

Valstybinė vaistų kontrolės tarnyba
prie Lietuvos Respublikos sveikatos apsaugos ministerijos

DARBO SU VAISTINIŲ PREPARATŲ ELEKTRONINĖMIS BYLOMIS PIRMŲJŲ METŲ PATIRTIS

Pranešėja **A.MASIUKAITĖ**



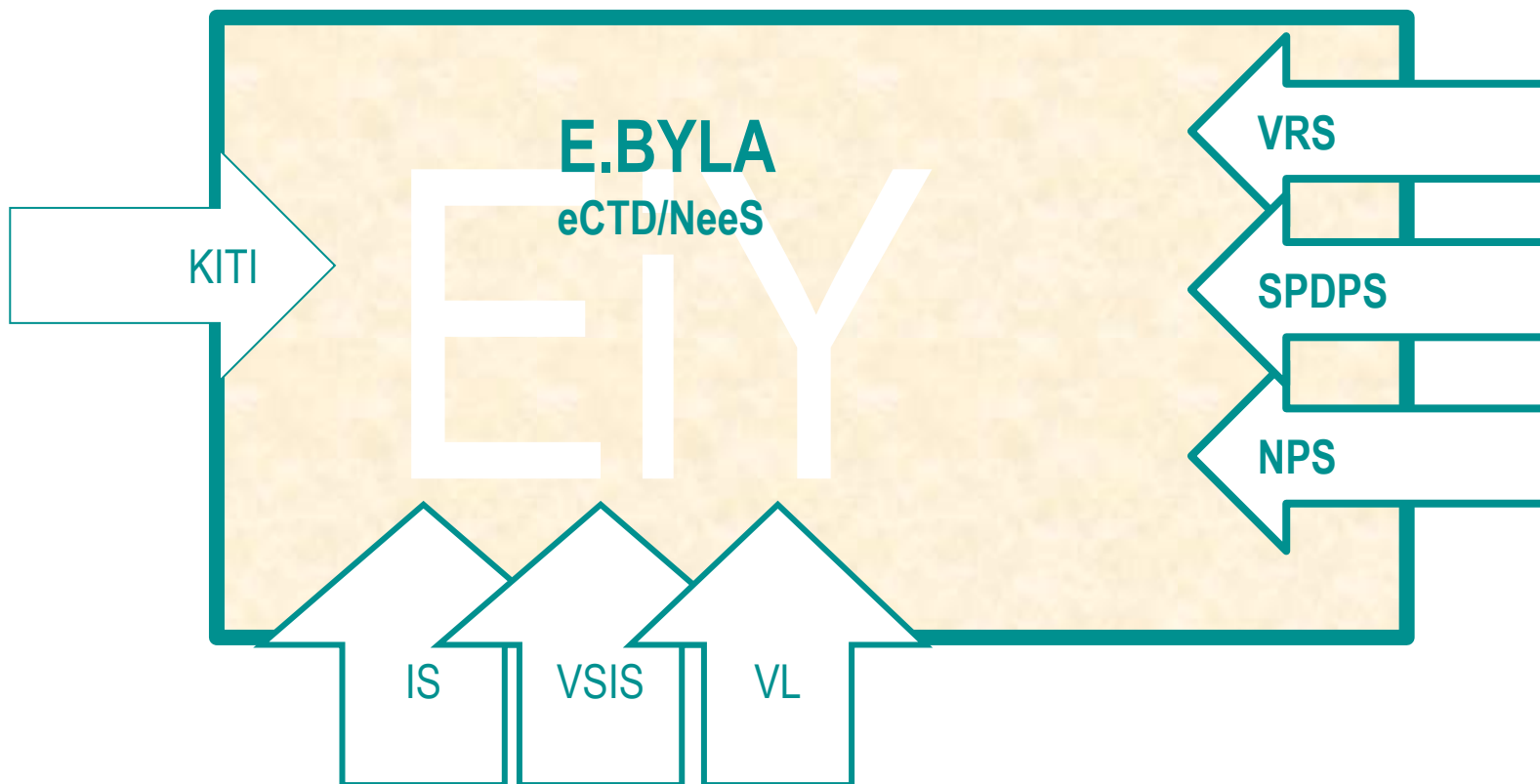
E. BYLŲ ADMINISTRATORIUS

2012 m. Vilnius

Bylų pateikimas

2010 11 16

Priimama	2011	2012	2013	2014 →
eCTD / NeeS * Numatomas pereinamasis laikotarpis , kai dar bus galima pateikti popierines bylas				
Tik eCTD / NeeS				
Tik eCTD? su elektronine paraiškos forma? / e-parašas?				



VVKT

SAM projektas “Europos farmacijos teisyno (politikos) poveikis vaistų prieinamumui Lietuvos gyventojams”

- EURS is Yours (EiY)
- PS/SERVERIAI
- VAIZDUOKLIAI
- *Acrobat Professional*
- Specialistų (ekspertų) parengimas

APIE KĄ

- E.bylos VP rinkodaros teisei suteikti/atnaujinti ; registruoti/perregistruoti (MRP/DCP/RUP/NP)
- E.bylos įteisinti VP rinkodaros teisės/registracijos pažymėjimų sąlygų reglamentinius keitimus ir keitimus, nepriskiriamus reglamentiniams keitimams (MRP/DCP/RUP/NP)
- Šiek tiek statistikos
- **PROBLEAMOS**

SRAUTAI

Paraiškos rinkodaros teisei suteikti/registruoti
(MRP/DCP/RUPNP)

Paraiškos rinkodaros teisei atnaujinti/perregistruoti
(MRP/DCP/RUP/NP)

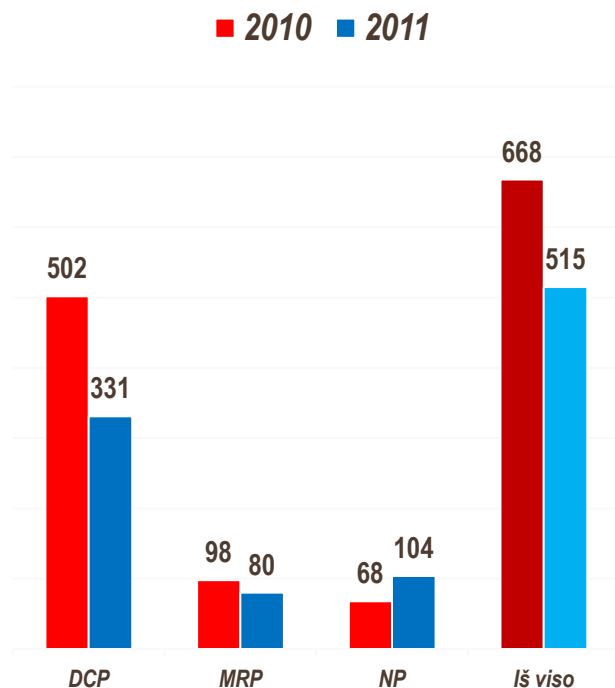
Paraiškos rinkodaros pažymėjimo sąlygoms pakeisti
(NP; reglamentiniai keitimai)

Paraiškos rinkodaros pažymėjimo sąlygoms pakeisti
(MRP/DC/RUP; reglamentiniai keitimai)

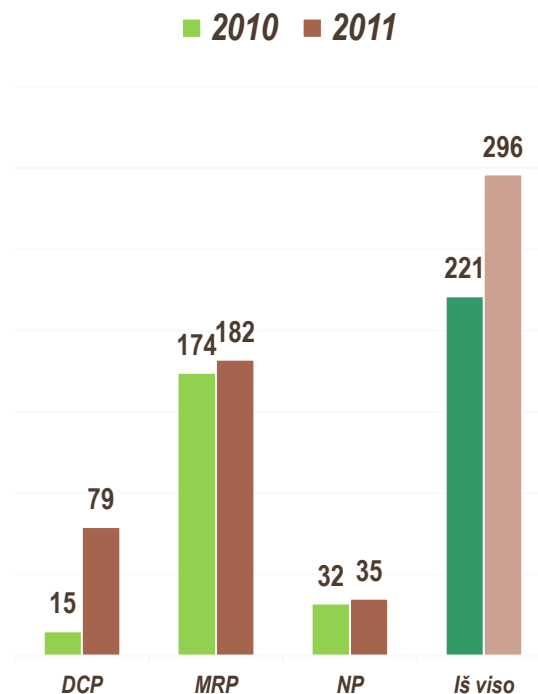
Paraiškos rinkodaros pažymėjimo sąlygoms pakeisti
(keitimai, nepriskiriami reglamentiniams keitimams)

GAUTOS REGISTRACIJOS/PERREGISTRACIJOS PARAIŠKOS 2010-2011 m.

REGISTRACIJA

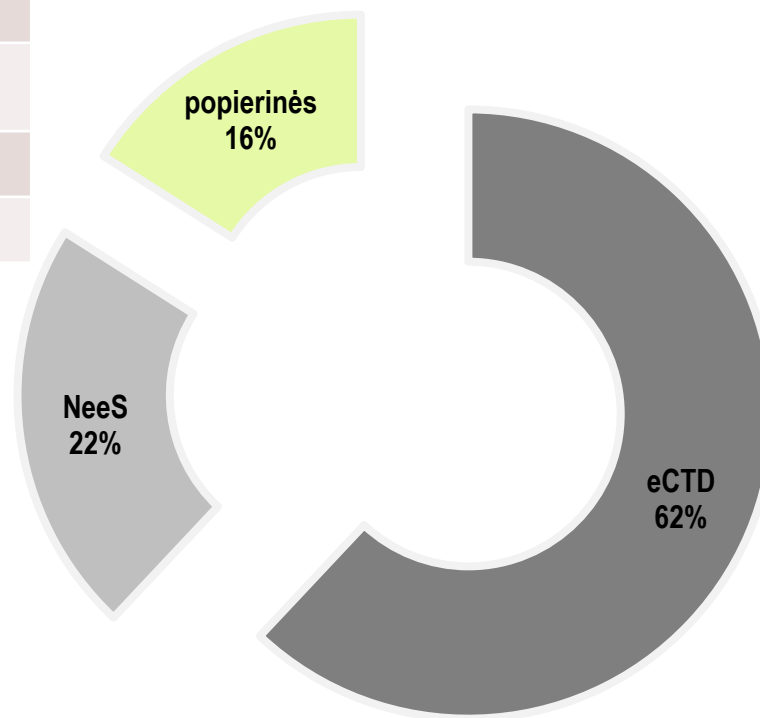


PERREGISTRACIJA

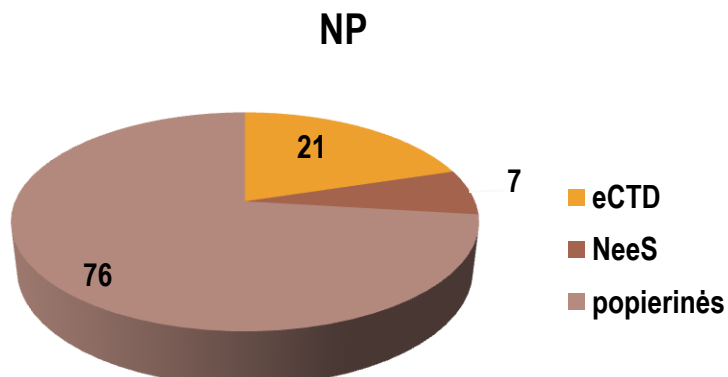
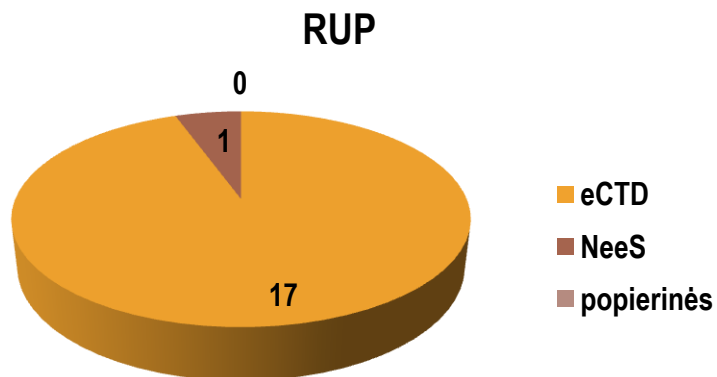
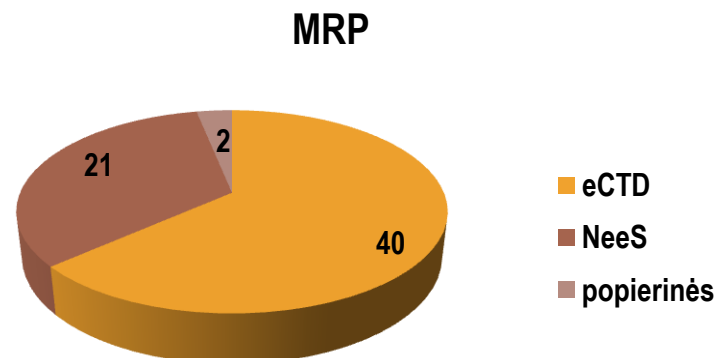
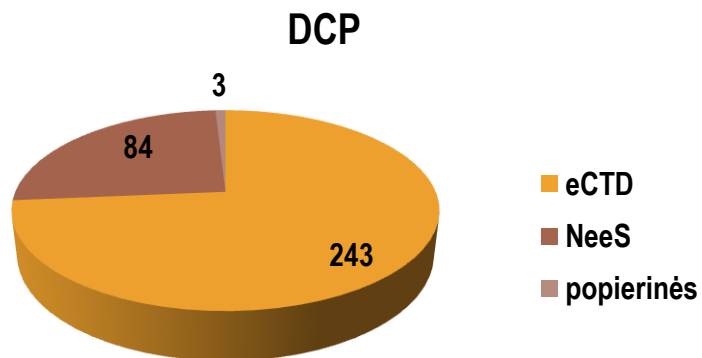


2011m. REGISTRACIJA (1)

	eCTD	NeeS	popierinēs	Iš viso
<i>DCP</i>	243	84	3	330
<i>MRP</i>	40	21	2	63
<i>RUP</i>	17	1	0	18
<i>NP</i>	21	7	76	104
	321	113	81	515

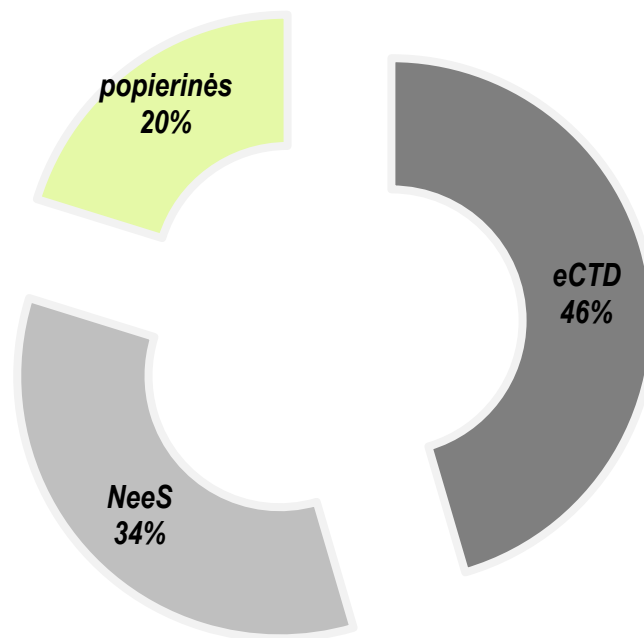


2011m. REGISTRACIJA (2)



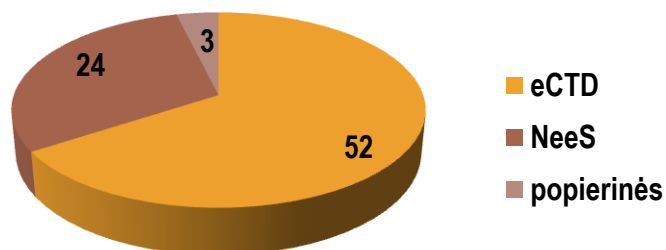
2011m. PERREGISTRACIJA (1)

	eCTD	NeeS	popierinēs	Iš viso
<i>DCP</i>	52	24	3	79
<i>MRP</i>	73	72	33	178
<i>RUP</i>	3	1	0	4
<i>NP</i>	7	3	25	35
	135	100	61	296

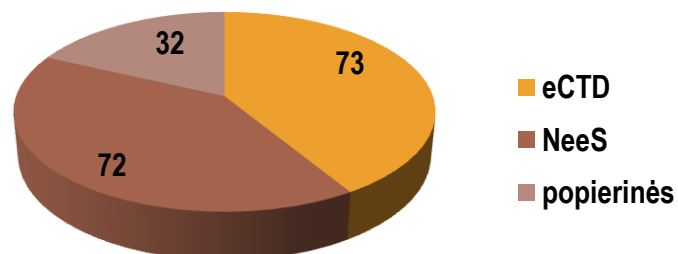


2011 m. PERREGISTRACIJA (2)

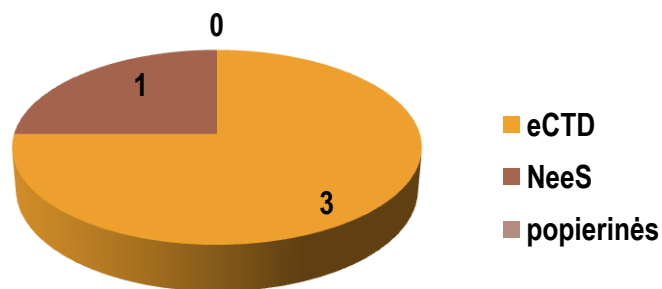
DCP



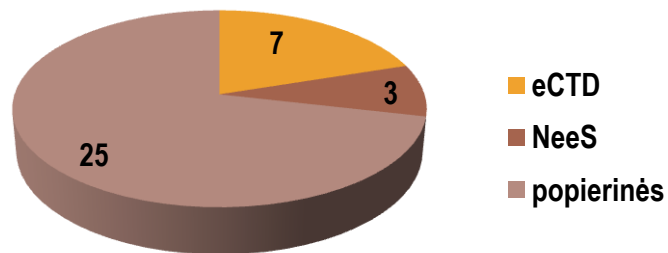
MRP



RUP

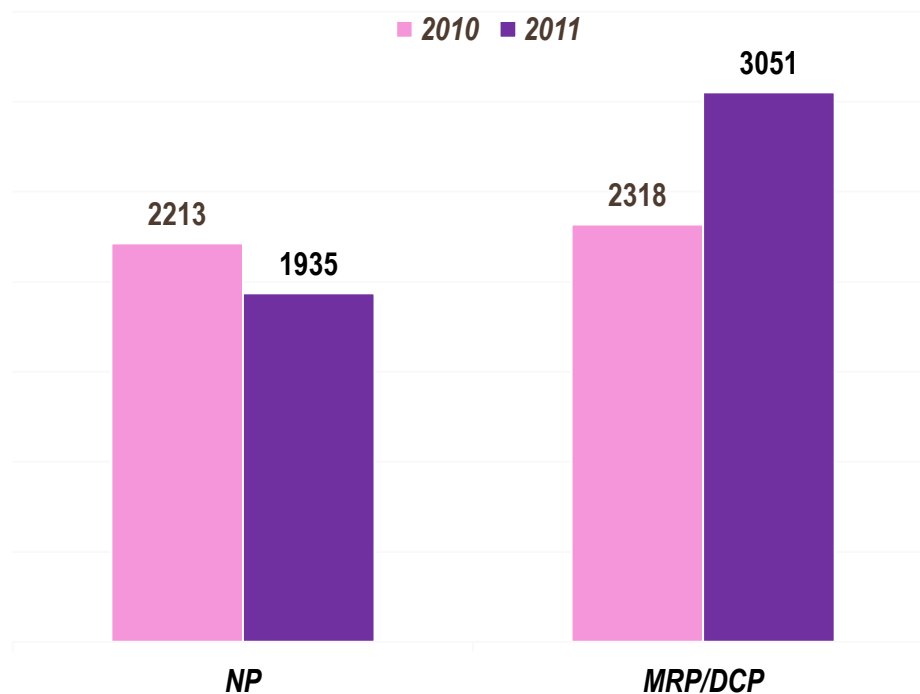


NP



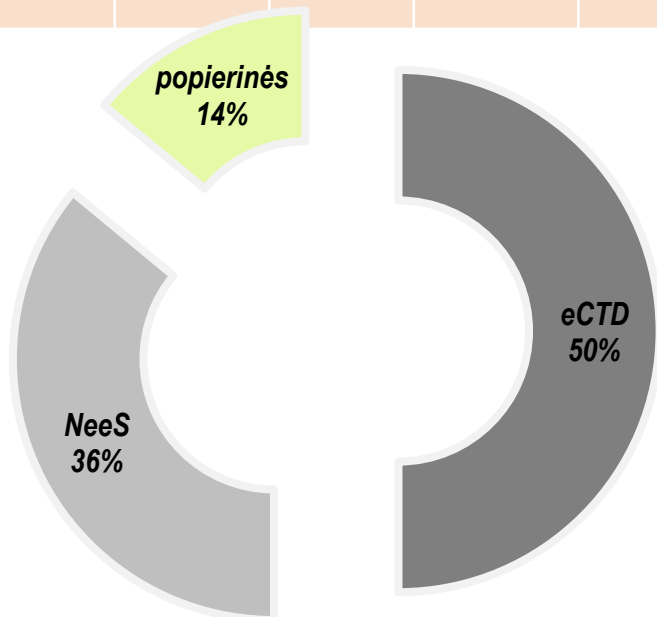
GAUTOS REGLAMENTINIŲ KEITIMŲ PARAIŠKOS 2010-2011 m.

Reglamentiniai keitimai

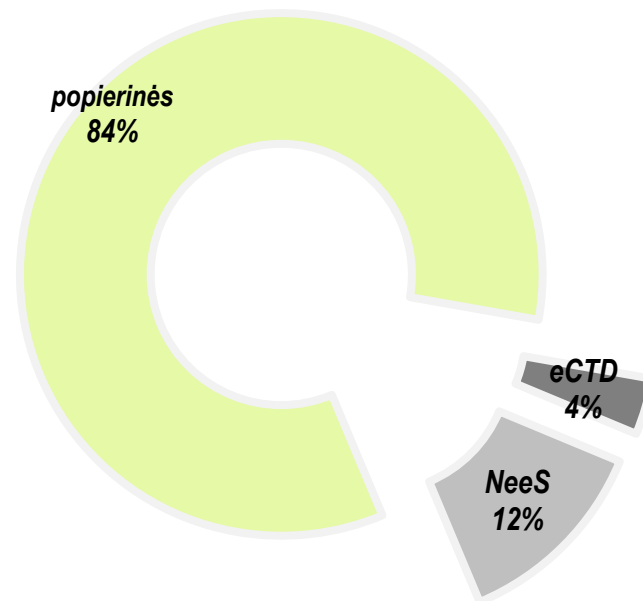


2011 m. REGLAMENTINIAI KEITIMAI /KEITIMAI

	eCTD	NeeS	popierinės	Iš viso
DCP	808	521	209	1538
MRP	715	560	231	1506
RUP/mix	3	4	0	7
	1526	1085	440	3051

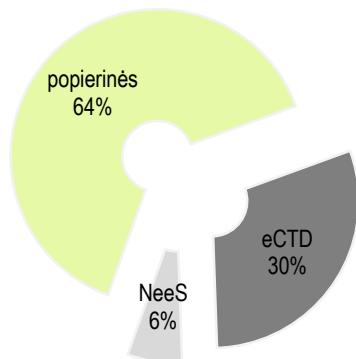


	eCTD	NeeS	popierinės	Iš viso
KNPŽ	3	4	303	310
NP	68	241	1626	1935

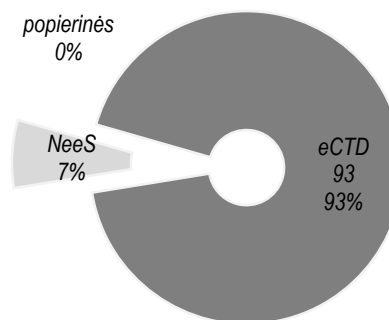


2012 m. gautos paraiškos (1)

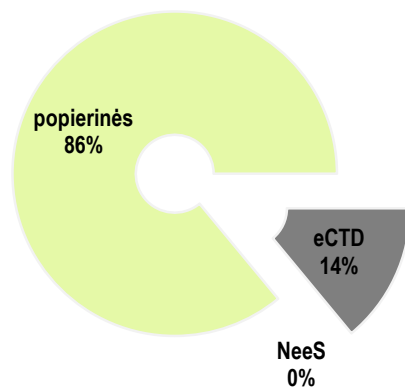
NP REGISTRACIJA



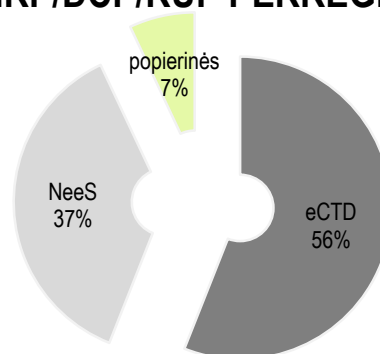
MRP/DCP/RUP REGISTRACIJA



NP PERREGISTRACIJA

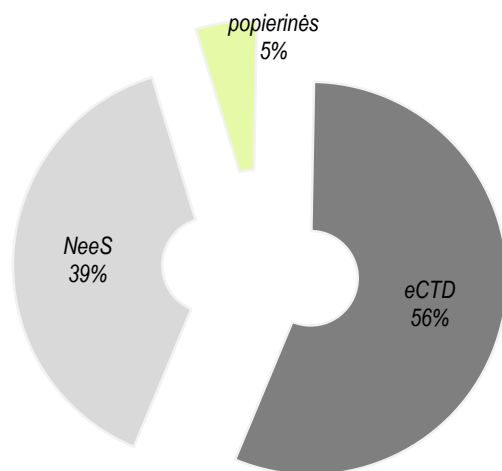


MRP/DCP/RUP PERREGISTRACIJA

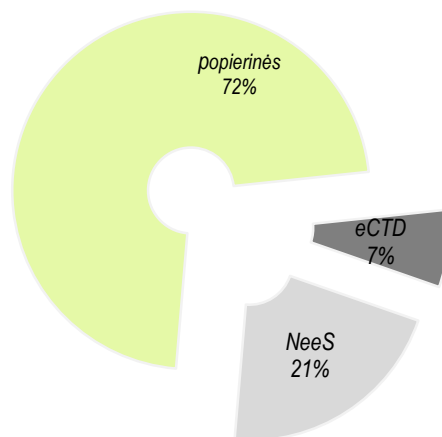


2012 m. gautos paraiškos (2)

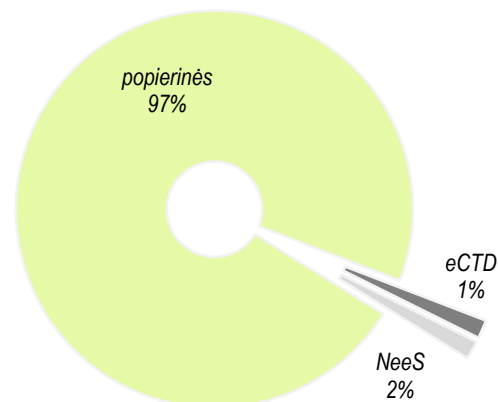
MRP/DCP KEITIMAI



NP KEITIMAI



KNPŽ

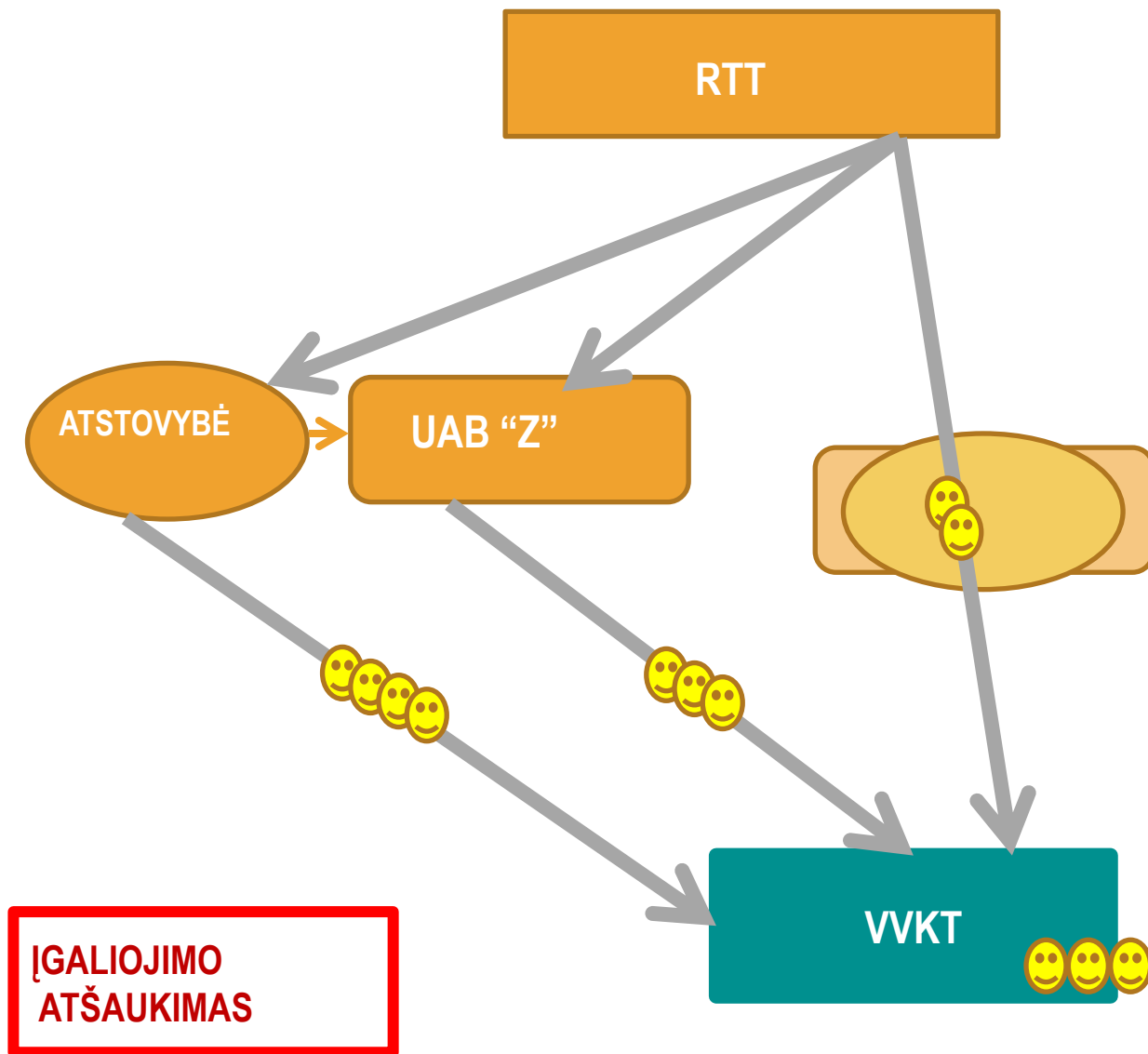


Pagrindiniai europiniai dokumentai

- ☐ **TIGes Harmonised Guidance for eCTD Submissions in the EU (2011)**
- ☐ **TIGes Harmonised Guidance for Non-eCTD electronic Submissions (NeeS) for human medicinal products in the EU (2011)**
- ☐ **CMDh Best Practice Guide on the use of the Electronic Common Technical Document (eCTD) in the Mutual Recognition and Decentralised Procedures (2011)**
- ☐ **Requirements on Electronic submissions (NeeS and eCTD) and paper documentation for New Applications within MRP, DCP or National procedures (2011)**
- ☐ **Requirements on Electronic submissions (NeeS and eCTD) and paper documentation for Variations and Renewals within MRP or National procedures (2011)**
- ☐ **Technical validation of eCTD submissions for new MAAs in DCP .Start of pilot phase (voluntary) (2012)**



ĮGALIOJIMAI



Nacionaliniai reikalavimai (1)

10. Dokumentai turi būti parengti lietuvių arba anglų kalba bei pateikti kaip elektroninė (eCTD arba NeeS formatu) arba neelektroninė (1–2 moduliai susegti į bylą kietu viršeliu ir 1–5 moduliai – CD arba DVD; preparato charakteristikų santraukos, rinkodaros sąlygų, pakuotės ženklinimo tekstų ir pakuotės lapelio (jei yra) projektai 1 modulyje turi būti įrašyti redaguojamu formatu, o vidinės ir išorinės pakuočių išklotinės turi būti spalvotos) vaistinio preparato rinkodaros teisės suteikimo byla. **Paraiška, lydraštis, įgaliojimas atstovauti pareiškėjui, jeigu pateikiamas, dokumento, patvirtinančio, kad sumokėta nustatyto dydžio valstybės rinkliava, kopija visais atvejais turi būti popieriniai ir pasirašyti pareiškėjo ar jo įgalioto asmens.**

(Žin., 2011, Nr. 30-1402)



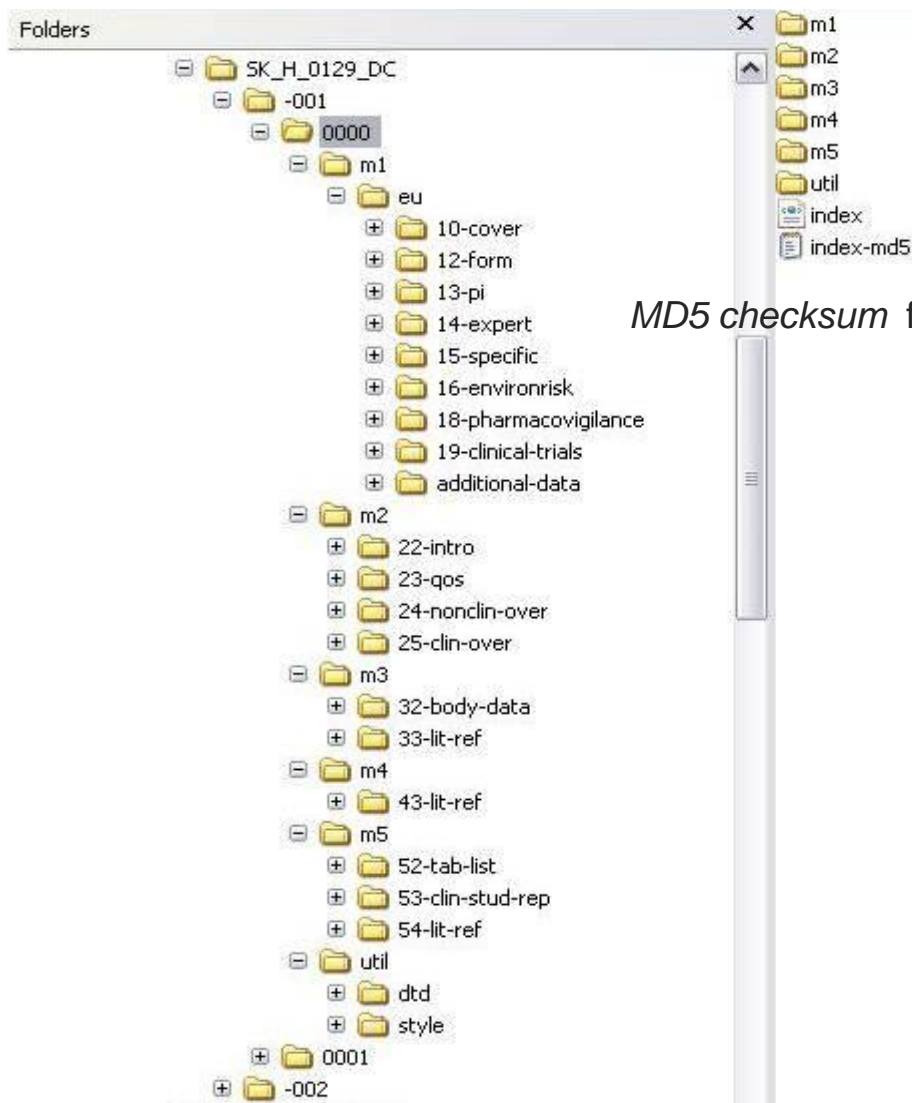
Nacionaliniai reikalavimai (2)

Kartu su e.byla privalo būti pateikta:

- lydraštis (*cover letter*), originaliai pasirašytas;
- užpildyta paraiška (*application form*), identiška pateiktai e-byloje ir originaliai pasirašyta;
- valstybės rinkliavos sumokėjimą patvirtinančio dokumento kopija (*proof of payment*), patvirtinta originaliu parašu ir mokėtojo arba įgalioto juridinio asmens spaudu. Tais atvejais, kai vienu metu buvo sumokėta už daugiau paraiškų, pridedamas išsamus paaiškinimas.
- originaliai pasirašytas įgaliojimas atstovauti pareiškėją (rinkodaros teisės turėtoją);
- *techninio validavimo ataskaita, nurodant validavimo datą, laiką ir naudotą validavimo įrankį.*



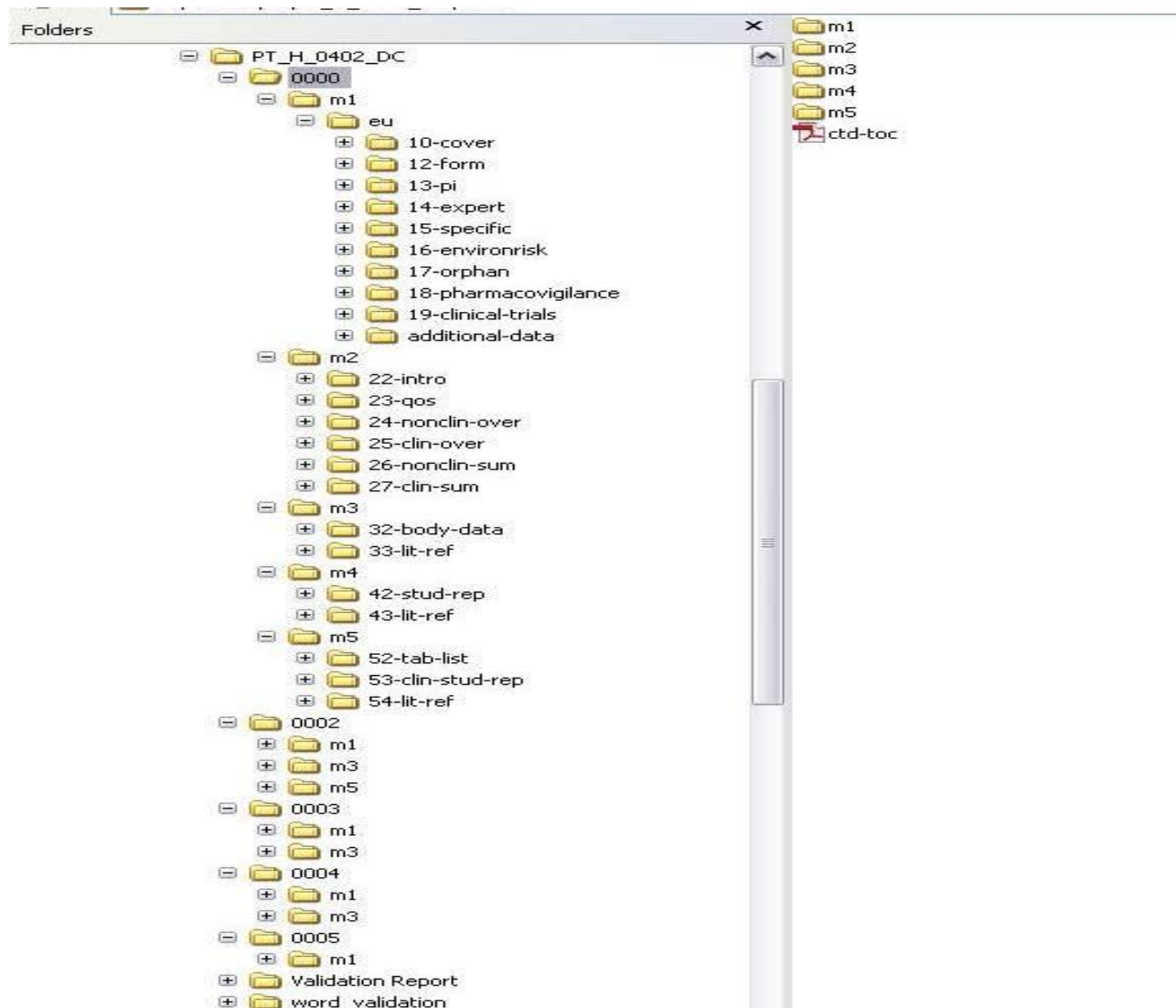
eCTD



MD5 checksum fdb89749290812cf1c6db8b8e2c8f45d



NeeS



<Applicant> <Address>
<Post code> <Town> <Country>

<Date>
<Reference>

<National Agency>
<Address>
<Address>
<Post code> <Town>
<Country>

Subject: Submission of Application Dossier(s) for Marketing Authorisation of <Product Name(s) in the MS where the application is submitted> <Full Procedure Number(s)>

Dear Sirs,

We are pleased to submit our Application Dossier(s) for a <Mutual Recognition> / <Decentralised> Procedure which details are as follows:

Name of the medicinal product(s) (in the RMS):

Pharmaceutical form(s) and strength(s):

INN/active substance(s): ATC Code(s):

Legal Basis of the Application(s):

When appropriate, please indicate:

- | | |
|---|--|
| - Use of European Reference Medicinal Product | |
| - If the strength(s) of the Reference MP differs between RMS/CMS | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| - If the pharmaceutical form(s) of the Reference MP differs between RMS/CMS | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| - If the indication(s) of the Reference MP differs between RMS/CMS | <input type="checkbox"/> Yes <input type="checkbox"/> No |

You will find enclosed the submission dossier as specified hereafter:

- ☐ eCTD format
Sequence number: <Four digit number>
☐ Nees format
Sequence number (if used): <Four digit number>

<Number> media units per application and <number> copies are provided.

☐ We confirm that all future submissions for this specific product will be submitted in this same format (Nees format may be upgraded to eCTD later).

☐ The <eCTD>/<Nees> has passed the applicant's internal technical validation (all P/F criteria passed and all BP criteria have been fulfilled up to our best knowledge) using <name and version number of the validation software>

☐ We confirm that the electronic submission has been checked with an up-to-date and state-of-the-art virus checker.

☐ The dossier is submitted in paper format (Note: Full paper dossiers can only be submitted to NCAs still accepting paper submissions and should only be used exceptionally when a valid electronic format dossier really could not be provided.)

☐ An identical electronic copy of the paper dossier is also provided

Number of paper binders provided:

- Module 1: <xx> enclosures
- Module 2: <xx> enclosures
- Module 3: <xx> enclosures
- Module 4: <xx> enclosures
- Module 5: <xx> enclosures

☐ Different formats (eCTD, Nees, other electronic or paper) are submitted to different RMS/CMS (specify differences to different NSAs in text below): (This is not recommended and do require an explanation if needed.)
<Text field>

<- Multiple duplicate applications are submitted.>¹

<- A transfer of ownership (MAH) for the medicinal product is to take place in the national step after finalisation of the procedure.>²

<- The relevant fees have been paid.>

<Free text field – when appropriate and if important for the validation of the application(s) additional information can be provided e.g. location of Notes to Reviewers, National file number if provided before submission etc.>

☐ We, <Applicant>, hereby certify that the dossier submitted to the RMS and CMS(s) are fully identical.

☐ There are, however, some different national documents <cover letter><application form><specific national requirements> that are submitted to the relevant RMS/CMS only, outside the eCTD/Nees dossier

☐ There are, however, some different national documents <cover letter><application form><specific national requirements> that are submitted to the relevant RMS/CMS only, within the eCTD/Nees dossier

Yours sincerely,

<Signature>
<Name>
<Title>
<phone number>
<Email address>
<Email address for technical validation issues>

¹ When duplicates are not submitted simultaneously, a reference to the first application should be given.

² Confirmation that transfer during that step is possible, to be obtained from MSs concerned.

Versijų pateikimo lentelė

Sequence/submission tracking table (STT)

eCTD

- **3.2.3.2 Tracking Table**

A tracking table should **always** be included as an annex to the cover letter for MRP and DCP. This is also highly recommended for CP and NP.

NeeS

- **2.4.2 Submission numbering**

The folder in which ctd-toc.pdf is placed should be named with a four digit number. This number is not required to be unique or sequential for the NeeS submission. However, it is recommended that a sequential number system is used where possible and if so, a tracking table **would be helpful**

[...]

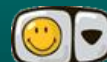
- **3.1 Module 1.0 Cover Letter and Tracking Table**

A cover letter should always be provided. Please see also the CMDh website for requirements of signed paper copies of the cover letter and application form to each NCA.

If a sequential numbering system is used, a tracking table **would be helpful**.



Sequence	Submission Description	Date	QDA/Task 1										QDA/Task 2										QDA/Task 3									
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
0021	Variation XX/H/1111/001/IA/027/G	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0020	XX/H/1111/001/II/017 and XX/H/1111/001/II/024 - Final update of eCTD	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0019	Additional documentation according to LoC dated 14.06.2010	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0018	XX/H/1111/001/II/026 - Increase in infusion speed and single dose	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0017	XX/H/1111/001/II/022 - Final update of eCTD	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0016	XX/H/1111/001/II/023 - Response to PVAN	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0015	XX/H/1111/001/II/017 - Additional documentation according to LoC	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0014	XX/H/1111/001/II/022 - Response to PVAN	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0013	XX/H/1111/001/IA/027/G - PMU 2nd step procedure	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0012	XX/H/1111/001/II/024 - Introduction of bulk pooling and further minor MOP changes at Octapharma Lingolsheim	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0011	XX/H/1111/001/II/023 - Final of additional freeze-drying at Octapharma Vienna	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0010	XX/H/1111/001/II/023 - Renunciation of SPC, PIL and labelling after repeat use (SIR)	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0009	XX/H/1111/001/II/021 - Response to RSI	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0008	XX/H/1111/001/II/017 - Response to RSI	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0007	XX/H/1111/001/II/021 - Introduction of new biophilisation stoppers and new lys-cycle at Octapharma Vienna	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0006	XX/H/1111/001/IA/020 - Octapharma GmbH subsidiary: Detrau as additional secondary packager	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0005	XX/H/1111/001/II/019 - Establishment of a maximum process time limit and definition of the maximum valid membrane pressure for nanofiltration	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0004	XX/H/1111/001/II/018 - Adapted limits for Protein C and S in Final Product Specification	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0003	XX/H/1111/001/II/017 - Introduction of the testing methods 1H NMR and CE for the excipient Heparin Sodium to comply with Ph. Eur.	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0002	Consolidated dossier after finalization of XX/H/1111/001/E/002	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0001	Response to day 50 questions XX/H/1111/001/E/002	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	
0000	Initial MAA XX/H/1111/001/E/002	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	



PAIEŠKA

A2-2 Documents that must always be text searchable

(i.e. the PDF should be produced wherever possible from a text source, such as MS Word, but if sourced from a scanned original then they **must be OCR'd.**)

- **Key administrative documents in Module 1 including, the cover letter, application form, product information documents**

- o Applicants are reminded that some NCAs regard logging in through a portal as sufficient to establish a users identity and do not require handwritten signatures on Cover Letters and Application Forms submitted this way.

- **Any document in Module 2 (QOS, Preclinical Overview and Summaries, Clinical Overview and Summaries).**

- **The main body of text and main tables in any preclinical or clinical report required to support the main claim of the application.**

- **The main body of text in any reports, methods, analytical procedures, etc. supplied in Module 3**

- **The main body of text of Periodic Safety Update Reports (PSURs)**

- **The main body of text of Risk Management Plans**

- **The main body of text of Environmental Risk Assessment**

- **Any English translation of a document originally written in a foreign language (see also below)**



TECHNINĖ VALIDACIJA

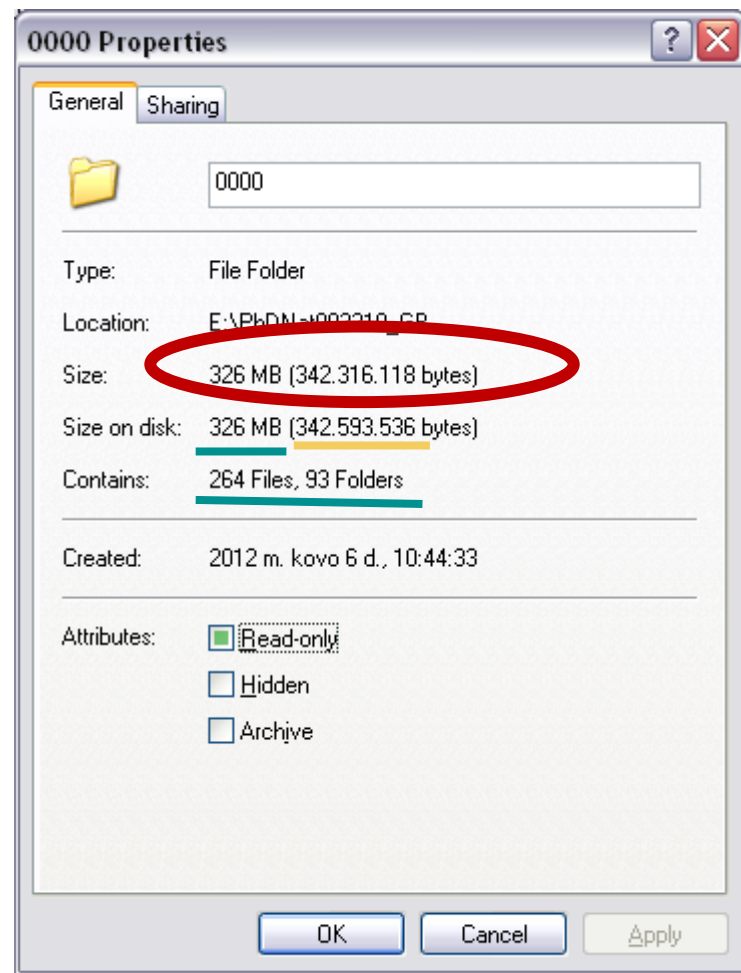
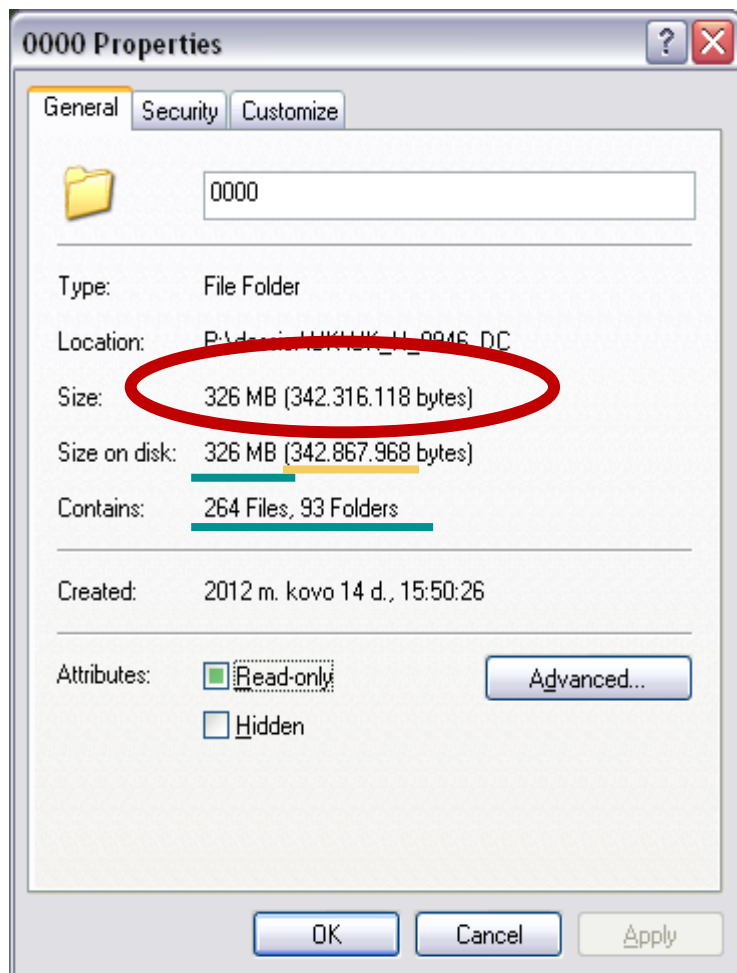
- Techninė validacija bet kuriuo tinkamu validatoriumi (*Lorenz, BfArm, **EURS*** ir kt.)
- Patikra įrašius į CD/DVD
- Tarnybai teikiamos tik versijos, praėjusios TV

Validation Comp. / Lib. Version:	1.0.20 / 1.2.20.25
Check Result:	Valid


- Spausdinti/ įrašyti į CD/DVD



TECHNINĖ VALIDACIJA (2)



TECHNINĖ VALIDACIJA (3)

EURSvalidator		
	Responsible:	Date/Sign:
	00068364	23 February 2012
Submission folder:	[REDACTED]	
Validation Set:	EU-eCTD v3.1 (DTD 1.4) eCTD 3.2 with EU M 1.4 regional part Version: EU validation criteria for EU M 1.4 release 3.1	
Validation Comp. / Lib. Version:	1.0.22 / 1.2.20.25	
Check Result:	Valid	

Submission Information:

Sequence number	0001
Procedure type	national
Invented name	[REDACTED]
Tracking number(s)	lt-400051-LT

Summary:

Total files	19
Valid files	19
Valid files with minor issues	0
Invalid files	0
Skipped files	0
Validation Start	23 February 2012, 09:13:50
Validation End	23 February 2012, 09:15:29

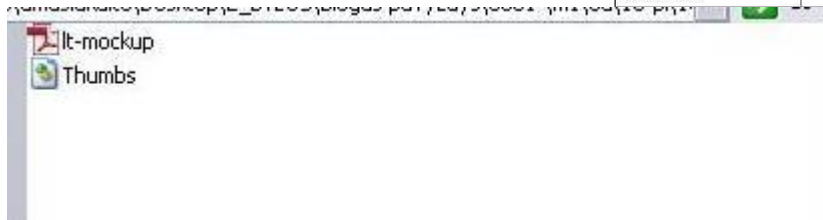
EURSvalidator		
	Responsible:	Date/Sign:
	amasiukaite	12 April 2012
Submission folder:	[REDACTED]	
Validation Set:	EU-eCTD v3.1 (DTD 1.4) eCTD 3.2 with EU M 1.4 regional part Version: EU validation criteria for EU M 1.4 release 3.1	
Validation Comp. / Lib. Version:	1.0.22 / 1.2.20.25	
Check Result:	Invalid	

Submission Information:

Sequence number	0001
Procedure type	national
Invented name	[REDACTED]
Tracking number(s)	lt-400051-LT

Summary:

Total files	20
Valid files	17
Valid files with minor issues	0
Invalid files	3
Skipped files	0
Validation Start	12 April 2012, 09:11:41
Validation End	12 April 2012, 09:11:43



FORMATO PAKEITIMAS (1)

- Iš popierinės bylos → NeeS / eCTD
- Iš popierinės bylos / NeeS → eCTD

*“[...] Changing format from paper or NeeS to eCTD can be done at a start of any **regulatory activity** such as an **extension**, a **renewal** or a **variation**, ideally when no other regulatory activities are ongoing for that product in another format. **A baseline submission is recommended at the time of changing to eCTD [...]**”*

[...]

“[...] When an applicant wants to switch from paper /NeeS to eCTD in a specific CMS and has already an up to date eCTD used elsewhere in the procedure for other countries, on agreement with the RMS, the lifecycle should continue and earlier sequences should be provided to the RMS and all CMSs. However, the “old” sequences should in these cases not be technically validated by this CMS, but accepted as they are [...]”

- Baseline /Consolidated dossier

“[...] A baseline submission is a compiled submission of the current status of the dossier, i.e. resubmission of currently valid documents that have already been provided to an agency but in another format. [...]



FORMATO PAKEITIMAS (2)

Dear Sirs,

We are pleased to submit our Dossier(s) for a Decentralised Procedure which has been reformatted from the paper version to eCTD format.

We would like to note that this is the baseline eCTD (sequence 0000) and the content of the current dossier has not been changed, only the format.

We, [REDACTED], finally hereby certify that the dossiers submitted to the RMS and CMS(s) are identical.

Dear Madam/Sir,

We are pleased to submit a Baseline submission for [REDACTED]

Please note that due to technical reasons and because of the replacement of our software we had to reformat the existing submission. The enclosed e-CTD Baseline submission, sequence 0000, contains no content change (includes all approved documentation up to now) and therefore there is no need to be subject to review.

We kindly ask you to handle the enclosed e-CTD Baseline submission, sequence 0000, as a new submission which will replace all the previous sequences [REDACTED]

We, [REDACTED] hereby certify that the Baseline submission is submitted to RMS and all CMS simultaneously.

In case you need any further information, please do not hesitate to contact us.



FORMATO PAKEITIMAS (3)

Subject: Submission of consolidated dossier (eCTD baseline sequ. 0000) for

[Redacted]

Dear Madam or Sir,

On behalf of the Marketing Authorisation Holder [Redacted] (see letter of authorisation), we submit the consolidated dossier in eCTD format (baseline sequ. 0000) resulting after the finalisation of the Decentralised Procedure which details are as follows:

Applicant:

[Redacted]

Name of the medicinal product(s) (in the RMS):

[Redacted]

Pharmaceutical form(s) and strength(s):

[Redacted]

INN/active substance:

[Redacted]

All amendments and updates made to the dossier during the DC procedure and all responses to questions are included in the consolidated eCTD dossier.

In parallel, an application for variation is submitted with the baseline sequence. The respective sequence 0001 is submitted in the same package. We certify that the dossiers submitted to the RMS and the CMSs are identical.



Kitos problemos (1₁)

Keli stiprumai/skirtingos farmacinės formos



Kitos problemas (1₂)

Keli stiprumai/skirtingos farmacinės formos

The screenshot displays a software interface with a file tree on the left and a detailed view on the right. The file tree on the left shows a folder 'EE_H_0162_DC' with subfolders '-001', '-002', '-003', and '-004', each containing '0000', '0001', '0002', '0003', and '0004'. The folder '-001' is circled in red. The detailed view on the right shows the contents of the selected folder, with the folder name 'EE/H/0162/001/DC' circled in red. The contents include 'MAA, LT/1/12/2854/, Authorised' and a list of items: '0000, INITIAL', '0001, UPDATE', '0002, D106', '0003, D160', and '0004, D180'. The items '0002, D106' and '0004, D180' are circled in red.



Kitos problemas (2₁)

Vaizdas CD/EiY

DC\0000\m1\eu\12-form\common

- common-form-1
- common-form-2
- common-form-3
- common-form-cep
- common-form-flowchart
- common-form-gmpdishman
- common-form-gmpgepharmaceutical
- common-form-gmpmega
- common-form-gmpstatement
- common-form-listofmockups
- common-form-listofnames
- common-form-mlgepharmaceutical
- common-form-mlmega
- common-form-poa
- common-form-poe
- common-form-pop
- common-form-popbg
- common-form-popee
- common-form-popit
- common-form-popro
- common-form-popsk
- common-form-qppv
- common-form-tsea
- common-form-tseb

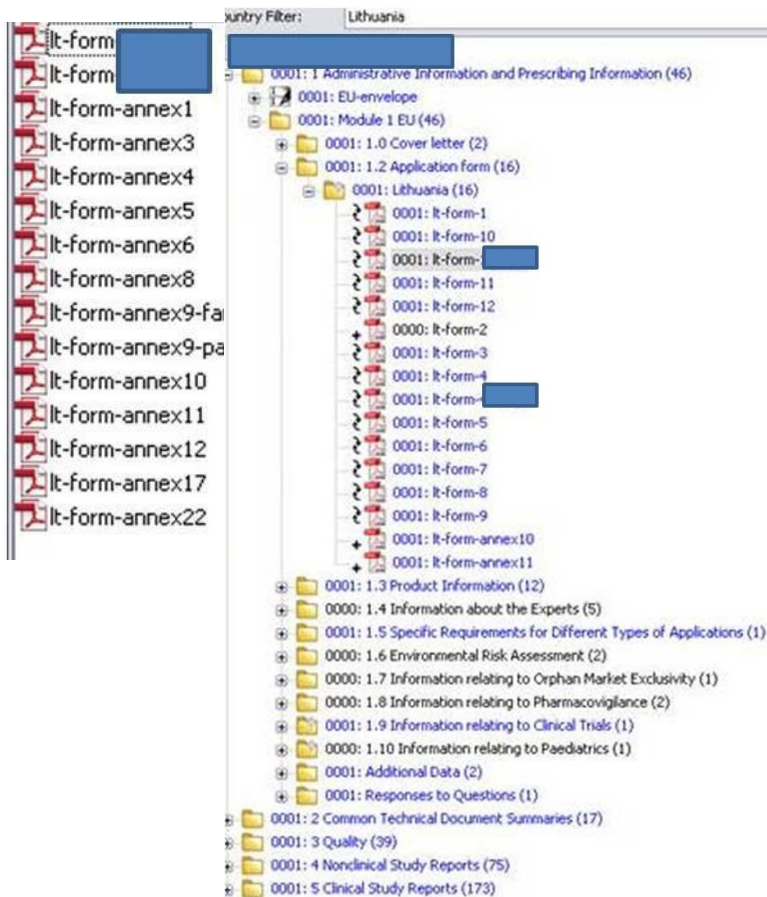
0000: Common (24)

- + 0000: m1-2-10-cep
- + 0000: m1-2-12-tse-cep-a-r1-cep-2001-424-rev-01
- + 0000: m1-2-12-tse-cep-b-r1-cep-2003-172-rev-00
- + 0000: m1-2-17-list-of-mock-ups-samples-specimen
- + 0000: m1-2-19-list-of-names
- + 0000: m1-2-1-pop
- + 0000: m1-2-1-pop-bg
- + 0000: m1-2-1-pop-ee
- + 0000: m1-2-1-pop-lt
- + 0000: m1-2-1-pop-ro
- + 0000: m1-2-1-pop-sk
- + 0000: m1-2-22-gmp-statement
- + 0000: m1-2-3-poe
- + 0000: m1-2-4-poa
- + 0000: m1-2-5-cv-qppv
- + 0000: m1-2-6-manufacturing-authorisation-a-ge-pharmaceutical
- + 0000: m1-2-6-manufacturing-authorisation-b-mega
- + 0000: m1-2-8-flow-chart
- + 0000: m1-2-9-gmp-certificate-a-ge-pharmaceutical
- + 0000: m1-2-9-gmp-certificate-b-mega
- + 0000: m1-2-9-gmp-certificate-c-dishman
- + 0000: m1-2-application-form-0-25-mcg
- + 0000: m1-2-application-form-0-50-mcg
- + 0000: m1-2-application-form-1-mcg



Kitos problemas (2₂)

Vaizdas CD/EiY



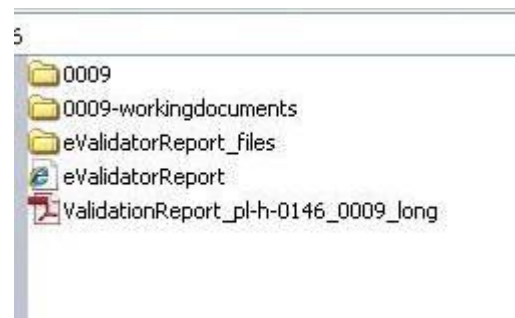
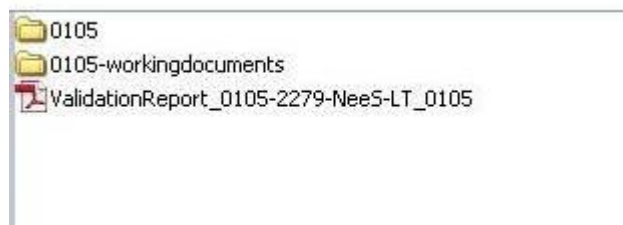
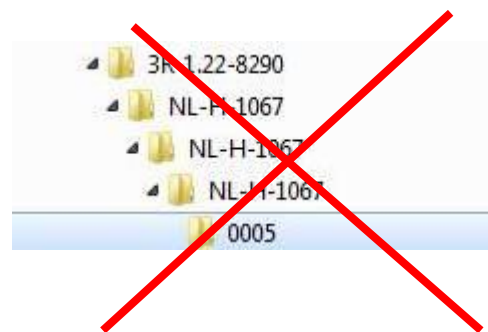
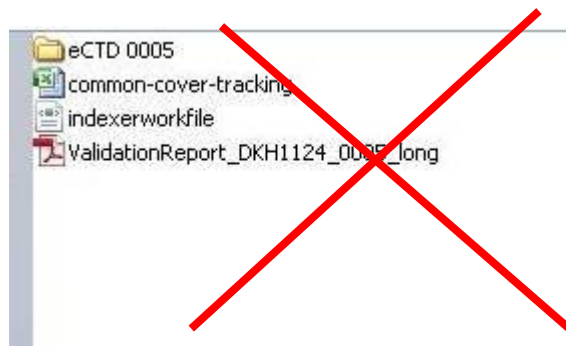
5. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

- ☒ 5.1 Proof of payment
- ☐ 5.2 Informed consent letter of marketing authorisation holder of authorised medicinal product.
- ☒ 5.3 Proof of establishment of the applicant in the EEA.
- ☒ 5.4 Letter of authorisation for communication on behalf of the applicant/MAH.
- ☒ 5.5 Curriculum Vitae of the Qualified Person for Pharmacovigilance.
- ☒ 5.6 Manufacturing Authorisation required under Article 40 of Directive 2001/83/EC (or equivalent, outside of the EEA where MRA or other Community arrangements apply); any proof of authorisation in accordance with Article 8(k) of Directive 2001/83/EC.
- ☐ 5.7 Copy of the 'Qualification of SME Status'.
- ☒ 5.8 Flow-chart indicating all manufacturing and control sites involved in the manufacturing process of the medicinal product and the active substance.
- ☒ 5.9 GMP certificate(s) or other GMP statement(s); Where applicable a summary of other GMP inspections performed.
- ☒ 5.10 Letter(s) of access to Active Substance Master File(s) or copy of Ph. Eur. Certificate(s) of Suitability.
- ☒ 5.11 Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I of Directive 2001/83/EC.
- ☒ 5.12 Ph. Eur. Certificate(s) of suitability for TSE.
- ☐ 5.13 Written consent(s) of the competent authorities regarding GMO release in the environment.
- ☐ 5.14 Scientific Advice given by CHMP and/or by member state(s).
- ☐ 5.15 Copy of Marketing Authorization(s) required under Article 8(j)-(L) of Directive 2001/83/EC in the EEA and the equivalent in third countries on request (a photocopy of the pages which give the marketing authorization number, the date of authorisation and the page which has been signed by the authorizing competent authority will suffice).
- ☐ 5.16 Correspondence with European Commission regarding multiple applications.
- ☒ 5.17 List of Mock-ups or Samples/specimens sent with the application, as appropriate (see Notice to Applicants, volume 2A, chapter 7).
- ☐ 5.18 Copy of the Orphan Designation Decision.
- ☐ 5.19 List of proposed (invented) names and marketing authorisation holders in the concerned member states.
- ☐ 5.20 Copy of EMEA certificate for a Vaccine Antigen Master File (VAMF).
- ☐ 5.21 Copy of EMEA certificate for a Plasma Master File (PMF).
- ☒ 5.22 For each active substance, attach a declaration(s) from the Qualified Person of the manufacturing authorisation holder in Section 2.5.1 and from the Qualified Person of each of the manufacturing authorisation holders (i.e. located in EEA) listed in Section 2.5.2 where the active substance is used as a starting material that the active substance is manufactured in compliance with the detailed guidelines on good manufacturing practice for starting materials. Alternatively, such declaration may be signed by one Qualified Person on behalf of all QPs involved (provided this is clearly indicated).



Kitos problemas (3)

CD/DVD



Kitos problemos (4)

Elektroninė paraiška (e-AF)



Report from the CMDh meeting held on 12th, 13th and 14th March 2012

Electronic submissions – electronic application forms – Pilot phase

A four-month pilot of electronic application forms for submission of initial marketing authorisation applications, variations and renewals has been launched on **12 March 2012**. These forms can be used for **centralised procedures, mutual recognition or decentralised procedures**.

For further details, please refer to the press release published on the European Commission website: http://ec.europa.eu/health/documents/new_en.htm.

Applicants/MAHs willing to participate to this pilot are invited to submit their applications according to the instructions given in the electronic application forms pilot guidance published on the EMA website under “eSubmission”: <http://esubmission.ema.europa.eu/eaf/>



AČIŲ UŽ DĖMESĮ

