EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 September 2012
EMA/MB/526812/2012

EMA mid-year report 2012 from the Executive Director (January – June 2012)

Management Board meeting 4 October 2012

Background note

The mid-year report from the Executive Director to the Management Board provides an overview of the Agency's progress in implementing the work programme 2012. The reports presents information about the performance of the evaluation activities, the implementation of objectives and reaching set performance targets measured by indicators.

Matters for consideration

The document consists of the three parts:

1. **Highlights** (pages: 3-6) by **priority** area which were set out in the work programme for this year.
2. A **summary table** (pages: 7-10) to provide an overview of performance under main activity areas against the three parameters:
   - The number of applications and procedures
   - The implementation of the main objectives and key projects
   - Reaching targets set for the performance indicators.

   When printing these pages, please note that the summary table is colour coded.
3. **The annex** containing the **detailed mid-year report** (starting on page 11).

Navigation in the document is facilitated through the use of the symbols indicating:

- Volumes of applications and activities which are 'in line' (▪), 'over' (⇧) or 'under' (⇩) the numbers compared to the same period in the previous year; and
- Activities which are progressing 'in accordance' (✓) with plans or constitute a 'deviation' (×).

The symbol (▪) indicates general information or a comment.

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European Medicines Agency mid-year report 2012 from the Executive Director

(January – June 2012)

Highlights by priority area

Assessment activities for human medicines

- ⇧ Significant increase is seen in the number of **orphan designation** applications (30% above the same period in 2011).
- ⇧ **Scientific advice** and protocol assistance 14% and 24% respectively above Q2 2011 figures.
- ⇩ Decrease in **generic** medicinal product initial applications compared to Q2 2011 (11 vs 21 in 2011).
- ⇧ 32% increase in type **IB variations** received by Q2 compared to 2011.
- Expected decrease in **type IA** and **type II** applications compared to 2012 forecast.
- For **paediatric medicines**: requests for PIP modifications increased by 22% to 99, in Q2 2011.
- No certification applications received for **advanced therapy medicinal products**.
- Other applications for human medicines are largely in line with 2011 figures.
- A new project on **analysis of raw data** submitted in applications has been started.
- Main performance indicators have been met. Of note is that the percentage of applications evaluated within regulatory timeline of 210 days has decreased to 91% (96% in 2011, target 100%).

Assessment activities for veterinary medicines

- ⇧ Requests for **MUMS classification** are significantly higher (12 vs 5 in 2011).
- The number of **initial applications** is similar to 2011 (3 applications).

- Except for increase in reviews of draft Codex MRLs, the situation regarding other **MRLs** remains largely unchanged from previous years.

⇧ 30 **Type II** applications received vs 9 in 2011.

The budget

✓ The **budget** situation is considered **stable**. Current forecasts indicate that the estimated 1% shortfall in revenue can be off-set by expenditure savings.

⇧ Consumption of the **orphan fund** is **above targets**. Reinforcement of the fund from the general EU contribution will be sought.

Pharmacovigilance legislation

✓ Preparation for the implementation of the new pharmacovigilance legislation progressed **as planned**, following significant efforts at the EMA and HMA levels.

✓ Timely input was provided to the European Commission's Implementing Measures. A first set of **GVP modules** was published on 25 June 2012 and 2 further GVP modules were released for publication on 27 June 2012.

✓ Revised legal notice and detailed guidance on the **article 57(2) implementation** was published on 5 March 2012 following discussions with pharmaceutical industry. A **data entry tool** was delivered the same day. Training was provided (either face-to-face or through e-learning) to support pharmaceutical industry.

✓ Preparation for the **PRAC** inaugural meeting (July 2012). Aspects such as PRAC mandate and tasks, PRAC outputs, PRAC Rapporteur appointment principles, transparency and communication, PRAC-CHMP-CMD(h) interaction have been widely discussed within the EU Regulatory Network to allow for a smooth establishment and functioning of the PRAC.

✓ Two Stakeholders' meetings were held with patients, healthcare professionals and pharmaceutical industry associations' representatives.

Anti-falsification legislation

✓ Planning for the implementation of the falsified medicines legislation progressed **as planned**.

✓ Planning of the **EudraGMP extension** has started.

✓ Work is near completion on the **EudraGMP third country planning** module.

✓ Extensive support is being provided to the European Commission on the new **import rules for active substances**.

Transparency and communication

- ✓ **Protocol-related information** for eligible new **trials** which is loaded by National Competent Authorities is **made public**.
- × Public access to clinical trials' **summary results** is **delayed**, pending the launch of the database.
- ✓ Publication of **therapeutic areas and INNs** for new marketing authorisations has started to further increased transparency.
- ✓ **PDCO** meeting **agendas and minutes published** since June 2012.
- ✓ Preparation for publication of **PRAC** committee **agendas and minutes** is progressing in line with plans
- ✓ **Communication strategy** has been adopted. Implementation has started focusing on **on-line strategy**.
- ✓ HMA and EMA finalised the guidance on **commercially confidential information** and personal data that should be protected
- ▪ The AskEMA project is progressing with the aim to centralise all requests for **access to documents** and information, automate workflows and enable web-based submission of requests.
- ✓ Publication of **EudraVigilance aggregated data** for centrally authorised products for human use took place on 31 May 2012.
- × **Access** to **Eudravigilance veterinary** reports is delayed, following the decision to prioritise access to human reports in the first instance.

Public health needs and availability of medicines

- ✓ As part of the Agency's strategy to address the needs of **older patients**, all applications started in 2012 are subject to detailed assessment and reporting on geriatrics population.
- ✓ Similarly, geriatric requirements are considered in all CHMP safety and efficacy guidelines that are under consultation.
- ✓ The Agency completed the **mapping** exercise regarding **disease areas** where medicines are still needed ahead of Q4 target date. A report will be published by the end of the year.
- × Additional activities related to the use of medicinal products in **pregnancy** are **delayed**.
- ✓ Two of 5 planned **multi-stakeholder scientific advice procedures** in 2012 were completed as part of cooperation with HTA bodies.
- ✓ As a new task, the Agency is involved in the work on medicinal product **supply shortages** caused by manufacturing/GMP compliance problems.

Veterinary medicines

- ✓ The system of internal **quality review** by EMA secretariat has been further **strengthened** with an established internal review scheme and assessment team meetings.
- ▪ CVMP considered not necessary to update CVMP guidance on **benefit risk methodology**.
- ▪ The whole approach to the delivery of **Euravigilance Veterinary 3** is currently being re-assessed as part of the revision of the ICT strategy. This will include a reflection on how a central veterinary pharmacovigilance database will be created and used.
- ✓ The efforts to combat **antimicrobial resistance** development continued through in particular implementing the CVMP strategy, the ESVAC project on the collection of sales data for antimicrobials in the EU and contributions on initiatives on EU and international level (TATFAR).

Governance topics

- × The **discharge** by the European Parliament for the budget 2010 has been **delayed**. The European Parliament requested further improvements in a number of areas, and in particular in managing conflicts of interest by the Agency. Information requested by the Parliament has been provided. Taking in to account the improvements the Agency has implemented, the discharge is expected in the fourth quarter of the year.
- ✓ The revised policies on **managing conflicts of interest** of experts and Management Board and related **breach of trust policies** entered **into force**.
- ✓ The **new rules** on handling of **staff declared interests** were **adopted** by Management Board on 1 February 2012.
- ✓ The Agency **published declarations of interests** and **CVs** of all managers, CVs of Management Board members, declarations of interests of all experts included in the European expert database. Declarations of interests of scientific committee and Management Board members had been published on EMA website for a number of years.
- ✓ The implementation of the project to move the **Agency to new premises** ('Project 2014') is progressing in line with plans.
- ✓ **Business continuity** arrangements for the **Olympic Games** period have been implemented.
- ✓ The Operational Excellence (OpEx) programme is being implemented to **increase efficiency** of the Agency's processes. An implementation plan is being prepared. A number of processes are being subject to process improvement reviews.

Summary of performance by activity area

The tables below summarise performance by activity area. The table presents the performance against three parameters by area:

- Number of applications
- The implementation of main objectives and key projects
- Reaching targets set for performance indicators

Colour coding is used to indicate whether the volume of applications is above the same period last year (blue), the performance against objectives or the volume of applications are in line with targets (green), below targets (amber), significant deviation (red).

Human medicines

Activity area	Number of applications/ activities in the area	Main objectives /key projects	Majority of performance indicators
Orphan medicinal products designation and fund	30 % increase compared to the same period in 2011 (15% vs 2010) 63% of the €6mln orphan fund used	The implementation of planned objectives is underway. No significant deviations expected	The main indicators are on target
Scientific advice and protocol assistance	Scientific advice and protocol assistance 14% and 24% above Q2 2011 figures	The implementation of planned objectives is underway. No significant deviations expected	The main indicators are on target
Initial evaluation applications	Overall the number of applications is expected to decrease below forecast. Increase in orphan and similar biological applications, and decrease in generic medicinal product applications is seen compared to Q2 2011 (11 vs 21 in 2011)	The implementation of planned objectives is underway. No significant deviations expected	91% of applications evaluated within 210 days (target 100%)
Type IA	9% reduction expected compared to 2012 forecast	The implementation of planned objectives is underway. No significant deviations expected	Indicators are on target, except for percentage of applications meeting the legal timeline of 27 days for the
Type IB	32% increase compared to Q2 2011		

Activity area	Number of applications/ activities in the area	Main objectives /key projects	Majority of performance indicators
Type II and line extensions	21% increase compared to Q2 2011. But expected overall 8% reduction compared to 2012 forecast.		linguistic post-opinion check (84% vs target 100%)
Pharmacovigilance	Reporting of ADRs is as expected in line with the forecast	The implementation of planned objectives is underway. No significant deviations expected	
Referrals	22 referral procedures started (vs 27 in 2011; estimate for 2012 is 52)	The implementation of planned objectives is underway. No significant deviations expected	Delay in sending opinion annexes (translations) to European Commission.
Paediatric medicinal products (PIPs, waivers, etc.)	Compared to Q2 2011: PIP/waiver applications decreased by 10% to 88 Requests for modifications increased 22% to 99	The implementation of planned objectives is underway. No significant deviations expected	Performance indicators are on target
Herbal medicinal products		The implementation of planned objectives is underway. No significant deviations expected	9 final Community herbal monographs and 6 released for public consultation (2012 target in both cases 20); no Community list entries so far (2012 target is 5)
Advanced therapy medicinal products	No certification applications received	The implementation of planned objectives is underway. No significant deviations expected	Performance indicators are on target

Veterinary medicines

Activity area	Number of applications/ activities in the area	Main objectives /key projects	Majority of performance indicators
Scientific advice	The number of SA requests remains in line with 2011 figures, however requests	The implementation of planned objectives is underway. No significant	Performance indicators are on target

Activity area	Number of applications/ activities in the area	Main objectives /key projects	Majority of performance indicators
	for MUMS classification are significantly higher (12 vs 5 in 2011)	deviations expected	
Initial evaluation applications	3 initial applications received as in 2011 (8 in 2010). Increase is expected later in the year. The number of generic applications is expected to remain low.	The implementation of planned objectives is underway. No significant deviations expected	Performance indicators are on target
Maximum residue limits	6 reviews of draft Codex MRLs (vs 0 in 2011). The situation regarding other MRLs remains largely unchanged with low level of applications.	The implementation of planned objectives is underway. No significant deviations expected	Performance indicators are on target
Type I	Growth of Type I variations decreased but in line with 2011 figures	The implementation of planned objectives is underway. No significant deviations expected	Performance indicators are on target
Type II	30 applications vs 9 in 2011		
Line extensions	4 line extension applications (2 in 2011)		
Pharmacovigilance	Some increase in reporting compared to forecasts	No significant deviations expected, except for delay in implementing access to EV veterinary reports the review of priorities in the area.	Performance indicators are on target
Referrals (Art. 29 and 30)	4 procedures started (9 in 2011)	The implementation of planned objectives is underway. No significant deviations expected	Performance indicators are on target

Inspections and compliance

Activity area	Number of applications/ activities in the area	Main objectives /key projects	Majority of performance indicators
Inspections	The number of GMP inspections is in line with the same period in 2011. 42GCP/Pharmacovigilance inspection	The implementation of planned objectives is underway. No significant deviations expected	Performance indicators are on target

Activity area	Number of applications/ activities in the area	Main objectives /key projects	Majority of performance indicators
	requests received compared to 34 in 2011). The number includes 8 pharmacovigilance inspections of 9 planned for 2012.		
Parallel distribution	The number of initial notifications received (1,199) is below target (total expected for 2012 is 2,600), whilst the number of notifications of change received is above target (1,524 the 2012 target being 2,000)	The implementation of planned objectives is underway. No significant deviations expected	Performance indicators are on target
Certificates	The number of certificate requests is on target	The implementation of planned objectives is underway. The urgent procedure for certificates has not been launched.	16% of certificates issued within timelines. Target 90%. Process has been improved. Figures at the end of June are in line with the 90% target.

Revenue and expenditure

Area	Performance
Revenue (registered)	54% (€120.2 mil of €222.5 million planned)
Expenditure (committed)	71% (€158.1 mil of €222.5 million planned)
Orphan medicinal products fund	63% of the fund used (€3.79 million of €6 million)

The progress on the development of corporate IT and Telematics system is reported in chapter 5 'Information technology'.

Annex – detailed mid-year report 2012

1. European Medicines Agency in Europe and the World

1.1. European medicines network

Management Board

- ✓ The Board adopted the policy on the handling of conflicts of interest of Members of the Board and its respective breach of trust procedure.
- ✓ The Board also adopted the Agency's breach of trust procedure for scientific experts and delegates.
- ▪ The Board appointed a new Accounting Officer.
- ✓ The Board adopted the new rules on handling of staff declared interests.

The EMA's scientific network

- ✓ The Agency has set up the Scientific Coordination Board, which reflects on the working methodology of the current system to identify possible areas where effectiveness can be increased. Amongst others, this includes review of the effective coordination and liaison among the scientific committees (in particular considering the establishment of the new committee), sourcing the right expertise taking into account the number and level of activities in the individual committees, as well as reflecting on the challenges arising from new scientific developments such as advanced therapies and personalised medicines that require an integrated scientific and regulatory approach.
- ✓ The implementation of the updated Agency's Policy on the handling of conflicts of interest of Scientific Committees' members and experts continued and a new updated electronic Declaration of interest form integrating both experts and Management Board members was rolled out at the end of June 2012. Systematic recording of conflicts of interest declared at start of scientific meetings in minutes.
- ✓ The HMA liaison officer has been appointed.
- ✓ The HMA/EMA guidance on commercially confidential information and personal data that should be protected has been finalised.

Influenza pandemic plan

- ▪ Revision is underway as planned.
- ✓ Vaccine scientific advisory group established.

Meetings at the European Medicines Agency

- The number of face-to-face meetings is decreasing while the number of virtual meetings is growing (more data will be provided during the annual reporting).

Activity	2012 Q1-Q2 (actual)	2012 (forecast)	2011 Q1-Q2	2010 Q1-Q2	2009 Q1-Q2
⇩ Number of face-to-face meetings	221	450	287	316	297
⇩ Number of delegates that visited the EMA	4035	8600	4316	4310	4510

Preparations for future enlargement

✓ The implementation of the Instrument for pre-accession assistance (IPA) programme is on track. No deviations are noted.
The linguistic review of product information of centrally authorised products is delayed in line with the revised date of accession.
The programme aims to support participation of Croatia, the former Yugoslav republic of Macedonia, Turkey, Serbia, Albania, Bosnia-Herzegovina, Montenegro, and Kosovo under UNSC resolution 1244/99 in EMA activities.

✓ Preparation of pre-accession measures for Croatia are in line with plans.
Nominations to participate in meetings as active observers received.
Training is organised as required.
Organisation of the conference and related tender is progressing in line with plans.

1.2. European cooperation

- Collaboration with European Commission and contribution to core work packages of EUnetHTA continued.
- As part of collaboration with HTA bodies, HTA bodies participate in scientific advice meetings: 2 initiated, 4 in pre-submission phase.
A workshop has been postponed.

✓ Working arrangements were signed with EFSA.

- The Agency cooperates with the EMCDDA in the area of misuse, risk assessment and risk management of new psychoactive substances.
Working arrangements have been recently amended and will be signed later this year.

- The Agency works with the ECDC on issues relating to vaccine effectiveness studies in EU.
- The Agency is promoting 3R principles (replacement, reduction, refinement) through the work of the "3R" working group.

1.3. International cooperation

✓ The Agency appointed a new FDA Liaison officer based in FDA.

- FDA-EMA-EC meeting held.

✓ New Japanese Liaison official appointment.

- The Agency provided support to Commission for collaboration with Russia on GCP and with Chinese SFDA on GMP for API in the context of the Falsified Medicines Directive.

✓ Terms of reference for pilot collaboration on Orphan medicinal products with Japanese MHLW/PMDA agreed and published.

✓ As part of the pilot programme for the parallel assessment between EMA and US FDA of quality by design aspects in marketing applications, a parallel evaluation in a first submission has been completed. Harmonisation of lists of questions has been undertaken.

✓ EMA representative was appointed to the UN Commission on life-saving commodities for women and children which was launched in March 2012.

1.4. Communication, provision of information and transparency

Communication strategy

✓ The communication strategy has been adopted.
The implementation of activities outline in the strategy has commenced.

✓ The project to consolidate the websites managed by the Agency has been initiated.

Transparency initiatives

✓ Protocol-related information for eligible new trials which is loaded by National Competent Authorities is made public.

× Public access to summary results is delayed, pending the launch of the database.

✓ Publication of therapeutic areas and INNs for new marketing authorisations has started to further increased transparency.

✓ Publication of EudraVigilance aggregated data for centrally authorised medicines for human use took place on 31 May 2012.

✓ Preparation for publication of PRAC committee agendas and minutes is progressing in line with plans.

✓ Publication of PDCO meeting agendas and minutes has started.

Engaging with patients

✓ The role of patients as members of the EMA human Scientific Committees has been defined and the related document is published.

✓ A procedure for patients' participation in Scientific Advisory Group meetings has been put in place, as part of the efforts to involve civil society in the benefit/risk evaluation

Access to documents and requests for information

- A total of 109 requests for access to documents has been received (Q2 2011: 103).
  The number of pages released 381,000 (Q2 2011: 574,420)
- 2,614 requests for information were received (Q2 2011: 2,404).
- The AskEMA project is progressing.
  It aims to centralise all requests for access to documents and information, automate workflows and enable web-based submission of requests.

Performance indicators in the area

× The KPI for the publication of initial EPARs is 66% (Q2 2011: 63%, target 80%).

✓ The KPI on publication of withdrawal Q&A documents is slightly below target (85% vs target 90%), but will improve by end of the year.

✓ All other performance indicators have been met.

1.5. Support for innovation and availability of medicines

Small and medium size enterprises

- 77 SME companies requested administrative assistance. This is in line with forecasts. (Q2 2011: 74)

⇧ 456 requests for qualification as SME were received. 69 requests to renew SME status (Q2 2011: 172 and 50 respectively)

Unmet needs

- ✓ As part of the Agency's strategy to address the needs of older patients, all applications started in 2012 are subject to detailed assessment and reporting on geriatrics population.
- ✓ Similarly, geriatric requirements are considered in all CHMP safety and efficacy guidelines that are under consultation.
- × Additional activities related to the use of medicinal products in pregnancy are postponed to later months of 2012.
- ✓ The Agency completed the mapping exercise regarding disease areas where medicines are still needed ahead of Q4 target date.
  A report will be published by the end of the year.

1.6. Methodology and outcomes assessment projects

- ✓ The project on adaptive clinical trial designs and new methods clinical drug development is on track.
  Planned concept papers and draft guidelines were prepared, assessor training organised, a workshop on multiplicity is being prepared.
- ✓ As a new initiative, a new project on analysis of raw data submitted in applications has been started.
  Discussion with FDA held. A staff visit to FDA is planned.
- ✓ Commissioning of studies on outcome assessment was finalised making use of the ENCePP network in the fields of isotretinoin (PPP), oral contraceptives (usage patterns), pioglitazone (effectiveness of risk minimisation), bisphosphonates (cardiac valve disorders).

1.7. Governance

- × The discharge by the European Parliament for the budget 2010 has been delayed. The European Parliament requested further improvements in a number of areas, and in particular in managing conflicts of interest by the Agency. Information requested by the Parliament has been provided.
- ✓ The Agency published declarations of interests and CVs of all managers, CVs of Management Board members, declarations of interests of all experts included in the European expert database. Declarations of interests of scientific committee and Management Board members had been published on EMA website for a number of years.
- ✓ Implementation of staff rules on conflicts of interest for product-related activities was completed ahead of schedule.
- ✓ The budget situation is considered stable. The current forecasts indicate that the estimated 1% shortfall in revenue can be off-set by expenditure savings. However, the situation will continue to be monitored and managed closely.

- ✓ Recruitments are progressing in line with plans. The target to remain within the 3% vacancy rate should be achieved.
  Currently there are 559 temporary agents, 113.5 contract agents and 93 other staff (national experts, interims, trainees).
- ✓ Business continuity arrangements for the Olympic Games period have been implemented.
- ✓ The implementation of the project to move the Agency to new premises ('Project 2014') is progressing in line with plans.
- ✓ The Agency's readiness mechanisms were tested at a BCP exercise on 27 April 2012 with positive outcomes.
  Lessons learned were taken into account in the BCP arrangements for the Olympic period.
- The Operational Excellence (OpEx) programme and related projects are being implemented.
  Preparation of detailed implementation plan is in progress.
- The project on quality of opinions progressed well.
  It focused on legacy of the ex-follow-up measures, the tracking of the new Post-Authorisation Measures, update of opinion templates for referrals.
- The development of SAP II is postponed to next year, instead the focus was on developing the Activity Based Costing and Activity based Budgeting reporting structure.
  It is expected to implement the structure by the end of 2012.
- ✓ The Agency supported the European Commission in developing the pharmacovigilance fees structure.
  DG Sanco launched a public consultation on the concept paper on 18 June 2012.
- ✓ Project prioritisation methodology and process have been reviewed and applied to reassess the portfolio of ongoing projects in ICT and non-ICT domains.
- The Directorate services were reorganised, with the establishment of two sectors: the sector for Communications and the sector for International and European cooperation.

2. Medicines for human use

2.1. Orphan medicinal product designation

Evaluation activities

Procedure	2012 Q1-Q2 (actual)	2012 (forecast)	Revised forecast	2011 Q1-Q2	2010 Q1-Q2	2009 Q1-Q2
⇧ Orphan designation applications (30% above 2011)	103	180	+10	79	89	80

Orphan medicinal products fund

⇧ Fee reductions total €3.79 million (63%) of €6 million available in 2012 (Q2 consumption - 2011: €2.75 million, 2010: €4.2 million, 2009: €2.74 million).
Due to an anticipated increase in Orphan applications, the Agency is going to propose to the Commission a transfer from the EU general contribution to the special contribution for orphan medicinal products.

Bottlenecks in orphan medicines development; needs of orphan ATMPs; communication of significant benefit decisions

- The implementation of planned objectives is underway. No deviations are expected.

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ Percentage of designation applications evaluated within 90-day timeline	100%	100% (70 out of 70)	100%
× Percentage of summaries of opinion published within 1 month of the Commission decision on designation	95%	89% (39 out of 44)	100%
✓ Percentage of public assessment reports (on review criteria) published within one month of the European Commission's decision on marketing authorisation	90%	100% (1* out of 1)	100%
✓ Number of orphan products designated in parallel with FDA	15% of total designated products	31% (22 out of 70)	51%

**Additional three ready awaiting EC Decision on MA*

2.2. Scientific advice and protocol assistance

Evaluation activities

Procedure	2012 Q1-Q2 (actual)	2012 (forecast)	Revised forecast	2011 Q1-Q2	2010 Q1-Q2	2009 Q1-Q2
⇧ Scientific advice*(14% above 2011)	211	413	-3	185	187	157
⇧ Protocol assistance (23.7% above 2011)	47	80	Unchanged	38	37	33

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

Engagement with HTA bodies

✓ The implementation of planned objectives is underway.
Two of 5 planned multi-stakeholder scientific advice procedures completed.

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ Scientific advice and protocol assistance requests evaluated within the procedural timelines	100% of requests	99%	99%
✓ Percentage of marketing authorisation applications for new technology products (with outcome in 2012) having received scientific advice or protocol assistance	50% of applications	60%	57%

2.3. Initial evaluation

Evaluation activities

- Overall the number of applications is in line with forecasts and similar to Q2 2011.

⇧ Significant increase compared to 2011 is seen in the number of non-orphan medicinal product (25 vs 15 in Q2 2011) and similar biological products (6 vs 0).

⇩ Significant decrease in the number of generic products (11 vs 21 in Q2 2011).

Procedure	2012 Q1-Q2 (actual)	2012 (forecast)	Revised forecast	2011 Q1-Q2	2010 Q1-Q2	2009 Q1-Q2
⇧ New non-orphan medicinal products	25	52	-2	15	18	14
▪ New orphan medicinal products	8	13	+4	8	6	4
⇧ Similar biological products	6	5	+3	0	0	1
⇩ Generic	11	32	-14	21	8	31
⇩ Hybrid and abridged applications	2	7	-2	4	2	1
▪ Scientific opinions for non-EU markets	0	1	Unchanged	0	1	0
▪ Paediatric-use marketing authorisations	0	0	Unchanged	1	0	0
▪ Advanced therapy re-registration	1	2	Unchanged	0	0	n/a
▪ **Total number**	**53**	**112**	**-11**	49	35	51

Benefit-risk methodology; quality of assessment reports; quality assurance of initial evaluation; Early dialogue

- ✓ Benefit-risk methodology: Work package 4 report adopted in Q1 and project has entered work package 5. Proposed tool is currently being tested by CHMP sponsors.
- ✓ Assessment reports: majority of non-generic applications are peer-reviewed.
- ✓ Early dialogue with rapporteur: draft impact analysis to be completed. Further activities to be initiated later in the year.

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
× Percentage of applications evaluated within regulatory timeline of 210 days	100% compliance	91%	96%
✓ Percentage of accelerated assessment applications evaluated within regulatory timeline of 150 days	100% compliance	100%	100%

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ 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

⇧ The number of Type IB and Type II applications is higher than Q2 2011 (32% and 21% respectively).
The overall number of Type IA and Type II applications for 2012 is however expected to be lower than forecast due to impact of the new Pharmacovigilance legislation.

Procedure	2012 Q1-Q2 (actual)	2012 (forecast)	Revised forecast	2011 Q1-Q2	2010 Q1-Q2	2009 Q1-Q2
▪ Type IA	1478	3300	-300	1547	620	412
⇧ Type IB	739	1350	+231	558	406	218
⇧ Type II	468	870	-60	386	335	464
▪ Extensions of marketing authorisations	8	25	-8	7	11	11

Ensuring quality of assessment reports; strengthening consistency of scientific assessment

- Assessment reports: the implementation of the action plan is progressing well.
- Work to strengthen consistency of assessment will start later in the year.

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ Percentage of Type IA variations completed in the legal timeframe	100% compliance	96%	94%

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ Percentage of Type IB variations completed in the legal timeframe	100% compliance	100%	94%
▪ Percentage of Type II variations completed in the legal timeframe	100% compliance	n/a	100%
▪ Percentage of Agency recommendations on classification of variations delivered in the procedural timelines	100% compliance	No requests received	No requests received
▪ Percentage of grouping and work-sharing procedures completed in the procedural timelines	100% compliance	n/a	100%
✓ Submission of outcome reports for post-authorisation commitments (PACs) to applicants/MAHs within 2 weeks of the CHMP meeting	90% of reports	90%	83%
× Percentage of applications meeting the legal timeline of 27 days for the linguistic post-opinion check	100% of applications	84%	82%

2.5. Pharmacovigilance activities

- ✓ The implementation of pharmacovigilance legislation is on track, in line with the prioritisation agreed by the Management Board at its December 2011 meeting
- ✓ The first set of finalised modules of the guideline on good pharmacovigilance practices published.
  Two further modules of the guideline on GVP were released for public consultation
- ✓ Data entry tool delivered on 5 March 2012 and first entries received from pharmaceutical industry in May.
  Training was organised to support pharmaceutical companies submitting structured product information data.
- ▪ The European Commission has proposed changes to art. 107 i of Directive 2001/83/EC on Urgent Union Procedures.
  Changes may impact on the number of referral procedures.
- ▪ The handover of "open" safety-related discussions to the PRAC may lead to additional, unforeseen referral procedures later this year and in 2013

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ Percentage of Risk Management Plans (RMPs) that are peer reviewed as part	100%	100%	100%

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
of the assessment of the initial marketing authorisation applications			
✓ 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 authorisation	100%	100%	100% for variations 100% for line extensions
✓ Percentage of ICSRs reported electronically for CAPs	100%	100%	100%
✓ Percentage of CAPs monitored at least monthly by the signal detection group	100%	100%	100%

2.6. Arbitrations, community referrals and opinions on scientific matters

- 22 referral procedures were started (Q2 2011: 27; the total forecast for 2012 is 52).

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ 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%	100%
× Publication of the CHMP opinion and assessment report for Art. 5(3) procedures at the time of the CHMP Opinion	100%	KPI was not met. Of note that no legal timeline is set.	0% (refers to one procedure)
× 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	80%	KPI was not met. Of note that no legal timeline is set.	0%
× Opinion annexes (translations) sent to the European Commission within the legal timeframe (27 days post opinion)	100%	11% (42% had up to 3 days delay, 47% had more than 3 days delay) reason: late submission of translations by the MAHs and translation	33%

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
		services related aspects.	

2.7. Medicines for paediatric use

Evaluation activities

- The number of PIP/waiver applications is 10% lower than in Q2 2011. Modification request are 22% over Q2 2011 figure.

Procedure	2012 Q1-Q2 (actual)	2012 (forecast)	Revised forecast	2011 Q1-Q2	2010 Q1-Q2	2009 Q1-Q2
⇩ Number of PIP/waiver applications	88	220	-22	99	228	128
▪ Number of indications in PIP/waiver applications	111	258	-22	117	268	179
▪ Compliance checks	25	55	+6	26	26	n/a
⇧ Requests for modifications	99	225	-16	81	68	n/a

Quality checks; increasing dialogue with applicants

- Random data quality and appropriateness checks of third-country clinical trials entered in EudraCT are being carried out.
- 100% of pre-submission meeting requests by applicants are accepted.
- EMA report on experience acquired with the paediatric regulation submitted to the Commission.

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ Number of PIP or waiver opinions and decisions within legal timelines	100% of opinions/ decisions	100% (opinions) 99% (decisions)	99.6%

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ Percentage of Agency decisions on paediatric investigation plans/waivers published within 6 weeks of the decision	95%	100%	100%

2.8. Herbal medicinal products

- In March 2012, the HMPC adopted the 100th Community herbal monograph.
  Since the establishment of the Committee in 2005, 104 Community herbal monographs and 10 Community list entries were finalised.
- 9 final Community herbal monographs and 6 released for public consultation (2012 target in both cases 20);
  It is expected that the KPI of 20 herbal monographs will not be reached at the end of 2012.

× No Community list entries released (2012 target is 5)
The KPI for Community list entries is likely not to be met by the end of the year.

2.9. Advanced therapies and other emerging therapies and new technologies

Evaluation activities

- One new initial marketing authorisation application for advanced therapy medical product was received (Q2 2011: 1)

× No certification applications were submitted (Q2 2011: 0).

- 11 requests for recommendation on advanced therapy classification were received (Q2 2011: 7)

Review of implementation of ATMP regulation; impact of genomics on personalised medicines; competence development

- Stakeholder survey completed as part of the review of implementation of advanced therapies regulation and processes.
- A report on personalised medicines is in preparation and will be submitted to the Commission.
- An international pharmacogenomics workshop is planned for October 2012.

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011

▪ 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% (1 out of 1)	100% (1 out of 1)
✓ Scientific recommendations on advanced therapy classification provided within the legal timeline	100% of requests	100% (11 out of 11)	100%
▪ Certification of quality and non-clinical data issued within the procedural timelines	100% of requests	No procedures on-going	No procedures on-going
✓ Percentage of innovation task force (ITF) reports on requests for CHMP scientific recommendation on eligibility as a medicinal product given within 60 days.	80%	100% (2 requests)	n/a

2.10. CMDh Coordination group

- 3 MRP applications (2011: 2) and 11 DCP (2011:5) applications have been referred to the CMDh.
- 1 MRP (2011:3) and 12 DCP (2011:2) referrals (of which 0 MRP and 5 DCP had been referred to the CMDh in 2011) have been agreed and finalised by the CMDh (both positive and negative outcomes).
- 1 MRP (2011:1) and 5 DCP (2011:1) applications have been referred to the CHMP (of which 1 MRP and 3 DCP had been referred to the CMDh in 2011).
- In the context of the implementation of paediatric legislation, 20 (2011:21) active substances were subject to work-sharing under article 45 and 33 (2011:21) submissions of paediatric studies under Article 46.
- In the context of the revised variations regulation, 7 (2011:11) requests for recommendations according to Article 5 of the variations regulation have been received by the CMDh and 4 recommendations were given by the CMDh.

3. Veterinary medicines

3.1. Scientific advice / MUMS

Evaluation activities

- ⇧ The number of scientific advice continues to increase, as are request for MUMS/Limited market classifications.
- 40% of scientific advice requests were received from SMEs
- One request for parallel scientific advice with the FDA is on-going and others are expected.
- 75% of requests for MUMS/Limited markets classification received financial incentives.
  Continued interests is shown in this policy since its start in 2009.
  Review of criteria at the Management Board later this year is possible.

Procedure	2012 Q1-Q2 (actual)	2012 (forecast)	Revised forecast	2011 Q1-Q2	2010 Q1-Q2	2009 Q1-Q2
▪ Scientific advice requests	15	26	Remained unchanged	13	14	4
⇧ Request for MUMS/Limited markets classification	12	24	Remained unchanged	5	Monitoring not initiated	Monitoring not initiated

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ Scientific advice requests evaluated within the procedural timelines	95% of applications	100%	100%

3.2. Initial evaluation

Evaluation activities

- The submission of new initial applications has been slow.
  An increase of new applications is expected in the second half of 2012, with the total year forecast revised from 9 to 11 applications.

- The number of generic applications is expected to remain low.

Quality assurance; benefit risk methodology

✓ The system of internal quality review by EMA secretariat has been further strengthened with an established internal review scheme and assessment team meetings.
Review of the assessor guideline and assessment review templates have been initiated.

- CVMP considered not necessary to update CVMP guidance on benefit risk methodology.

Procedure	2012 Q1-Q2 (actual)	2012 (forecast)	Revised forecast	2011 Q1-Q2	2010 Q1-Q2	2009 Q1-Q2
▪ Applications for new medicinal products	3	9	+2	3	8	5
▪ Abridged/generic application received	0	3	Remained unchanged	1	2	3

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ Percentage of products evaluated within the regulatory timeline of 210 days.	100% of applications	100%	100 %

3.3. Establishment of maximum residue limits

Evaluation activities

- The situation regarding MRLs remains largely unchanged.
- No application for a new MRL has been received.
  This is due to the very low number of new active pharmaceuticals being developed for food producing animals.
- There is a higher interest in extensions of MRLs to other species.
  This increases the potential availability of veterinary medicines to a wider range of species.
- No applications for biocides received.

- There has been intense activity in relation to several MRL opinions and requests for review of MRLs by the commission where complex issues of interpretation have arisen as a result of the new MRL regulation.

Procedure	2012 Q1-Q2 (actual)	2012 (forecast)	Revised forecast	2011 Q1-Q2	2010 Q1-Q2	2009 Q1-Q2
▪ MRL applications	0	3	-2	1	2	2
▪ MRL ext. / mod. applications	2	4	Remained unchanged	5	1	1
▪ MRL extrapolations	0	2	-1	0	0	0
▪ MRL for use of cascade	0	1	-1	0	5	0
▪ Biocides	0	3	-3	0	0	0
⇧ Review of Draft Codex MRLs	6	5	+1	0	Monitoring not initiated	Monitoring not initiated

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ Percentage of MRL applications evaluated within the legal timeline	100% of applications	100 %	100 %
▪ Assess biocide applications within agreed deadline	100% for new applications 90% for old biocidal products	No applications received	Monitoring not initiated

3.4. Post-authorisation activities

Evaluation activities

- The expected trend for continued increase of type I variations has slowed down.
- The number of line extensions remains low.

Procedure	2012 Q1-Q2 (actual)	2012 (forecast)	Revised forecast	2011 Q1-Q2	2010 Q1-Q2	2009 Q1-Q2
▪ Type I	84	275	-75	80	70	36
⇧ Type II	30	52	Remained unchanged	9	15	17
▪ Line extensions	4	7	+2	2	2	8

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ Post-authorisation procedures processed in accordance with legal requirements	95% of applications	100%	100%

3.5. Pharmacovigilance and maintenance activities

- ✓ Major progress achieved in putting in place a framework for routine signal detection of centrally authorised veterinary products.
- ✓ Major contribution has been provided to the internal reflection of the European Commission on pharmacovigilance as part of the review of veterinary legislation.
- ▪ The whole approach to the delivery of Euravigilance Veterinary 3 is currently being re-assessed as part of the revision of the ICT strategy. This will include a reflection on how a central veterinary pharmacovigilance database will be crated and used.
- × Access to Eudravigilance veterinary reports is delayed, following the reprioritisation of activities in the area.

Procedure	2012 Q1-Q2 (actual)	2012 (forecast)	Revised forecast	2011 Q1-Q2	2010 Q1-Q2	2009 Q1-Q2
▪ Periodic Safety Update Reports (PSURs)	67	125	+7	63	63	51
▪ Adverse Event Reports (AERs) for CAPs	2440	4500	+380	2256	1678	1579

Procedure	2012 Q1-Q2 (actual)	2012 (forecast)	Revised forecast	2011 Q1-Q2	2010 Q1-Q2	2009 Q1-Q2
⇧ Total AE reports	10047	18000	+2090	8011	8631	5439

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ Percentage of PSURs evaluated within the established timelines	90%	95%	94%
✓ Percentage of AERs for CAPs monitored within the established timelines	90%	100%	100% of the SARs.

3.6. Arbitration and community referrals

- Referrals under review often relate to antimicrobial resistance, MRL/withdrawal periods or environmental risk assessment.
- Work continues on possibilities for SPC harmonisation and on how to prioritise referrals or reduce the number of referrals. A proposal prepared and submitted to HMA and the Commission. It was discussed with industry stakeholders.

Procedure	2012 Q1-Q2 (actual)	2012 (forecast)	Revised forecast	2011 Q1-Q2	2010 Q1-Q2	2009 Q1-Q2
⇩ Arbitration and Community referral procedures	4	12	Remained unchanged	9	4	4

Performance indicators related to core business	Target	Outcome at the end of Q2 2012	Outcome at the end of Q2 2011
✓ Percentage of arbitration and referral procedures managed within the legal timeline	100% of procedures	100 %	100 %

3.7. Scientific committees

- The efforts to combat antimicrobial resistance development continued through in particular implementing the CVMP strategy, the ESVAC project on the collection of sales data for antimicrobials in the EU and contributions on initiatives on EU and international level (TATFAR).
- A lot of activity was in the area of improving the quality and consistency of the scientific output of the committee.

3.8. Coordination group

- ✓ All of the procedures initiated by the CMDv were accepted by the CVMP. This comes as a result of effective liaison between CMDv and CVMP.
- ✓ Agreement reached between EMA and CMDv on approach to take in drafting guidance on requests for access to marketing authorisation dossiers, as part of efforts to reach a common approach on access to documents and transparency within the network.

4. Inspections

4.1. Manufacturing and quality compliance

Inspection activities

- 196 request for GMP inspections were received (Q2 2011:183).
- ⇧ 82 quality defect reports received (Q2 2011: 66).
- ✓ 100% of inspections were managed within the legislative time (Q2 2011 performance: 100%).

Falsified medicines legislation

- ✓ Implementation of falsified medicines legislation progressed according to plans.
- ✓ Planning of the EudraGMP extension has started.
  This was only possible after extensive efforts to reach agreement among all 27 Member States.
- ✓ Work is also near completion on the EudraGMP third country planning module.
- Extensive support to the European Commission as regards the new import rules for active substances

Cooperation with EDQM

- ✓ Agreement reached with EDQM on a new 5-years framework contract for sampling and testing.

4.2. Clinical and non-clinical compliance

- ⇧ 42 GCP/Phv inspection requests received (Q2 2011: 34), of which 8 pharmacovigilance inspections (2012 estimate 9).
- No GLP inspections requested (Q2 2011: 1).

4.3. Clinical trial support

- ✓ Publication of the Reflection Paper on GCP and ethical aspects of clinical trials conducted outside the EU/EEA in April.
- ✓ Successful linking of the EU Clinical Trials Register information to the WHO International Clinical Trial Registry Platform

4.4. Parallel distribution

- 1,199 initial notifications received (Q2 2011: 1,281).
- 23 parallel distributed products were sampled to check for compliance with the Notices issued by the Agency (target 20).

✓ KPI: percentage of initial notifications checked for compliance within the regulatory timelines of 20 working days: 97% (target 90%).

4.5. Certificates

- 1,604 certificates were requested (Q2 2011: 1,527; 2012 estimate 3,200)

× 16% of certificates issued within timelines (KPI target for 2012: 90%).
Process improvements have been carried out in the 2Q 2012. Figures at the end of June are in compliance with the KPI.

× The urgent procedure for certificates of medicinal products has not been launched in 2Q2012 and it is currently suspended

5. Information and communications technology

Implementation and operation of ICT in support of internal activities

Objective		
Implement the projects that will improve the efficiency of the Agency's activities.		
Group of projects	**High level plan**	**Outcome of quarter 2 2012**
Resource-management projects	Phase 2 of HR project. The system will improve the administration of human resources within the Agency. Phase 2 is planned to follow on from the successful delivery of HR 1 in October 2011. The second phase of the FIN project will be started in 2012.	✓ Phase 2 of HR project will go live in January 2013 as planned.
Projects improving management of processes	Siamed II: Extend Siamed II to allow Siamed I to be phased out by Q3. Electronic signatures. A system allowing the Agency to receive and produce electronic signatures for electronic applications will be available by the end of Q4. Gateway: Automation of manual processes covering submission via the Gateway (receiving, validation, registration) by Q3.	✓ Siamed II is currently planned to go live in November. ▪ Electronic signatures: As a result of a review by the EMA Executive Group in July of all ongoing projects, the project is suspended pending clarification of the current scope and costs to ensure interoperability with future requirements. × Gateway: Automation of manual processes covering submission via the Gateway (receiving, validation, registration) is planned to go in pilot in early January 2014.
Projects improving quality of data input, processing and	Records management will be rolled out across further processes by Q2 2012. Enpr-EMA: A system to support the European Network of Paediatric Research will be made available in Q3. Quick Wins: A total of 15 systems with limited functionality, scalability	▪ Records management: as a result of a review by the EMA Executive Group in July of all ongoing projects, the project is suspended to re-discuss the project definition. ▪ Enpr-EMA: As a result of a review by the EMA Executive Group in July of all ongoing projects, the project is stopped.

management	and user community will be implemented.	✓ Quick Wins: These projects are ongoing with initial deliveries planned in in July.

Objective
Implement systems facilitating public access to documents and information.

Group of projects	**High level plan**	**Outcome of quarter 2 2012**
Regulation (EC) 1049/2001 on access to documents	Ask EMA: Deliver in Q4 a system to support the Agency policy on access to documents in line with Regulation 1049/2001.	▪ The technology to use to implement this is currently being assessed.
Requests for information	Ask EMA: Deliver in Q4 a system to support the Agency policy on requests for information.	▪ The technology to use to implement this is currently being assessed.

Performance indicators for the area

Performance indicator	**Target 2012**	**Actual 2012 at mid-year point**	**Actual 2011 at mid-year point**
▪ Projects delivered on time	85%	80% One project was delayed due to difficulties in getting input from the potential supplier	67% by number; 63% by value. For details please refer to 2011 mid-year report.
× Projects delivered to original specifications	100%	80% One project is planned to deliver less scope than planned due to technical challenges putting in place a stable architecture	54% by number; 84% by value. For details please refer to 2011 mid-year report.
▪ Projects delivered within budget	85%	80% One project is planned to consume more budget than planned due to technical challenges putting in place a stable architecture	85% by number; 72% by value. For details please refer to 2011 mid-year report.

EU telematics

Objectives

Objective		
Support the European medicines network through ICT systems.		
Group of projects	**High level plan**	**Outcome of quarter 2 2012**
Improved communication	EudraLink: A new version will be made available in 2012.	▪ EudraLink: As a result of a review by the EMA Executive Group in July of all ongoing projects, the scope of this project is currently being extended to include functionality related to electronic collaboration.
Efficient telematics systems that are fit for purpose	EudraVigilance Vet v3.0: Quarterly releases are planned that will deliver modules of the system such as integration with the medicinal products dictionary, improved data input and changes to assure compliance with guidelines and enhanced processes.	✓ EudraVigilance Vet v3.0: Two two-monthly releases have been delivered.
Projects improving quality of data input, processing and management	Central repository: Make available a central repository of marketing-application dossiers to the national competent authorities by Q3 and a next version in Q4. eSubmission gateway: Make available a system for piloting electronic submission of marketing-authorisation dossiers in Q1. Subject to the conclusion of the pilot and desirability of this by the EMRN, move into full production mode before end Q4. eAF: Put in production four EU forms by Q2.	× Central repository: An external supplier is being contracted to provide this solution. The contract is expected to be in place before the end of the year. ✓ eSubmission gateway: This system has been put in full production on 28 March 2012. ▪ eAF: This system has been put in full production in August 2012.

Objective		
Assure the coherent technical implementation of legislation.		
Group of projects	**High level plan**	**Outcome of quarter 2 2012**
Reducing redundant input of information	EUTCT – Full ISO compliance is scheduled, and interoperability across a number of systems is to be achieved. This will reduce the terminology maintenance burden.	✓ EUTCT: A first maintenance release has already been delivered. Two more releases are planned.
Increased transparency, communication and provision of information	eSPC: By end Q4, documented requirements and a proof-of-concept model will be provided to prove the applicability and use of information in the summary of product characteristics in clinical systems (e-Prescribing; decision support).	▪ eSPC: As a result of a review by the EMA Executive Group in July of all ongoing projects, the project is stopped.
EV MS edition	The Agency will continue to support this system in collaboration with the national competent authorities.	✓ The project has been successfully concluded in June 2012.
EudraCT programme	Further releases of EudraCT 8.x: Version 8.2 in Q1 and version 8.3 in Q2. Release 1.2 of the EU Clinical Trials Register (EU CTR) in Q1. Make available iterative releases of EudraCT 9.x, providing support for processing CT results.	✓ Further releases of EudraCT 8.x: Version 8.2 has been delivered. Version 8.3 and two additional releases will be put in production in October 2012. ✓ Release 1.2 of the EU Clinical Trials Register (EU CTR): This release has been subsumed in the EudraCT 8 releases. ✓ Make available iterative releases of EudraCT 9.x: Two iterations establishing the required architecture and one release providing initial functionality have been delivered.
EudraGDP	The good-distribution-practice database, foreseen in the legislation to support anti-falsification activities, is planned for the year.	▪ This project is on track to deliver early 2013.
EudraGMP	Conclude the inception phase of the good-manufacturing-practice database in Q1, the elaboration phase in Q2, and provide two	▪ This project is on track to deliver early 2013.

	construction iterations by end Q4.	

Objective		
Provide the Agency's contribution to international regulatory activities		
Group of projects	**High level plan**	**Outcome of quarter 2 2012**
Improved assimilation of EU requirements, leading to coherent EU position	International standardisation: The identification of medicinal products will be finalised, and specifications for the risk-management information and periodic safety update reports are also scheduled for completion. The regulated product submission (vehicle to replace the eCTD) is scheduled to complete its trial-use period, and the registration part of the clinical-trial registration and results standard is scheduled to reach the final draft international standard stage. All will have been shaped by EU requirements.	▪ The publication of the identification of medicinal products is planned to be published by Oct 2012. Specifications for the risk-management information and periodic safety update reports are finalised and a first draft of the standard will go in first ballot before end of this year. The regulated product submission (vehicle to replace the eCTD) is scheduled to enter is trial use period before end 2012. The registration part of the clinical-trial registration and results standard is currently on hold pending further funding from the internal community.
Reference data model	Version 4 of the RDM will provide integration of ISO ICSR and ISO IDMP.	▪ As a result of a review by the EMA Executive Group in July of all ongoing projects, this project will be halted until after September.

Performance indicators for the area

Performance indicator	**Target 2012**	**Actual 2012 at mid-year point**	**Actual 2011 at mid-year point**
× Projects delivered on time	85%	75%. A few projects were delayed because of support and maintenance activities over and above what was planned.	43% by number; 20% by value. For details please refer to 2011 mid-year report.
✓ Projects delivered to original specifications	100%	100%	61% by number; 62% by value. For details please refer to 2011 mid-year report.

✓ Projects delivered within budget	85%	100%	71% by number; 78% by value. For details please refer to 2011 mid-year report.

Maintenance and support of ICT

Core business performance indicators (covers EU telematics and corporate ICT)

Performance indicator	Target 2012	Actual 2012	Actual 2011
✓ Telematics and internal ICT systems availability measured against Agency working hours	98%	98.7%	98%