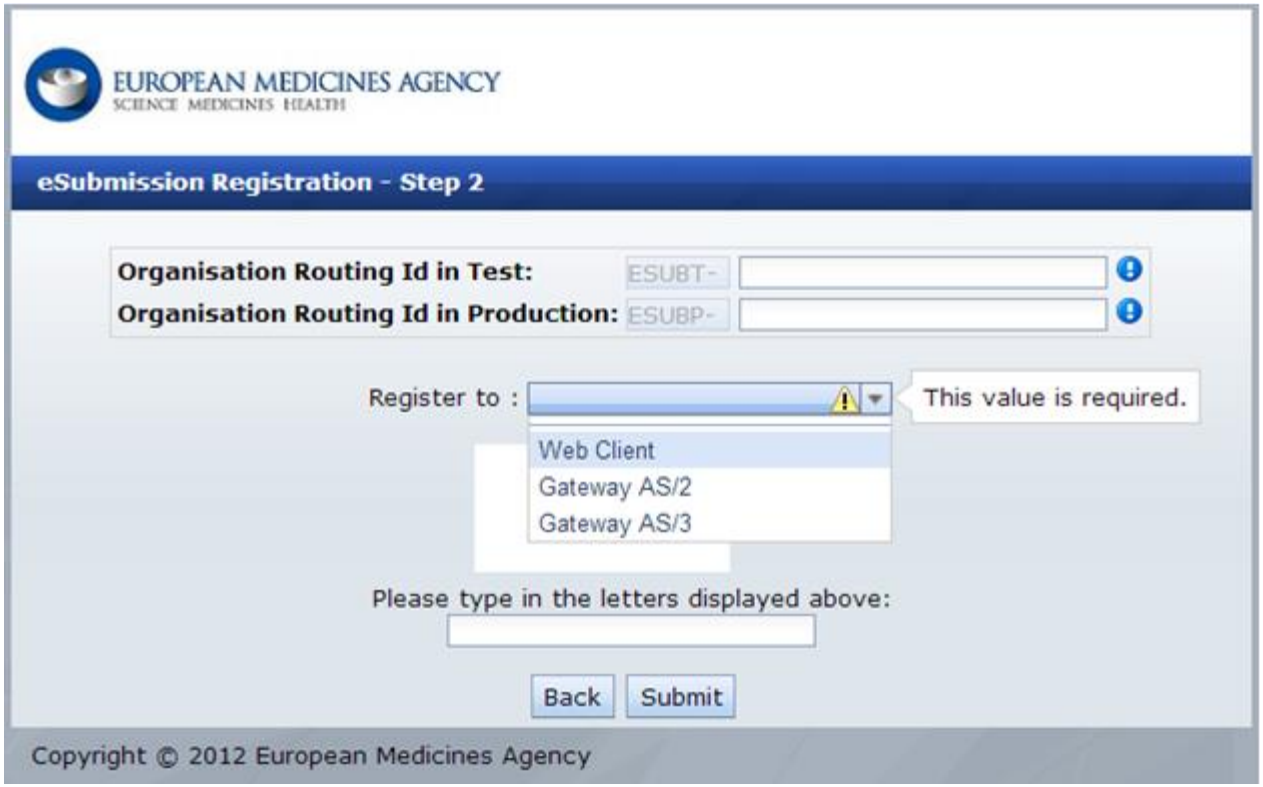


Testing is strongly recommended for webclient users even though it is stated *Optional* when registering online.

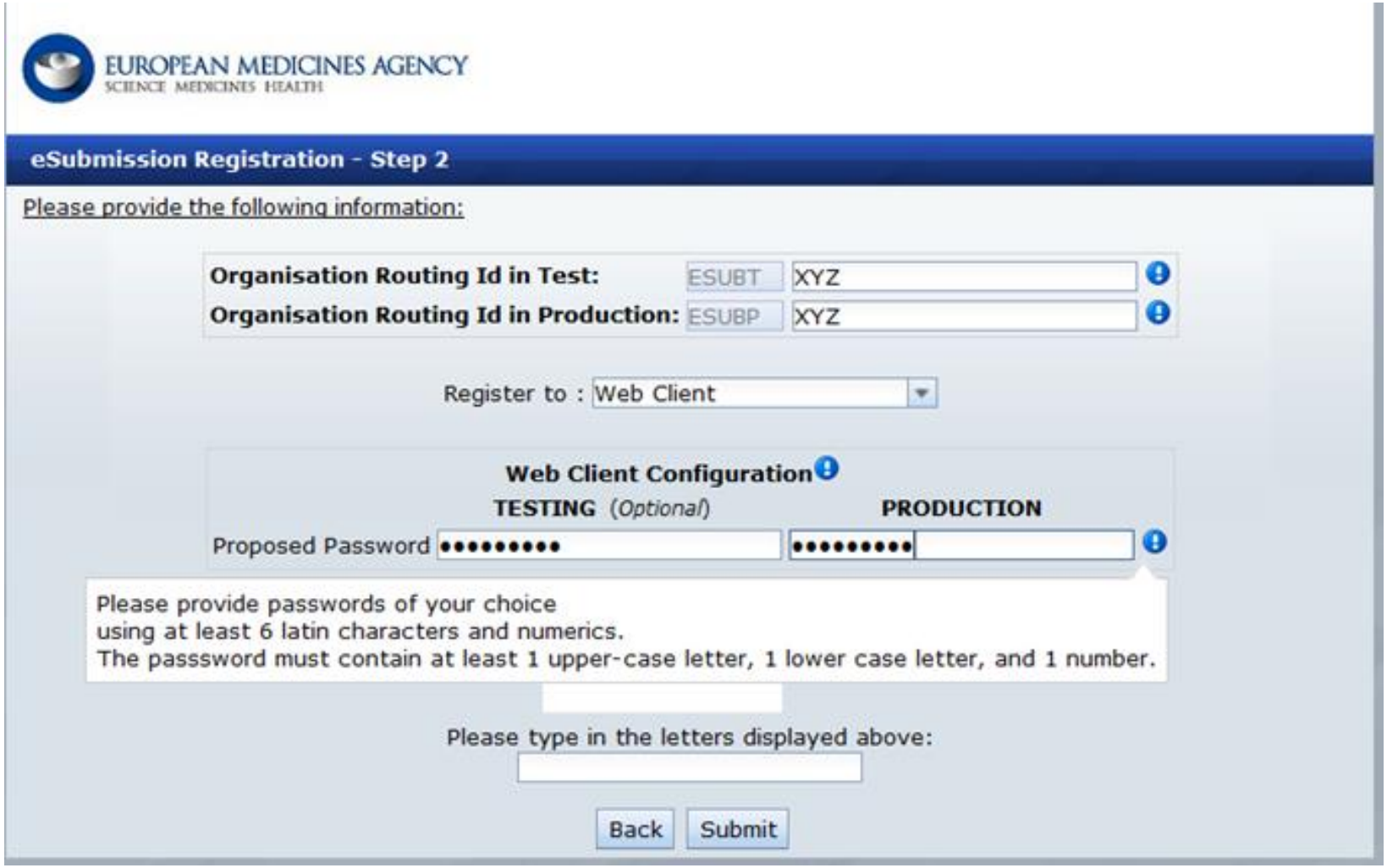
Webclient Registration - 1



Webclient Registration - 2



Webclient Registration - 3



Webclient Registration - 4

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Application to register to the Esubmission Gateway

Reference #:207

Emoji Limited 10 Corridor Road,London EC1P 9RE England	**Product (invented) name:** Emojium

Person Authorised For Communication: Title:Mr Name:Barry Last Name:Brixton Department:Media Tel: 0840064500 Fax: 0840064600 Email: azu.orioha@ext.ema.europa.eu	**Contact Point For IT Matters:** Title:Mr Name:Shelia Last Name:Ade-Williams Email:azu.orioha@ext.ema.europa.eu

Technical Details

	TESTING	PRODUCTION
Account Status	ENABLED	ENABLED
Routing ID	ESUBTTEST123	ESUBPTEST123

Details for eSubmissions web client

	TESTING	PRODUCTION
eSubmissions webclient url:	http://esubtestclient.ema.europa.eu	http://esubclient.ema.europa.eu
User ID:	ESUBTTEST123-admin	ESUBPTEST123-admin
proposed password:	Test123mo	Test123

Using The Webclient

1. Logon with the credentials supplied in communication from the registration team

2. Start Submitting!

Always select the *'send documents more than 10MB'* option to use "Large file applet", Note that receipts (MDN) are sent only when you use this option.

Gateway Filenaming Conventions for PSURs to EMA (1/3)

1. **PSURs submission <u>for substances in CAPs</u> only :** There is no change in the submission rules. PSURs should be presented in a new eCTD sequence in the respective eCTD lifecycle of the concerned product. To Note for EMA submissions, the use of eCTD format is mandatory, and it is strongly recommended to use the eSubmission Gateway and Web Client. Transmission via gateway will be mandatory from March 2014.

2. Example: ESUBPXYZ_ESUBPROD_HC000999_Wonderpill_PSUR_0020.zip

2. PSURs submission for <u>substances contained in both CAPs and NAPs</u>:

a) Submission for CAPs to EMA: in eCTD format only via eSubmission Gateway/Web Client. *Alternatively 1 DVD or CD-ROM with original signed cover letter is accepted.* The following filename (on next slide) should be used for the submission via the Gateway or the Web Client:

Gateway Filenaming Conventions for PSURs to EMA(2/3)

e.g.ESUBPXYZ_ESUBPROD_HCxxxxxx_Wonderpill_00000000_Substance_MAH_YYYYMM_psusa_00xx.zip

ESUBPXYZ	ESUBPROD	HCxxxxxx	Wonderpill	00000000
Sender's Routing ID for Gateway (communicated to Applicant by EMA's Gateway registration team)	Receiver's routing ID for Gateway (communicated to Applicant by EMA's Gateway registration team)	Centralised procedure Number (HCxxxxxx) – 6 digit ID (from the eligibility confirmation letter which is sent by EMA)	Product name	8 digit Unique identification number as included in the published EURD list (without the Data Lock point)
Substance	**MAH**	**YYYYMM**	**psusa**	**00xx.zip**
Substance as mentioned in the EURD list*	MAH submitting the PSUR*	Month and year of the DLP (as per the suffix of the Procedure number	Submission type for single assessment of PSUR	Sequence Number of the submission (4 digits

The submission description field in the eCTD envelope for CAPs should contain the following:

Submission Description:	**substance, psusa/00000000/YYYYMM** *Procedure number of the PSUR single assessment procedure for substances contained in both CAPs and NAPs (as in EURD list)*

Gateway Filenaming Conventions for PSURs to EMA (3/3)

2 (b) **Submission for <u>NAPs to the EMA</u>:** in eCTD or NeeS format only via eSubmission Gateway or eSubmission Web Client.

The following filename should be used:
ESUBPXYZ_ESUBPROD_00000000_substance_MAH_YYYYMM_psusa_00xx.zip

ESUBPXYZ	ESUBPROD	00000000	Substance	MAH	YYYYMM	psusa	00xx.zip
Sender's Routing ID for Gateway (communicated to Applicant by EMA's Gateway registration team)	Receiver's routing ID for Gateway (communicated to Applicant by EMA's Gateway registration team)	8 digit Unique identification number as included in the published EURD list (without the Data Lock point)	Substance as mentioned in the EURD list*	MAH submitting the PSUR*	Month and year of the DLP (as per the suffix of the Procedure number	Submission type for single assessment of PSUR	Sequence Number of the submission (4 digits

The submission description field in the eCTD envelope for NAPs should contain the following:

Submission Description:	**MAH name, NAP Invented name**

* Note: For substance and MAH name, please use a 'short' name, with a maximum of 30 characters. Use only letters as no special characters can be used in the file name. Underscore can be used to separate filenaming parts, e.g. substance_MAH. Do not leave spaces or use special characters. For example for INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED) / INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED, PREPARED IN CELL CULTURES) use 'InfluenzaVaccine' or Pharmaceuticals Company International Limited use 'PharmaceuticalsCompany'.

Technical Validation Issues

- eCTD Technical Validation identifies and rates the severity of the errors (P/F checks from the eCTD criteria) encountered in a typical eCTD submission, *results are indicated in Final Acknowledgement message as "SUCCESS or FAILURE".*
- The eCTD validation criteria for these are available here: http://esubmission.emea.europa.eu/tiges/tigesdocuments.html
- Duplicate Submission
- Typo in the product number(HC000xxx) or a procedure number (8 digit EURDID)
- If an already existing sequence (in EMA database) has been modified and sent to the agency as replacement !
- Incorrect Submission structure (4 digit folder not at the root of submission package)

Key Points during the Webclient Transmission -1

There are two automated messages sent during the transmission:

1. Always use the "Large File Applet" for All transmissions via the webclient.
2. The **Receipt** is sent once the submission has been successfully received by the EMA gateway webclient. It is a simple text file with reception timestamp and is merely a receipt - this does not indicate a successful technical validation. To note Receipt is sent only when using the "Large File applet".
3. The final **"Acknowledgement" is an xml file** sent after the system has completed the technical validation of the submission. It contains the result of the validation (SUCCESS or FAILURE). In case of a failure, a detailed description of the error is included in it.
4. Dependent on the submission size and webclient gateway queue, both automated messages can take anything between 5 mins ~ 4 hours for the delivery back to sender.

Key Points during the Webclient Transmission - 2

4. Where applicable, for multiple submissions, please trigger webclient transmission belonging to same product/dossier in sequential order.

e.g. If you need to send 0033, 0035, 0036 for same product please send them in that order and allow some gap between those transmissions. Failure in following this may result in Negative technical validation.

5. All submissions should be archived as a zip file. The compressed application file must comply with the ZIP open format.

Key Points during Webclient Transmission - 3

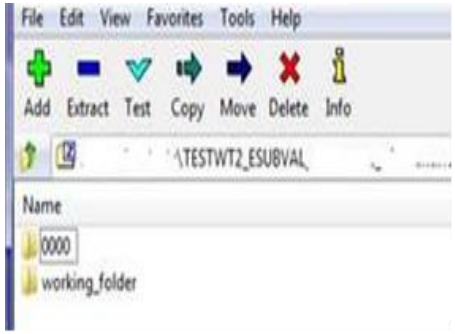
Sender's Inbox view showing Acknowledgement and Receipt:

Acknowledgement Example

```
        <originalMessageData>
            <senderRoutingId>TESTWT2</senderRoutingId>
            <receiverRoutingId>ESUBDEV</receiverRoutingId>
            <originalFileName>TESTWT2_ESUBDEV_HC002711_[redacted]var-type2_0009.zip</originalFileName>
            <emaProductNumber>HC002711</emaProductNumber>
            <productName>[redacted]</productName>
            <submissionType>var-type2</submissionType>
            <sequenceNumber>0009</sequenceNumber>
        </originalMessageData>
        <result>
            <result>FAILURE</result>
            <error>
                <errorCode>17179869184</errorCode>
                <errorMessage>Error reported during EURS batch import operation:
Error   Rule 0027, Severity A: Checks if the sequence folder matches the envelope sequence number.
Exception: ImportSubmission: import error
</errorMessage>
            </error>
        </result>
        <eurs-result>
            <result>FAILURE</result>
            <eursReport>Validation Report: Status Path/File Severity (Submission) / /m1/eu eu-regional.xm Not all modified
            <validationSet>EU-eCTD v2.1 (DTD 1.4)</validationSet>
        </eurs-result>
    </ProcessReport>
</eSubmissionAckMessage>
```

How to Avoid Problems - 1

1. Correct Routing ID's should be used for respective environments and reflected correctly in the Submission's filename – e.g.
   ESUBPXYZ_**ESUBPROD**_HC000999_Wonderpill_PSUR_0020.zip
2. Incorrect folder structure used in Zipped file sent to EMA. Always ensure that Sequence Number(0xxx) folder is at the root, as reflected below:



How to Avoid Problems - 2

4. Submissions should be compressed before transmission as a zip file. The compressed application file must comply with the ZIP open format.

5. **Duplicate submissions**

- Once is Enough!
- Webclient only processes the first submission not the duplicate.
- If the first submission was in error, contact eCTD support team at ectd@ema.europa.eu

6. Bad characters in the file names (NO Spaces!) – only underscore is allowed to separate the filenames. No other special characters are allowed.

7. Do not send duplicate submissions using both CD or DVD and webclient.

Why should you bother?

- These errors require us to manually process your gateway submission
- Manually processed submissions delay access to your material
- Sometimes these issues result in us rejecting your submission

Contact Information & Useful links

How to Submit PSUSA to the EMA: http://esubmission.emea.europa.eu/doc/How_to_submit_Periodic_Safety_Assessment_Reports.doc

Gateway Registration Documentation (contact info, forms, guidance documents): http://esubmission.emea.europa.eu/esubmission.html

Gateway Registration team: esubregistration@ema.europa.eu

for Technical issues during webclient set-up: gatewaysupport@ema.europa.eu

for Technical validation issues (e.g. 'Failure' Acknowledgements): ectd@ema.europa.eu

TIGes Guidance on eCTD & NeeS: http://esubmission.ema.europa.eu/tiges/tigesdocuments.html

EURD LIST: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/10/WC500133157.pdf

Dossier Requirements for CAPs: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500003980.pdf

Dossier Requirements for NAPs: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/05/WC500127656.pdf

Abbreviations

CAP: Centrally Authorised Product
CHMP: Committee for Medicinal Product for Human Use
CMDh: Coordination Group for Mutual Recognition and Decentralised Procedures – Human
DLP: data lock point
DCP: Decentralised procedure
DIR: Directive 2001/83/EC as amended
EMA: European Medicines Agency
EU: European Union
IBD: International Birth Date
MAH: Marketing authorisation holder
MA: Marketing Authorisation
MRP: Mutual Recognition procedure
NAP: Nationally Authorised Product (in the frame of this presentation includes also DCP/MRP)
NCA: National Competent Authority
PRAC: Pharmacovigilance Risk Assessment Committee
PSUR: Periodic Safety Update Report
REG: Regulation (EC) N. 726/2044 as amended

Thank You for your interest!

Questions?