

Experiences and observations from eCTD submissions to the Slovak Medicine Agency (SUKL)

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Slovak Medicine Agency, Slovakia***

Content

- Introduction , background, Setting scene
- eCTD in the system of existing databases, and hardware options , personal
- Outcomes from system – analysis – examples
- Future plans – communication and new option for MAH to follow the process

Introduction , background, Setting scene

eCTD system in SK Introduction - background

1. *State Institute for Drug Control in SK uses local validation and review tool.*
2. *System was implemented by agency in cooperation with company **Balajka M+A, s.r.o.**, www.sukl.sk, www.ectd.sk*
3. *System was implemented from QI/ 2010*
4. *System known as : eCTD Tracking System.*
5. *Actual version: 1.33 (version reflects previous updates based on requirements)*
6. *Validation criteria actual (used):*
eCTD – 5.0
NeeS – 4.0
7. *In 2013 major update of system – system converts NeeS format to eCTD format .*

Main objectives for implementation of eCTD/Nees

- Meet standard requirements for application submitted, harmonisation in EU (ICH for dossiers)
- Content of dossier is available to respective staff across all processes in agency (SIDC) – security access to dossiers
- Accessibility of content of eCTD documentation for complex analyses and assessment
- Both side communication (with PTL and Applicant – „discussion“)
- Optimization of process of receiving registration documentation
- Process of transparency

Feasibility for implementing system

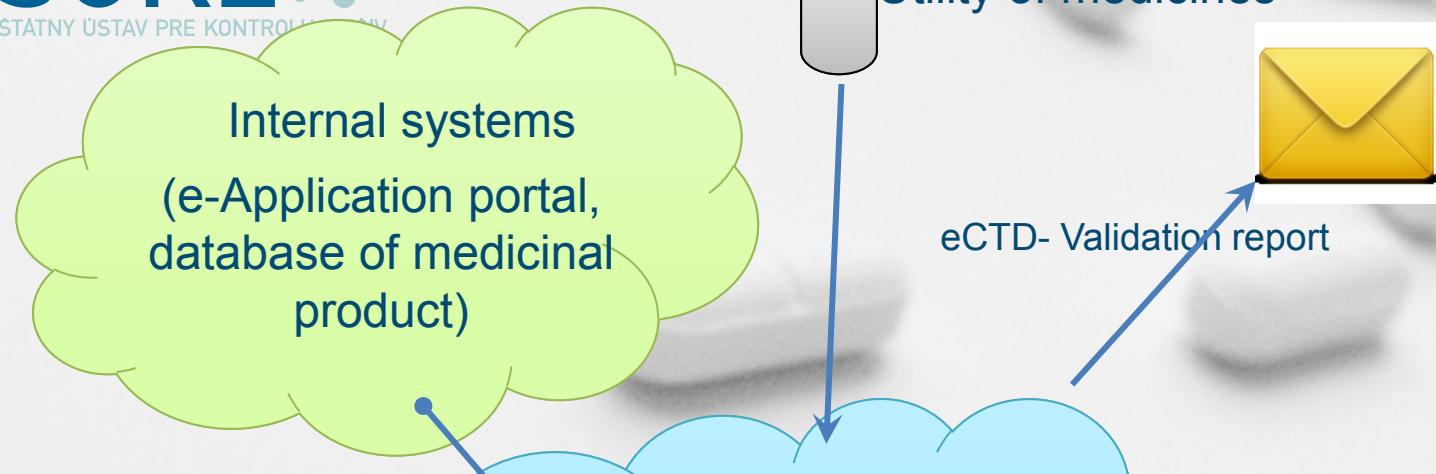
- Limited No. of Staff – need for optimizing of processes using eCTD
- Establishing effective processes to ensure progress towards the automation of processing, validation and acquisition of data from applications
- Retraining of staff for understanding eCTD, their role for technical and content- of -dossier validation, during life cycle of application and licensed medicine

Challenges for eCTD system supplier

- Cooperation of validation tool with existing databases systems
- The whole process of validation and acquisition of data from applications must be manageable with a limited number of staff
- Old hardware throughout the agency
- Concept of secure access for Applicants to get information about registration processes
- Implementation data warehouse
- Data capacity increasing

eCTD in the system of existing databases,
and hardware options , personal

Utility of medicines



Prehľad žiadosti
GENERICIS (BG) Ltd. I | Putter Bar,
Hertfordshire | UK
Battley Lane | Mytchett
Battley Lane | Mytchett GU2 5BB
GB-012014

Application choice

- A.7. | IB | Vypracovať nový výkaz v prípade činností lieku, ktorého je možné prepraviť iba do občín, mest, miest, miestností, ktoré sú v súlade s predpismi práv o preprave lieku do občín, mest, miest, miestností.
- B.8.1.a. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.1.b. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.2.a. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.2.b. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.3.a. | IB | Meny výkazu na základe výkazu prijatého.
- B.8.3.b. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.4.a. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.4.b. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.5.a. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.5.b. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.6.a. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.6.b. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.7.a. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.7.b. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.8.a. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.8.b. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.9.a. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.9.b. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.10.a. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.10.b. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.11.a. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.11.b. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.12.a. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.
- B.8.12.b. | IB | Vypracovať nový výkaz podľa žiadosti na vypracovanie.

Identified drugs

Alfuzosin Mylan 10 mg

Attribute list

Spotreba liekov

NeeS validacia:

1. Tables of Contents

1.7. All documents in the submission are referenced using a hyperlink in a TOC, either the main ctd-toe.pdf or in a module-specific TOC, as appropriate.

application code | nemo od/dst folder | 0000 sequence | not valid: File m1/w1/10-form/m1/Therape.m1 + Module m1 + Title = Title

application code | nemo od/dst folder | 0000 sequence | not valid: File m1/w1/Therape.m1 + Module m1 + Title = Title

application code | nemo od/dst folder | 0000 sequence | not valid: File Therape.m1 + Module m1 + Title = Title

2. Files/Folders

2.1. The files provided in the folders for Module 1 are in acceptable formats

application code | nemo od/dst folder | 0000 sequence | not valid: File m1/w1/10-form/m1/Therape.m1 + Module m1 + Title = Title

application code | nemo od/dst folder | 0000 sequence | not valid: File m1/w1/Therape.m1 + Module m1 + Title = Title

2.8. Only valid characters are used in file names

application code | nemo od/dst folder | 0000 sequence | not valid: 0000\m1\w1\2\drop-down\2\drop-down\product-dosage-form\2\drop-down\exempted-harmous-national.pdf + Module m1 + Title = Link

application code | nemo od/dst folder | 0000 sequence | not valid: 0000\m1\w1\2\drop-down\2\drop-down\product-dosage-form\2\drop-down\exempted-harmous-national.pdf + Module m1 + Title = Link

3. PDF Files

3.BP6. All PDF hyperlinks are relative

application code | nemo od/dst folder | 0000 sequence | not valid: File m1/w1/2\drop-down\2\drop-down\product-dosage-form\2\drop-down\exempted-harmous-national.pdf + Module m1 + Title = Link

application code | nemo od/dst folder | 0000 sequence | not valid: File m1/w1/2\drop-down\2\drop-down\product-dosage-form\2\drop-down\exempted-harmous-national.pdf + Module m1 + Title = Link

eCTD Tracking System | CHAN TENGRI SOLUTION LLC | v.1.21 | Specifar S.A. | 2012695410080 | petertazky@yahoo.com | petertazky@yahoo.com

Variabilný symbol: 2012695410080 | Počet liekov: 1 | Počet chýb: 2

Import eCTD / NeeS

Žiadost'	Tracking System
Aderegl 0,5 mg tabletbytl	Aderegl 0,5 mg tabletbytl
Aderegl 1 mg tabletbytl	
Aderegl 2 mg tabletbytl	

Cooperation with existing systems

RESUME:

Technical criteria:

- does not meet the "new EU validation Criteria v 4.1"
- missing the previous sequence /Life Cycle Management validation/

Result of technical validation

Identifikačné údaje (Envelope SK):

eCTD application meets the professional criteria.

VALIDATION REPORT:

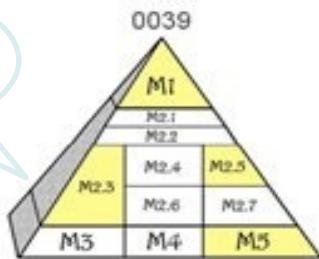
Application choice:

- Metoject 50 mg/ml injekčný roztok sol inj | 44065906-S | R | DCP | LD16A01

Name of a medicinal product, registration number,
→ imported from internal database SIDC

Identified drugs:

Metoject



Visualisation of sequences

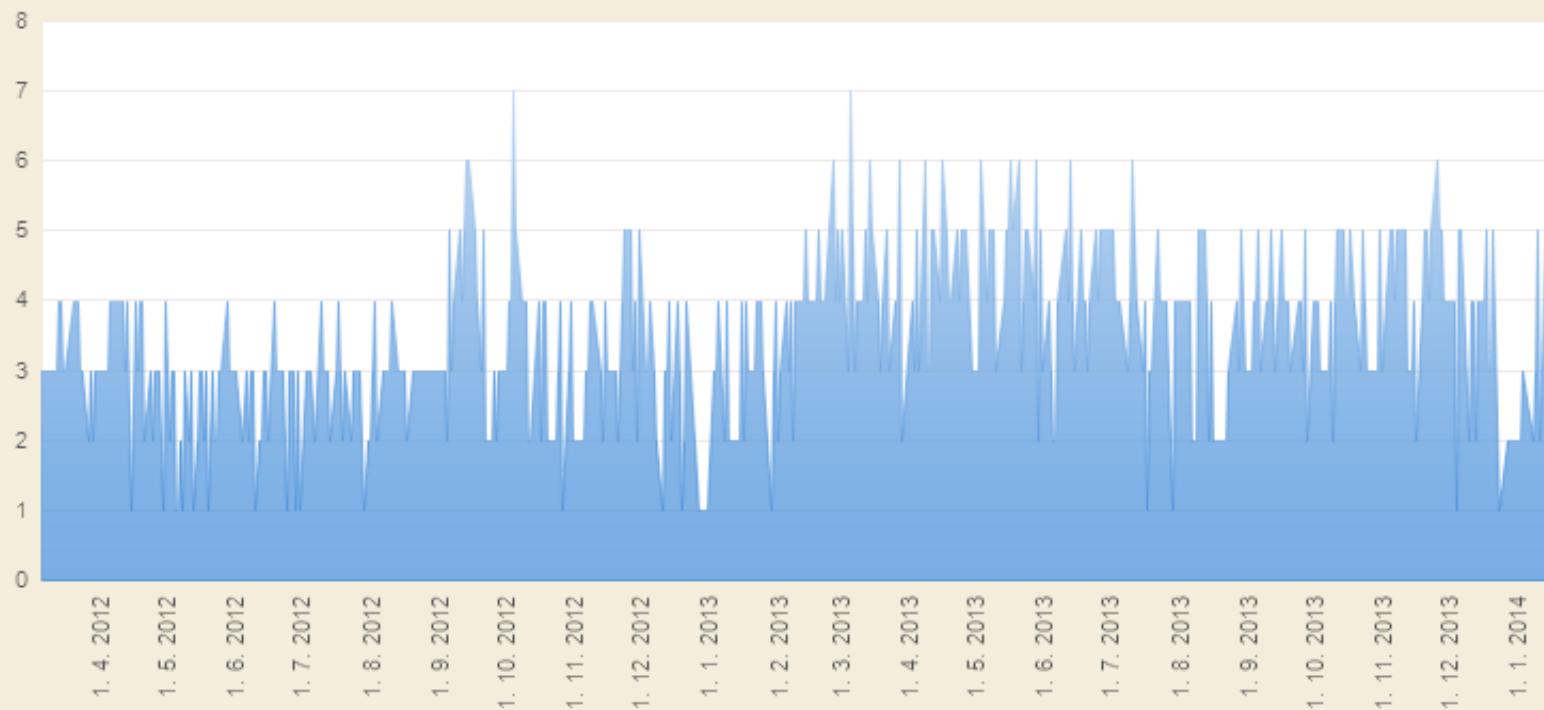
Data from eCTD

Applicant:	Envelope: medac GmbH e-Bedosf: medac Gesellschaft für klinische Spezialpräparate m.b.H
submission_type:	Envelope: renewal e-Bedosf:
Procedure_type:	Envelope: decentralised e-Bedosf: DCP
invented_name:	Envelope: Metoject e-Bedosf: Metoject 50 mg/ml injekčný roztok sol inj
inn:	Envelope: Methotrexate e-Bedosf: Metotrexát
import_date:	31.10.2012 01:58
MDS:	a90d467b58a23124a03462e77359d148

Data from portal e-Application

The whole process of validation and acquisition of data from applications must be manageable with a limited number of staff

Number of people which upload all eCTD sequences



System has to work in spite „Old hardware“ throughout the agency !

Median time which is necessary for identification of application and drug name 51 sec.

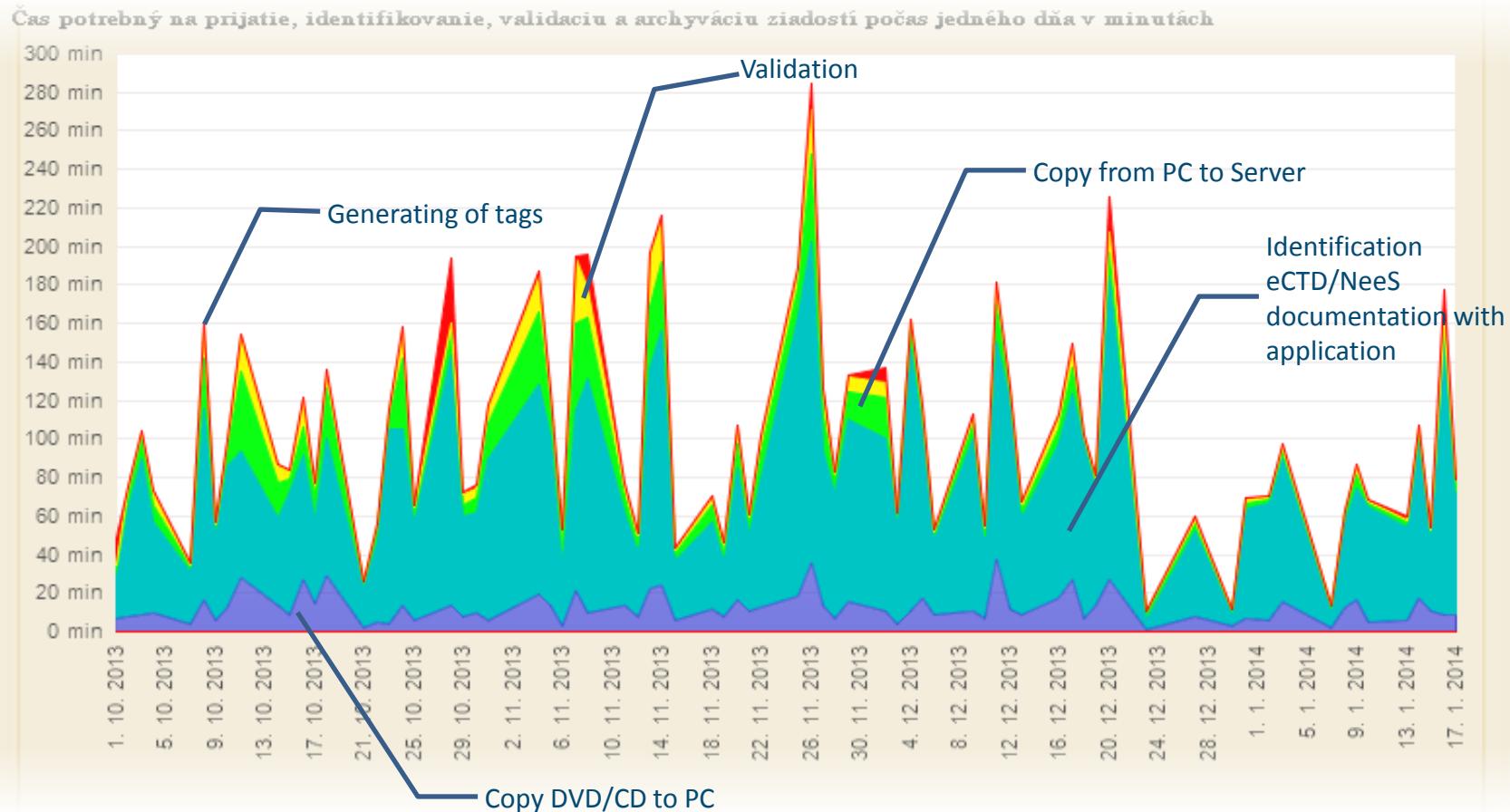
Mechanical processing of application..... 12 sec.



Older hardware at the Department of Administrative Support

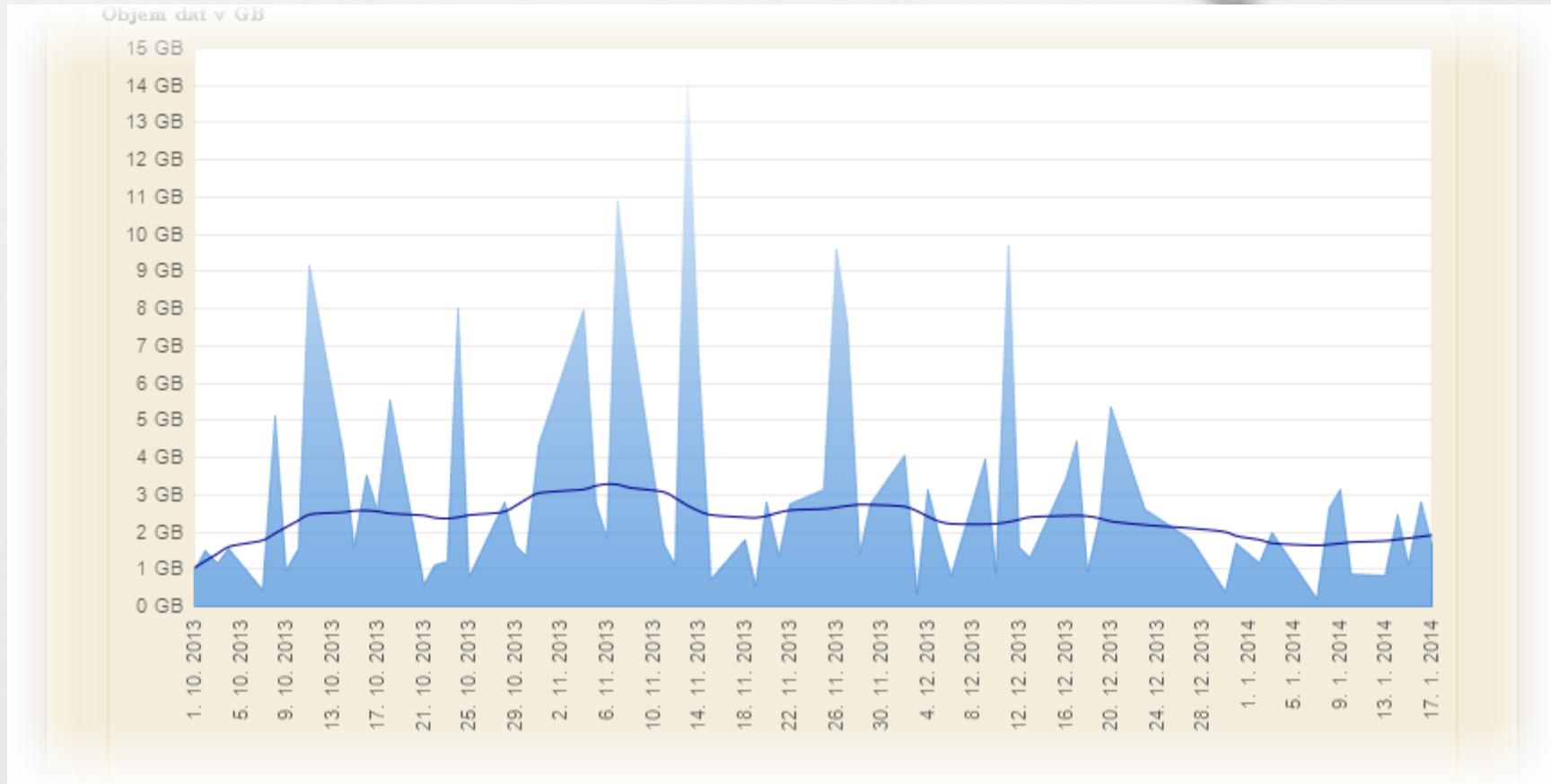
The applications are uploaded in 24hours after receiving documentation.

Sequences are uploaded 2-5 hours per day.



Data capacity

Champion for capacity data imported (at 14.11.2013 -14GB) - 220 minutes for complex processing.



Content of dossier available to respective staff across all processes in agency (SIDC)

m1.2 a 5.1 - Proof of payment	
common name	Annex 5.15 Cover of Marketing Authorisations
name	Annex 5.17 List of Mockups
name	Annex 5.19 List of Proposed Inventories of the Concerned Member States
name	Annex 5.19 List of Proposed Inventories of the Concerned Member States
replace	Annex 5.10 Certificate of Suitability
replace	Annex 5.19 List of Proposed Inventories of the Concerned Member States
replace	Annex 5.19 List of Proposed Inventories of the Concerned Member States
m1.2 a 5.2 - Informed consent letter of marketing authorisation holder	
common name	Annex 5.22 QP Declaration from Duma
name	Annex 5.22 QP Declaration
m1.2 a 5.8 - Flow-chart indicating all manufacturing and control sites medicinal product and the active substance	
common name	Annex 5.8 Manufacturing flow Chart
m1.2 a 5.9 - GMP certificate(s)	
common name	Annex 5.9 GMP2011 for CIT
name	Annex 5.9 Hungarian GMP cert reflec
name	Annex 5.9 GMP Certificate 2011 Alkot
name	Annex 5.9 GMP 2010 for Iresne
replace	Annex 5.9 GMP 2012 for CIT
m1.2, annex 5.5 - Curriculum Vitae of the Qualified Person for Pharmacovigilance	
common name	Annex 5.5 CV of QP Pharmacovigilance - Duma
replace	Annex 5.5 Curriculum Vitae of the Qualified Person for Pharmacovigilance - Share

Modul

Valid documents in time

Quick view to document

Attention
The same document is used for another drug

Sequence

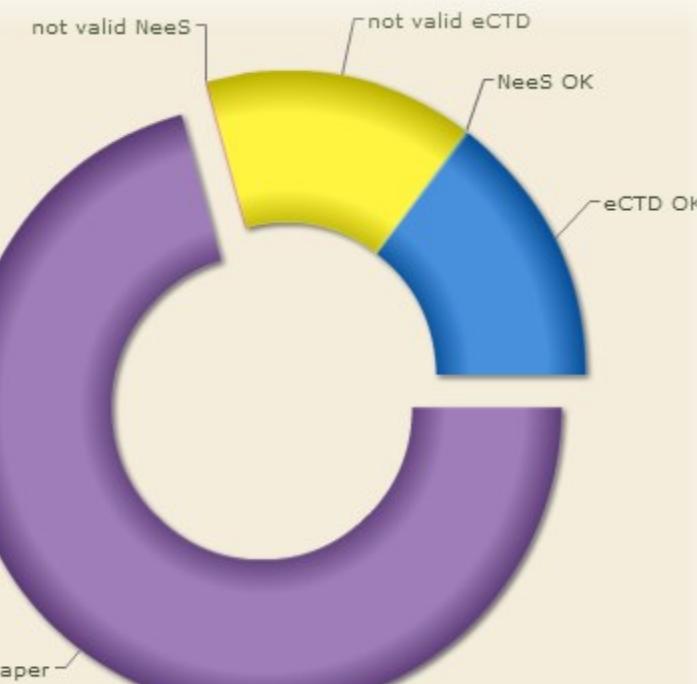
Outcomes from system – analysis – examples

Available ad hoc analysis from System

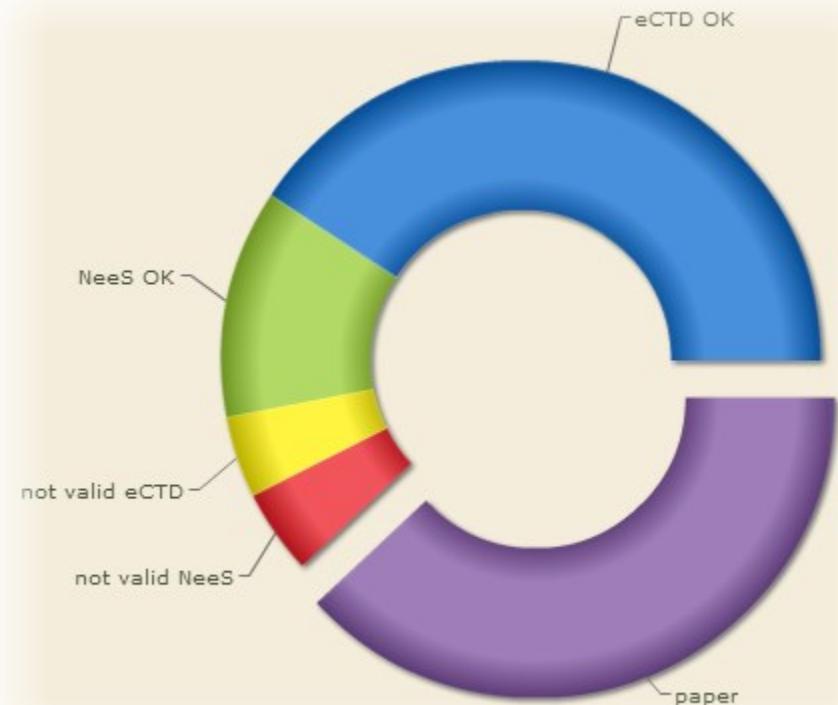
- What are the formats of registration documentation (eCTD, Nees, paper,...)?
- How many percent of applications are in eCTD format?
- Improving of quality of eCTD applications in timeframe (after trainings for applicants,...)?
- What are the most frequent errors in the eCTD dossiers based on validation protocol?
- Applicants with top number of applications?
- How many percent of applications met with validation criteria?
- How many applications have valid Life Cycle Management?
- Which companies have stopped to notify changes in status of documents? (each next change in document is marked as **new**)

What are the formats of registration documentation submitted

2011



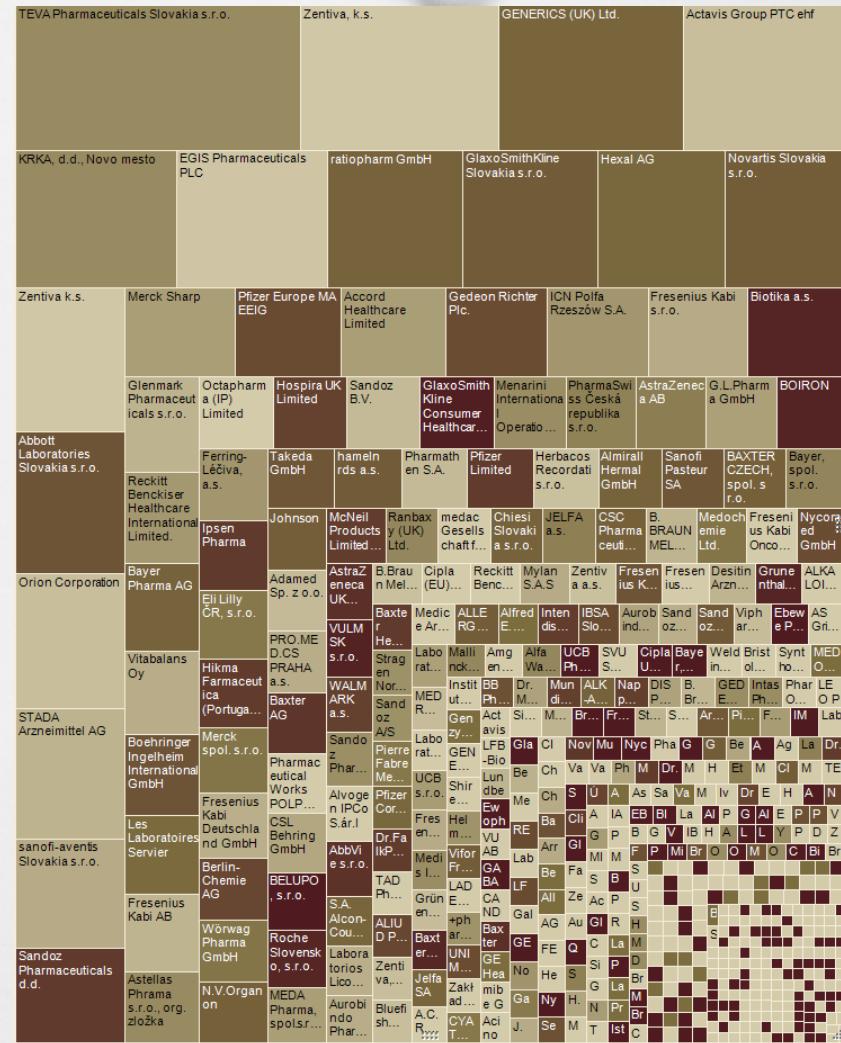
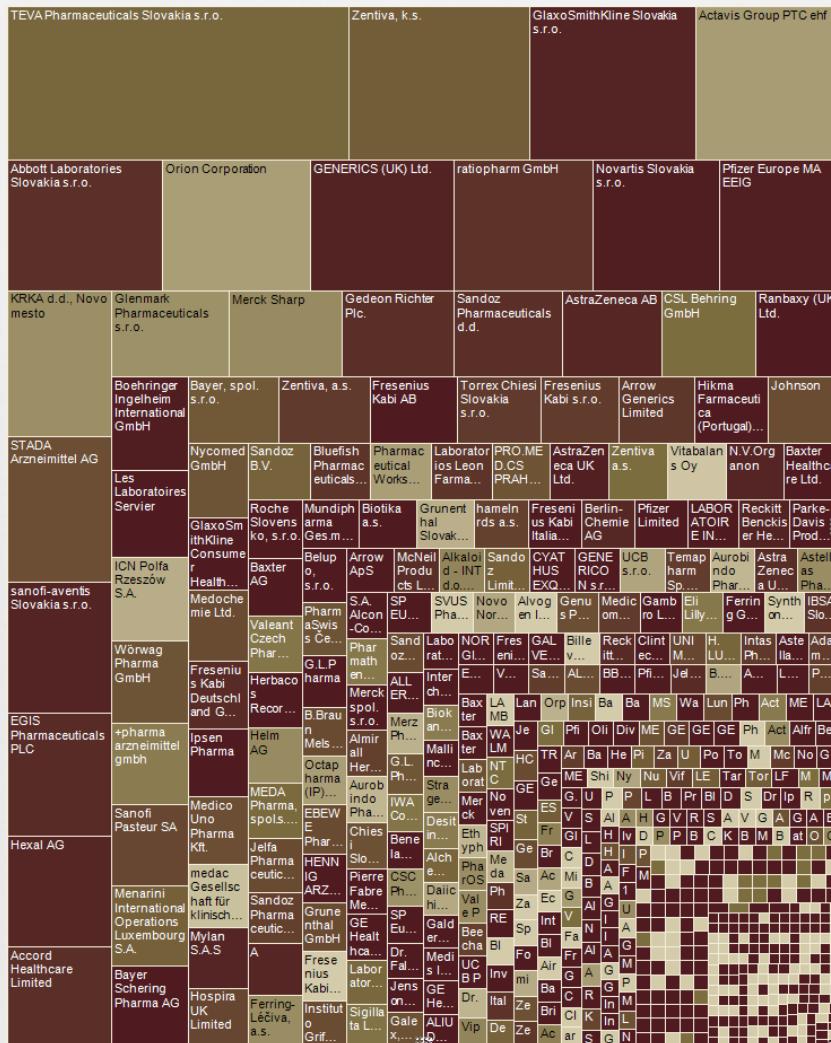
2013



Number of total submissions vs eCTD format - by MAH

2011

2013



Number of eCTD dossiers vs number of valid eCTD by MAH

2010

2013

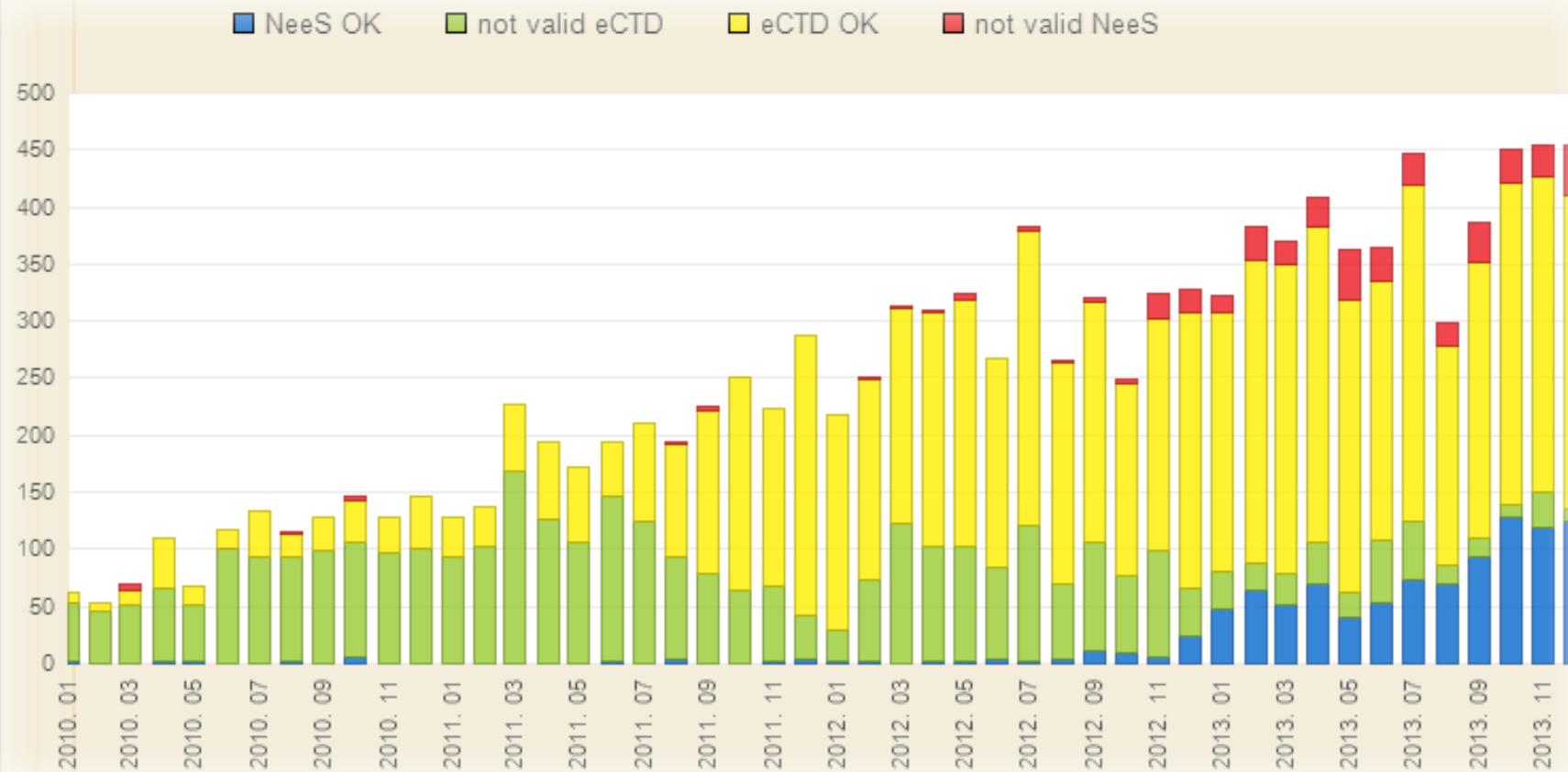
TEVA Pharmaceuticals Slovakia s.r.o.	Zentiva, k.s.	KRKA d.d., Novo mesto
Actavis Group PTC ehf	Orion Corporation	Pharmaceutical Works POLPHARMA SA

	Nycomed GmbH	Pharma, spo.s.r.o.	IBSA Slovakia s.r.o.	Arznei mitte...beck A/S	APOG EPH...	sp...	MED IP...	Reckitt...	Gene ric...	Mime r.M...	Mom aja...	Ada me...	Astra Ze...	Alkal oid...	Gede on...
Zentiva k.s.	Fresenius Kabi	mibe GmbH	ESP Pharma Ltd.	PharOS Pharm...	Tecnim ede...	Phar ma...	Phar ma...	Astel las...	Phar...	Grun...	Olink...	Heilm...	Fre...	Eir...	
	EBEWE Pharma Ges.m.b.H, Nfg.KG	Oncology Plc.	Cipla UK Ltd.,	Pharma select Inten...	Techni...de...	Nova...ris Slo...	CSC Pha...m...	ET Ch...	Fre...	Me...	Lo...	Myl...	IAS...	Ast...	Ph...
	medac Gesellschaf...t für klinische...	Arzneimitt...neuraxpharm	Jubilant Pha...	Labo rat...		Gen H...	Bl Ph...	Poi...	Oz...	Inf...	Pfi...	La...	rati...	B.B...	As...
Zentiva a.s.	Zentiva k.s.	Nycomed Praha...	Rivopharm Praha s.r.o.	MSD-SP Ltd.	Specifica...r S.A.	KRK A...	MED BioA...	Lu...	Fre...	Pfi...	Shi...	Sra...	AL...	ST...	GE...
Glenmark Pharmaceuticals s.r.o.	+pharma arzneimittel gmbh	Astellas Pharma s.r.o., org.zl...	Miklich Laboratoriums...	Phar...	Specifica...r S.A.	Phar bil...	NTC S.r.l.	Ch...	Ast...	Me...	Alc...	Ph...	UNI...	inst...	Ute...
	ratioipharm GmbH	Menarini Internationa...l Operato...	Zaklad Orphan...euticals d.d.	Glen Lill...	Specifica...r S.A.	Nucl...	BE...	Me...	La...	Sot...	Str...	Fe...	Vai...	J.W...	WI Ab...

Improving of quality of eCTD/NeeS applications in timeframe

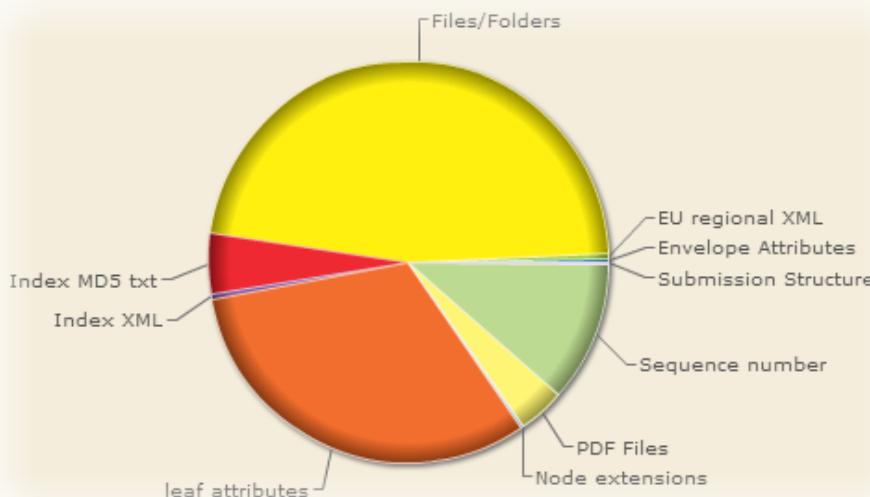
We have arranged two seminars in 2011, which have contributed to the increase of the quality and quantity of eCTD applications.

We started with uploading NeeS format in 2013. This format is automatically converted to eCTD .

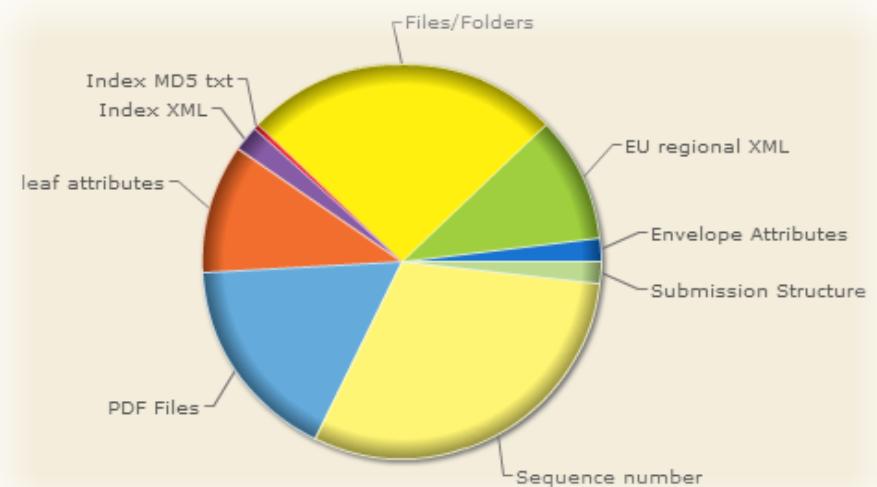


The most frequent errors in the eCTD dossiers based on validation protocol

2010



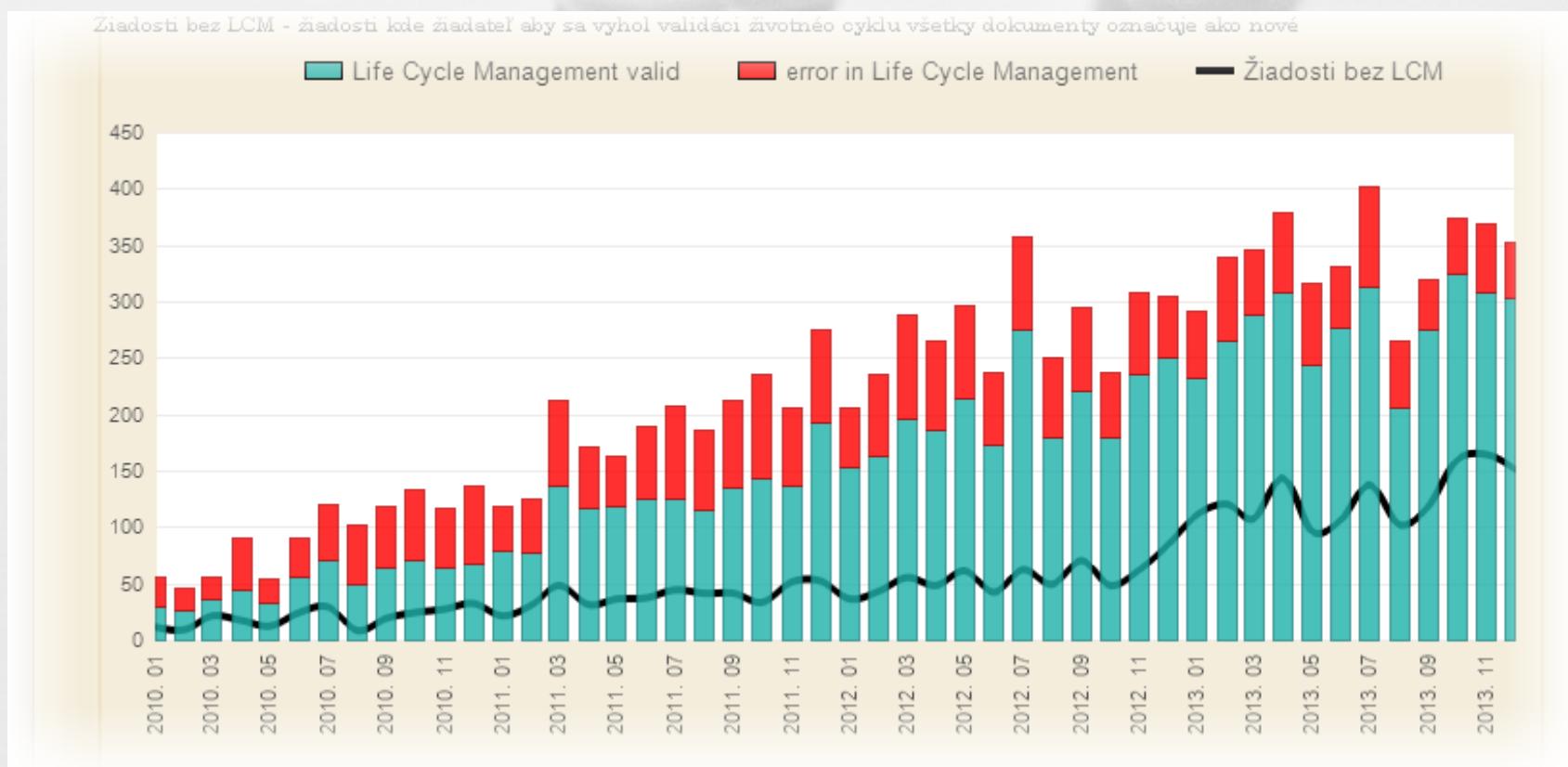
2013



POZOR – opakovane predložiť to isté číslo sekvencie ku žiadosti je možné len v prípade opravy technickej chyby, alebo poškodeného CD/DVD

Number of valid/invalid Life Cycle Management

Applicants have ceased with marking of validity of documents. Often are all documents marked as new, what complicates work with them.



Life Cycle Management valid – Medicinal product with min. two sequences and Life Cycle Management is valid

Error in Life Cycle Management – Sequence or document in sequence is missing or deleted

Applications without LCM – All documents in sequences are marked as new

Number of valid eCTD vs invalid Life Cycle Management

2012

2013

TEVA Pharmaceuticals Slovakia s.r.o.		Actavis Group PTC ehf				Zentiva, k.s.			
Orion Corporation		KRKA d.d., Novo mesto				ICN Polfa Rzeszów S.A.			
Pharmaceutical Works POLPHARMA SA		medac Gesellschaft für klinische Spezialpräpa...				Octapharma (IP) Limited			
PRO.MED.CS PRAHA a.s.		Vitabalans Oy				JELFA a.s.			
B. BRAUN MELSUNGEN AG		medac Gesellschaft für klinische Spezialpräpa...				ratiofham Gmbh			
Herbacos Recordati s.r.o.		Apotex Europe B.V.				+pharma arzneimittel gmbh			
CSL Behring GmbH		Hospira UK Limited				Ferring-Léčiva, a.s.			
Hexal AG		MEDA Pharma, spols.r.o.				Sandoz B.V.			
AstraZeneca AB		Bluefish Pharmaceuticals AB				Fresenius Kabi s.r.o.			
Astellas s.r.o., org. zložka		PharmaS wiss Česká republik...				G.L.Pharma GmbH			
Genericon Pharma Gesellschaft a.m.b.H.		UCB s.r.o.				N.V.Organon			
mibe dica A/S		Billev Pharma ApS				Merck s.p.o.			
Novo Nordisk (UK)...		Wörwag Pharma				Nycomed			
GENERICOS (UK)...		Medico m Intern...				AS Grindeks			
Laboratorios PHARMA...		Les Laboratoires Licon...				Stillek...			
Alvego n IPC...		Laboratori...				Billev...			
Daiichi Sankin...		Acino...				Wörwag...			
Adame d Sp...		Astella s Ph...				Merz Pharmaceutic...			
d f...		MediG en...				Nycomed...			
LADEE PHARMA...		Merck s...				AS Grindeks...			
Stalle...		Pierre Fab...				hamelein...			
Reckitt Actavi...		Jenso n P...				Johnson & Johnson			
t Be... s G...		A.C.R. GE...				Vipharm m S.A.			
s G...		Sandoz...				MEDRE G s.r.o.			
Regione dica		B. BRAUN MELSUNG EN AG				Sanofi Pasteur S.A.			
GMBH		Boehringer Ingelheim Internat...				Gedeon Richter Plc.			
KRKA d.d., Novo mesto		Reckitt Benckiser Healthcare International Limited.				ALKALOID INT d.o.o.			
TAD Pharma		Novartis Slovakia s.r.o.				Ranbaxy (UK) Ltd.			
GmbH		Sandoz B.V.				Aurobindo Pharma Limited			
Zentiva, a.s.		G.L.Pharma GmbH				Herbacos Recordati s.r.o.			
Kontrola		Fresenius Kabi Deutschland GmbH				medac Gesellschaft für klinische Spezialprä...			
Regione dica		Pharmatech S.A.				Zentiva k.s.			
GMBH		Zentiva k.s.				KRKA, d.d., Novo mesto			
Merck Sharp		KRKA d.d., Novo mesto				Orion Corporation			
sanofi-avents Slovakia s.r.o.		Orion Corporation				STADA Arzneimittel AG			
Pharmatech S.A.		STADA Arzneimittel AG				Hexal AG			
Nymcomed GmbH		Hexal AG				EGIS Pharmaceuticals PLC			
Synthon BV		Hexal AG				Zentiva k.s.			
Desitin Arzneimittel GmbH		Hexal AG				KRKA, d.d., Novo mesto			
Menarini International Oper...		Hexal AG				Orion Corporation			
Eli Lilly CR s.r.o.		Hexal AG				STADA Arzneimittel AG			
Zentiva a.s.		Hexal AG				Hexal AG			
Actavis Group PTC...		Hexal AG				Hexal AG			
Accord Healthcare Limited		Hexal AG				Hexal AG			
Jeifa SA		Hexal AG				Hexal AG			
Bayer, spol. s.r.o.		Hexal AG				Hexal AG			
Aurobindo Pharma Limited		Hexal AG				Hexal AG			
Bayer, spol. s.r.o.		Hexal AG				Hexal AG			
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Bayer, spol. s.r.o.		Hexal AG				Hexal AG			
Bayer, spol. s.r.o.		Hexal AG				Hexal AG			
Bayer, spol. s.r.o.		Hexal AG				Hexal AG			
Bayer, spol. s.r.o.		Hexal AG				Hexal AG			
Bayer, spol. s.r.o.		Hexal AG				Hexal AG			
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Bayer, spol. s.r.o.		Hexal AG				Hexal AG			
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Future plans – communication and new option for MAH to follow the process

FUTURE PLANS:

Diskusia

2011384322964 | P | MRP | DE/H/0268/001-00

Nycomed GmbH | Konstanz | DE

Mandelikova Stanislava | Nycomed sro | Bratislava | Stanislava.mandelikova@nycomed.com

28.03.2011

Obsah: m1 m1-0- m1-2- m5 m5-3- X

Atribúty: be GERD X

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FUTURE PLAN

Transparency of processes - communication PTL vs Applicant - discussion

Objective: to follow procedure from MAH

Applicant can communicate with coordinator as now or could utilize new offered options:

- To see comments of coordinator in eCTD documentation
- To upload own comment to eCTD documentation
- To upload new working document to eCTD documentation
- To monitor status of application
- To monitor if the application waits for answer/feedback from applicant
- To monitor dates
- To see the valid version of document in dossier

Ďakujem!

Najčastejšie nedostatky s ktorými sa stretávame

- CD/DVD neobsahuje žiadne súbory
- súbory na CD/DVD sú vo formáte ZIP, RAR
- nie je dodržaná štruktúra zložky, ktorá obsahuje dokumentáciu
- pri oboch formátoch (NeeS, eCTD) pomocné súbory a dokumentácia v jednotlivých moduloch nie sú uložené v spoločnej zložke s názvom sekvencie
- názov zložky je nesprávny (nesprávne 0001 - 20mg)
- pri dokumentácii vo formáte NeeS chýba na CD/DVD súbor ctd-toc.pdf
- na CD/DVD sa nachádzajú aj sekvencie, ktoré už boli použité v predchádzajúcich podaniach (predkladať iba aktuálne sekvencie k danej žiadosti)
- pri dokumentácii vo formáte eCTD sú poškodené súbory XML (uvedenému problému sa dá predísť znížením rýchlosťi pri napálení CD/DVD)
- CD/DVD sú predkladané na ŠÚKL bez povinného označenia a bez ochranného obalu