

eCTD Implementation Survey Report

By the French Presidency of the EU - 2008

(Covering the period from July 2007 to June 2008)

Introduction

ICH-eCTD is an internationally driven standard designed to reduce cost in the administration, assessment and archiving of applications for marketing authorisation of medicinal products for human use, to reduce the use of paper and streamline the assessment process making the system more efficient.

At the February 2005 HMA meeting in Reykjavik HMA committed to a target of end of 2009 for the implementation of eCTD, meaning that the European Medicines Regulatory Network will be ready to accept “paperless”¹ applications for marketing authorisation in eCTD format by that date. NCA would therefore need to have the infrastructure, the processes and the legal framework in place to handle paperless applications in eCTD format efficiently.

The Telematics Implementation Group for Electronic Submission (TIGes) develops and updates the regional European Module 1 of the eCTD in line with the EU CTD guidance and both standards are published by the European Commission in the Notice to Applicants.

Unlike CTD the eCTD is not mandatory in Europe and progress in eCTD implementation has been slow.

NCA are progressively adapting their infrastructure, processes and legislation to be able to receive and handle paperless applications for marketing authorisation by 2009. Even though electronic support is extensively provided by applicants together with the legally required paper application in support of regulators for their assessment work, the switch of European industry to eCTD has been scarce.

The TIGes has elaborated an EU guidance aiming the harmonisation of existing electronic support of applications for marketing authorisation as a first step towards full eCTD implementation (the so called NeeS or Non-eCTD electronic submission guidance). This guidance is expected to further help the transition from paper to eCTD. Its main benefit is to streamline the structure of the application in line with CTD structure although the full benefit of eCTD is not achieved. The main difference between the NeeS guidance and the eCTD specification is the absence of the XML backbone that facilitates the management of the regulatory activity during the life cycle of a medicinal product.

The TIGes has also set up a subgroup to develop guidance for electronic application for marketing authorisation of medicinal products for veterinary use, acknowledging the different requirements of the smaller veterinary industry and the fact that veterinary CTD has not been developed at ICH level. A first guidance has been published and considering that the mandate of almost 2/3 of NCA covers both medicinal products for human and veterinary use it seems sensible that development in this field should progress in parallel. The veterinary sector joined the human sector in its commitment to be ready to accept paperless marketing authorisation applications by the end of 2009.

At the November 2007 HMA meeting in Madeira the TIGes presented an eCTD Roadmap for 2009 including a survey report showing statistics of the implementation of eCTD in the Europe.

¹ Paperless applications mean without paper except for documents where a signature is required. Since there is no digital signature standard in the EU yet signed documents may still be required in paper.

HMA asked the TIGes to conduct a regular follow up of eCTD implementation and to update the survey twice a year. The aim is to show comparative results over time in upcoming reports. The goal of the survey report is to summarise the current status of readiness of the European Medicines Regulatory Network and eCTD implementation to monitor progress towards the target of 2009. The survey report includes comparative results relevant to the human sector between the last and the previous survey.

The survey report will be updated every second HMA meeting of each EU Presidency as a follow up of progress in the implementation of eCTD.

Methodology

A questionnaire has been elaborated by the TIGes and circulated among all of its members (see Annex 1). The HMA were informed and asked for support to complete it.

Two six month periods are covered by the Survey Report, corresponding to the period of the current and previous European Presidency of the Council.

The questionnaire has been divided into two parts, one on readiness for acceptance of paperless applications of marketing authorisations and the other on the numbers of electronic applications for marketing authorisation received in eCTD and other electronic formats during the periods covered by the surveys.

Results are presented with graphs showing the consolidated figures provided by all EU regulatory authorities for 2 periods of six months and with tables showing the results as a percentage of total applications in any format, and for all procedures covering 12 months and as a percentage of the evolution between both periods of six months.

Since not all NCA have the infrastructure in place to record the format of applications (paper or electronic) and the criteria to validate different types of electronic format are still not commonly used it was requested in the questionnaire to indicate for each figure whether they are the result of exact counting or of rough estimations. The overall estimation rate is reported in the survey, as well as the response rate for each question.

Finally, requirements of paper copies when applications were received in electronic format are also reported.

Outcome

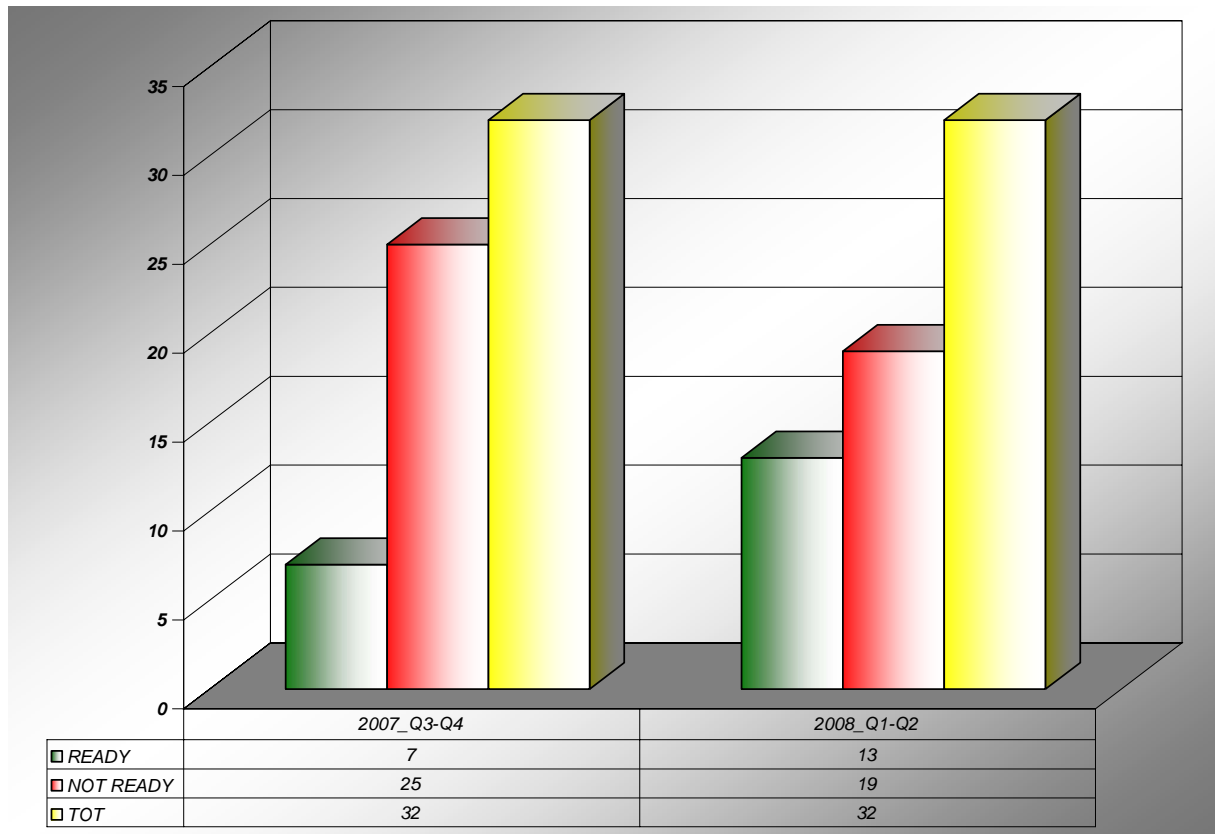
All 32 regulatory authorities (NCA + EMEA) of the European Medicines Regulatory Network competent for medicinal products in the human sector responded to the questionnaire.

Questionnaire response rate: 100%

Readiness

Q1 - % of authorities ready for management and evaluation of marketing authorisation applications in electronic format only.

Question response rate: 100%

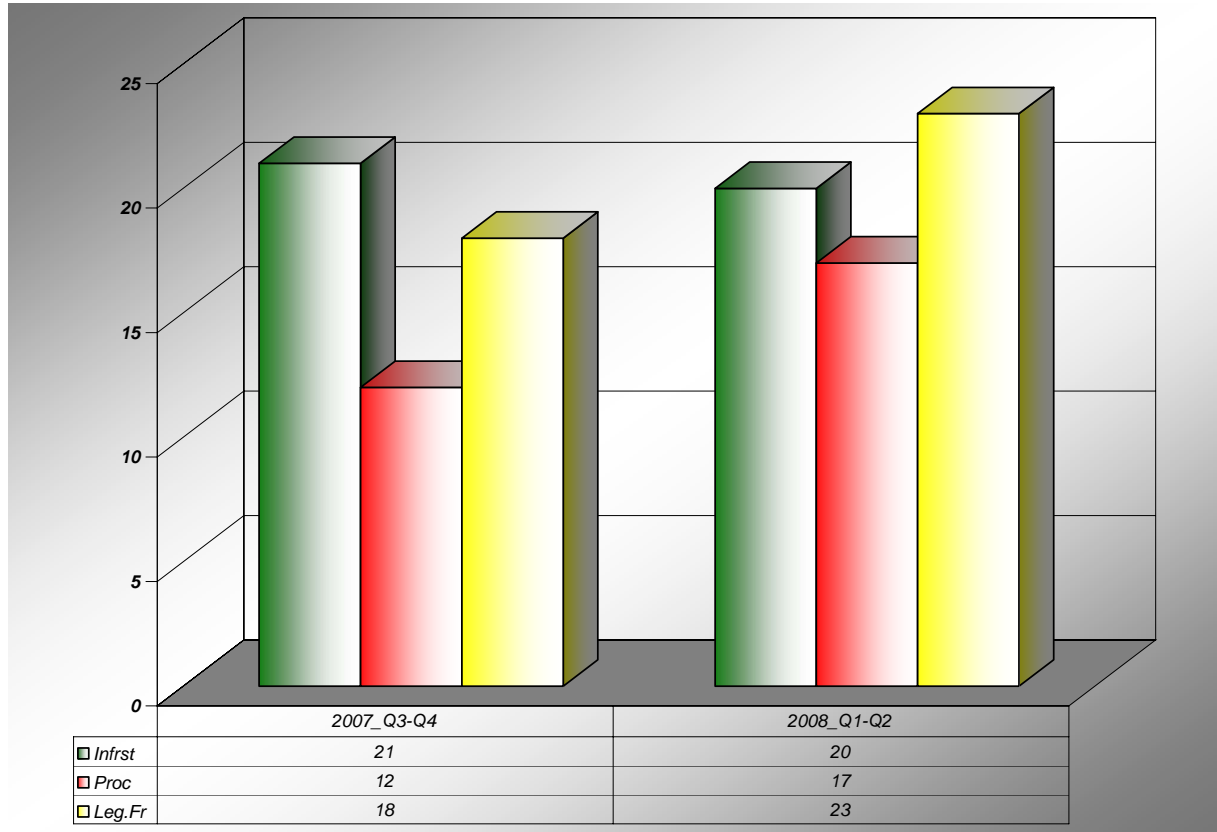


Results:

- **41% of EU Regulatory authorities are ready for management and evaluation of marketing authorisation applications in electronic format only (+ 86%).**
- **59% of EU Regulatory authorities are not yet ready for management and evaluation of marketing authorisation applications in electronic format only (- 24%)**

Q1 - % of authorities that have fulfilled the aspects identified as key for eCTD implementation: Infrastructure, Processes and Legal framework for paperless management of Marketing Authorisation applications.

Question response rate: 100 %

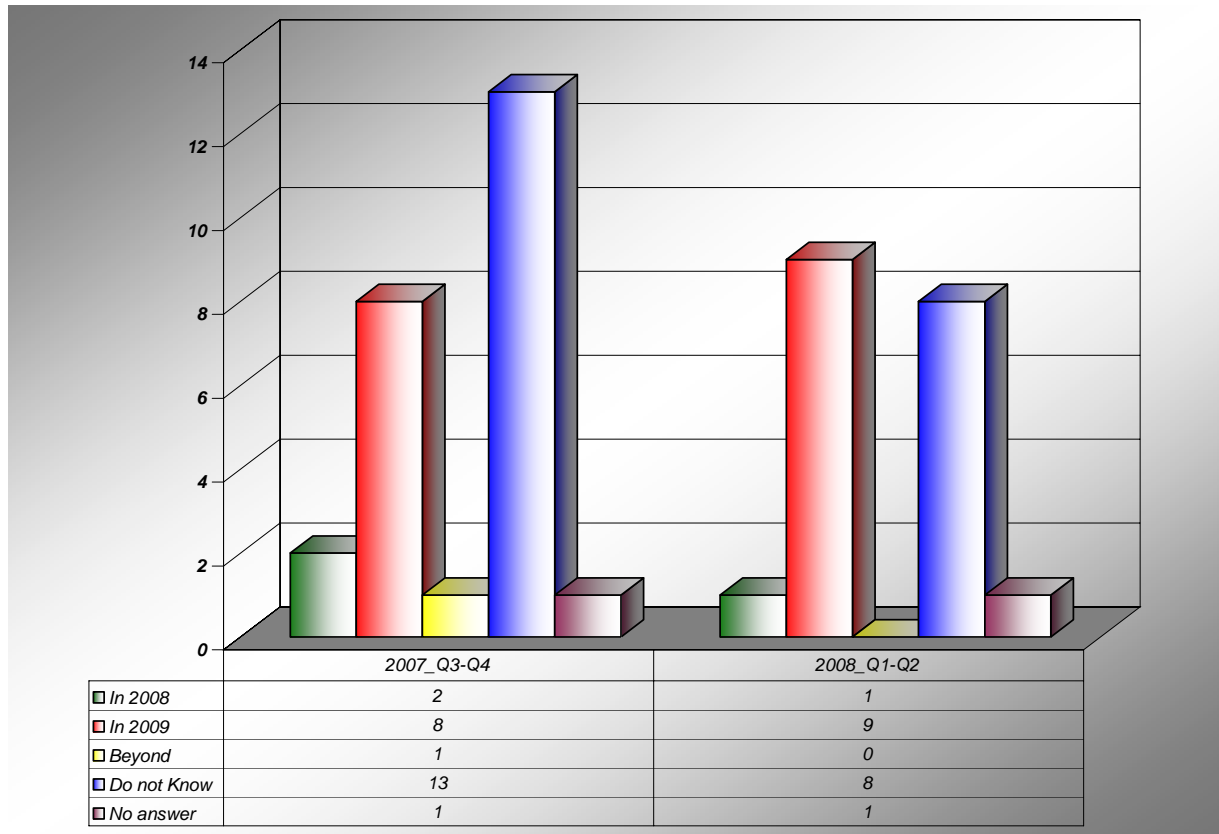


Results:

- **64% of EU regulatory authorities have the infrastructure for paperless management of Marketing Authorisation applications (- 5%).**
- **53% of EU regulatory authorities have the processes in place for paperless management of Marketing Authorisation applications (+ 42%).**
- **72% of EU regulatory authorities have the legal framework in place for paperless management of Marketing Authorisation applications (+ 28%).**

Q2 – When do EU regulatory authorities that are not ready expect to be ready for management and evaluation of marketing authorisation applications in electronic format only?

Question response rate: 95%

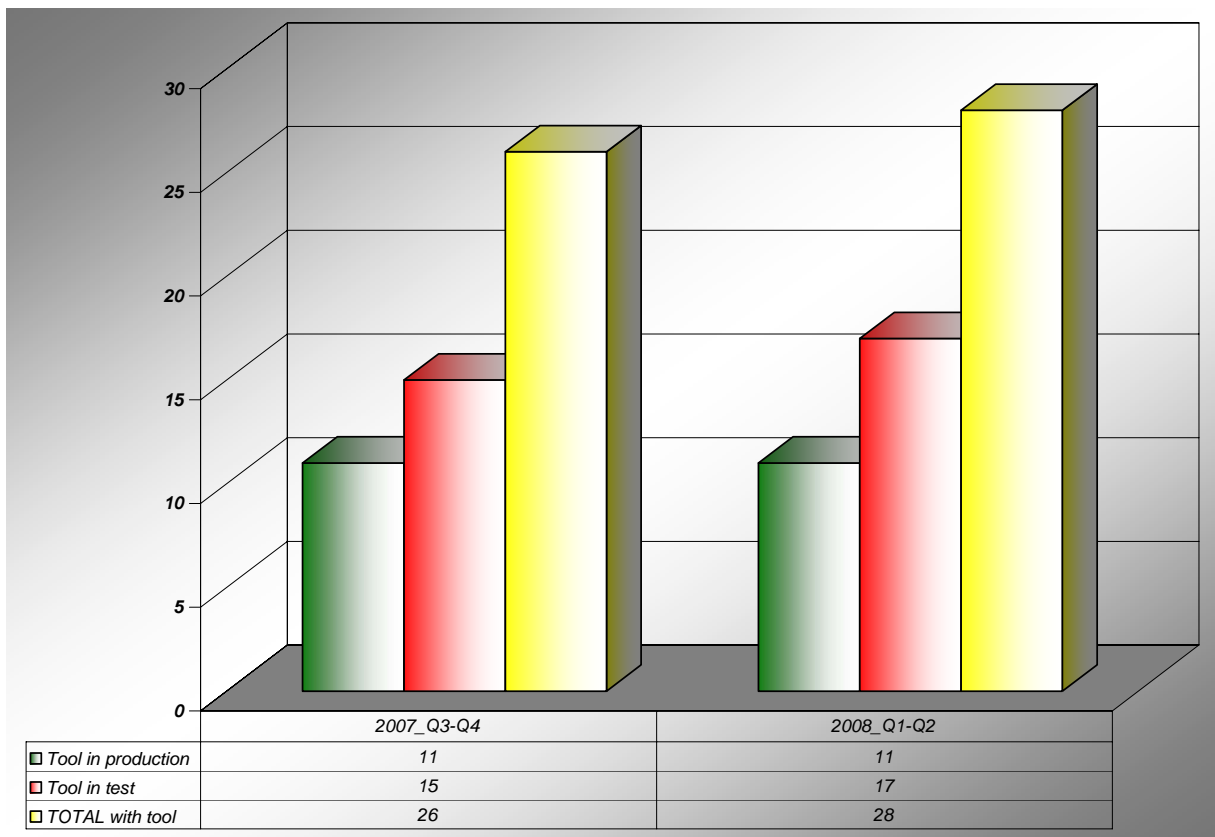
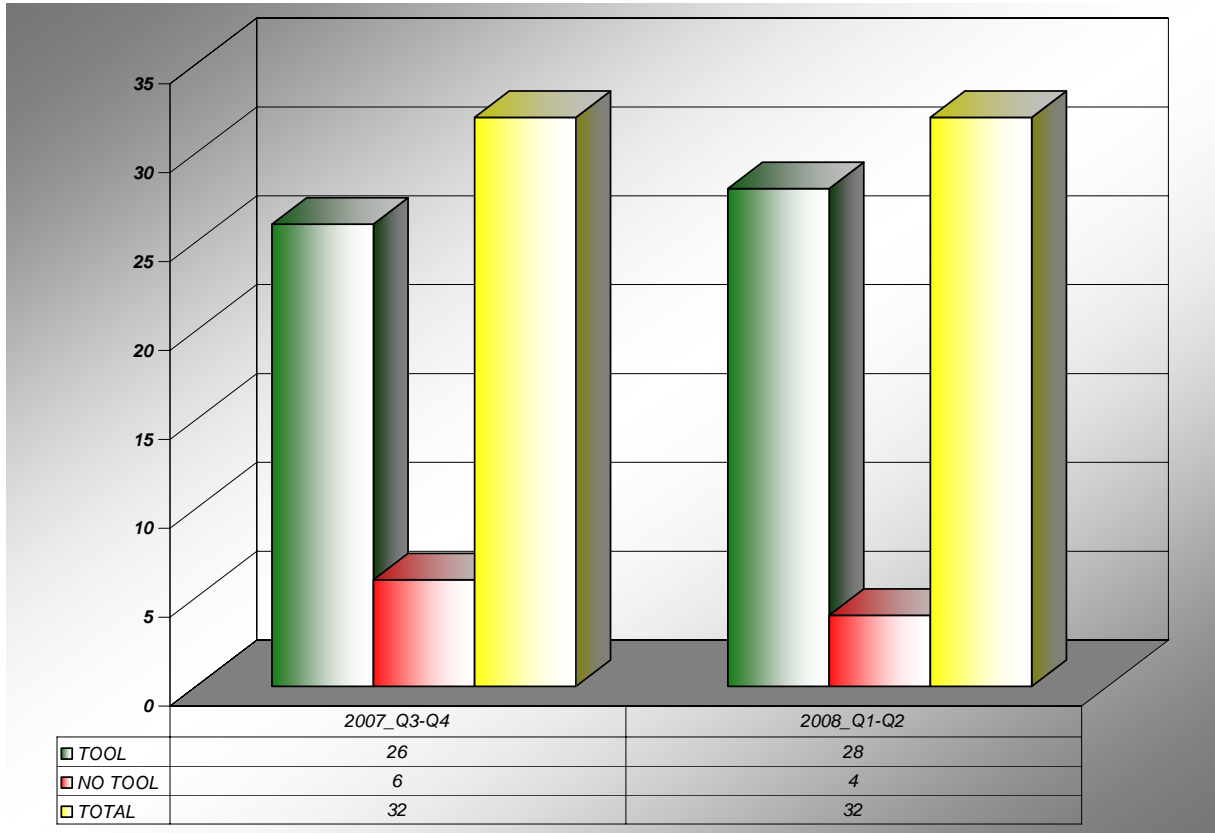


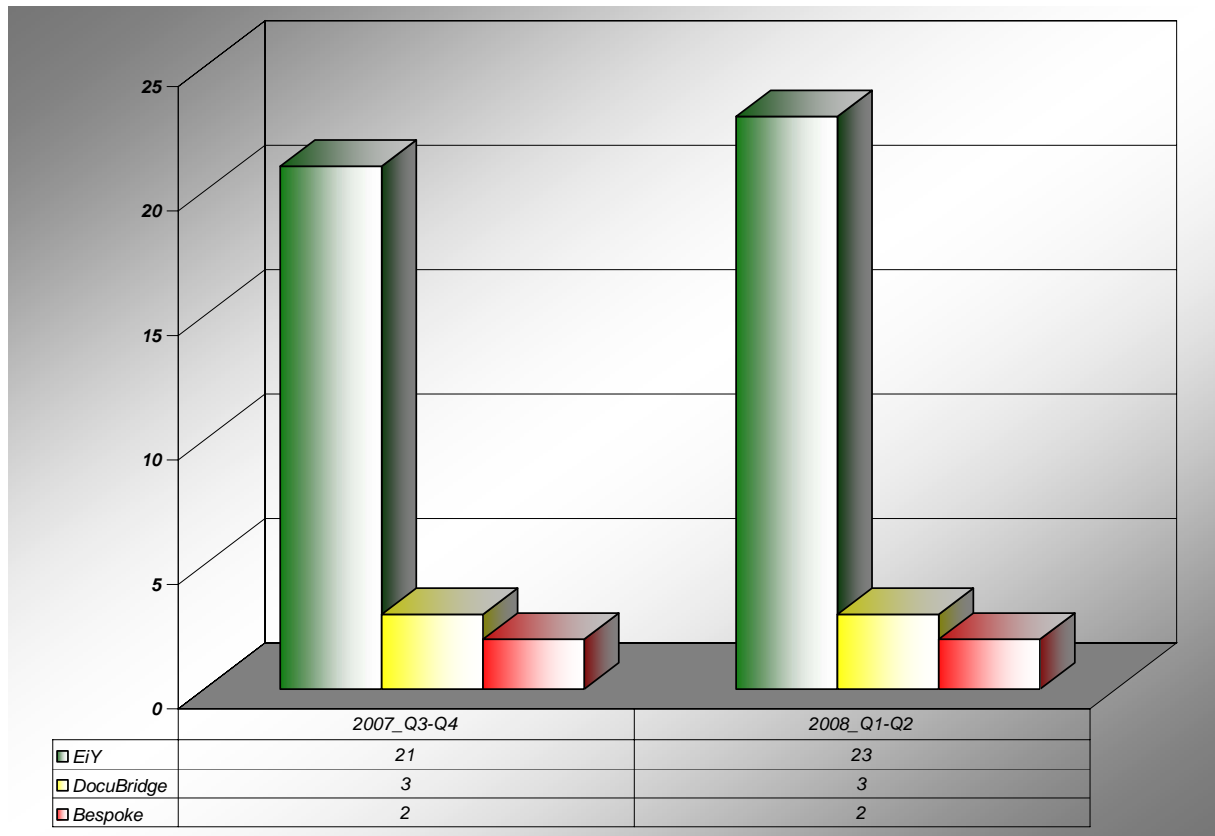
Results:

- **59% of EU regulatory authorities are not yet ready for management and evaluation of marketing authorisation applications in electronic format only. They responded to the question Q2 as follows:**
- **3% of EU regulatory authorities expect to be ready in 2008**
- **28% of EU regulatory authorities expect to be ready in 2009**
- **25% of EU regulatory authorities still do not know by when they will be ready (- 62%)**

Q3 – % of authorities that have a tool for review of eCTD in production or for testing (the tool is identified).

Question response rate: 100%



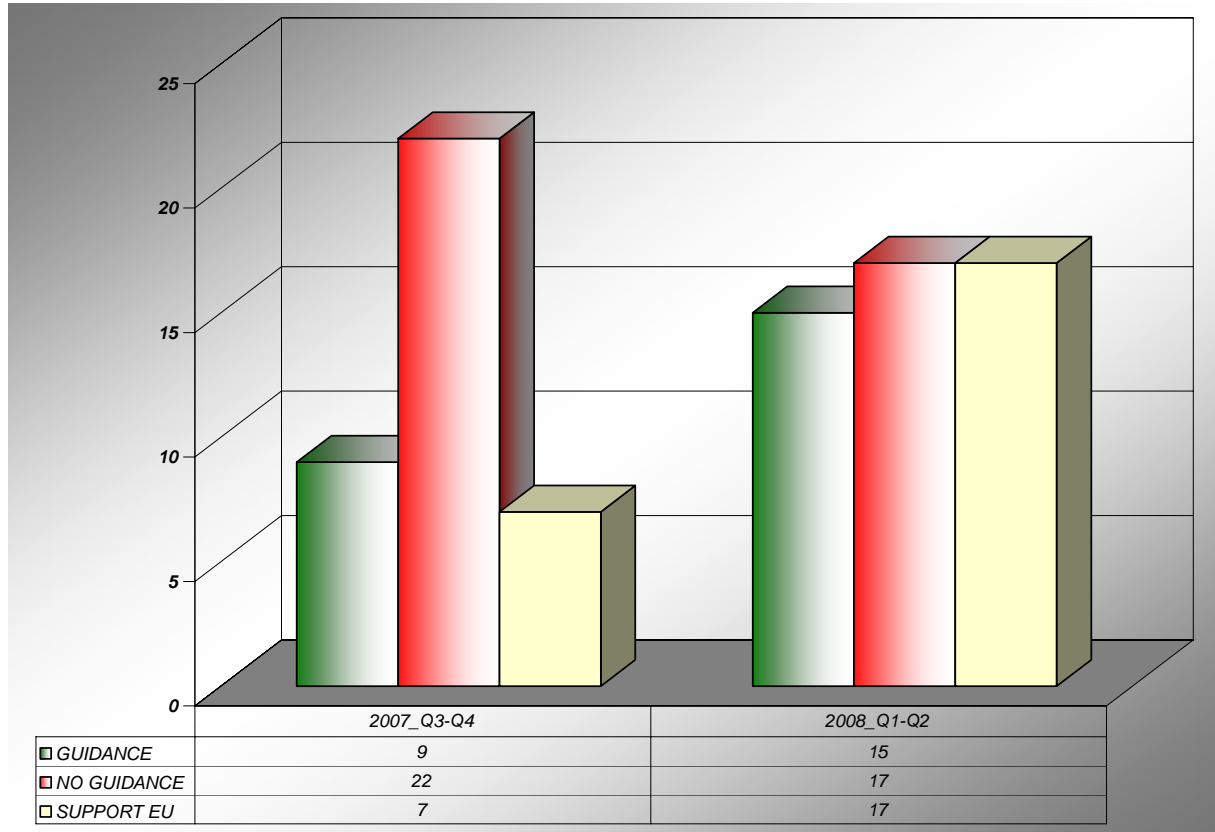


Results:

- **88% of EU authorities have a tool for review of eCTD (+ 8%)**
- **34% of EU regulatory authorities have a tool for review of eCTD in production (+ 0%)**
- **54% of EU regulatory authorities have a tool for review of eCTD in testing (+ 17%)**
- **72% of EU regulatory authorities have EiY as tool for review of eCTD (+10%)**
- **10% of EU regulatory authorities have DocuBridge as tool for review of eCTD (+ 0%)**
- **6% of EU regulatory authorities have a bespoke tool for review of eCTD (+0%)**

Q4 – % of EU regulatory authorities that have national guidance and/or that support published EU guidance on submission of marketing authorisation applications in electronic format.

Question response rate: 100%

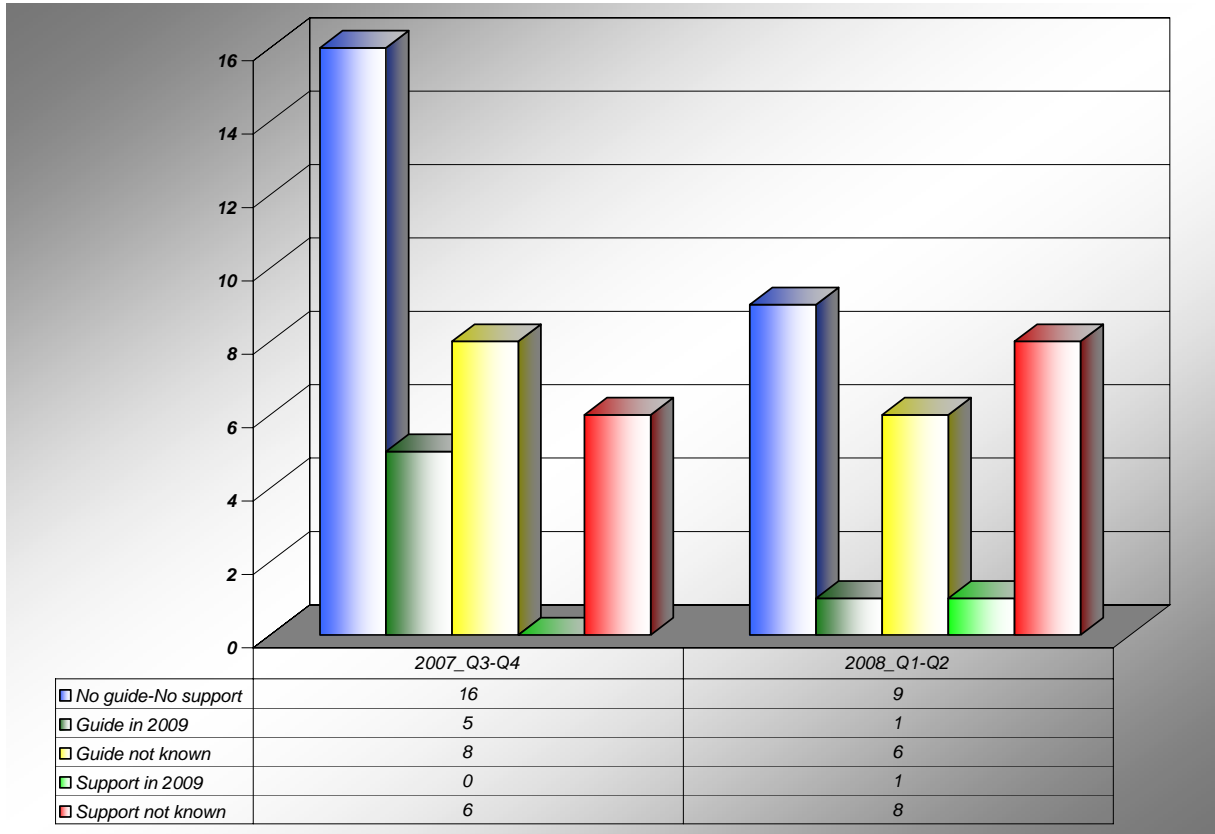


Results:

- **47% of EU regulatory authorities have national guidance (+ 67%)**
- **53% of EU regulatory authorities do not have national guidance (- 23%)**
- **53% of EU regulatory supports published EU guidance (+ 159%)**

Q5 – When do EU regulatory authorities that have no national guidance and do not support EU guidance on submission of Marketing Authorisation applications in electronic format expect to have/support guidance?

Question response rate: 100%



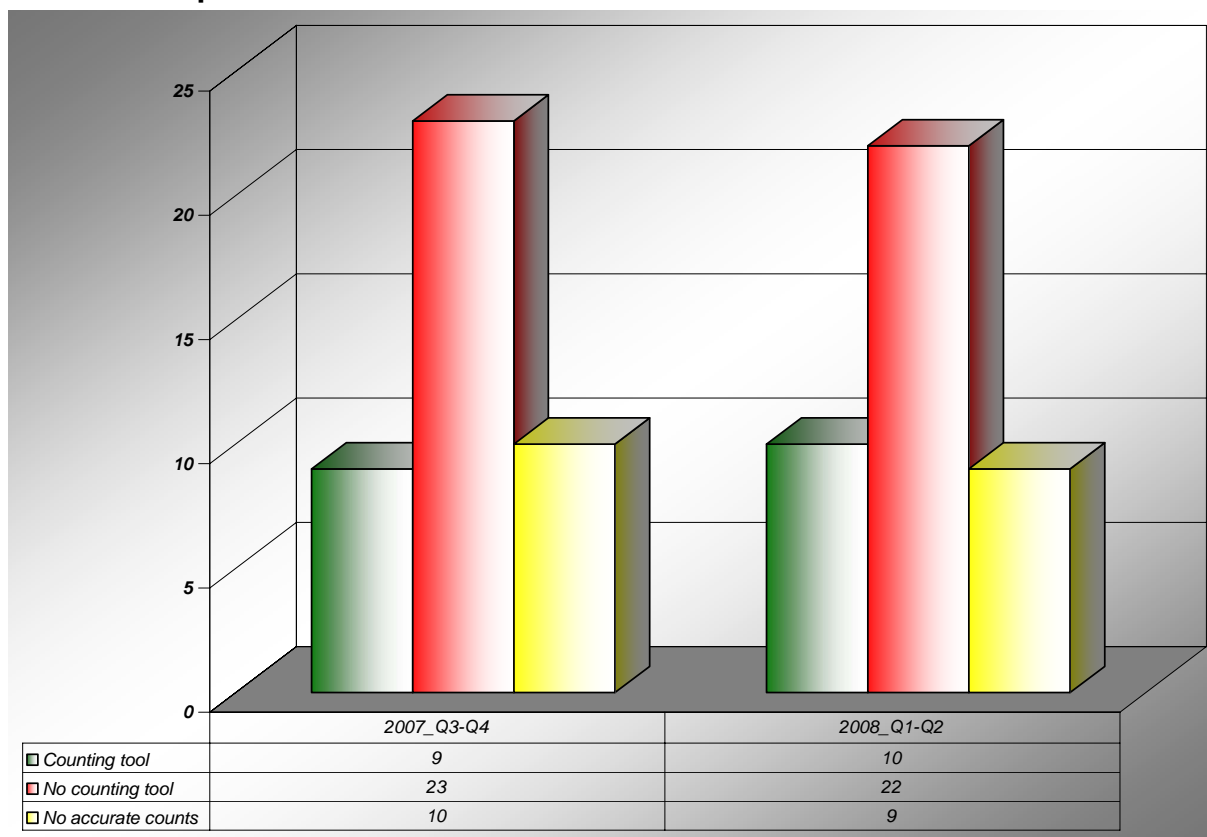
Results:

- **28% of EU regulatory authorities do not have national guidance and do not support EU guidance on submission of Marketing Authorisation applications in electronic format yet (- 44%).**
- **14% of these EU regulatory authorities (representing 5% of the EMRN) expect to have national guidance by the end of 2009**
- **68% of these EU regulatory authorities (representing 21% of the EMRN) do not know when they will publish national guidance.**
- **11% of these EU regulatory authorities (representing 5% of the EMRN) expect to support EU guidance by the end of 2009.**
- **90% of these EU regulatory authorities (representing 25% of the EMRN) do not know when they will support EU guidance.**

Statistics

Q6- Availability of tools for regular gathering of numbers of applications received in electronic format

Question response rate: 100%



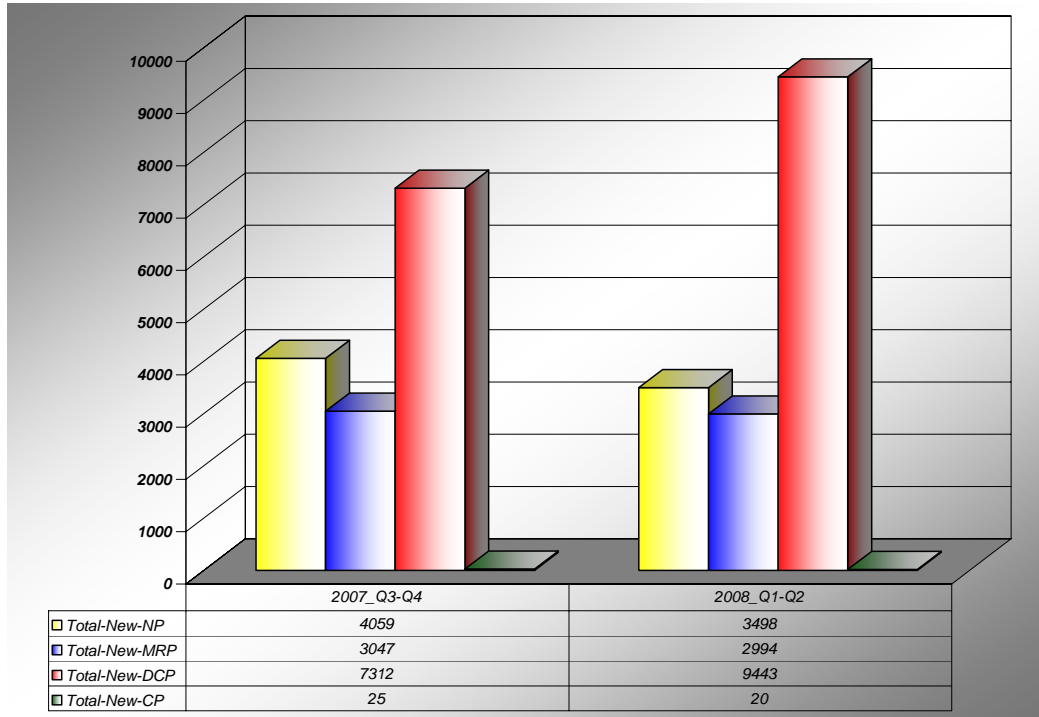
Results:

- 33% of EU regulatory authorities have tool for regular gathering of numbers of applications received in electronic format (+ 10%).
- 67% of EU regulatory authorities do not have tool for regular gathering of numbers of applications received in electronic format (- 4%).
- 29% of EU regulatory authorities declare being unable to provide accurate figures on applications received in electronic format (- 10%).

Estimation Procedure	Total applications				Electronic applications			
	NP	MRP	DCP	CP	NP	MRP	DCP	CP
% Estimated figures	18	8	3	100	58	54	52	100

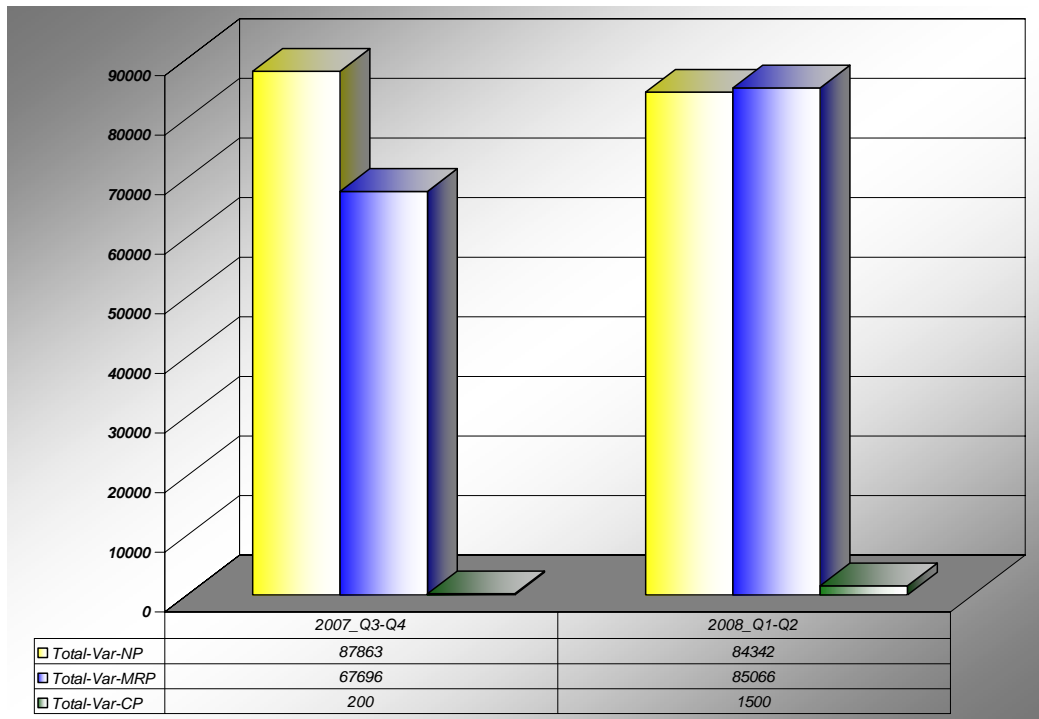
Q8 – Total number of New applications

Question response rate: 100%



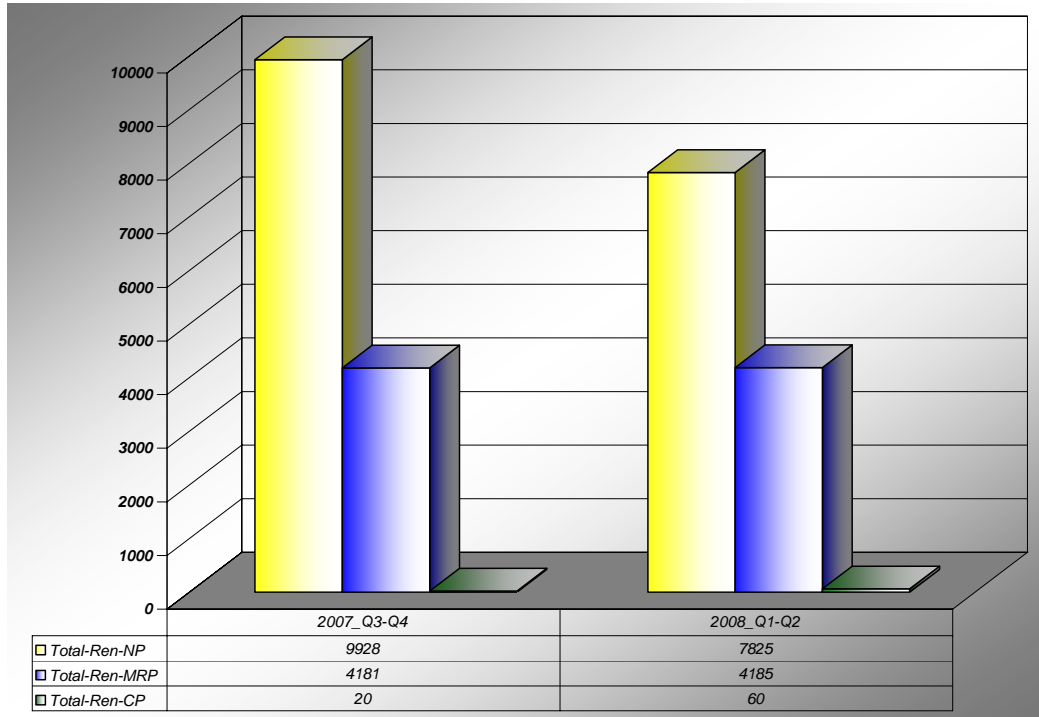
Q9 – Total number of Variation applications

Question response rate: 100%



Q10 – Total number of Renewal applications

Question response rate: 100%



Results:

For New applications:

	12 months	+/- 6 months
New-NP	7557	-14%
New-MRP	6041	-2%
New-DCP	16755	29%
New-CP	45	-20%
Total-New	30398	10%

For Variation applications:

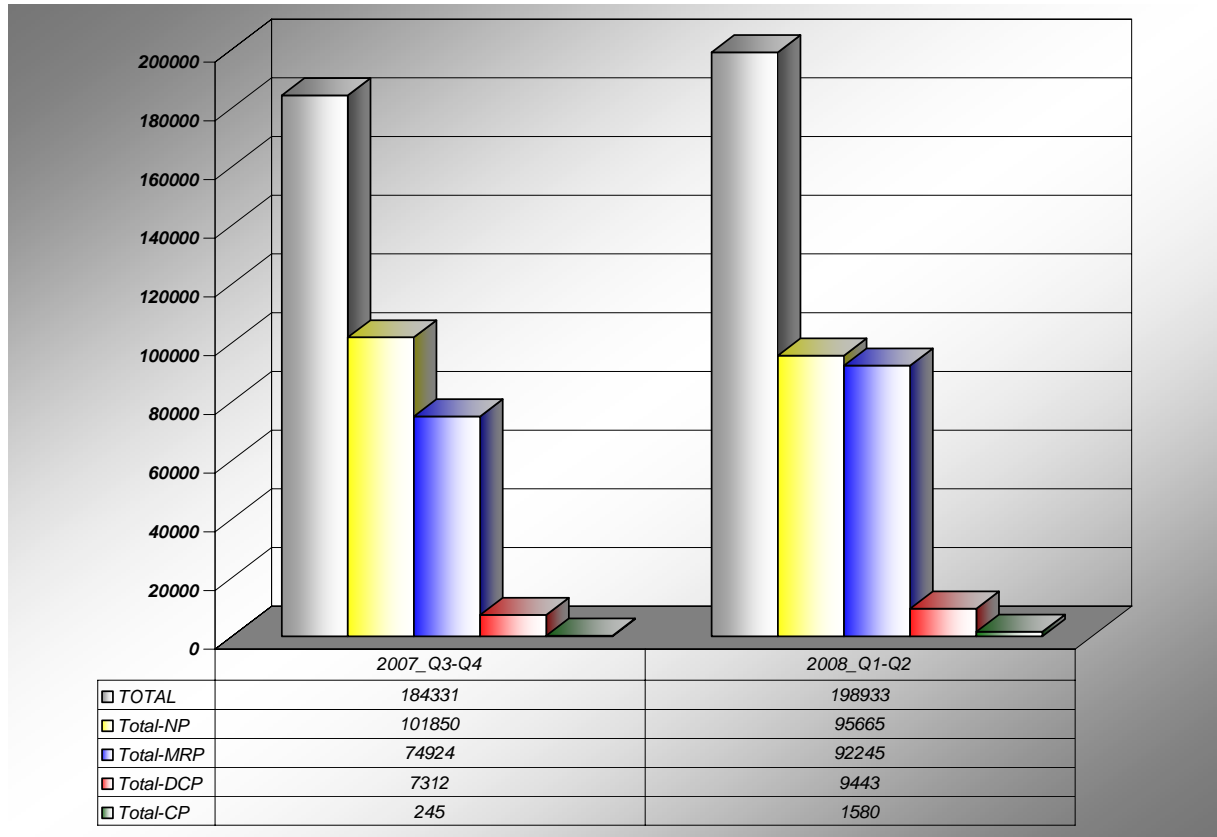
	12 months	+/- 6 months
Var-NP	172205	-4%
Var-MRP	152762	26%
Var-CP	1700	650%
Total-Variation	326667	10%

For Renewal applications:

	12 months	+/- 6 months
Ren-NP	17753	-21%
Ren-MRP	8366	0%
Ren-CP	80	200%
Total-Renewal	26199	-15%

Q10 – Total number of applications per procedure

Question response rate: 100%

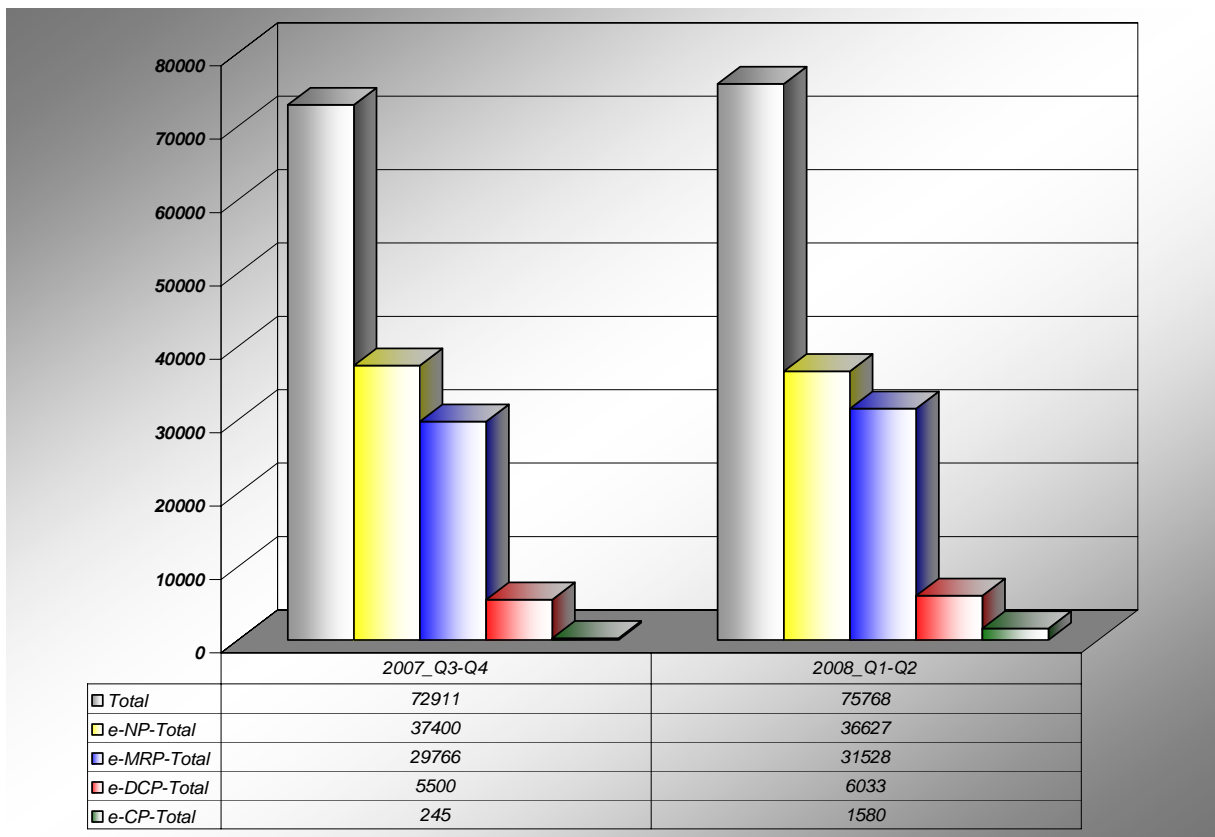
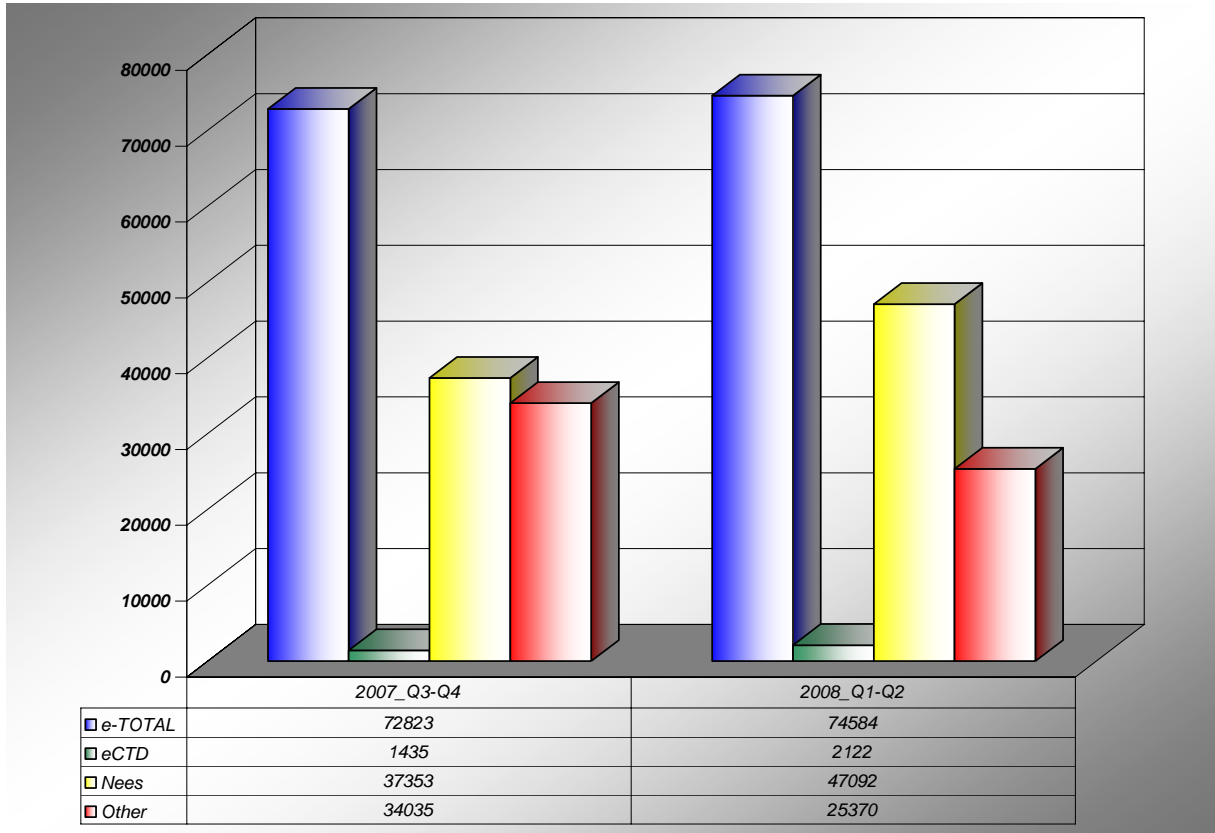


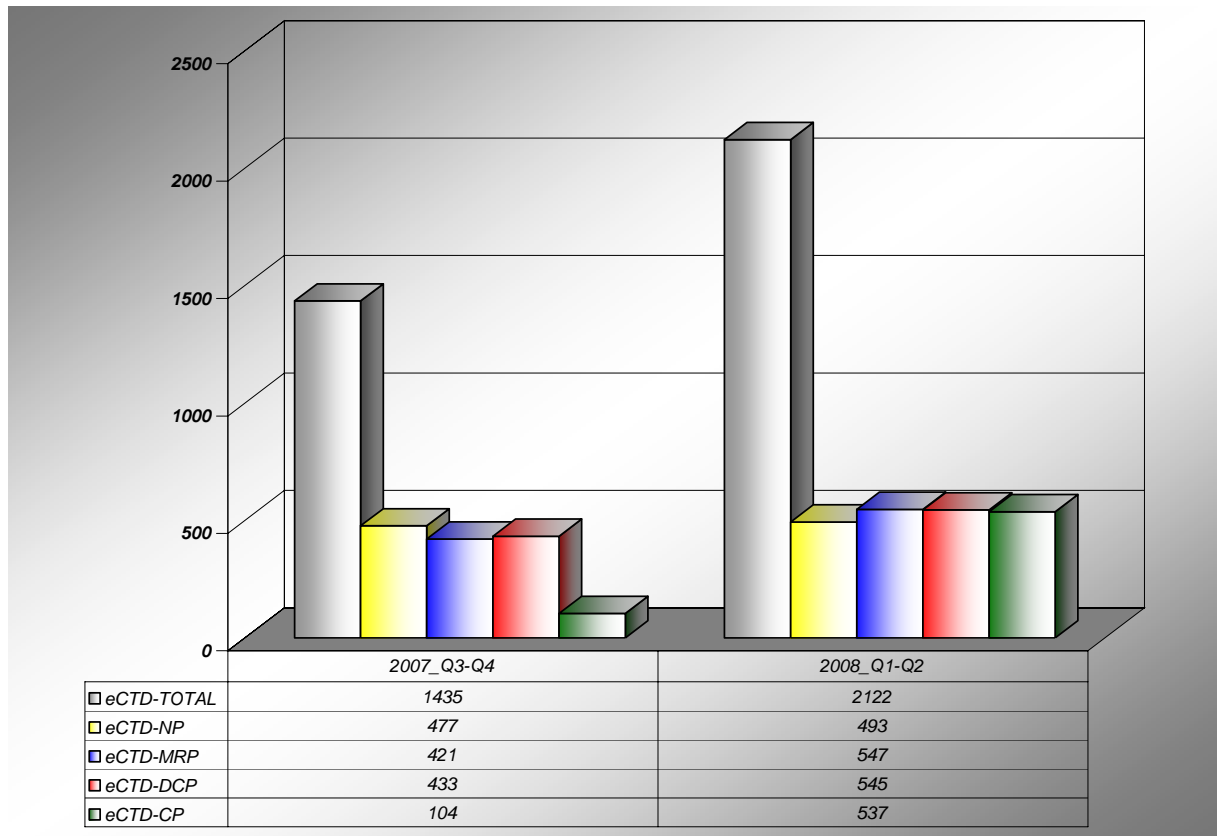
Results:

	12 months	% of TOTAL	+/- 6 months
TOTAL	383264	100%	8%
Total-NP	197515	52%	-6%
Total-MRP	167169	44%	23%
Total-DCP	16755	4%	29%
Total-CP	1825	0,5%	545%

Q11-Q13 – % of total applications received in electronic format and distribution across formats and procedures.

Question response rate: 100%





Results:

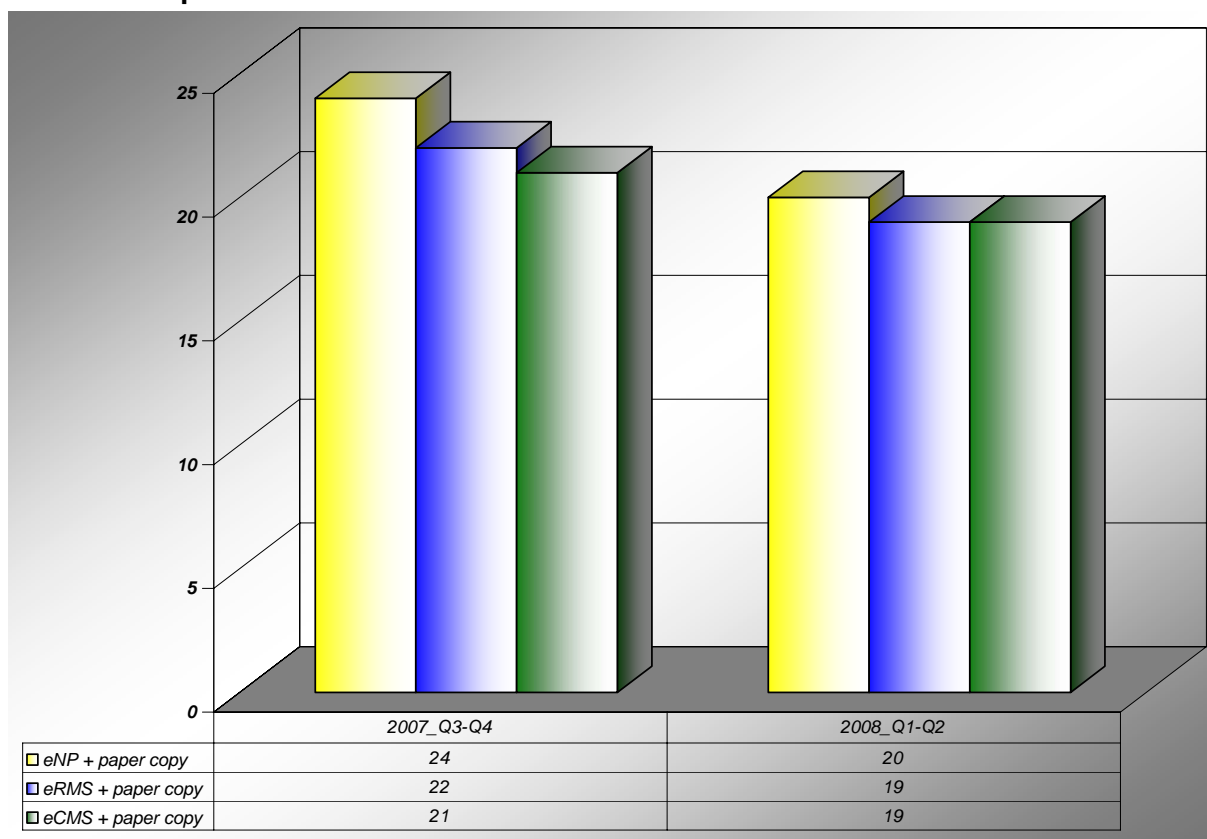
	12 months	% TOTAL	+/- 6 months
e-TOTAL	147407	38%	2%
eCTD	3557	1%	48%
Nees	84445	22%	26%
Other	59405	15%	-25%

	12 months	TOTAL	% of TOTAL	+/- 6 months
Total	147407	383264	39%	4%
e-NP-Total	74027	197515	37%	-2%
e-MRP-Total	61294	167169	37%	6%
e-DCP-Total	11533	16755	69%	10%
e-CP-Total	1825	1825	100%	545%

	12 months	TOTAL	% of TOTAL	+/- 6 months
eCTD-TOTAL	3557	383264	1%	48%
eCTD-NP	970	197515	0,5%	3%
eCTD-MRP	968	167169	0,6%	30%
eCTD-DCP	978	16755	6%	26%
eCTD-CP	641	1825	35%	416%

Q14 – Paper copies required for applications through NP or MRP received in electronic format.

Question response rate: 100%



Results:

- 63% of EU regulatory authorities requires paper when an application through the NP is received in electronic format (-17%)
- 59% of RMS EU regulatory authorities requires paper when an application through the MRP is received in electronic format (-14%)
- 59% of CMS EU regulatory authorities requires paper when an application through the NP is received in electronic format (-14%)

Conclusions

The questionnaire has had a 100% response rate.

On readiness

The number of EU regulatory authorities that are ready for management and evaluation of marketing authorisation applications in electronic format only almost doubled in the last six months and 41% of the EMRN is now ready. From the 59% of authorities that are not ready 31% plans to be ready within the target set at the end of 2009. However, there is still 28% of the authorities that do not know when they will be ready.

More than half of the EU regulatory authorities have already the processes in place to handle paperless Marketing Authorisation applications with a progression of 42% in the last 6 months. It is also important to note that the legal framework allowing paperless operation also evolved positively and 72% of the Network is ready from the legal point of view. Two thirds of the EU regulatory authorities have the infrastructure in place but there is still some effort needed in this area.

Almost 90% of the authorities have a tool for review of eCTD and this figure is increasing. However, half of the EU regulatory authorities are still testing the tools and did not use them in production.

The number of EU regulatory authorities that published guidance for management and evaluation of electronic marketing authorisation applications increased significantly in the last six months and almost half of the EMRN has now national guidance and/or support published EU guidance (see annex 2 for hyperlinks to the guidance). Still, 28% of the Network have no national guidance and do not support EU guidance on electronic Marketing Authorisation applications and 25% do not know when they will be able to have/support guidance.

On statistics

Before commenting on statistics it is important to note that a significant number of EU regulatory authorities is not well prepared to record the numbers of electronic applications and even paper applications received in the periods covered.

For this reason responders of the questionnaire were asked to indicate whether the figures provided were estimates or the result of accurate automated or manual counting. The survey shows that for total applications, the numbers generally obtained counting paper applications, estimates vary between 3% and 18% and for the electronic applications between 52% and 58%, with the exception of the centralised procedure where the figures provided by EMEA were all estimates.

With this in mind the survey shows that 38% of all applications in Europe is submitted in electronic format with or without paper, but only **1% is submitted in eCTD format**. However the increase of eCTD applications in the last six months was of almost 50%, in particular in the centralised and decentralised procedures.

It was mentioned in the introduction of this survey that EU authorities are used to receive electronic support together with the paper copies to support assessors in their assessment and that a first guidance aiming to introduce harmonisation of the current electronic support in preparation of the implementation of eCTD (Nees guidance) was published. The figures shown for Nees applications are still very unreliable because there is still no tool available to validate the application against clear validation criteria. It is expected that this situation will improve in the near future.

Final remarks

It can be seen that progress towards the target has been very important in the last six months and that the EMRN is committed and preparing for management and evaluation of marketing authorisation applications in electronic format only.

The legal environment in Europe seems to be favourable to paperless operation and all EU authorities are working to streamline the regulatory process and improve its efficiency in a resource constrained situation.

The eCTD could certainly be used to leverage this evolution of practice and organisation.

The infrastructure is a very important factor in this transformation and the tools available to handle electronic applications still need to prove fit for purpose in some cases. The good monitoring of progress also needs some technical assistance that should be considered when developing systems.

Guidance is been provided throughout Europe that will help applicants to understand and implement the new rules.

In order to meet the target set there is still some way to go and there is hope that in the next year the tendency will keep its pace. However, electronic applications in eCTD format only represents 1% of all applications and 2,4% of electronic applications in Europe and the commitment of industry to move to eCTD is equally important to make this standard a success and be able to collect the expected benefits.

ANNEX 1

EU eCTD Implementation Questionnaire

Who is/are the contact(s) in your agency for eSubmission/eCTD?

(N.B If the contact point is not the TIGes member, it is the responsibility of the TIGes member to identify and provide details of the appropriate colleague(s))

Name:

Position:

Email:

TIGes member? Yes

No

Readiness

Q1: Is your agency ready for management and evaluation of Marketing Authorisation *applications* in electronic format only²?

(a) Yes

(b) No

If the answer to Q1 is No, please indicate which aspects of implementation are already solved:

(a) Infrastructure

(b) Processes

(c) Legal framework

(d) Other (Specify.....)

Q2: If the answer to Q1 is No, when does your agency plan to be ready for management and review of the Marketing Authorisation *applications* in electronic format only?

(a) Month/Year:

(b) Timeline not known

Comments:

Q3: Does your agency have a tool for review of eCTD?

(a) Yes, installed

(b) Yes, in production (with real live applications)

- Eurs is Yours (EiY)

- DocuBridge

- Other, specify :

(c) No

Comments:

Q4: Does your agency have any published national guidance for applicants on submission of Marketing Authorisation *applications* in electronic format?

(a) Yes

(b) No

(c) Supports EU guidance on applications in electronic format

- Link(s) to guidance:

Q5: If the answer to Q4 is just No, when does your agency plan to publish national guidance/support EU guidance for applicants on submission of electronic Marketing Authorisation *applications* in electronic format?

² “Electronic format only” means without paper except for documents where a signature is required. Since there is no digital signature standard in the EU signed documents may still be required in paper.

(a) Publish

(b) Month/Year:

(b) Timeline not known

Comments:

Support EU guidance

Q6: Does the IT infrastructure in your agency allow for regularly gathering of details/statistics on numbers of *applications* received in electronic format (eCTD and Nees)?

(a) Yes

(b) No

Q7: If the answer to Q6 is No, would the lack of such functionality prevent you to gather the details/statistics on numbers of *applications* received in electronic format twice a year (e.g. manually)?

(a) Yes

(b) No

Comments:

Statistics

Six months statistics on processed marketing authorisation applications are requested. Please indicate the period considered for which information is available from [MM/YYYY] to [MM/YYYY] (ex: 06/2007 to 12/2007). If the period for which figures are available is shorter or longer the figures will be recalculated on a six month basis for comparison and reporting purposes.

Figures will be reported in the eCTD Roadmap as consolidated global percentages.

Reporting period:

From Month/Year:

to Month/Year:

NOTE: When answering the questions below please indicate whether the figures given are the result of accurate counting (C), ex: 1243 (C), or the result of rough estimation (E), ex: 1500 (E)

Q8: Please indicate the **total** number of NEW applications* received in this period:

8.1. Purely national:

8.2. MRP (RMS + CMS):

8.3. DCP (RMS + CMS):

Comments:

* *In all formats, paper or electronic for which a first MA would be granted.*

Q9: Please indicate the **total** number of VARIATIONS applications* received in this period:

9.1. Purely national:

9.2. MRP (RMS + CMS):

Comments:

** In all formats, paper or electronic for which a MA would be granted.*

Q10: Please indicate the total number of **RENEWAL applications*** received in this period:

10.1. Purely national:

10.2. MRP (RMS + CMS):

Comments:

Q11: Please indicate the total number of **NEW applications*** received in electronic format :

11.1. Purely national: N° eCTD: N°NeeS: N°Other:

11.2. MRP (RMS + CMS): N° eCTD: N°NeeS: N°Other:

11.3. DCP (RMS + CMS): N° eCTD: N°NeeS: N°Other:

Comments:

Q12: Please indicate the total number of **VARIATIONS applications** received in electronic format:

12.1. Purely national N° eCTD: N°NeeS: N°Other:

12.2. MRP (RMS + CMS): N° eCTD: N°NeeS: N°Other:

Comments:

Q13: Please indicate the total number of **RENEWAL applications*** received in electronic format:

13.1. Purely national: N° eCTD: N°NeeS: N°Other:

13.2. MRP (RMS + CMS): N° eCTD: N°NeeS: N°Other:

Comments:

Q14: Please indicate whether or not **paper copies** of all or some parts of the dossier (signed documents excluded) are still required for **applications** received in electronic format for:

14.1 Purely national:

(c) Yes

(d) No

14.2 MRP/DCP (RMS):

(e) Yes

(f) No

14.3 MRP/DCP (CMS):

(g) Yes

(h) No

Comments:

ANNEX 2 : GUIDANCE

Contry Code	Hyperlink to guidance on electronic Marketing Autorisation applications
AT	http://www.basg.at/servlet/sls/Tornado/web/ages/content/D3C91BD4E6DB804AC1
BE	https://portal.health.fgov.be/pls/portal/docs/PAGE/INTERNET_PG/HOMEPAGE_MENU/GENEESMIDDELEN1_MENU/HUMAANGEBRUIK1_MENU/REGISTRATIE17_MENU/TOLERANCEZERO9_HIDE/TOLERANCEZERO9_DOCS/ESUBMISSION%20GUIDELINES-2-7_0.PDF
BG	http://bda.bg/ru/ukazania/Guidance_for_eCTD/BG/30.09.2008.pdf
CZ	http://www.sukl.cz/reg-84-version-1
DE-BFARM	http://www.bfarm.de/clin_029/nn_1200072/EN/drugs/2__Authorisation/procedures/amgSub/amgsub-node-en.html__nnn=true
DE PEI	http://www.pei.de/clin_047/nn_162566/EN/infos-en/pu-en/09-submission-dossier-en/sub-node-en.html?__nnn=true
DK	http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=11487
EE	http://esubmission.emea.europa.eu/doc/eGuidance_Document%201.4.pdf
ES	http://www.agemed.es/en/aplicaciones/dossi-Electro.htm
FR	http://afssaps.sante.fr/pdf/3/avammfr.pdf
GR	http://www.eof.gr/eof_en/Dossier_efomat.zip
NL	http://www.cbg-meb.nl/NR/rdonlyres/C56DC125-3460-4038-930C-AD9B8F5FAEC3/0/eGuidance_Document14.pdf
PT	http://www.infarmed.pt/portal/page/portal/INFARMED/MAIS_NOVIDADES/DETALHE_NOVIDADE?itemid=43876 http://www.infarmed.pt/portal/page/portal/INFARMED/MAIS_NOVIDADES/DETALHE_NOVIDADE?itemid=43886 http://www.infarmed.pt/portal/page/portal/INFARMED/MAIS_NOVIDADES/DETALHE_NOVIDADE?itemid=43926
SK	www.sukl.sk

ANNEX 3 : CONTACT POINTS

Country	Title	Last Name	First Name	Organisation Name	Email
Austria	Mr.	Binder	Harald	AGES PharmMed	harald.binder@ages.at
Belgium	Mr.	Vankeerberghen	Pieter	Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten - Agence Fédérale des Médicaments et des Produits de Santé	pieter.vankeerberghen@fagg-afmps.be
Bulgaria	Mr.	Antonov	Lyudmil	Изпълнителна агенция по лекарствата	lyudmil.antonov@bda.bg
Cyprus	Mr.	Kontemeniotis	Antonis	Ministry of Health	akontemeniotis@phs.moh.gov.cy
Czech Republic	Ms	Šínová	Ivana	Státní ústav pro kontrolu léčiv	ivana.sinova@sukl.cz
Denmark	Dr	Helboe	Per	Lægemiddelstyrelsen	ph@dkma.dk
Estonia	Mrs	Viispert	Aet	Ravimiamet	Aet.Viispert@ravimiamet.ee
Finland	Mr	Hartikka	Jaakko	Lääkelaitos	Jaakko.Hartikka@nam.fi
France	Mrs	Auriche-Benichou	Caroline	Agence Française de Sécurité Sanitaire des Produits de Santé	caroline.auriche@afssaps.sante.fr
Germany	Dr	Menges	Klaus	Bundesinstitut für Arzneimittel und Medizinprodukte	k.menges@bfarm.de
Germany	Dr	Giess	Siegfried	Paul-Ehrlich-Institut	giesi@pei.de
Greece	Dr	Michaleas	Sotirios	ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ	smichaleas@pharm.uoa.gr
Hungary	Mr	Haraszi	Csaba	Országos Gyógyszerészeti Intézet	haraszi.csaba@ogyi.hu
Iceland	Mr	Benediktsson	Benedikt	Lyfjastofnun	benedikt.benediktsson@imca.is
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