EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA mid-year report 2011 from the Acting Executive Director (January - June 2011)

Management Board meeting 6 October 2011

Background note

This mid-year report from the Acting Executive Director to the Management Board is intended to provide an interim overview of the Agency's activities and performance, based on the objectives and targets set out in the Agency's work programme 2011.

Please refer to the work programme 2011 for the details of objectives set.

Matters for consideration

The document consists of the three sections:

- Summary of progress under **the priority** areas (pages: 2-5).
- Overview of performance under main **activity areas** (pages: 6-10). When printing these pages, please note that the overview uses colour coding.
- **The annex** containing the **detailed mid-year report** (starting on page 11). Comments are included only for those objectives which were planned to be completed or were advanced towards by the mid-year. Navigation in the Annex is facilitated through the use of the symbols indicating:
  - volumes of applications and activities which are 'in line' (✓), 'over' (⇧) or 'under' (⇩) the forecast figures; and
  - activities which are progressing 'in accordance' (✓) with plans or constitute a 'deviation' (×). The symbol (▪) indicates general information on progress, a comment or a highlight.

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European Medicines Agency mid-year report 2011 from the Acting Executive Director

(January – June 2011)

Summary of progress on priorities

Core business

- ✓ Activities during the first half of 2011 are largely on track. The workload in the majority of areas is largely in line with forecasts. There were no major deviations during the period. For more details please read below.
- ✓ Both revenue and expenditure for 2011 are in line with plans.

Implementation of new legislation

Pharmacovigilance legislation

- ✓ The implementation of the new pharmacovigilance legislation was planned in the 2011 Work Programme. However, aspects such as the management and coordination of the project, consensus-building with all involved parties, changing priorities due to an evolving budgetary situation have resulted in additional work to be undertaken. For more information please read section 2.5.

Antifalsification legislation

- ✓ Although the new legislation was only published on 1 July 2011, preparation for the implementation of the legislation started with a number of activities including the development of a project plan, outlining ICT requirements and the preparation of initial estimates of human, financial and ICT resource requirements.

Veterinary legislation

- ✓ The Agency prepared reflection papers and proposals for certain topics regarding the future revised veterinary legislation for discussion with CVMP and CMDv and directly to the Commission, as requested, and participated in the discussions at HMA – EMA Task Force, and meetings with stakeholders (HMA Focus group meeting, IFAH Europe conference).

Clinical trials legislation

- ✓ Comments were provided to the European Commission on their concept paper on the revision of the clinical trials legislation. The Agency is preparing its contribution to the European Commission's impact assessment.

Effective monitoring of the balance of benefits and risks of medicines, while contributing to a more rational use of medicines

- ✓ ENCePP is delivering in line with its work plan. Highlights are listed in section 1.6. Outcome assessment progressed in the areas of H1N1 pregnancy monitoring, the impact of the withdrawal of Avandia and the safety of isotretinoin (through EMA funded ENCePP studies).
- ✓ The IMI funded 'EU Protect project' to improve methodologies in pharmacovigilance was effectively coordinated by the Agency. Reasons for a slower than anticipated progress for the work package on benefit/risk are being reviewed.

Communicating and engaging with stakeholders, empowering patients and enabling their participation in healthcare decisions, as well as increasing transparency of the Agency's activities

- ✓ Considerable efforts have been directed towards further increasing the transparency and openness of operation at the Agency. The Agency has launched the EU Clinical Trial Registry and granted public access to EudraGMP. The EudraVigilance Access Policies for medicines for human and veterinary use have been published, albeit with a revised implementation plan as a result of the evolving budgetary situation. The HMA/EMA guidance document on the identification of commercially confidential information and the protection of personal data within the structure of the marketing authorisation dossier was released for a three month public consultation period.
- × Work on the policy to provide access to agendas and minutes of scientific committees and working parties has not yet started.
- ✓ The framework of interaction with healthcare professionals is being finalised with the CHMP Working Group with Healthcare Professionals and will be presented to the Management Board later this year.
- × The implementation of the revised framework of interaction with Patients and Consumers' Organisations has been postponed to 2012 awaiting first the outcome of the pilot phase on the participation of patients' representatives in the Scientific Advisory Groups.

- ✓ The Agency met with the European Vaccine Association and with EFPIA during the two-yearly EMA-EFPIA Infoday to discuss specifically the status of implementation of the paediatric legislation, its impact and the process improvement expectations.
- ⇧ Over half a million of pages were released following requests for accesses to documents. The increase can be related to the publication of the Agency's new Transparency Policy (November 2010), which gave wider access to documents held by the EMA. It also shows a high interest in the Agency's activities.
- For more details please read section 1.4.

Contributing to international activities and responding to globalisation of pharmaceutical research, development and manufacturing

- ✓ In the context of FDA-EMA's bilateral collaboration, a new cluster on Biosimilar Medicinal products was established. In addition, the EMA-FDA pilot initiatives on API and GCP Inspections collaboration were successfully completed and final reports were published. Both initiatives will continue as operational programmes.
- ✓ Activities with WHO have continued to increase, with increasing activities within the paediatric network, Article 58 applications for scientific advice and collaboration on high-profile vaccine safety issues.
- ✓ In addition to a cooperative meeting with the Chinese SFDA, the Agency organised a GCP training session inviting representatives from WHO and Regulators from more than 18 countries from outside the EU as part of its capacity building and training initiatives.
- ✓ In the field of international standardisation important progress was made including agreement on the final draft ISO standard on Individual Case Safety Reports (ICSR), final draft ISO standards on Identification of Medicinal Products (IDMP).

Responding to public-health needs, including the availability of medicines

- ✓ The geriatrics medicines strategy published.
- ✓ The workload in relation to the operation of the EU Incident Management Plan further increased during the first half of 2011. In total 11 emergency issues were discussed by the Incident Review Network. This has allowed proactive management of emerging issues in relation to medicinal products for human use, hence preventing incidents from developing into crisis situations.
- ✓ The number of requests for Minor Uses Minor Species applications continues to increase which demonstrates the success of the measures taken by the Agency in this domain.

Fostering the European regulatory network

- ✓ Significant interaction is of note in the context of the implementation of the pharmacovigilance legislation, the work in the area of management of conflicts of interests, work in the area of capacity building in various domains, notably the area of non-clinical safety and alternative testing methods with the establishment of an ad hoc working group in the area of 3R principles (replacement, refinement and reduction).
- Interaction with other EU Agencies has been focused on ECDC particularly as regards the respective roles and responsibilities of both agencies in the field of substances of human origin (SoHO). There is also a need to further invest in clarifying the roles and responsibilities of both the EMA and ECDC regarding post-authorisation aspects of vaccines.

Unplanned activities

- Significant activities in relation to the Mediator case. Considerable resources were allocated to address queries from interested parties and media, to respond to access to documents requests, to organise visits by the French Parliament, Senate and IGAS as well as participating in hearings at national and European Parliaments to clarify the function of the EU pharmacovigilance system in the late nineties up to 2003, and the remit, role and responsibilities of the EMA in the Mediator proceedings. Work in this area will continue since OLAF has announced that it will conduct an investigation at the EMA.
- Preparatory work to discuss the role and responsibilities of the EMA in the future handing of substances of human origin.
- Following the radiation leak from the Fukushima Daiichi nuclear power plant as a result of the earthquake which hit Japan in spring this year, the Agency has coordinated within the EU Regulatory Network the activities to monitor and evaluate the possible risk of radioactive contamination of medicines manufactured in Japan for human or veterinary use. This required extensive discussions with the European Commission, the Member States as well as the Japanese Health Authorities and the Japanese pharmaceutical industry associations, and other non-EU Regulatory Authorities. Such work is still ongoing.

Summary of performance by activity area

Legend for forecasts

Above the previous year's figures (usually more than 20% above)	Largely similar to the previous year (usually within 20%)	Below the previous year's figures (usually more then 20% below)

Legend for the implementation of objectives, projects and performance indicators

Completed	In line with plans (within 5% of targets)	Delay compared to plans or some deviation from performance indicator targets (more than 5-10%)	Significant deviation from targets (more than 10%)

Revenue and expenditure

Area	Performance
Revenue (received)	42% (€88.4 mil of €208.9 million planned)
Expenditure (committed)	73% (€152.8 mil of €208.9 million planned)
Orphan medicinal products fund	56% of the fund used (€2.75 million) of €4.9 million

Human medicines

Activity area	Number of applications/ activities in the area	Core business/key projects/ main objectives	Majority of performance indicators
Orphan medicinal products designation and fund	11% below the Q2 2010 level	Key objectives are on target	The main indicators achieved
Scientific advice and protocol assistance	In line with the numbers by Q2 2010	Key objectives are on target	The main indicators achieved (except for the involvement of external experts (15% vs target 30%).
Initial evaluation applications	40% more than in the same period in 2010. The total forecast for the year increased by 14 applications	Key objectives are on target	The main indicators achieved. 96% of applications evaluated within 210 days timeline (target 100%).
Type IA	2.5 times more than by Q2 2010. The annual forecast increased to 2750 applications	Key objectives are on target	The outcomes for the legal timeline indicators were slightly below targets but within the 5% limit, except for the linguistic post opinion check which achieved 82% (target 100%).
Type IB	37% above the same period in 2010		
Type II and line extensions	14% above the same period in 2010.		

Activity area	Number of applications/ activities in the area	Core business/key projects/ main objectives	Majority of performance indicators
Pharmacovigilance	Activities for the implementation of the pharmacovigilance legislation are above estimated workload.	Key objectives are on target	The main indicators achieved
Referrals	Remain at the 2010 level.	Key objectives are on target	Procedures evaluated within the legislative timelines, however indicators for publication of opinions, assessment reports and provision of translations to the European Commission have not been met
Paediatric medicinal products (PIPs, waivers, etc.)	PIP/waiver applications and indications are 56% below the number for the same period in 2010. Requests for modifications are 19% above 2010 level.	Key objectives are on target	The main indicators achieved
Herbal medicinal products	12 monographs released for consultation and 5 approved (target 10 and 10 respectively) The genotoxicity data issue is not resolved. No list entries released or transmitted to European Commission	Key objectives are on target	N/A
Advanced therapy medicinal products	One ATMP application was submitted. No new applications for certification submitted. 7 requests for scientific recommendations compared to 13 in the same period in 2010	Key objectives are on target	The main indicators achieved

Veterinary medicines

Activity area	Number of applications/ activities in the area	Core business/key projects/ main objectives	Majority of performance indicators
Scientific advice	In line with the levels in the same period last year.	Key objectives are on target	The main indicators achieved
Initial evaluation applications	3 compared to 8 applications by Q2 2010. Annual forecast reduced from 22 to 14.	Key objectives are on target	The main indicators achieved
Maximum residue limits	6 applications or requests compared to 8 last year (including new, extension, extrapolations MRS, cascade, biocides and Codex)	Key objectives are on target	The main indicators achieved
Type I	80 applications compared to 70 by Q2 2010	Key objectives are on target	The main indicators achieved
Type II	9 applications compared to 15 by Q2 2010		
Line extensions	In line with the same period in 2010		
Pharmacovigilance	Activities are in line with forecasts	Key objectives are on target	The main indicators achieved
Referrals (Art. 29 and 30)	9 procedures compared to 4 in the same period in 2010	Key objectives are on target	The main indicators achieved

Inspections and compliance

Activity area	Number of applications/ activities in the area	Core business/key projects/ main objectives	Majority of performance indicators
Inspections	GMP inspections 40% above the same period in 2010. Quality defect reports increased by 22% compared to 2010. GCP/PhV 28% below the same period in 2010.	The main objectives are on target. However, EDQM was not able to locate a sufficient number of parallel distributed products for this year's programme	The main indicators achieved

Activity area	Number of applications/ activities in the area	Core business/key projects/ main objectives	Majority of performance indicators
Parallel distribution	Initial notifications are in line with the same period in 2010.	Key objectives are on target	50 products were sampled and checked compared to 20 planned
Certificates	27% above the Q2 2010 level	Key objectives are on target	Due to workload turnaround time dropped to 74% compared to 90% target.

For the status of Corporate IT and Telematics system development please read section 5 'Information technology' on page 38.

Annex – detailed mid-year report 2011

1. European Medicines Agency in Europe and the World

1.1. European medicines network

Management Board

- ✓ The Board nominated **Guido Rasi** as the **Executive Director-Designate**.
- ✓ **Sir Kent Woods** was elected as the **Chair of the Management Board**.

Capacity building in alternative testing methods

- ✓ A joint CHMP/CVMP ad hoc multidisciplinary **'3R'** (Replace, Refine, Reduce) **working group established**.

Availability of expertise

- The implementation of the revised Agency's **Policy on the handling of conflicts of interest** of Scientific Committees' members and experts continued and the **implementation is planned for 29 September** 2011.
- ✓ New **electronic Declaration of Interest form** was **rolled out** end of June 2011.

Meetings at the European Medicines Agency

- ✓ The number of face-to-face **meetings** has **decreased** by 9% compared to 2010 figures.
  287 meetings have taken place (2010: 316, 2009: 297, 2008: 292).
- ✓ The number of **virtual meetings** increased by 20% compared to 2010 figures.
  203 virtual meetings have taken place (2010: 165)
- ✓ The number of **delegates** remained **at 2010 level.**
  4,316 delegates visited the EMA (2010: 4,310, 2009: 4,510, 2008: 4,261).

Preparations for future enlargement

- ✓ A conference – "Reinforcing patient safety in Europe" – took place in Zagreb in the second quarter. Further training is planned at the EMA.
- ✓ Preparations are underway to enable **Croatia** to participate in **Telematics meetings**.
- ▪ Linguistic **review of product information** of centrally authorised products **delayed** due to postponement of the date of accession.
- ✓ Preparation of a **project plan** for the follow up Instrument for Pre-accession Assistance (**IPA**) programme is progressing **in line with timelines**.

1.2. European cooperation

- ✓ Significant time and resources were dedicated to a project for the improvement of **quality of opinions** of the Scientific Committees (human and veterinary) initiated in collaboration with the European Commission.
- ▪ Work progressed with the ECDC as regards the respective roles and responsibilities of both Agencies in the field of **substances of human origin** (SoHO).
- ✓ Work to enhance co-operation with ECDC in the area of **pharmacovigilance and risk management for vaccines** progressed **in line with plans**. Finalisation of detailed annex on vaccines collaboration is pending.
- ✓ Taking into account increasing difficulties in terms of supply of medicinal products, **a lessons learnt** document on **product shortages** has been **drafted**. This will be shared with the relevant EMA scientific fora in order to progress further development of policy and processes in the network, via HMA, in the second half of 2011.
- ✓ **Geriatric medicines strategy** was adopted by CHMP and **published** in February 2011.

Cooperation with HTA bodies

- ✓ **Assessment report templates rolled-out** with agreed changes responding to the requests from health technology assessment bodies.
- ✓ **HTA** bodies participated in **scientific advice** meetings.
- ✓ A meeting took place with EUnetHTA and the European Commission on collaboration with EMA.

1.3. International cooperation

Bilateral cooperation

- ✓ In the context of its **confidentiality arrangements with FDA**, a first joint report on annual interactions with the US FDA was completed and published. The vaccine cluster was reactivated and a new cluster on Biosimilar Medicinal products was established.
  As expected, the EMA-FDA pilot initiatives on **API and GCP Inspections** collaboration were successfully completed and final reports were published. Both initiatives will continue as operational programmes. Netherlands, Sweden, Denmark and Belgium will now also participate in the API Inspection programme.

Cooperation with WHO

- ✓ Activities with **WHO** have continued to increase, with increasing activities within the paediatric network, Article 58 applications for scientific advice and collaboration on high-profile vaccine safety issues. The Agency contributed to a key stakeholder to a project on regulatory capacity building for Eastern African countries.
- ✓ Feedback from the European Commission is awaited on the proposed mutual **confidentiality agreement** between the Agency and the **WHO**.

Cooperation with other partners and capacity building

- ✓ The Agency participated at a closed meeting and open workshop with the **Chinese SFDA** with particular focus on GMP and GCP inspection collaboration.
- ✓ The Agency organised a **GCP training session** inviting representatives from WHO and Regulators from more than 18 countries from outside the EU as part of its capacity building and training initiatives.
- ✓ In the ICH area, **networks for exchange of information** on emerging safety issues, GCP and GMP inspections with non-ICH regulators have been developed.

International standardisation

- ✓ In the field of international standardisation important progress was made including **agreement on the final draft ISO standard** on Individual Case Safety Reports (ICSR), final draft ISO standards on Identification of Medicinal Products (IDMP). Work was initiated at HL7 on electronic PSURs and RMPs.

Other public health topics

- ✓ The Agency completed its input into the **TATFAR** (Trans Atlantic Task Force on Antimicrobial Resistance) discussions and a final report is expected in the second half of 2011.

1.4. Communication, provision of information and transparency

Provision of information

Publication of paediatric trials

✓ **Work plan** for publication of more details on measures and waivers **agreed**.

Further integration of patients, consumers and healthcare professionals in the agency's activities

× The implementation of the revised **framework** of **interaction with Patient and Consumers'** organisation has been **postponed** to 2012 awaiting first the outcome of the pilot phase on the participation of patients' representatives in the scientific advisory groups.

✓ Preparation of the **framework of interaction with Healthcare Professionals** is **on target**.
The document will be submitted to the Board in December 2011.

Performance indicators

× The number of initial **EPARs published within 4 weeks** of the Commission decision is 63% (target: 80%).

✓ All other **performance indicators** in this domain have been **met**.

Transparency

Clinical trials

✓ Major achievements have been the **launch of the EU Clinical Trial Registry** (22 March 2011) and **access for the public to EudraGMP** (February 2011).

× Publication of **trial results summaries** will require a major upgrade to the existing system and is currently **pending due to resource limitations**.

✓ **EudraGMP** now provides information on manufacturing authorisations and GMP certificates from **all EEA countries**, including active substance GMP certificates

EPAR usability project

✓ Work continues on the **EPAR usability** project **according to plan**.
The project aims to increase the transparency and the quality of the EPARs.

Transparency policy

✓ The HMA/EMA guidance document on the **identification of commercially confidential information** and on the protection of personal data within the structure of the marketing authorisation dossier was released for a 3 month **public consultation** period on 1 June 2011.

× The work on the policy on **publication of agendas and minutes** of the scientific committees **has not yet started**.

Access to Eudravigilance

▪ The **EudraVigilance Access Policy** for medicines for human use has been **published**, albeit with a **revised implementation plan** as a result of the evolving budgetary situation.
This will lead to a stepwise implementation, starting with the publication of pre-produced monthly reports for Centrally Authorised Products by the end of 2011 for health care professionals and the general public.

× The publication of **aggregate data for CAPs** has been **delayed**.

Access to documents

⇧ 103 requests for access to documents have been received.
In total, **574,420 pages** were released (2010: 7,090, 2009: 7,603, 2008: 2,204). This is due to the fact that their requests were mainly for access to clinical study reports, the type of document which is very extensive.
Product requests account for 90% of applications.

▪ The comments received on the **draft EMA Transparency Policy** following the public consultation are being **reviewed**.

1.5. Support for innovation and availability of medicines

Support to SMEs

✓ Activities of the SME office are continuing to increase.
172 **requests for qualification** as SMEs were received (2010: 145, 2009:104, 2008: 132)
The increase is due to alignment of MedDRA/Eudravigilance fee waiver with SME criteria.

✓ 50 requests for **renewal of SME status** received (2010: 55, 2009: 42, 2008: 39).
The majority of renewals is expected in Q4.

✓ 74 requests for **administrative assistance** received (2010: 51, 2009: 46, 2008: 52).

✓ A **survey** of SME companies and stakeholders on SME incentives and support measures **completed**

IMI

✓ The IMI funded 'EU **Protect project**' to improve methodologies in pharmacovigilance **continued**.
Reasons for slow progress on the work package on benefit/risk are being reviewed.

Elderly population

✓ Analysis of applications started in 2010 regarding the assessment of clinical data on geriatric population has been **completed**

▪ The CHMP ad hoc group of experts on geriatrics has been **established**.

1.6. Methodology and outcomes assessment projects

Outcome measures for paediatric clinical trials

× **Gap analysis** of outcome measures for paediatric clinical trials has **not started** due to lack of resources.

Methodologies for benefit-risk assessment of medicinal products

✓ Field tests of work package 3 **completed** and report adopted by the steering group in Q2 2011.
Modelling will be applied to ongoing procedures in Q4.

▪ Work **ongoing** on work package 4.
Adoption of the report expected Q4 2011.

Impact of emerging science

✓ Report **drafted** on the implementation of the Agency-CHMP think tank report. The report will be published in Q3 2011.

Utilising ENCePP network

✓ **ENCePP** has delivered **in line** with its work plan.
Highlights include: finalisation of the guideline on methodologies for pharmacoepidemiological studies; initiation of a review of the code of conduct including major review of access to investigational data set; initiation of dialogue with EUnetHTA on ENCePP as a bridge between medicines regulation and HTA; successful workshop with Medical Journal Editors on sharing study results, and ENCePP as a tool for transparency and quality.

× A study assessing the outcome of **risk minimisation measures** for isotretinoin is planned for the fourth quarter.

Measuring the effectiveness of risk management plans

✓ Identification of the **key outcomes** for four medicinal products is **ongoing** according to plan.
Evaluation of the regulatory actions undertaken has been performed for Avandia (study interim report presented at ENCePP plenary in June 2011).

1.7. Governance

× The budgetary authority has **postponed** the **discharge** for the budget 2009.
Issues raised are in the area of procurement, management of conflicts of interest, recruitment procedures.
Responses were provided to the Parliament and the final decision on discharge is expected in October 2011.
Contract agent selection procedures overhauled to ensure full compliance with rules and expectations of Court of Auditors.

✓ Revenue is **on target**
42% of planned revenue has been received (2010: 44%).

✓ Expenditure is **on target**.
73% appropriations have been committed (2010: 71%).

▪ The **budget situation** remains **stable**.
The revision of the **fee income** for the human medicines products resulted in an overall **increase** of estimates and a **decrease** for veterinary products.

▪ The introduction of a new **Enterprise Resource Project** based on a SAP database **went well**.
The launch of the **human resource module** of the SAP system is **planned** on 1 October 2011.

▪ The revision of **Fee Regulation** was split into **two stages**: the introduction of fees referred to in the pharmacovigilance legislation followed by the overall review of the Fee Regulation.

✓ Preparation for the **Olympic games** period 2012 is progressing **in line with plans.**
Meetings which have to be cancelled, rescheduled, transferred to other locations or held virtually have been identified.
The identification of key processes which should continue during the Olympic period is ongoing.

▪ The feasibility study for **Project 2014 was completed** in June 2011.
The budgetary authority and the Management Board approved the proposal to relocate to a new building in 2014.

✓ Draft Staff Regulations implementing rules on the **handling of declared staff interests** were agreed by the Management Board on 9 June 2011.
Implementation is progressing as planned.

Product data and application management

- ✓ The strategy for **operational excellence** has been **approved**.
  A number of short term projects are on-going including validation process improvement, e-opinion, e-workflow.
- ✓ The project proposal to improve the **handling of requests for access to documents** and information has been **approved**.

2. Medicines for human use

2.1. Orphan medicinal product designation

Evaluation activities

Procedure	2011 Q1-Q2 (actual)	2011 (forecast)	Revised forecast	2010 Q1-Q2	2009 Q1-Q2	2008 Q1-Q2
✓ Orphan designation (11% below 2010)	79	180	Unchanged	89	80	54

- Common FDA applications for orphan designation: 42 out of 79 applications received (53%).

Orphan medicinal products fund

✓ Fee reductions total €2.75 million (56%) of €4.9 million (2010: €4.2 million, 2009: €2.74 million, 2008: €2.68 million).

Collaboration on added value of orphan medicinal products

✓ A framework and aim for collaboration with the European Commission and HTA bodies **defined**.
Discussions with stakeholders on the framework are now planned.

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Percentage of designation applications evaluated within 90-day timeline	100%	100%	100%
✓ Percentage of summaries of opinion published within 1 month of the Commission decision on designation	90%	100%	100%
✓ Percentage of public assessment reports (on review criteria) published within one month of the European Commission's decision on marketing authorisation	80%	100%	Monitoring not initiated

2.2. Scientific advice and protocol assistance

Evaluation activities

Procedure	2011 Q1-Q2 (actual)	2011 (forecast)	Revised forecast	2010 Q1-Q2	2009 Q1-Q2	2008 Q1-Q2
✓ Scientific advice*	185	374	Unchanged	187	157	148
✓ Protocol assistance	38	73	Unchanged	37	33	31

** Includes biomarker validation and pilot scientific advice with health technology assessment bodies*

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Scientific advice and protocol assistance requests evaluated within the procedural timelines	100% of requests	99%	99%
× External experts involved in procedures	30% of SA and PA requests	15%	32%
✓ Percentage of marketing authorisation applications for new technology products (with outcome in 2011 having received scientific advice or protocol assistance	50%	57%	n/a

2.3. Initial evaluation

Evaluation activities

✓ Applications are **in line with forecasts**.
The Agency expects that the number of applications in the second half of the year will exceed the original forecast. The total estimate for the year is **increased by 14** applications from 97 to 111.

Strengthening peer review of generic applications

- **Proposal** for peer review of generics by CHMP will take place later in the year.

Procedure	2011 Q1-Q2 (actual)	2011 (forecast)	Revised forecast	2010 Q1-Q2	2009 Q1-Q2	2008 Q1-Q2
✓ New non-orphan medicinal products	15	40	+7	18	14	26
✓ New orphan medicinal products	8	12	+1	6	4	6
▪ Similar biological products	0	1	+2	0	1	0
⇧ Generic	21	37	-4	8	31	3
✓ Hybrid and abridged applications	4	5	+7	2	1	7
✓ Scientific opinions for non-EU markets	0	1		1	0	0
▪ Paediatric-use marketing authorisations	1	0	+1	0	0	0
▪ Advanced therapy re-registration	0	1		0	n/a	n/a
⇧ **Total number**	**49**	**97**	**+14**	**35**	**51**	**42**
▪ Compassionate use	0	1	-1	1	0	0
⇧ PMF	9	21	-5	3	7	8
▪ VAMF	0	1	-1	0	0	0

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Percentage of applications evaluated within regulatory timeline of 210 days	100% compliance	96%	99%
✓ Percentage of accelerated assessment applications evaluated within regulatory timeline of 150 days	100% compliance	100%	100%
✓ Percentage of opinions sent to the European Commission within the regulatory timeline of 15 days	100% compliance	100%	100%
✓ Percentage of plasma master file applications evaluated within the regulatory timeline	100% of applications	100%	100%

2.4. Post-authorisation and maintenance activities

Evaluation activities

⇧ Higher than expected number of Type IA notifications received.
The 2011 forecast for Type IA was based on figures available in December 2010 which did not provide a complete picture for a more precise forecast.

✓ 50 (2010: 32) work-sharing, 283 (2010: 200) grouping applications received.

Review of the variations process

✓ Process improvement implementation for Type IA progressed **according to plan**.

PSURs

✓ 300 (2010: 238) of periodic safety update reports were received.

Procedure	2011 Q1-Q2 (actual)	2011 (forecast)	Revised forecast	2010 Q1-Q2
⇧ Type IA	1547	1600	+1150	620
⇧ Type IB	558	995	+5	406

Procedure	2011 Q1-Q2 (actual)	2011 (forecast)	Revised forecast	2010 Q1-Q2
✓ Type II	386	975	-75	335
✓ Line extensions	7	24	-2	11

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
× Percentage of Type IA variations completed in the legal timeframe	100% compliance	94%	98%
× Percentage of Type IB variations completed in the legal timeframe	100% compliance	94%	98%
▪ Percentage of Type II variations completed in the legal timeframe	100% compliance	100%	100%
▪ Percentage of Agency recommendations on classification of variations delivered in the procedural timelines	80% compliance	No requests received	82%
▪ Percentage of grouping and worksharing procedures completed in the procedural timelines	100% compliance	100%	100%
× Submission of outcome reports for post-authorisation commitments (PACs) to applicants/MAHs within 2 weeks of the CHMP meeting	90% of reports	83%	91%
× Percentage of applications meeting the legal timeline of 27 days for the linguistic post-opinion check	100% of applications	82%	52 %

2.5. Pharmacovigilance activities

✓ Project to improve the **EudraVigilance data quality** is **on track**.
Significant progress in data management was made with the contractor on duplicate detection, recoding of product information in case reports and quality checks.

✓ Work to improve the monitoring of **pharmacovigilance compliance** is **on target**.
Preparation of compliance monitoring strategy links to the ongoing development of the good vigilance practice.

Work on the **European signal management initiative** progresses according **to plans**.
The process of signal detection is moving to electronic format to improve efficiency and to prepare for the enlargement of the scope of the signal detection activities to include non-centrally authorised products.

✓ The workload in relation to the operation of the EU **Incident Management Pan** further **increased**.
In total 11 emergency issues were discussed. Work will now start to fully implement the Incident Management Plan taking into account experience gained during the pilot phase.

Implementation of the pharmacovigilance legislation

- The **workload** to implement the pharmacovigilance legislation is **exceeding expectations**, in terms of aspects such as the management and coordination of the project, consensus-building with all involved parties, changing priorities due to an evolving budgetary situation.

✓ The following deliverables are of note:

- Establishment of a dedicated governance structure allowing involvement of the EU Regulatory Network.
- Timely publication of the legal notice and detailed guidance on submission of medicinal product information under Article 57.
- Timely delivery of the EMA technical contributions to the European Commission's implementing measures.
- Strategic steer for EudraVigilance and EU TCT agreed upon at Management Board level (depending on the available budget) and first draft of a fall-back scenario prepared in case the budgetary situation would not allow for the implementation of the strategy agreed by the Management Board.
- Preparation of more than 15 reflection papers to orientate policy and strategy on the implementation, for discussion within the governance structure.
- Agreement within the EMA on a common methodology for the development and rationalisation of business processes for the new legislation. High-level business processes mapped for all the main business areas.
- Stakeholder fora established and meetings held to discuss implementation of the legislation with the key stakeholder groups.

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Percentage of Risk Management Plans (RMPs) that are peer reviewed as part of the assessment of the initial marketing authorisation applications	90%	100%	n/a
✓ Percentage of RMPs that are peer reviewed by the Agency as part of the assessment of variations and line extensions which result in a significant change to a marketing	90%	100% for variations 100% for line extensions	100% for variations 100% for line extensions

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
authorisation			
✓ Percentage of ICSRs reported electronically for CAPs	100%	100%	n/a
✓ Percentage of CAPs monitored at least monthly by the SD group	100%	100%	n/a

2.6. Arbitrations, community referrals and opinions on scientific matters

- The workload has been **high**.
  27 new **referral procedures started** (2010: 25, 2009: 20, 2008: 18) of which 8 were Article 20 procedures.
  This corresponds to 71% of the procedures expected for 2011. The forecast has been increased from 38 to 48 procedures for 2011.
  The increase is to a certain extent influenced by the Mediator case.
- The **complexity** of referral procedures **increased**.
  There are longer and more complex referral procedures (e.g. articles 31, 107 and 20) and less short, straight forward procedures (e.g. articles 29 and 30).

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Percentage of arbitration and referral procedures evaluated within the legal timeline	100%	100%	100%
✓ Publication of question-and-answer documents for Community-interest referral procedures (Art. 31, 36, 107(2)) and Art. 20 procedures at the time of the CHMP opinion.	100%	100%	n/a
× Publication of the CHMP opinion and assessment report for Art. 5(3) procedures at the time of the CHMP Opinion	100%	0% *	n/a
× Publication of the CHMP Opinion and Assessment Report for referrals other than Art. 5(3) procedures no later than 2 weeks following the Commission Decision	100%	0% **	0%
× Opinion annexes (translations) sent to the European Commission within the legal timeframe (27 days post opinion)	100%	33%	25%

* There was only one procedure; due to high workload, the publication had a 12 day delay

** Out of the 13 referral procedures to be published, only 4 have been published so far due to very high workload (delays between 31 and 115 days)

2.7. Medicines for paediatric use

Evaluation activities

Procedure	2011 Q1-Q2 (actual)	2011 (forecast)	Revised forecast	2010 Q1-Q2	2009 Q1-Q2	2008 Q1-Q2
⇩ Number of PIP/waiver applications	99	300	-47	228	128	129
⇩ Number of indications in PIP/waiver applications	117	420	-133	268	179	194
✓ Compliance checks	26	40		26	n/a	n/a
✓ Requests for modifications	81	70	+92	68	n/a	n/a

Guidance for conduct of paediatric medicinal product development

✓ The development of **specific guidance** on the conduct of paediatric medicinal product development for model PIPs is **on track**.
Work is ongoing on 2 oncology and rheumatology model PIPs.
Updated procedural advice published on the website.

European paediatric network (Enpr-EMA)

✓ The network **coordination group established**.

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Number of PIP or waiver opinions and decisions within legal timelines	100% of opinions/ decisions	99.6%	100%
✓ Percentage of Agency decisions on paediatric investigation plans/waivers published within 6 weeks of the decision	95%	100%	n/a

2.8. Herbal medicinal products

Improving the output of the HMPC by increasing the quality and ensuring the quantitative output

- 12 draft Community herbal monographs were **released for public consultation** and 5 final monographs were **approved** (10 draft and 10 final estimated for the first half of 2011).
  The first report on the uptake of the Traditional Use Registration (TUR) scheme was **published** on the EMA website in May 2011.
- The **transition period** by which the Member States shall apply the provisions of Directive 2004/24/EC to traditional herbal medicinal products already on the market on 30 April 2004 has finished.

× **No final** Community **list entries** were transmitted to the European Commission (target 5) (2010: 0).

× **No draft** Community **list entries** were released for public consultation (target 5) (2010: 2).
It should be noted that such KPI was dependent on progress to be made with the genotoxicity data situation. No progress in this field has been achieved.

× HMPC received clarification that National Competent Authorities **cannot provide** the HMPC with the non-clinical and clinical data included in dossiers submitted by applicants.
Likewise, companies involved in the Kooperation Phytopharmaka's collaborative genotoxicity testing initiative are reluctant to provide the HMPC with the proprietary results. The HMPC will now look into other options.

✓ Further to the 2010 consultation with stakeholders, **the priority list** of herbal substances, preparations and combinations thereof for assessment was **updated** in May 2011.

2.9. Advanced therapies and other emerging therapies and new technologies

Evaluation activities

× **One** new initial marketing authorisation application for advanced therapy medicinal product (ATMP) (2010: 1).

× **No certification** applications were submitted in the first half of 2011 (2010: 0).

× 7 requests (2010: 13) for **scientific recommendations** on advanced therapy classification of 25 forecast for 2011 were received.

✓ Data on ATMPs legally on the market was collected and **analysed**.
A report on the analysis and the experience on the implementation of Article 29 of Reg. 1394/2007 will be prepared in the next months.

- ✗ The work to promote **competence development** in the area of **nanomedicines** is progressing.
  One training planned by end 2011.
- ✓ A report as part of the process to review the **impact of pharmacogenomic tests and biomarkers** in regulatory procedures is in progress.
- ✓ The **procedural advice** on the evaluation of combined advanced therapy medicinal products and the consultation of Notified Bodies **published**.

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Percentage of applications handled by the Committee for Advanced Therapies within the procedural timelines (allowing adoption of the opinion by the CHMP within the legal timeline of 210 days)	100% of applications	One application handled within the timelines	100%
✓ Scientific recommendations on advanced therapy classification provided within the legal timeline	100% of requests	100%	100%
▪ Certification of quality and non-clinical data issued within the procedural timelines	100% of requests	N/A *	100%

* No certification procedures were finalised

2.10. Scientific Committees (CHMP), Working Parties and Scientific Advisory Groups

- ✗ The draft procedure on **interaction between CHMP and PDCO** was considered by the CHMP.
  A new proposal will have to be drafted following this discussion.

2.11. CMDh Coordination group

- 2 MRP applications (2010: 6, 2009: 9, 2008: 27) and 5 DCP (2010: 2, 2009: 8, 2008: 19) applications have been **referred to the CMDh**.
- 3 MRP (2010: 5) and 2 DCP (2010: 0) referrals (of which 2 MRP and 0 DCP had been referred to the CMDh in 2010).
- 1 MRP (2010: 2) and 1 DCP (2010: 1) application have been referred to the CHMP.
- In the context of the implementation **of paediatric legislation**, 21 (2010: 37) active substances were subject to **work-sharing** under article 45 and 21 (2010: 20) submissions of **paediatric studies under Article 46**.
- In the context of the revised **variations regulation**, 11 (2010: 24) **requests for recommendations** according to Article 5 of the variations regulation have been received by the CMDh and 16 recommendations were given by the CMDh.

- Concerning the preparation for the pharmacovigilance legislation with regards to the CMDh, the implementation plan for CMDh secretariat specific activities will be prepared once decisions are made regarding the tasks in which the CMDh secretariat will be involved.

3. Veterinary medicines

3.1. Scientific advice

Evaluation activities

- ✓ The number of scientific advice applications **continues to increase** and 13 of the 26 applications forecast for 2011 have been received (2010: 14, 2009: 4, 2008: 2).
  The 26 applications forecast remains unchanged and will represent a 20% increase on last year.
- ✓ The number of requests for MUMS applications **continues to increase**. Of the 13 Scientific Advice requests received in the first six months of 2011, five related to products indicated for MUMs/Limited Market with or without financial incentives. More significantly, the number of SMEs requesting scientific advice has increased and 6 out of the 13 Scientific Advice requests received within the past six months came from SME companies.
  An annual report for MUMs/Limited market applications is planned for October and at the same time a review whether the MUMS criteria attract the intended product developments, or whether the criteria need to be revised.

Cooperation with FDA

- ✓ **One parallel scientific advice** with the FDA for a veterinary medicinal product intended for ophthalmic use in dogs was **successfully run**.
  Other companies have indicated strong interest for parallel scientific advice recently and further applications are expected

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Scientific advice requests evaluated within the procedural timelines	95%	100%	100%

3.2. Initial evaluation

Evaluation activities

- ⇩ The number of applications in 2011 **has decreased** with 3 applications received (2010: 8, 2009: 5, 2008: 12).
  The **forecast** for 2011 was **reduced** from 22 to 14 applications.
- ✓ **1 generic** application received (2010: 2, 2009: 0, 2008: 3) of the 4 forecast for 2011.

Future veterinary legislation

✓ The Agency prepared reflection papers and proposals for certain topics regarding the **future revised veterinary legislation** for discussion with CVMP and CMDv and directly to the Commission, as requested.
The secretariat also took an active role in the discussions at HMA – EMA Task Force, and meetings with stakeholders (HMA Focus group meeting, IFAH Europe conference).

Quality assurance

✓ Continued efforts are being made in respect to **quality assurance** of assessments and opinions.
The CVMP has embraced the peer review concept and **peer reviewers are appointed** for all relevant assessment procedures.
The actual submission of peer review reports at 73% was below the target of 90% and will be addressed with the chair/vice chair of the CVMP and the Committee to try to increase the rate of submission.

Promoting authorisation of vaccines against epizootic diseases

✓ Work to promote authorisation through the centralised procedure of **vaccines against epizootic diseases** of livestock **progresses well**.
At the mid-year point one bluetongue application has been validated, two bluetongue applications have received marketing authorisations and two bluetongue applications have received positive opinions.

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Percentage of products evaluated within the regulatory timeline of 210 days.	100% of applications	100% (seven of the 13 opinions were evaluated in less than 210 days)	100 %

3.3. Establishment of maximum residue limits

Evaluation activities

⇧ **One new** (2010: 2, 2009, 2, 2008 1) and **five extension/modification** applications (2010: 1, 2009: 1, 2008: 1) were received.
The forecast for extension modification applications was therefore increased from 3 to 6.

- **No MRL extrapolation** applications were received (2010: 0, 2009: 0, 2008: 5).
A number of applications are however expected and the forecast is increased from 2 to 5.

⇩ **No** MRL for **use in cascade** and **no** MRLs for **biocidal products** were received (2010: 5 and 0, 2009: 0 of each).
The annual forecast for MRLs for use in cascade was therefore reduced from 5 to 0, and for biocidal products from 3 to 1.

⇩ **No reviews** of draft **codex** MRLs took place.
The forecast decreased from 6 to 2.

- CVMP **peer reviewers** submitted comments to **100% of applications** (target 90%)

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Percentage of MRL applications evaluated within the legal timeline	100% of applications	100 %	100 %

3.4. Post-authorisation activities

Evaluation activities

✓ The number of **type-I applications exceeded** predictions, and the number of **type-II** applications was **lower** than foreseen.
This was mainly due to the new Variations Regulation. The forecast for type II variations has therefore been reduced to 25 type II applications.

Procedure	2011 Q1-Q2 (actual)	2011 (forecast)	Revised forecast	2010 Q1-Q2
✓ Type IA	80	130	0	70
⇩ Type II	9	35	25	15
✓ Line extensions	2	7	5	2

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Post-authorisation procedures processed in accordance with legal requirements	100%	100%	100%

3.5. Pharmacovigilance and maintenance activities

✓ The predicted **slowing down** of spontaneous serious adverse reaction and human reaction reports being submitted (doubling previously each year) was **confirmed** in 2011.
It became apparent that the high number for 2010 was mainly due to the high number of reports for Bluetongue vaccines (1200 reports), which has not been observed this year with only 110 reports on Bluetongue vaccines up to now. The forecast for 2011 has been reduced to 5,000 reports. The submission and assessment of PSURs is according to forecast.

Development of the EudraVigilance database

✓ The **processing of pharmacovigilance** information and access to EVVet data has **improved**.
Performance of the Data Warehouse queries has been improved significantly and an additional Filemaker database has been developed and made available to process and follow the new surveillance procedure for centrally authorised products CAPs.

Access to EudraVigilance data

- The **Access policy** for Eudravigilance Veterinary has been **published.**
  However the implementation will be gradual and is subject to the availability of adequate funding (project proposal for public Access to CAPs data by end 2012).
- Significant **progress** has been made with full **product data transfer** from five Member States to the Eudrapharm database and with the manual data transfer of a large data set for one further Member State. Regular recoding is in place for CAPs. Recommendations for risk-based surveillance are being developed by the PhVWP-V signal detection subgroup. The new surveillance procedure for CAPs due to start in August is already partially risk-based.

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Percentage of PSURs and SARs evaluated within the established timelines	80% PSURs 100% of SARs	94% of the PSURs; 100% of the SARs.	94% of the PSURs; 100% of the SARs.

3.6. Arbitration and community referrals

⇧ The number of **referrals/requests for arbitration** was **higher** than predicted with 9 referrals already received by mid-year (2010: 4, 2009: 4, 2008: 5). The forecast was therefore revised from 12 to 18.

- By mid July 2011 **no re-examination procedures** were requested by the applicants/MAHs.

- ✓ Task Force document with proposal on strategy to reduce the number of inappropriate referrals was submitted to HMA in April and **approach** and **direction** of work **approved**.
  Further work will be continued when the group will consider best ways in which its output can be captured.

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Percentage of arbitration and referral procedures managed within the legal timeline	100% of procedures	100 %	100 %

3.7. Scientific committee

- ✓ The activities of the CVMP are included elsewhere in this report as part of the reports on objectives achieved.
- ✓ CVMP strategy 2011-2015 on **antimicrobial resistance** finalised following public consultation and **published** in July 2011.
  Action plan will now be prepared.
- ✓ The historical ESVAC report on **trends of sales of antimicrobials** has been **compiled** based on data from 9 countries.
  The estimated publication date is September 2011.

3.8. Coordination group

- ✓ 100% (3/3) of referral procedures initiated by the CMDv were accepted by the CVMP.
- ✓ A working group of EMA and CMDv to prepare a document outlining the principles for **commercially-confidential information** and the protection of personal data within the dossier for veterinary marketing authorisation applications has been initiated. It is anticipated there will follow closely the principles adopted for the dossiers for human products, suitably adapted to reflect the particular requirements of the veterinary sector.
  A first draft of the document is anticipated in Q3 2011
- ✓ The CMDv pilot on SPC harmonisation procedure aiming to reduce the number of avoidable referrals to the CVMP is nearing completion in Q3 2011.

4. Inspections

4.1. Inspections

4.1.1. Manufacturing Quality Compliance

⇧ Requests for **GMP inspections** are 40% above 2010 figures.
183 GMP inspection requests were received (2010: 129, 2009: 120, 2008: 105) of 245 planned for the year.

⇧ The number of quality defect reports increased by 22% (to 66) compared to the same period in 2010.

✓ Preparation for the implementation of the new **EU legislation on counterfeit** products is **on track**.
Discussion with the European Commission has been initiated. Draft proposal provided to May GMDP IWG meeting.

✓ A trial programme on sampling and testing of generic medicinal products is progressing **in line** with plans.

× According to EDQM it has not been possible to locate sufficient samples of the parallel distributed products for this year's programme (3 products were planned for 2011).

✓ In a separate initiative with GMDP IWG some 50 samples of parallel distributed products have been subject to label compliance checks.

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Management of inspections within legislative timelines	100% of inspections	100%	100%

4.1.2. Clinical and non-clinical compliance

⇩ Inspection requests are below the number during the same period in 2010, but in line with this year's forecast.
34 GCP/PhV inspection requests were received (2010: 47, 2009: 39, 2008: 48). 1 GLP inspection was requested.

- The GCP IWG and CTFG subgroup finalised their draft reflection paper on **risk based quality management in clinical trials** and it will be released for public consultation in Q3 2011.
- **EudraCT version 8.0** containing important additional functionality and an updated Clinical Trial Application Form were **deployed** on 10 March 2011.

- ✓ As part of the EMA's commitment to contribute to capacity building in emerging countries, a three-day basic GCP Inspectors training course with participants from the EU, as well as 17 countries outside the EU took place.
- ✓ Preparations to extend the **EMA - FDA GCP** initiative following completion of the pilot phase are on track.
  A report of the pilot phase of the EMA - FDA GCP initiative including the way forward was scheduled for publication in July 2011.
  3 **observational inspections** scheduled for July 2011 and 63 exchanges of information on 29 products of mutual interest took place.
- × Due to the need for resources as regards the implementation of the new pharmacovigilance legislation, initiatives to develop **international cooperation** in the field of **pharmacovigilance inspection** will be **postponed**.

4.2. Clinical trials support

- The draft reflection paper on 'Ethical and GCP aspects of clinical trials for human medicines conducted outside the EU and submitted in marketing authorisation applications to European Regulatory Authorities', has been revised and will be circulated **for final agreement** by HMA and the Management Board.
- ✓ A procedure for liaising between the EMA, the CHMP and the CTFG on the potential CHMP negative opinion, pre-opinion or post-authorisation withdrawal, suspension or revocation of a MAA with impact on EU clinical trials has been **prepared** with the input from the CTFG.
- ✓ Comments were provided to the European Commission on the concept paper on the revision of the **clinical trials legislation**.
  A preliminary **impact assessment** based on the scenarios outlined by the European Commission and in the EMA response will be undertaken.
- ✓ In the context of the development of EudraCT, the Technical **Guidance on the publication of results** related data (EudraCT v 9.0) has been revised with the comments from the public consultation and **sent to the European Commission** for discussion.

4.3. Parallel distribution

- ✓ 1,281 initial notifications have been submitted (2010: 1,305, 2009: 1,020, 2008: 792), representing **91.5% of the target** for mid-year.
  The figures are similar to 2010 in spite of a significant reduction of parallel importation products in Europe.
- ✓ The process improvements introduced in parallel distribution have enabled 93% of the notifications to be turned around within their target timeline.
  This is above the performance target set, and the **first time this has been achieved**.
- ✓ A **pilot** with the UK MHRA **has started** to check product information of CAPs by parallel distributors.
  Of products checked during the first 6 months, many critical deficiencies were identified leading to regulatory action in a number of cases. It is expected to extend the pilot phase to other Member States at a later stage.

✓ The **electronic system** is now used in **more than 95% of the information submitted**, compared to the expectation of 80%.
The EMA will continue promoting its use in case of new parallel distributors.

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Percentage of initial notification checked for compliance within the regulatory timeline of 35 working days	80%	93%	71%.
✓ Number of parallel distributed products sampled on the EU market checked for compliance with the notices issued by the EMA	20 products	50	7

4.4. Certificates

⇧ 1,527 requests for certificates have been received (2010: 1,205, 2009: 1,062, 2008: 1,057) which is **27% more** than during the **same period in 2010**.

× Higher workload caused a consequent **drop in turnaround time to 74%** (2010: 97%, target 90%).
It is hoped to introduce some improvements to bring this back closer to schedule but workload will need to be closely monitored to ensure improvement.

✓ The **majority of the proposals** (i.e. trade mark name in the country of destination, addition of annex II, etc) discussed with WHO and stakeholders have been **implemented**. Fast track procedure and electronic certificates are still under discussion.

5. Information technology

5.1. ICT to support internal activities

- ✓ The first **financial module** (known as FIN 1) of the enterprise resource planning (ERP) system **launched**.
- ✓ Phase 1 of **human resource** module of the ERP system is **on track** with planned delivery in Q3
- × Phase 2: Realisation will be **postponed** to Q2 of 2012.
  The initial plan to develop elements of phase 1 and phase 2 in parallel has proved not feasible.
- ✓ As at 30, June the development of **SIAMED** II version 3.0 was **on track** for delivery in Q3
- ▪ Implementation of **electronic signatures** is scheduled to start in September.
  The original target of delivery is Quarter 4.
- ✓ The development of the system to support **plasma master files** is **on track** for delivery in Q4
- ▪ The EMA **Enterprise Information Architecture** project has been **closed.**
- ▪ The pilot for the **unique product identifier** has is scheduled to start in September
  The original delivery was foreseen for quarter 3.
- ✓ The project to launch the **document register is in progress**.
  The delivery timeline for the first phase is quarter 4.
- ✓ The system to register **electronic declaration of interests** has been **delivered** in quarter 2.
  The publication of the register is scheduled for quarter 3.
- ✓ Implementation of improvements to systems supporting electronic submission include a new release of EURS, the Central Repository and electronic submission of applications via the Eudra Gateway. These projects are in progress and **on track** for delivery in Q4.

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
✓ Corporate IT and telematics systems availability	98%	Above 99% for all systems, except for EV pre production and EV production (73.35% and 93.03% respectively)	99.2% (corporate), 98.1% (telematics)

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
measured against EMA working hours			
× Projects delivered on time	85%	62%	87%
▪ Projects delivered to original specifications	100%	92%*	100%
× Projects delivered within budget	85%	69%	86%

* Some projects have delivered more than the original requested scope.

5.2. EU telematics

- ✓ The Management Board Telematics Committee strategy for increasing use of **virtual meetings technology** has been **endorsed** by the Management Board and **is being implemented**.
- ✓ The review of the **governance structure** of EU Telematics **is in progress**.
- ✓ Due to the early availability of the ISO standard, it was decided to extend the scope of the first iteration of the medicinal products and substances database within **EUTCT** to be fully ISO compatible instead of partially-ISO compatible. This **is in progress** and scheduled for delivery in quarter 4.
- ✓ The project to launch a revised **data warehouse** offering business intelligence functionality on **EudraVigilance Human** data is **on track** for delivery in quarter 4. The scope of the delivery has changed in line with the provisional decision of the Management Board in March 2011.
- ▪ The project to launch a **data warehouse** offering business intelligence functionality on **EudraCT** data is **on track** for delivery in quarter 3.
  An intermediate release has already been delivered in quarter 2.
- ✓ The implementation of the **EV data access policy** is in progress and **on track** for delivery in quarter 4.
  The scope of the delivery has changed in line with the provisional decision of the Management Board in March 2011.
- ✓ New legislative functionalities are being implemented in EV human, the data warehouse and the eSubmission systems.
  A first release of EudraVigilance, implementing Article 57.2 will be released in quarter 3.
- × The publication of a new version of the **Telematics website** for the European Medicines Network has **is deferred**.

✓ **EudraCT version 8.0** was **released** in Q1, providing the new CTA paediatrics protocol.
The EU Clinical Trials Register was **released** in Q1.
The delivery of increased electronic communication between registries and other stakeholders is **on track** for delivery in quarter 3.

▪ The complete analysis and design and delivery of a first prototype of **EudraCT 9** is planned to start in September.

✓ NCAs from four Member States are using **lists from EUTCT**. At least three other NCAs are currently looking into making use of lists.
The target is that 70% of NCAs will use at least one list from EUTCT in quarter 4.

▪ The **eAF** project is **in progress**.
The completion of the system is postponed to quarter 4.

✓ As of end July, eight NCAs provide data to **EudraPharm** in production. An additional four NCAs are currently in test.
The target is to publish product information from 55% of NCAs in Q4.

Performance indicators related to core business	Target	Outcome at the end of Q2 2011	Outcome at the end of Q2 2010
× Projects delivered on time	85%	40%	77%
✓ Projects delivered to original specifications	100%	100%*	108%
× Projects delivered within budget	85%	67%	84%

* Some projects have delivered more than the original requested scope

Service Desk (Eudra) - meeting of service level agreement's per system/ priority level:

Severity rating	Description	Resolution time	Target	Outcome at the end of Q2
1. Critical	Users are unable to use the system.	▪ 4 hours	80%	0%
2. Severe	The system is operational but severely restricting use.	▪ 1 business day	80%	43.82%
3. Important	The system is operational, but one or more functions are restricted.	▪ 10 business days	80%	85.04%
4. Minor[1]	The system is operational and no functions are restricted.	▪ 120 business days	80%	69.79%

[1] Although fixing the minor defect might take very little time it might take up to 120 business days until the fix is released as part of the scheduled release management. This is done to keep costs down.