16 September 2010
EMA/MB/511982/2010

European Medicines Agency mid-year report 2010 from the Executive Director (January - June 2010)

Management Board meeting of 7 October 2010

Background note

This mid-year report from the 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 2010. Please refer to the work programme 2010 for the details of objectives set.

Matters for consideration

The document consists of three sections:

- Overall summary of progress under **the priority** areas (pages: 2-5).
- Overview of performance under **main activity areas** (pages: 6-9).
- **Detailed mid-year report** in Annex (starting on page 10). 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 (▪) also indicates general information on progress, a comment or a highlight.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

European Medicines Agency mid-year report 2010 from the Executive Director

(January – June 2010)

Summary of progress on priorities

The majority of activities are on track. Workload in general is as forecast, although with variation from forecasts in some areas. The budget situation for 2010 is good: revenue and expenditure are on target. Below are highlights from the first half of the year under the priority areas agreed by the Management Board.

- **Conducting the Agency's core activities to the highest quality standards, amid the increasing volume and complexity of activities**
  - The evaluation of the Agency as part of the network carried out by the European Commission was completed. The Agency and the network received a positive assessment.
  - The Executive Director received discharge from the European Parliament for the implementation of the 2008 budget.
  - A number of areas have seen workload significantly above predicted levels: number of type-IB variations for human medicines (58% above forecast), paediatric investigation plans and waiver requests (52% above forecast), initial parallel distribution notifications (45% above forecast), veterinary initial marketing authorisation applications (45% above forecast), veterinary scientific advice (55% above forecast) and GCP/pharmacovigilance inspections (75% above forecast).
  - With regard to human medicinal products, the number of applications for initial evaluation and applications for generic medicines is significantly lower than forecast (24% and 29% respectively) with a number of applications shifting to the second half of the year or delayed until 2011.
  - As summarised in the next section, there are no major deviations from achieving main objectives or performance indicators.
    Legal timelines were met for the majority of core activities. The regulatory timelines for processing of parallel distribution notifications were not met to the expected level, due to increased workload in the area. However, measures are being taken to address the issue.
    Timelines for the publication of paediatric decisions and of EPARs will need to be improved.
    The number of herbal monographs is lower than planned, and no list entries were sent to the European Commission. However, it is expected that year-end targets will be met.

- 60% of the total orphan fund for 2010 has been used. The expenditure is 53% higher than in the same period in 2009.
- Pandemic activities were higher in intensity than predicted, with extensive work within the Agency and the network, as well as cooperation with DG SANCO, ECDC and WHO.
- There are some deviations from the planned delivery of certain ICT projects.

- **Implementing tasks vested by new legislation**
  - Legislation on advanced therapy medicinal products is operating well. The first year of CAT activities was marked in January 2010. The first opinion on the certification of experimental data generated for an ATMP was issued. One new ATMP application was submitted. Requests for scientific recommendations on advanced therapy classification are being received. Effective interaction between the CAT and CHMP has been established.
  - There has been a high workload associated with the entry into force of the new Variations Regulation[1] on 1 January 2010. The Agency is applying provisions of the new legislation on variations both for human and veterinary medicines. It is still too early to estimate the workload impact of the new regulation; the financial impact is being analysed. These areas will continue to be closely monitored.
  - The new regulation on maximum residue limits is in operation and applications originating from the new provisions are received and evaluated.
  - The Agency began preparing for implementation of future legislative changes in the areas of pharmacovigilance and falsified medicines. A task force is reviewing the arrangements to be put in place and is looking at the impact of the future legislation.
- **Strengthening the European medicines network**
  - The development of the European Medicines Agency's Road Map to 2015 is progressing in line with plans. External consultation has been completed and comments are being reviewed. The Road Map will be submitted to the Board for adoption in December 2010.
  - The results of the evaluation of the Agency were positive for the European medicines network. A conference to discuss evaluation results was organised, with the participation of 140 partners and stakeholders. Outcomes of the conference will be published by the end of the year.
  - Proposed principles for revision of the conflicts of interest policy have been extensively discussed. Adoption of a revised policy is expected later this year.
  - The proposal for a revised system for remuneration for scientific work carried out by NCAs was not supported by the Management Board. Proposed changes in the remuneration system will not be implemented.

[1] Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products Text with EEA relevance.

- Revised contractual arrangements have been agreed between EMA and HMA.

- **Continuing to improve the safety-monitoring of medicines**
  - The evaluation of the tender procedure for EudraVigilance Data Quality Management was completed. The setup phase is expected to start in the third quarter, following the signature of the framework contract.
  - A policy on the communication on (emerging) safety-related issues was prepared and will be published in July.
  - The second release of the database of research centres and data sources in the context of ENCePP was launched to the public.
  - A detailed EudraVigilance project plan for 2010 to 2013 was prepared and approved by the EudraVigilance steering committee.
  - Inclusion of medicinal products for human use in the updated Eudra data warehouse is in progress.
- **Cooperating with international partners and contributing to international activities**
  - Bilateral agreements continued to operate. Regular meetings take place between the EMA and the FDA.
  - A number of initiatives were undertaken with the WHO. A memorandum of understanding will be prepared.
  - The 'Reflection paper on ethical and GCP aspects in clinical trials conducted in third countries in marketing authorisation applications submitted in the EEA' was released for consultation. A workshop is planned for September as part of the consultation.
- **Fostering communication, provision of information and increasing transparency**
  - Work on the new website approached completion, albeit with some delay. The planned launch of the new website is July 2010.
  - Building on the pilot phase carried out in 2009, two representatives of patients were nominated permanent observers to the Pharmacovigilance Working Party.
  - Work to revise the draft access to documents policy continued and is scheduled for finalisation by the end of the year. The final policy will take into account recommendations of the European Ombudsman.
  - The development of the transparency policy is delayed due to resource issues. Priority has been given to the finalisation of the access to documents policy.
  - Work on developing the EudraVigilance access policy progressed, albeit with some delay. The policy will take into account recommendations of the European Data Protection Supervisor and the European Ombudsman. The first publication of aggregated data for centrally authorised products will not take place in 2010. In the context of the influenza pandemic, the Agency published regular pandemic pharmacovigilance updates.

- **Contributing to an environment that stimulates innovation and improved availability of medicines**
  - SME Office received an award for 'Most significant contribution to mediscience sector'.
  - Grant agreements for PROTECT project, which is part of the Innovative Medicines Initiative (IMI), were signed in February 2010.
  - The Agency's initiatives to support the availability of veterinary medicinal products for minor uses and minor species are producing results. There are a large number of requests for classification by CVMP and, as a consequence, an increase in the number of requests for scientific advice and marketing authorisation applications.
  - Projects in the field of outcomes assessment are progressing well. These include work on the methodology for benefit-risk assessment and completion of the work on assessing the impact of scientific advice on marketing authorisation applications.
  - The Agency is in the process of establishing the CHMP ad hoc group of experts on geriatric medicines. It also intends that 50% of applications started in 2010 will have detailed assessment and reporting on geriatric populations. Work to prepare for this task is in progress.

Summary of performance by activity area

Legend for forecasts

Above target (usually more than 20% above forecast)	Largely on target (usually within 20% of forecast)	Below target (usually more then 20% below forecast)

Legend for the implementation of objectives, projects and performance indicators

Completed	In line with plans	Delay compared to plans	Significant deviation from targets

Human medicines

	Number of applications/ activities in the area	**Core business/key projects/ main objectives**	**Majority of performance indicators**
Revenue	The revenue and expenditure are in line with forecast	N/A	N/A
Orphan medicinal products designation and fund	Designation applications are in line with forecasts. However, 60% of the orphan medicinal products fund has been used.	Key objectives are on target	The main indicators achieved
Scientific advice and protocol assistance	13% above forecast	Key objectives are on target	The main indicators achieved.
Initial evaluation applications	The overall number of applications is less than forecast as several applications have been shifted to second semester of 2010 or delayed until 2011. The number of generic applications is lower than expected following European Commission's interpretation of multiple applications; however several generic applications are expected in the second half of the year.	Key objectives are on target	The main indicators achieved

Type IA	Close to forecast	Key objectives are on target	The main indicators achieved. However, the percentage of applications meeting the legal timelines of 27 days for the linguistic post –opinion check is 52% (the target 100%)
Type IB	58% above forecast		
Type II	In line with forecast		
Line extensions	In line with forecast		
Referrals	In line with forecast	Key objectives are on target	The main indicators achieved, except for the transmission of translations to the European Commission where delays occurred.
Pharmacovigilance	Activities are in line with forecasts	Key objectives are on target	The main indicators achieved
Herbal medicinal products	N/A	7 of 10 herbal monographs finalised. No list entries transmitted to European Commission (3 planned). It is expected that year end target will be met.	N/A
Paediatric medicinal products (PIPs, waivers, etc.)	Applications are 52% above forecast	Key objectives are on target	Decision legal timelines met 100%. However, compliance with the timelines for the publication of decisions is low due to unrealistic targets (less than 50% compared to planned 95% compliance)
Advanced therapy medicinal products	One ATMP application was submitted. No new applications for certification submitted. 13 requests for scientific recommendations compared to 25 forecast.	Key objectives are on target	The main indicators achieved
Parallel distribution	Initial notifications are 45% over forecast	Key objectives are on target	71% of initial notifications checked within 35-days (target 80%)
Interaction with and provision of information to patients and	N/A	Key objectives are on target	All performance indicators met, with the exception of publication of EPARs within 2 weeks of Commission decision: 21% achieved compared to 80% target.

healthcare professionals			

Veterinary medicines

	Number of applications/ Activities in the area	**Core business/key projects/ main objectives**	**Majority of performance indicators**
Scientific advice	55% increase over forecast	Key objectives are on target	The main indicators achieved
Initial evaluation applications	Above forecast, year end total forecast increased from 14 to 20 applications.	Key objectives are on target	The main indicators achieved
Maximum residue limits	MRL workload is in line with forecasts	Key objectives are on target	The main indicators achieved
Type I	70 applications were received of 65 planned for the whole of 2010	Key objectives are on target	The main indicators achieved
Type II	33% of end of year forecasted applications have been received by end of June.		
Line extensions	33% of end of year forecasted applications have been received by end of June.		
Pharmacovigilance	Activities are in line with forecasts	Key objectives are on target	The main indicators achieved
Referrals (art. 29 and 30)	In line with forecast	Key objectives are on target	The main indicators achieved

Inspections

	Number of applications/ Activities in the area	**Core business/key projects/ main objectives**	**Majority of performance indicators**
Inspections	GCP/pharmacovigilance inspections are 75% above forecast. GMP inspections are 12% above forecast.	Key objectives are on target, with somewhat slower progress on certain activities with international partners	The main indicators achieved

IT projects

EU telematics

EudraVigilance veterinary 3	Implementation of EudraVigilance access policies for human and veterinary medicines	Eudra data warehouse	EudraVigilance data management
EudraCT version 8	PIM Review System 6.x	Light Authoring Tool	PIM Data Validation Engine
Reference Data Model version 3	Reference Data Model version 3	e-Application forms	

Corporate IT projects

Enterprise Resource Planning system	Full implementation of eCTD for all applications for marketing authorisation	SIAMED II

Annex

1. European Medicines Agency in Europe and the World

1.1. European medicines network

Management Board

- Pat O'Mahony was elected as the Chair of the Management Board for the second term.

Evaluation of the Agency and preparation of Road Map to 2015

✓ **Positive** results from the **evaluation** of the Agency as part of the network. A joint European Commission/EMA **conference** to discuss evaluation results **with stakeholders** took place.

✓ **Public consultation** on draft EMA Road Map 2015 launched and completed.
Meetings with stakeholders groups (European Industry Associations (Human and Veterinary), Patients' and Consumers' Organisations and Healthcare Professionals' Organisations) took place in first quarter 2010 as part of the consultation exercise. Initial results **presented** at the conference of 30 June 2010. Adoption of the Road Map is expected at the **December Management Board meeting**.

Implementing a new payment system

× The **Management Board did not support** the proposal by the Executive Director which aimed to introduce a payment system based on costs of evaluation incurred by national competent authorities.
The decision is based on the understanding that only those countries which participated in the pilot demonstrated ability to identify hourly rates for services provided and to record time spent on centralised applications. A number of countries chose not to participate in the pilot. The Board also stressed that Member States continued to have reservations as to the ability to record time on an ongoing basis.

Management of conflicts of interest

- The **process for the handling of conflicts of interests** at the Agency is currently **being reviewed**. The key principles of the revised policy were presented at the June Management Board meeting. Final proposal will be submitted for adoption at the October Management Board meeting.

Other

✓ The **cooperation agreement** has been adopted by **HMA** and the **Management Board**. Signing of the agreement is expected by the end of 2010.

Meetings at the European Medicines Agency

- The number of meetings has increased from 2009.
  316 meetings have taken place so far (2009: 297, 2008: 292).
- The number of delegates has decreased compared to 2009.
  4,310 delegates visited the EMA (2009: 4,510, 2008: 4,261).

Preparations for future enlargement

- The Agency continued to **provide information** on CHMP Opinions and Assessment Reports for all Safety variations, Extensions (Annex II), Annual re-assessment and Renewal applications adopted by the CHMP relevant **to the CADREAC regulatory authorities** (Croatia).
- To facilitate the integration of candidate countries, representatives were invited to meetings of **GMDP inspectors working group**.
  Bosnia, Croatia, FYR Macedonia, Kosovo, Montenegro, Serbia and Turkey participated.

1.2. European cooperation

Influenza Pandemic activities

⇧ The workload in this area was **higher than originally foreseen**. Work was carried out in relation to the intensive monitoring of centralised vaccines and anti-virals, analysis and validation of safety data, regulatory WHO phase-out strategy discussions and impact analysis. Review of operation of **influenza pandemic** crisis plan initiated and **lessons learnt exercises** organised.

- EMA continued close **cooperation with ECDC** on the topic.
  Working arrangements are being drafted regarding post authorisation benefit/risk monitoring of vaccines.

Collaboration of EU agencies in similar fields

- **Memorandum of understanding** with **EMCDDA** concluded and published.

Changes to EPAR in the context of cooperation with health technology assessment bodies

- Collaboration with DG SANCO-Member States **joint action on HTA** was initiated.
  EPAR improvements have been agreed. Revised templates will be rolled out in autumn 2010.

1.3. International cooperation

Bilateral cooperation

- **Bilateral** cooperation activities progressed well. There are some delays in cooperation with some authorities in the field of inspections.
- Cooperation with the FDA progressed well.
  Draft outline of implementation plan for **blood product cluster** finalised. **New clusters will not be established** for the time being. Process for Agency-FDA **common submission** of **annual reports on orphan drugs after designation** has been put in place.

Cooperation with the WHO

- A **memorandum of understanding** on the **cooperation** between **WHO** and EMA, in close collaboration with the European Commission, will be prepared.
- WHO representatives were involved in the **scientific advice** work in the framework of medicinal products for use in non-EU countries.
- A **project of regulatory capacity building** with **Eastern African countries** was started.
  The concept of an internationally co-ordinated group of "mature" regulatory authorities to assist with regulatory resources is being discussed.

Other activities

- International workshop on **nanomedicines organised** with involvement of FDA, Health Canada, Japanese authorities and European Commission.

ICH and VICH – standardisation activities

- The workload in this area has been very high. Delays have occurred in achieving the **Final Draft of the International Standard ICSR**. The expected completion of the International Standard has now been set for Q3 2011.
- Work continued on the **standard for the identification of medicinal products**, and on the preparation for the implementation of **ICH E2(B) guidelines** and related standards.
- Veterinary VICH pharmacovigilance guidelines were signed off in June 2010 following several years of negotiation in which the Agency was heavily involved

Certificates

- The number of requests for certificates is **on target**.
  1,205 requests for certificates have been received, which is slightly less then forecast (5.6 % less) but 13% more than in the same period of 2009 (2009: 1,062, 2008: 1,057).

Performance indicators related to core business	Target	Outcome
✓ Percentage of certificates of medicinal products issued to requesting parties within the timeline	90% compliance	97%

Mutual recognition and other agreements

- Work in the field of mutual recognition agreements is progressing well
  Informal agreement on **extension of MRAs** to cover inspection outside of respective territories was reached for active pharmaceutical ingredients (APIs) with **Switzerland, Australia** and **New Zealand**.
  Discussion on **extension to APIs** initiated with all partners **except Japan and Canada**.
  Cooperation with **Israel started**.

1.4. Communication, provision of information and transparency

Provision of information

Quality and accessibility of the Agency's written information

- The development of the **new website approached completion**.
  The website was planned for launch in July.

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

- ✓ Building on the pilot phase carried out in 2009, two representatives of **patients** were nominated **permanent observers to the Pharmacovigilance Working Party**.
- ✓ Following the reflection for further involvement of patients and consumers in the Agency's activities, different initiatives have taken place including involving patients and consumers systematically **in safety communication** and preparing the structure for **involving patients/consumers in the**

Scientific Advisory Groups discussion. Because of the need identified by the CHMP to run first a pilot on the involvement of patients in benefit-risk evaluation, the **revision of the framework of interaction with patients will be delayed**.

- The endorsement of the **framework of interactions with healthcare professionals** is planned for December 2010.

Performance indicators

✓ **All performance indictors** in this domain have been **met**, with the exception of publication of documents following the scientific review process. The number of initial **EPARs published within 2 weeks** of the Commission Decision was published for 21% of the marketing authorisations granted (target: 80%).

Transparency

Transparency and Access to documents policies

- Work on the **Access to Documents Policy** continued during the 1st half of 2010. A draft recommendation from the European Ombudsman is being addressed and may lead to an **important change in policy**. The finalisation of the Access to Documents Policy is scheduled for the 2nd half of 2010.
- In relation to the **EudraVigilance Access Policy** it was important to ensure that the European Data Protection Supervisor (EDPS) recommendations and the recommendations of the European Ombudsman were adequately addressed. Following consultation with the EudraVigilance Steering Committee and the HMA, the policy will be submitted to the Management Board by the end of the year.

× No progress on the EMA **Transparency Policy** was made due to resource issues and the need to give priority to the finalisation of the access to documents policy. Finalisation will be delayed until 2011.

× As a result of the delay in the finalisation of the EudraVigilance Access Policy, the first **publication of aggregated data** for centrally authorised products **will not take place in 2010**

× Work on EudraCT (including public **information on paediatric clinical trials**) continues with some delays.
Data migrations in progress but takes longer than expected. Guideline for the submission of results of clinical studies released for consultation in June 2010.

1.5. Support for innovation and availability of medicines

Support to SMEs

- ✓ SME Office received an **award for 'Most significant contribution to mediscience sector'** at the European Mediscience Awards Dinner 2010.
  The event is the largest annual gathering of quoted healthcare, biotech and life-sciences companies in Europe.
- ✓ Activities of the SME office are progressing well.
  145 **requests for qualification** as SMEs were received (2009:104, 2008: 132) (45% more than expected).
  55 Requests for **renewal of SME status** arrived (2009: 42, 2008: 39).
  51 requests for **administrative assistance** received (2009: 46, 2008:52). 2010 forecast is 100.
- Consultation on **public database** to provide online **information on assigned companies** from SME database was carried out with stakeholders.

PROTECT project

- ✓ The **Grant Agreement for the IMI Project** was signed by all parties and the research work has started.
  Work in the various **Work Packages is progressing well**. EMA has received very positive feedback from partners and IMI Joint Undertaking on its coordination work.

EMA input in the field of medicines used in geriatric populations

- The Agency is establishing the CHMP **ad hoc group** of experts **on geriatric medicines**.
  Call for nominations has been sent to CHMP, identified members will be involved in the drafting of the geriatric plan.

Authorisation of MUMS products

- The Agency's **initiatives** to support the **availability of veterinary medicinal** products for minor uses and minor species are **producing results**. There is a large number of requests for classification by CVMP and as a consequence increase in the number of requests for scientific advice and marketing authorisation applications.

1.6. Methodology and outcomes assessment projects

- Methodology for **benefit-risk assessment**:
  Assessment of the applicability of current tools and methods for regulatory benefit-risk assessment has been drafted.
  Tools and methods will be field tested in parallel with normal procedure.

- ✓ A detailed methodology for **assessment of the impact of scientific advice on the outcome of marketing authorisation applications** was set up and the impact was assessed by product.
  A report was published in a scientific journal.

- Some other ongoing projects include:
  Analysing the **outcome of PIP/waiver applications** compared with applicant's requests
  Establishing a template for **outcome research on novel biomarkers** and related statistical methods impact on MAA.
  Results of the work will be published in scientific journals.

- ✓ The Agency **completed** the project describing the **effectiveness of additional risk minimisation measures** as reported by marketing authorisation holders.

1.7. Corporate governance

Budgetary management

- ✓ The budgetary authority has **granted** the **discharge** to the Executive Director for the implementation of the budget for the year 2008.

- ✓ The **revenue** is on target and the amounts received are in line with the revised estimates.
  44% of planned revenue has been received.

- ✓ The **total commitments** and **payments** are **in line with the estimates** for his time of the year.
  Commitments amount to 71% of planned expenditure.

Review of implementation of Fee Regulation

- ✓ The Agency was requested by the Commission to present its **view with the experience gained** since the implementation of the current **fee legislation** in 2005. The Agency has submitted a report to DG SANCO. The report was presented to the Management Board. The content of the report was also presented at the conference on the outcomes of evaluation of the Agency on 30 June 2010.

Revised organisational structure

- ✓ The Agency has **completed** the **reorganisation**.
  All management posts have been filled and Sectors and Sections established.
  Handover of activities among units have been completed.

- ✓ The **sector for product data management** has been created and the head of sector appointed.

Staff related topics

- 529 **posts are occupied** of the 567 authorised.
- The development of e-courses is on track.
  Initial pilot completed. A second pilot will be arranged.

Other governance activities

- Other governance activities are on track, including the implementation of the **audit** plan, **management review** and **self assessment activities** (BEMA, internal control standards).

2. Medicines for human use

2.1. Orphan medicinal product designation

Evaluation activities

✓ Applications for **orphan designation** are 8% **above the forecast** (89 applications received) and 11% above the same period in 2009 (2009:80, 2008: 54). The forecast for 2010 remains unchanged.

Orphan medicinal products fund:

⇧ Fee reductions total €4.2 million (60%) of €7 million (2009: €2.74 million, 2008: €2.68 million).

Communication related to orphan designation activities

✓ **Templates for public assessment report** on review of designation criteria at the time of marketing authorisation drafted and first documents ready for COMP adoption and publication.

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

2.2. Scientific advice and protocol assistance

Evaluation activities

✓ Applications for **protocol assistance** are 6% above the forecasts: **37 applications** received (2009: 33, 2008: 31).
The forecast for 2010 was 70 applications. However, the Agency expects that 67 applications will be received. The forecast reduced accordingly.

⇧ Applications for **scientific advice** are above forecast and 20% above 2009 input: **187 applications** received (2009: 157, 2008:148).
The forecast for scientific advice and follow-up requests for 2010 was 327 applications. The forecast is **increased** by 15 applications to **342**.

Support SMEs in developing high-quality data on advanced therapy medicinal products (ATMPs) for certification and initial evaluation procedures

✓ The Agency aimed that 20% of initial evaluation procedures for **advanced therapy medicinal products** will be **preceded by scientific advice**.
One application was received and preceded by scientific advice.

Reassessment of biomarker qualification procedure to determine impact of procedure on qualification of novel methodologies

- Not started as critical numbers not yet reached.

Performance indicators related to core business	Target	Outcome at the end of Q2
✓ Scientific advice and protocol assistance requests evaluated within the procedural timelines	100% of requests	99%
× External experts involved in procedures	40% of SA and PA requests	32%

2.3. Initial evaluation

Evaluation activities

⇩ The number of applications received during the first semester is 45% **below forecast**, since two thirds of applications are planned for the second semester (65 applications forecast for first half, with a total of 130 for 2010).
Reduction in forecast applications for 2010 is in the area of **new non-orphan medicinal products** (from 55 to 42, 24% reduced forecast), with several applications forecasted for 2010 now expected in 2011, and **generic applications** (from 52 to 37, 29% reduced forecast).. The number of generic applications is lower than expected following European Commission's interpretation of multiple applications; however most of generic applications are expected in the second half of the year.

Procedure	Applications originally planned for 2010	Applications received by Q2 2010	Applications received by Q2 2009	Applications received by Q2 2008	Revised forecast 2010, if applicable
⇩ New non-orphan medicinal products	55	18	14	26	42 (-13)
⇧ New orphan medicinal products	9	6	4	6	12 (+3)

Procedure	Applications originally planned for 2010	Applications received by Q2 2010	Applications received by Q2 2009	Applications received by Q2 2008	Revised forecast 2010, if applicable
⇩ Similar biological products	3	0	1	0	1 (-2)
⇩ Generic	52	8	31	3	37 (-15)
✓ Hybrid and abridged applications	6	2	1	7	7 (+1)
✓ Scientific opinions for non-EU markets	1	1	0	0	No change
⇩ Paediatric-use marketing authorisations	2	0	0	0	1 (-1)
⇩ Advanced therapy re-registration	2	0	n/a	n/a	0 (-2)
⇩ **Total number**	**130**	**35**	**51**	**42**	**101 (-29) -22%**
▪ Compassionate use	1	1	0	0	No change
⇩ PMF	21	3	7	8	19 (-2)
▪ VAMF	1	0	0	0	No change

Assessment of clinical data relating to geriatric populations

- The Agency plans that 50% of applications started in 2010 will have detailed assessment and **reporting on geriatric populations**. Work is in progress, with agreement on final plan to achieve this objective pending.

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

the regulatory timeline of 15 days		
✓ Percentage of plasma master file applications evaluated within the regulatory timeline	100% of applications	100%

2.4. Post-authorisation and maintenance activities

Evaluation activities

✓ Overall, post authorisation applications are **close to target**, with **Type IB** variations being **58% over forecast**. 32 work-sharing and 200 grouping applications received.

Procedure	Applications originally planned	Applications received by Q2 2010	Revised forecast 2010, if applicable
✓ Type IA	1,196	620	1,225 (+29)
⇧ Type IB	514	406	664 (+150)
✓ Type II	837	335	826 (-11)
✓ Line extensions	23	11	27 (+5)

✓ 238 of periodic safety update reports were received.

Strengthening of the quality assurance for major marketing authorisation changes

- The Agency works to introduce a peer-review system at CHMP for assessment reports by the end of the year.

Performance indicators related to core business	Target	Outcome at the end of Q2
✓ Percentage of Type IA variations completed in the legal timeframe	100% compliance	98%

Performance indicators related to core business	Target	Outcome at the end of Q2
✓ Percentage of Type IB variations completed in the legal timeframe	100% compliance	98%
✓ Percentage of Type II variations completed in the legal timeframe	100% compliance	100%
✓ Percentage of Agency recommendations on classification of variations delivered in the procedural timelines	80% compliance	82%
✓ Percentage of grouping and worksharing procedures completed in the procedural timelines	100% compliance	100%
✓ Submission of outcome reports for post-authorisation commitments (PACs) to applicants/MAHs within 2 weeks of the CHMP meeting	90% of reports	91%
× Percentage of applications meeting the legal timeline of 27 days for the linguistic post-opinion check	100% of applications	52% (116 out of 221) (Out of the 105 delayed applications, 96 (91%) were due to delays at Agency level, and further 9 (9%) we delayed by MS or MAH)

2.5. Parallel distribution

⇧ The number of initial notifications is well **over forecast**.
In the first half 1,305 initial notifications (**45% more than forecast**) (2009: 1,020, 2008: 792) and 2,839 notification of change (3% more than forecasted) (2009: 2,398, 2008: 2,457) were received. This has resulted in a significant increase in the workload. Improvements will be implemented to cope with the extra workload.

✓ The **pilot phase** for **electronic submission of parallel distribution notifications** was introduced faster than anticipated (Q1 instead of Q3). This includes electronic check. The participants have expressed their satisfaction with the new system due to the increase in the accuracy of the checking and the decrease in the handling time. Consultation with all parallel distributors has been initiated to implement the new electronic submission system by all of them in August 2010.

▪ **Consultation** with parallel distributors on a new **proposal to reduce the notifications of a change** has been initiated in June 2010. It is estimated that the proposed changes will lead to a 50% reduction of the total workload for notifications of a change.

Performance indicators related to core business	Target	Outcome
× Percentage of initial notification checked for compliance within the regulatory timeline of 35 working days	80%	71%. It is expected to improve these figures in second half of the year due to some process improvements and new staff.
× Number of parallel distributed products sampled on the EU market checked for compliance with the notices issued by the EMA	20 products	7 products have been checked. A reminder will be sent to NCAs to provide samples

2.6. Pharmacovigilance activities

- ✓ The **peer review** of submitted Risk Management Plans (RMPs) was achieved to a higher extent than forecasted. **100% of RMPs** were peer reviewed as part of the assessment of variations and line extensions which result in a significant change to a marketing authorisation. The initial target was to review 80% of such plans.
- ✓ The evaluation of the **tender procedure for EudraVigilance Data Quality Management** was completed in Q2, which was slightly later than anticipated (Q1). The Framework contract with the awarded company should be signed in August. The setup phase is expected to start in the 3Q 2010.
- ✓ The first yearly **signal detection report** (covering the whole of 2009) was finalised and presented to the Management Board meeting in June. As well as the EudraVigilance and signal detection activities, it includes signal management activities (EPITT utilisation and feedback from Rapporteurs), responses to queries from stakeholders and influenza pandemic related activities. As a result of comments made by the Board the report will be revised prior to publication.
- ✓ A **policy on the communication on (emerging) safety related issues** use was prepared and will be published in July.
- ✓ A detailed **EudraVigilance project plan for 2010 to 2013** was prepared and approved by the EudraVigilance steering committee in February 2010 to ensure a coordinated development of the system in line with the expectations of Medicines Regulatory Agencies and the need to support public health protection, and in preparation for the new Pharmacovigilance legislation.
- ▪ Work has started to prepare for the **implementation of the new Pharmacovigilance legislation**. The Agency is reviewing the arrangements to be put in place and is evaluating the impact of the future legislation.

ENCePP

- ✓ The second release of the **database of research centres and data sources** in the context of ENCePP was launched to the public in May 2010. As of 25 June there were over 80 data source entries.

✓ The newly formed **ENCePP steering group** has adopted the **Code of Conduct** for ENCePP studies and the **Checklist** of **Methodological standards for Protocols**, cornerstones of the novel "ENCePP study" seal for independent and transparent studies. The first request for an ENCePP seal was received in June 2010.

2.7. Arbitrations, community referrals and opinions on scientific matters

- The workload has been very high. **14** new **referrals** and **11 Article 20 procedures** were started (2009:20, 2008: 18). In addition, several procedures from 2009 are ongoing and the EC requested revision of 5 referral Opinions.
  All **legal timeframes** for the scientific review were **complied with**, as well as the publication of Q&A documents at the time of the CHMP Opinion.

× **Delays** occurred in the **transmission of translations** to the European Commission.

Performance indicators related to core business	Target	Outcome
✓ Percentage of arbitration and referral procedures evaluated within the legal timeline	100%	100%

2.8. Medicines for paediatric use

Evaluation activities

⇧ 228 of 300 (52% above forecast) **PIP and waiver applications** (representing 268 indications) were received (2009: 179, 2008: 194).
The number is significantly above the forecast for the first half of the year, as a recent change in German law now requires applications for allergens to go through the PIP procedure as medicinal products, with a deadline of December 2010.

- 26 **compliance checks** and 68 **requests for modification** of an agreed PIP were received.

Guidance for conduct of paediatric medicinal product development

✓ Work is progressing **in line with plans**.
Revised procedural advice and new 'intelligent' PDF forms for part A, non-clinical and clinical studies, and letter of intent published in February. Guidance on compliance check will be published in the third quarter.

Interaction between the CAT and PDCO on paediatric aspects of advanced therapy medicinal products

✓ The Agency planned that 70% of PIP applications for advanced therapy medicinal products will be **discussed with the Committee on Advanced Therapies**. 8 products were identified and discussed with CAT.

Interaction with applicants on paediatric-related activities

- The Agency plans to organise **pre-submission meetings** and teleconferences with applicants for PIPs / waivers for 20% of applications.

Process improvement to handing of quality aspects of PIPs

- **Areas for improvement** have been **identified**. Agreement on an **implementation plan is pending**.

Performance indicators related to core business	Target	Outcome at the end of Q2
✓ Number of PIP or waiver opinions and decisions within legal timelines	100% of opinions/ decisions	100%
× Percentage of Agency decisions on paediatric investigation plans/waivers published within 4 weeks of the decision	95%	No statistics available, but outcome is less than 50%. Performance indicator to be reviewed for 2011 in line with current practice.

2.9. Herbal medicinal products

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

- As in 2009, a **lower number** of Herbal Monographs than forecasted were finalised by the end of June (7 instead of the average 10 for a 6 month period), but sufficient Monographs are under preparation to meet the end of year target.
  Action Plan for herbal medicines for 2010 and 2011 to address a number of difficulties currently encountered in this field was prepared and adopted by the Management Board and HMA.
- × **No List Entries** were transmitted to the European Commission. Two list entries were published for consultation. Where the plan for 2010 was to finalise 5 List Entries, probably 3 will be sent the European Commission by the end of the year.
- A set of activities are ongoing as part of **cooperation with EDQM**. These include exchange of representatives in meetings, joint meetings and exchange of comments on draft texts with the aim to **achieve harmonisation**.
- As part of **cooperation with EFSA**, a joint EFSA/EMA explanatory document on herbal ingredients' assessment by EFSA (health claims for food) and by EMA (therapeutic indications for herbal medicinal products) will be provided to DG SANCO.

2.10. Advanced therapies and other emerging therapies and new technologies

Evaluation activities

- The work in the field of ATMPs is **on track**.
  One new ATMP application was submitted in the first half of 2010.
  The **first opinion on the certification** of experimental data generated for an ATMP under development by an SME was issued by the CAT.
  No new applications for certification of quality and non-clinical safety data for ATMP were received. The expected number for 2010 was 10 applications and will be reduced.
  13 requests for **scientific recommendations** on advanced therapy classification of 25 forecasts for 2010 were received.

Performance indicators related to core business	Target	Outcome at the end of Q2
✓ 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	100%
✓ Scientific recommendations on advanced therapy classification provided within the legal timeline	100% of requests	100%
✓ Certification of quality and non-clinical data issued within the procedural timelines	100% of requests	100%

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

- Dr Eric Abadie was re-elected in June 2010 as CHMP-Chair and Dr Thomas Salmonson as Vice-Chair for a second three-year term.
- Two new working parties were established: biostatistics working party and SmPC virtual advisory group.

Interaction between CHMP, PDCO and CAT

- **Discussions on effective interaction among the committees are progressing well.**
  A procedure on interaction between the different Committees will be developed.
- Interaction between the **CAT** and the **CHMP** is well established.

Consultation with interested parties on clinical guidelines of public health interest

- ✓ **Criteria** to **identify interested parties** established. Framework of interaction currently under discussion.
- 31 guidelines were sent to a total of 804 interested parties (26 on average) during the first half of 2010. The Agency will continue systematic dissemination of all guidelines to interested parties during 2010.

Working party framework

- The draft **mandate for working parties** and drafting groups was discussed by CHMP.

2.12. CMDh Coordination group

- 6 MRP applications (2009: 9, 2008: 27) and 2 DCP (2009: 8, 2008: 19) applications have been **referred to the CMDh**.
- **Agreement was reached** for 5 MRP and 0 DCP.
- 2 MRP and 1 DCP application have been referred to the CHMP.
- In the context of the implementation **of paediatric legislation**, 37 active substances were subject to **work-sharing** under article 45 and 20 submissions of paediatric studies under Article 46.
- In the context of the revised **variations regulation**, 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.

3. Veterinary medicines

3.1. Scientific advice

Evaluation activities

⇧ The number of requests for **scientific advice** considerably exceeded predictions. 14 applications were received which is 55% increase from planned (2009: 4, 2008: 2). The 2010 forecast was increased from 18 to 24 applications.

✓ The **MUMS scheme** is starting to attract a lot of interest from industry, as predicted particularly from SMEs, leading to a large number of requests for classification by CVMP and as a consequence increase in the number of requests for scientific advice and marketing authorisation applications.

Cooperation with FDA

- **No requests for parallel scientific advice** received to date. The Agency continues to identify and foster opportunities for parallel scientific advice.

Promoting scientific advice in relation to products for minor use minor species

✓ 28% (4 out of 14) of scientific advice requests in the first 6 months were for MUMS products. 27% of requests in the full year 2009 were for MUMS products. Therefore on target to reach 34% of requests by year end.

Performance indicators related to core business	Target	Outcome
✓ Scientific advice requests evaluated within the procedural timelines	100%	100%

3.2. Initial evaluation

Evaluation activities

⇧ The number of marketing authorisation applications received **is above predictions**.
Eight applications for new medicinal products were received (2009: 5, 2008: 12). The year end forecast increased from 11 to 17 applications.

✓ Applications for **generic medicines** are **on target**.
Two applications for generic medicinal products received (2009: 0, 2008: 3). Forecast year-end total is 3 applications.

- ✓ There had been a **high interest** in requests for **MUMS/limited market classification** with 10 valid applications. However, as these requests are made in early stage of product development, no such MUMS/limited market classification resulted yet in a marketing authorisation application, but several led to scientific advice applications.

Strengthening the quality assurance system

- ✓ The 80% **target exceeded**. All appointed peer reviewers reliably submit reports.

Promoting authorisation through the Centralised Procedure of vaccines against epizootic diseases of livestock

- ✓ At the mid year point **one bluetongue application** has been validated, two applications are expected and **two bluetongue vaccines** have received marketing authorisations.
- ✓ **Multistrain dossier requirements** finalised and published March 2010. CVMP is expected to give a positive opinion for an authorisation under exceptional circumstances for a vaccine against **Q Fever** in **cattle and goats**. This is intended to provide an important tool to aid in control of the current epidemic of this zoonotic disease of major public health significance in some Member States.

Performance indicators related to core business	Target	Outcome
✓ Percentage of products evaluated within the regulatory timeline of 210 days.	100% of applications	100 % (Target fully met. Two bluetongue applications were on accelerated timetables and so were evaluated within 145 and 168 days respectively.)

3.3. Establishment of maximum residue limits

Evaluation activities

- ✓ **Two new** and **one extension/modification** applications were received (2009:2 and 1, 2008: 1 of each).
  The forecast for extension modification applications was increased from 2 to 3.
- **No MRL extrapolation** applications were received (2009: 0, 2008: 5).
  The forecast was reduced from 3 to 2.
- **Five** MRL for **use in cascade** or **no** MRLs for **biocidal products** were received (2009: 0 of each).
  The annual forecast for MRLs for use in cascade increased from 3 to 5, and for biocidal products reduced from 5 to 3.
- The CVMP is currently dealing with an urgent availability issue related to products for the treatment of liver fluke for which MRLs need to be set for milk.

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

3.4. Post-authorisation activities

Evaluation activities

- The number of type I variations has exceed predictions and the number of type II variations been less than expected. This is thought to be mainly the result of the **new variations regulation** and the situation is constantly being monitored.

Procedure	Applications originally planned	Applications received by Q2 2010	Revised forecast 2010, if applicable
⇧ Type I	65	70	90 (+25)
⇩ Type II	45	15	n/a
✓ Line extensions	6	2	n/a

- In general the implementation of the new regulation has gone well but there are some areas of concern, particularly in relation to **handling of grouped variations.**

Implementation of the new variations regulation

✓ The Commission's classification and procedural guidance documents and updated application form were in place for the coming into force of the new Regulation.

- In addition work has progressed on the updating of the complete Veterinary post-authorisation guidance and on the revision of the appropriate SOPs.

Performance indicators related to core business	Target	Outcome
✓ Post-authorisation procedures processed in accordance with legal requirements	100%	100%

3.5. Pharmacovigilance and maintenance activities

Processing of pharmacovigilance information – signal detection tools

- A pharmacovigilance working party (veterinary) pilot group for signal detection has **developed and is testing** two new/improved **Datawarehouse queries** to facilitate surveillance of data in EudraVigilance Veterinary and a new procedure for evaluation of adverse reports for CAPs. Implementation foreseen for January 2011.

✓ The adverse reactions known for CAPs and published in the SPC have been made available in the Datawarehouse to facilitate distinguishing known from new adverse reaction terms.

- The product data for authorised medicinal products in the UK have been transferred from Eudrapharm to EVVet. The manual recoding exercise for these products has been initiated and should allow the VMD to use the DWH for the surveillance of its authorised products.

Eudravigilance Veterinary Access Policy

- The first revision following the consultation period **did not get the agreement of HMA** that requested a maximum of transparency for the general public in line with the human access policy. The HMA-V reiterated this view following presentation of the second revision that had the support of the CVMP and still included a different approach to access for MAHs compared to the EVHuman access policy. A **revised proposal is being prepared** taking into account the comments received as well as ongoing discussions between the EMA, the European Ombudsman and the European Data Protection Supervisor.
- VICH adopted a suite of guidelines on pharmacovigilance after many years of development.

Performance indicators related to core business	Target	Outcome
✓ Percentage of PSURs and SARs evaluated within the established timelines	80% PSURs 100% of SARs	94% of the PSURs and 100% of the SARs were evaluated within the established timelines.

3.6. Arbitration and community referrals

- The workload on referrals continues to be unpredictable but high. **Four procedures** were started (2009: 4, 2008: 5). The year total forecast of 12 remains unchanged.
  The difficulties remain with regards to referrals of products with 'old' dossiers that are not harmonised at Member State level.

- The joint CVMP/CMDv Task Force on referrals has made steady progress so far in highlighting the areas for **prioritisation of referral procedures**. A strategy document for referrals, including proposals regarding prioritisation, is being prepared for subsequent consideration by the Commission and HMAs.

Performance indicators related to core business	Target	Outcome
✓ Percentage of arbitration and referral procedures managed within the legal timeline	100% of procedures	100 %*

*For one referral there was a clock stop due to a request for an oral explanation by a MAH, which was however later withdrawn.

3.7. Scientific committee

- Dr Anja Holm was elected as a chair of the Committee for Medicinal Products for Veterinary Use (CVMP).
- Considerable effort continues to be focussed on activities related to minimising the risk to human health from the **use of antimicrobials in veterinary medicine**. Work is ongoing on several papers on risk assessment and the CVMP strategy on antimicrobials is being finalised. The Agency and the network have commenced work on the pilot phase of the **ESVAC project** to collate data on sales of veterinary antimicrobials at EU level.
- ✓ Highlight of the first six months was a contribution from the CVMP to the European Commission review of veterinary legislation which required considerable input from the Agency.

3.8. Coordination group

- ✓ A trial procedure has been developed to promote **prioritised harmonisation of SPCs**. A pilot SPC harmonisation project will commence in the 3rd quarter.
- There **were no CMDv procedures referred to CVMP** between January and June 2010.

4. Inspections

4.1. Inspections

4.1.1. Clinical and non-clinical compliance

⇧ The requests for **GCP/Pharmacovigilance** inspections is **75% above forecast**. 47 GCP/PhV inspection requests were received (2009: 39, 2008, 48). It should be noted that in several cases the improved exchange of information with FDA have triggered these requests.

✓ The Reflection Paper on **ethical and GCP aspects in clinical trials** conducted in 3rd Countries in MAAs submitted in the EEA was released for consultation. A workshop is planned for September as part of the consultation.

✓ The **pilot EMA FDA initiative** is progressing well. Activities are above planned with 14 teleconferences performed, 5 joint/2 observational inspections already done and others planned, and many exchanges of information not only relating to inspections but GCP procedures/policies.

▪ The **preparation** of various procedures in the area of **pharmacovigilance** is ongoing and progressing well.

✓ The **Action Plan** to increase the **link** between **marketing authorisation assessments and clinical trials supervision** processes agreed by CTFG, HCG, CHMP in Q1 was also agreed by HMA at its April 2010 meeting.

× The review of the quality/completeness of **EudraCT** is delayed until the recruitment of necessary staff.

× The **international GCP network** of GCP inspectors has not been initiated yet.

▪ A **reduced** corporate **GXP module** on **GCP/pharmacovigilance is under development**.
The reduction is due to the lack of sufficient budget and the extra iteration needed for the critical issues on the GMP module.

4.1.2. Manufacturing Quality Compliance

▪ Requests for **GMP inspections** are 12% above forecast.
129 GMP inspection requests were received (2009: 120, 2008: 105).

▪ The increase in suspected **quality defects** handled relative to 2009 continues but has tailed off and is now running at +35% compared to 2009.

▪ **Five non-compliance reports** have been entered in 2010 in **EudraGMP** after the finalisation of the module 2 (non-compliance reports) in August 2009.

- ✗ The initial target for the **joint inspections with the FDA** (5 joint pre-authorisation inspections with FDA on dosage forms) looks too ambitious. An amendment of the Terms of Reference to include post-authorisation joint inspections has been agreed.
- ✗ **Engaging the Japanese authorities on the MRA** remains difficult. At this time agreement on a workplan to extend the scope of the EU-Japan MRA looks unlikely to be achieved in 2010. A corresponding negative impact is foreseen with all other MRA related activities identified in the workplan involving Japan.
- ✗ Implementation of the **Sectoral Annex for the agreement** on conformity assessment and acceptance of industrial products **with Israel** will not be achieved this year as the legislation for both parties is not expected to be in force until mid 2011.
- ✓ **Access to EudraGMP has been finalised** with EDQM, Switzerland, FDA, Canada and WHO.
- ✓ The **XML transfer to EudraGMP** has been finalised with France, Italy, Denmark, Poland and Spain resulting in a significant increase (around 60%) in data population. Transfer from Germany and The Netherlands is still in progress. Austria has decided to use XML and the preparations are in progress.
- ✓ The **GMP module in Corporate GxP database has become operational** on 17 June and the first inspection request using the system was adopted by CHMP at its June meeting.

Performance indicators related to core business	Target	Outcome
✓ Management of inspections within legislative timelines	100% of inspections	100%
✓ Coordinate Quality Defects for centrally authorised products in accordance with EMEA and Community procedures	100%	100%
✗ Response given to external queries on GMP and Quality related matters within time lines set in EMA policies	95%	71%

4.2. Sampling and testing

- ✓ The sampling and testing programme is **on track**. The risk-based approach for veterinary medicinal products has been implemented. Veterinary medicinal products were analysed against agreed risk criteria. CVMP adopted the result of this analysis. The results will be used to prepare sampling and testing programme for 2011.

5. Information technology

5.1. EU telematics

- International **standardisation**:
  the Agency contributed to the work on the following international standards: ISO ICSR, IDMP, Regulated product submissions (RPS) standards, HL7 pre standard for Clinical Trials Registries and Reporting

✓ **Reference Data Model version** 3.
Completed.

- **EudraVigilance veterinary 3**:
  Requirements gathering phase is in progress. Planned completion Q4 maintained.

× Work to implement an amended **Eudravigilance Access Policy** for human and veterinary medicines progressed.
The completion date is dependent on reaching agreement within the network on the final access policy to be implemented.

× **Eudra data warehouse**:
Inclusion of medicinal products for human use in the updated data warehouse is in progress. Finalisation was planned Q2.

- **EudraVigilance data management**:
  Completion of 70% of backlog planned by the end of the year. Work is **yet to start**. Planned completion Q4 maintained.

× **EudraCT**:
Work on **version 8** is **in progress**, albeit with delay.
Work on **version 8.5** (integration of Eudra gateway) has **not started**. Planned completion Q4 maintained.

- **PIM Review System** 6.x:
  In **progress**. Planned completion Q3 maintained.

- **Light Authoring Tool**:
  Not **started**. Planned completion Q3 maintained.

- **PIM Data Validation Engine**:
  Not started. Planned completion Q3 maintained.

- **E-Application Form project**
  In **progress**. Planned completion was Q2. Pilot phase will start in October.

Performance indicators related to core business	Target	Outcome at the end of Q2
✓ Telematics systems availability measured against EMA working hours	98%	98.1%
▪ Projects delivered on time	85%	77%
✓ Projects delivered to original specifications	100%	108%
✓ Projects delivered within budget	80%	84%

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

Severity rating	Description	Response Time	Target	Outcome at the end of Q2	Resolution time	Target	Outcome at the end of Q2
1. Critical	Users are unable to use the system.	✓ 30 minutes	90%	100%	✓ 4 hours	80%	100%
2. Severe	The system is operational but severely restricting use.	✓ 1 hour	90%	100%	✓ 1 business day	80%	90%
3. Important	The system is operational, but one or more functions are restricted.	✓ 1 day	90%	100%	✓ 10 business days	80%	94%
4. Minor[2]	The system is operational and no functions are restricted.	✓ 3 days	90%	100%	✓ 120 business days	80%	100%

5.2. Corporate ICT projects

- **SIAMED II** (implementation of support for the processing of marketing authorisation applications):
  In **progress**. Planned completion Q4 maintained.
- Implement **Enterprise Resource Planning** system:
  Go-live for financial modules, originally planned Q3, **postponed** to January 2011.

[2] 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.

Blue printing for human resource modules. Originally planned Q3. Phase 1 completed. Phase 2 – completion planned Q4.
Realisation phase for **human resource** modules. Originally planned Q3. Will start in Q3.

- Phase II of EMA **Enterprise Information Architecture Management** project was completed. Phase III has been deferred until the strategy for its implementation has been defined.

✓ Full implementation of **eCTD for all applications** for marketing authorisation.
Completed.

Performance indicators related to core business	Target	Outcome at the end of Q2
✓ Corp IT systems availability measured against EMA working hours	98%	99.2%
✓ Projects delivered on time	85%	87%
✓ Projects delivered to original specifications	100%	100%
✓ Projects delivered within budget	80%	86%

Severity Rating	Description	Response Time	Target	Outcome at the end of Q2	Resolution Time	Target	Outcome at the end of Q2
1. Critical	Users are unable to use the system.	✓ 30 minutes	90%	100%	✓ 4 hours	80%	100%
2. Severe	The system is operational but severely restricting use.	✓ 1 hour	90%	100%	▪ 1 business day	80%	77%
3. Important	The system is operational, but one or more functions are restricted.	✓ 1 day	90%	100%	✓ 10 business days	80%	89%
4. Minor[3]	The system is operational and no functions are restricted.	✓ 3 days	90%	100%	✓ 120 business days	80%	100%

[3] 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.