



Slovenská asociácia spoločností v oblasti liekovej regulácie
Slovak Association of Regulatory Affairs Professionals

Seminár SARAP k problematike eCTD

Skúsenosti a pohľad
farmaceutického priemyslu

SARAP

DoubleTree by Hilton, Bratislava, 9.4.2014

Obsah

Validačné reporty k eCTD - súčasný stav a problémy

Eudralink

CESP

Validačné reporty súčasný stav a problémy (1)

validačný report oznamuje v rámci validácie kompletnosti dokumentácie:

„0000 This sequence not exist ! To resolve this problem, please send the valid sequence number: 0000“

- Identifikované problémy:
 - Nesprávna informácia, sekvencia predložená bola
 - V ďalšej časti validačného reportu je vymenovaná údajne chýbajúca sekvencia medzi importovanými
 - Paralelne bola podávaná zmena, ktorá práve túto chýbajúcu sekvenciu obsahuje
 - V prípade re-submission nemusí byť už validná, pretože medzičasom boli aktualizované validačné kritériá

Validačné reporty súčasný stav a problémy (2)

- Niektoré sekvencie nie sú v reporte uvedené ani medzi chýbajúcimi ani medzi importovanými
- Často hlásený nedostatok: „All PDF hyperlinks are relative“ pri implementácii textu o hlásení nežiaducich účinkov do SPC/PIL je nutné, aby hyperlinky boli aktívne

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Posielanie dokumentácie cez Eudralink

- Ak firma posiela z centrály priamo na ŠÚKL dokumentáciu cez Eudralink, je potrebná nejaká ďalšia aktivita z lokálnej pobočky?

Obsah

Validačné reporty k eCTD - súčasný stav a problémy

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CESP

CESP

- Currently the following countries (21) for human medicines are participating:
 - AT, BE, CY, DE, DK, EE, ES, FI, HR, IE, IS, IT, LU, LT, MT, NL, NO, PT, SI, SE, UK
- France started a pilot with using CESP from 1st October 2013
- Latvia is interested

- For the usage of CESP a web training is needed
- Signing in for a training possible on <http://cesp.hma.eu/Announcements>
CESP Demonstration Schedule

CESP - FAQs

- How will the implementation of CESP impact other national portals such as the MHRAs and the IMBs? Will the national portals be replaced or will CESP be used in addition to these?
- *It is envisaged that for agencies participating in CESP with national portal that each agency will review their requirement for a national system once the system is fully operational.*



CESP – Using status countries

- Who use CESP for national submissions
 - DE, DK, EE, FI, IS, NO, SE, IE, NL
- Which countries plan to use CESP
 - AT October/November 2013
 - BE January 2014, as HA BE is aiming on making CESP mandatory
 - When MRP/DCP NeeS variation can be submitted via CESP:
DE, DK, EE, ES, FI, IE, IS, LT, NL, NO, PT, SE, UK

CESP - Why countries do not use CESP

- AT due to capacity problems
- BE variations can sent by email, much easier
- CY original documents needs to submitted anyway
- ES national submissions are only allowed through national portal
- IT everything sent through national portal and post, Agency see CESP still as test and not checking the CESP submission server regularly
- IE due to the CESP issues which cause delays
- LT national variations submitted by third party
- LU taking care mostly by BE, CD is sent now
- MT no knowledge and access to CESP
- PT mandatory to use national portal
- SI original documents and CD has to be submitted anyway
- UK national variations are submitted through national portal

Necessary when submitted via CESP

	cd necessary	additional requirements
AT	no	no
BE	no	no
CY	no	signed application form/cover letter
DE	no	no
DK	no	no
EE	no	no
ES	no	application form upload via national portal
FI	no	no
HR	no	signed cover letter,application form, letter of authorisation
IE	no	no
IS	no	no
IT	yes	signed cover letter with stamp for new submission, paper package of variation + proof of online submission
LT	no	signed cover letter,application form, letter of authorisation, proof of payment
LU	no	no
MT	no	no
NL	no	no
NO	no	no
PT	no	signed cover letter/application form when PT is RMS, upload package via national portal mandatory
SE	no	no
SI	yes	signed si cover letter / English application form
UK	no	no

CESP - How do countries submit MRP/DCP

Nees variations now (some countries also national variations)

- AT CD by post
- BE by email
- CY CD and originals by hand to Agency
- DE CD and originals by post
- ES national portal, when too big CD via courier
- EE CD by post
- IE CD by post
- IT paper and CD by post
- LU CD by post
- MT CD and originals by hand to Agency
- NL CD by post
- Nordic (DK, FI,IS,SE,NO) CD by post
- SI CD and originals by post
- UK CD by post