European Medicines Agency

EMEA/MB/503751/2009
1 October 2009

Mid-year report 2009 from the Executive Director (January – June 2009)

Background note

This half-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 2009.

The report maintains its previous format and the report provides information by individual objective of the work programme where relevant.

Navigation 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.

Matters for consideration

The summary of progress at the start of the document and highlights preceding each chapter present a high level summary of main points of the report.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu www.emea.europa.eu

EMEA mid-year report 2009

Table of contents:

Summary of progress 3

1 EMEA in the European system 5

2 Medicines for human use 13

3 Medicines for veterinary use 27

4 Inspections 33

5. EU Telematics strategy and corporate IT 36

Summary of progress

Human medicines:

	Number of applications/ Activities in the area	Core business/key projects/ main objectives	Majority of performance indicators
Revenue	Increase in fee revenue	N/A	N/A
Orphan medicinal products	Increase in designation applications	Key objectives are on target	The main indicators achieved
Scientific advice	In line with forecast	Key objectives are on target	The main indicators achieved
Initial evaluation applications	Applications on track. Received 44% of 2009 forecast applications with a significant number of generics and overall increase in orphans including SME applicants	Key objectives are on target	The main indicators achieved
Type IA	14% below forecast, but close to 2008 figures	Key objectives are on target	The main indicators achieved
Type IB	In line with forecast	Key objectives are on target	The main indicators achieved
Type II	In line with forecast	Key objectives are on target	The main indicators achieved
Line extensions	Below forecast and 2008 figures.	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
Pharmacovigilance	Activities are in line with forecasts	Key objectives are on target	The main indicators achieved
Herbal medicinal products	N/A	Key objectives are on target	Four of 10 planned monographs were finalised. No list entries completed of 2 planned.
Paediatric medicinal products	The forecast for 2009 remains unchanged	Key objectives are on target	The main indicators achieved
Advanced therapy medicinal products	In line with forecast	Key objectives are on target	The main indicators achieved
Parallel distribution	In line with forecast	Key objective relating to the handing time for initial notifications is on target. Checking of parallel distributors' compliance with notification process will be progressed towards the end of the year.	The main indicators achieved
Interaction with and provision of information to patients and healthcare professionals	N/A	Key objectives are on target	28% of EPARs published within 2 weeks. 39% of assessment reports published in 2 weeks following withdrawals. 0% of refusal reports published in 2 weeks.

Veterinary medicines:

	Number of applications/ Activities in the area	Core business/key projects/ main objectives	Majority of performance indicators
Scientific advice	In line with forecast	Key objectives are on target	The main indicators achieved
Initial evaluation applications	5 applications received (2009 forecast is 17, now revised)	Key objectives are on target	The main indicators achieved
Maximum residue limits	No MRL extrapolations and no MRL for use of cascades received	Key objectives are on target	The main indicators achieved
Type IA	In line with forecast	Key objectives are on target	The main indicators achieved
Type IB	In line with forecast	Key objectives are on target	The main indicators achieved
Type II	In line with forecast	Key objectives are on target	The main indicators achieved
Line extensions	Line-extensions are significantly above the forecasts	Key objectives are on target	The main indicators achieved
Pharmacovigilance	Activities are in line with forecasts	Key objectives are on target	The main indicators achieved
Referrals (art. 29 and 30)	Significant increase in complex referrals	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	Inspections stand at 61% of the total for the year	Key objectives are on target	The main indicators achieved

Legend:

Forecasts

Above target (usually more than 15% above forecast)	Largely on target (usually within 15% of forecast)	Below target (usually more then 15% below forecast)

Implementation of projects, indicators

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

1 EMEA in the European system

Highlights

- The European Parliament granted the discharge for the implementation of the 2007 budget.
- The preparation of the Agency's road map to 2015 has started. The draft will be delivered to the Management Board in December.
- The novel A/H1N1 influenza has dominated the Agency's public health activities since May 2009. Intensive cooperation is taking place both in the EU and internationally.
- A draft EMEA Transparency Policy was published for public consultation on 19 June 2009.
- Revision of the Agency's organisational structure is progressing according to plans. Internal launch of the new structure took place in September.
- Work on the new EMEA website and the new corporate identity is progressing in line with plans. The launch is expected by the end of 2009.
- An emerging risk for the future budgets is the cancellation of the reserve facility for the Agency.

1.1 European medicines network

Enhancing the overall quality and capacity of the network

- Work has been undertaken to simplify the **contractual arrangements** with the Member States for the services provided.
  Following extensive discussions at the Management Board and Heads of Medicines Agencies level it is expected that a Cooperation Agreement (including quantitative KPIs) can be agreed upon by the relevant fora before the end of 2009.
- Revision of the policy on the handing of **conflicts of interest is underway**.
  A reflection paper was discussed at the June Management Board meeting.
- The development of the **training strategy** is progressing.
- Experience with the **regulatory action** taken for 2 centrally authorised products was reviewed.
  The results of the analysis were discussed at PhVWP, CHMP and HMA level. A set of recommendations was agreed upon and implementation is now underway.
- 615 new experts were entered into the **European expert database**. 1511 expert updates were carried out.

Road Map

- The Agency started preparing the **Road Map to 2015**.
  The draft document will be delivered to the Management Board for the December 2009 meeting.

(Co)rapporteurs appointment procedure

- Revision of the (co)**rapporteurs appointment procedure** has not yet taken place. The procedure will reflect the appointment of CAT (co)rapporteurs and CHMP coordinators for ATMPs.

Review of the remuneration system to (co)rapporteurs

- **Pilot** is ongoing.
  Two meetings of costing group took place. A report is expected in October 2009.

Meetings and conferences at the EMEA

Core activities

- The number of meetings has remained at the 2008 level.
  297 meetings took place (2008: 292).
- The number of delegates has increased compared to 2008.
  4,510 delegates visited the EMEA (2008: 4,261).

✓ Web based Meeting Management System for booking was launched.

Preparation for enlargement

- Instrument for Pre-Accession Assistance (IPA) contract was extended to mid-September 2009. A new contract will be signed later this year.

✓ A new IPA programme was drafted for 2 years and is expected to be launched in September 2009.

1.2 Communication and transparency

Re-launch of EMEA website

- Work is in progress to launch a new EMEA website in December 2009.

EMEA corporate-identity project

✓ At its meeting of 11 June 2009, the Agency's Management Board **endorsed plans for the development of a new corporate identity** for the Agency, to be rolled out at the same time as the public launch of the Agency's new external website, scheduled for December 2009.

EMEA transparency policy

✓ A draft EMEA **Transparency Policy** was published for **public consultation** on 19 June 2009.
The final EMEA Transparency Policy along with a Consequence Analysis and Implementation Plan is planned to be published on the EMEA website by the end of December 2009 (further to agreement at the December 2009 Management Board).

Transparency initiatives

- Work is progressing in the area of **publication of agendas and minutes** of scientific committees:
  Project action plan includes development of draft policy on publication, identification of options for operational processes and impact assessment by mid 2010.

✓ The public **consultation** on the draft **EudraVigilance Access Policy** was **completed** in March 2009.
The comments have been consolidated and presented to HMA-H, the PhVWP and EV-EWG. Work is now underway to finalise the document before the end of the year on condition that outstanding issues with the European Ombudsman and the European Data Protection Supervisor can be resolved.

✓ The concept of **Pharmacovigilance working party monthly reports** has been further progressed and a revised proposal has been put to HMA in view of a launch as of September 2009.

Access to documents and information

- 68 requests for access to documents were received (2008:61), during which 2,445 pages were released (2008: 786).
  The forecast for the year is 205.
- Following a public consultation on the draft EMEA **Access to Documents Policy**, comments have been reviewed and finalisation at senior management level is expected later this year.
- 2,043 requests for information received (2008: 2,060).
  The forecast for the year is 4,800.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
✓ Percentage of external requests for documents processed within established timelines	95%	99%	100%
✓ Percentage of external requests for information processed within established timelines	80%[1]	80%	Data not available at the time
✓ Percentage of translations (non-product information) processed within established timelines	100%	100%	100%

For more information in the field of information provision, please refer to section 2.10 ‘Provision of information to patients and healthcare professionals’.

[1] The target reviewed.

1.3 Support for innovation and availability of medicines

Small and medium sized enterprises

Core activities

- Activities of the SME office are progressing well:
  104 requests for **qualification** as SMEs (2008: 132) and 42 applications for **renewal** of SME status (2008: 39) were received.
  45 **fee reductions** and **waivers** were requested (2008: 44).
  46 requests for **administrative assistance** received (2008: 52).
- 23 fee **reductions and deferrals** granted amounting to € 1.3 million.

Support during the period of scientific advice and marketing authorisation applications

- Activities to provide further assistance in light of experience in the marketing authorisation process started.
  Increased attendance at pre-submission meetings and in the certification activities of the Committee for Advanced Therapies planned.

Support with the electronic reporting

- Support provided through guidance in the testing and implementation of the electronic reporting activities or as part of the EudraVigilance training programmes.

Minor uses and minor species

✓ The Management Board adopted the changes to the implementing rules for the fee regulation.
The changes will now enable the Agency to grant **incentives** for veterinary medicinal products indicated for **minor use minor species** (MUMS) limited markets.

1.4 European cooperation

- Novel **A/H1N1 influenza** work has been the area of greatest focus and highest priority.
  Crisis management plan was activated in April immediately following the initial outbreak and subsequently stepped up as WHO raised the pandemic level in June. Significant EMEA and Network resources involved. The EMEA Task force involving the Vaccine Working Party, CHMP and PDCO members and (co-) rapporteurs was activated.
  The work ranged from providing additional guidance on the use of antivirals to very close and active cooperation with European, International partners and the industry in the area of development and authorisation of novel influenza vaccines. Rolling review of vaccines based on mock-up authorisations initiated.

✓ Work in the other fields of public health activities progressed **according to plan.**
Discussions with the **ECDC** ongoing in the areas of vaccine surveillance and establishment of a relevant forum. Collaboration is ongoing in the field of resistance to antivirals.

- ✓ The Agency prepared a list of **priorities in the area of health safety** issues in the Community.
  The list will be reviewed by DG Research in the context of the 7th framework programme.

- Much effort was expended in the area of **antimicrobial resistance** with completion of the EMEA contribution to the gap project, which is a topic of high political interest in the EU and internationally.
  A particular highlight was the joint meeting with HMA and stakeholders to discuss how best HMA and EMEA should cooperate with respect to implementing CVMP recommendations on AMR and promoting the prudent use agenda. Work is on schedule to produce a joint short report on AMR for the European Commission with EFSA, ECDC and SCENIHR and to develop proposals for the future role of the Agency with respect to coordinating the collection of data on sales of antimicrobials used as veterinary medicines within the EU.

1.6 International cooperation

International strategy

- The preparation of the **International strategy** is **in progress**.
  The drafting work should be completed by the end of 2009.

Bilateral relations

- ✓ The EU/**FDA** and EU/Health **Canada Confidentiality Arrangements** were operated in accordance with the Implementation Plans. Interactions with both partners showed an almost twofold increase relative to the previous period last year, a large part of this relating to cooperation in the context of the pandemic crisis.

- Cooperation with **FDA** on the Critical Path initiative and the Clinical Trial Transformation Initiative (CTTI).

- Collaboration with **Japan** also showed an increase in the overall level of activity.

- FDA's European **liaison official** started work in the Agency in July. Work is underway to send an EMEA liaison official to the FDA's US offices.

- Extensive collaboration has also taken place in the area of **novel H1N1 vaccines**, including aspects of the safety surveillance (for more information please refer to the section on public health activities). This collaboration has also involved the Japanese and Australian authorities.

Collaboration with other non-EU countries

- Discussions are in progress with regards to draft monographs for **Indian medicinal plants** submitted by the Indian Ministry of Health.

- The Agency has provided support to the European Commission in the context of visits to the **Russian** and **Chinese** authorities.

International organisations and fora

- Input into international **harmonisation activities** (ICH, VICH) continued to demand scientific support from European experts.

- Major input (as rapporteur, topic lead, editor or expert) has been provided in **international standardisation** work both at the level of ICH and the SDOs and the workload this year will remain very high. The work in this field concerned the definition of requirements as part of the development of the standards and the definition of requirements as regards the future maintenance of the content related to the IDMP (identification of medicinal products) standard.
- Cooperation with the **WHO** also showed a significant increase relative to previous years.

Inspections

- Significant international cooperation takes place in the field of **GMP** and **GCP inspections**. For some of the highlights in this area, please refer to the section on Inspections further in the document.

Certificates of medicinal products

- At the beginning of the year certificates requests have been below the forecast with 1,062 requests received (2008: 1,057).
  The recent data shows increasing number of received requests; thus the end-year data may be closer to the forecast.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
✓ Percentage of certificates issued to requesting parties within the target turnaround time.	90%	99%	92%

1.7 Integrated management at the Agency

✓ The European Parliament **granted** the **discharge** to the Executive Director for the implementation of the budget for the year 2007.

✓ **Fee revenue** for 2009 is positive and has slightly increased compared with forecasts.
An amending budget has been submitted to the Management Board for adoption by written procedure.

✓ One of the significant highlights is the ongoing revision of the Agency's **organisational structure** as part of the process improvement work.
The work is progressing in line with plans and the 'internal' launch of the new structure is planned in September 2009, and 'external' launch by the end of the year.

- The **evaluations** of the EMEA by the DG Enterprise and DG Budget are ongoing.

Supervision and self-assessment activities

✓ The **audit work** progressed **in line with plans**.
The Agency was subject to 5 internal audits, one audit by the Internal Audit Service of the Commission, one audit by the Court of Auditors and 2 audits in the Information technology area carried out by external auditors. Two meetings of the Audit advisory committee took place
Considerable work carried out in the follow-up to the 2008 Internal Audit Service audit on certain aspects of procedures contributing to scientific evaluation.

Some aspects highlighted in the IAS' findings link into other initiatives such as the drafting of a cooperation agreement with the Member States and the ongoing revision of the Conflicts of Interests Policy.

- In addition the Agency carried out a number of **ex post controls** on compliance with various internal procedures.

✓ The **review of the internal control standards** was completed earlier in the year, and highlighted the need to further improve the procedures for the management of conflicts of interests of experts and staff.
The management has approved the Agency's **records management** policy. Progress is achieved with regards to improving the **business classification scheme** and preparation are ongoing to prepare for the implementation of the new system.

Risk management

- The periodic review of **risk environment** of the Agency and of the related plan of mitigating actions shows that the Agency needs to focus its attention in areas such as:
    - Finance (due to the elimination of the reserve by the European Commission; possible changes in the system for rapporteur remuneration; exchange rate fluctuations; the new variations regulation; and the global financial downturn).
    - Management of conflicts of interest (recent audit recommendations).

Staff matters

✓ A survey on **equal opportunities** at the Agency has been completed and report in preparation.

✓ For the staff with high scientific competences and other specific qualifications **reinforced training** and competence development has been put in place.
The number of recorded training days per staff member is 3.64 days.

Enterprise resource planning system

- Work is ongoing to replace the Agency's **financial and accounting system** with the Enterprise Resource Planning system.
Blueprint phase completed. The realisation phase is awaiting the appointment of an implementation partner.

Accommodation

- Significant **refurbishment** work has been undertaken and continues. The work takes into account the changes of the organisational structure.
This involves refurbishment of 1st floor and partial refurbishment of 4th, 5th and 8th floors.
- **Rent reviews** and negotiations for the acquisition of **additional office** accommodation have been carried out.

1.8 EMEA outcomes assessment

Pilot projects in the field of outcomes assessment

- ✓ An assessment of the impact of Scientific Advice on the outcome of marketing authorisation applications has been **completed** and will soon be publicised.
- A project on improving **the methodology of Benefit-Risk assessment** has been **successfully initiated** and the first deliverable is expected by the end of 2009.
- A project on **Benefit-Risk communication** (exploring stakeholders' expectations with a view to improving EMEA's communication strategy on Benefit-Risk) is currently **underway**. First deliverable is expected by the end of 2009.
- A project to present **SPC information** in a format that could lend itself to use by electronic decision support systems at the point-of-care has been **initiated**.

2 Medicines for human use

Highlights

- Activities are largely on target. No significant deviations with regard to main objectives are observed.
- The number of orphan medicinal products designation applications is significantly above the forecast.
- The number of initial evaluation applications is on track largely due to a sharp increase in the number of marketing authorisation applications for generic products. Applications for orphan products including SME applicants have increased.
- A major milestone in the implementation of the Advanced Therapies Regulation was reached with the composition and start of operations of the Committee for Advanced Therapies. First applications received, first opinion adopted.
- Delays in the circulation of the (Co)-Rapporteurs' assessment reports for post-authorisation activities continued to occur. Also, although the legal timeframes for the handling of assessments for post-authorisation procedures have been adhered to, delays have occurred as regards the post-Opinion processing time.
- Improvements in the area of spontaneous reporting of adverse drug reactions focussed on initiatives to improve the quality of the submitted data.
- In terms of the strengthening of the EU Pharmacovigilance System Network, a pilot phase for signal management in the EU was conducted
- The public consultation on the draft EudraVigilance Access Policy was completed in March 2009 and the comments made have been consolidated and presented at various fora.
- A draft EMEA Transparency Policy was published for public consultation.
- Work continued on the implementation of the new variations regulation and analysis of related consequences for the EMEA.
- The EMEA led project PROTECT to address an IMI call has been successful. The project will address the development and testing of new quantitative signal detection methods.

2.1 Orphan medicinal products

Core activities

⇧ **Applications** for orphan designation are **23% above the forecast** (80 applications received) and **48% above the same period in 2008** (2008:54**).**
With 80 applications received, the forecast for 2009 remains unchanged.

⇧ Orphan medicinal products **fund**:
Fee reductions in the first half of the year totalled €2.74 million (2008: € 2.68 million) of €5.5 million budgeted for 2009.
The Agency revised its policy on incentives for orphan medicinal products in February to provide more pre- and post-authorisation fee reductions to SMEs.
Estimated **required contribution has increased** from €5.5 million to €6.7 million after the June revision of the forecast of orphan marketing authorisation applications.

International collaboration (common application, annual reporting)

- Review of experience with the common application form together with the FDA took place. Discussions on sharing of information at the time of submission of applications started. Analysis of data from common orphan designation applications and evaluation of the impact will be completed by the end of the year.

Review of the period of market exclusivity

- Implementation of the Commission guideline on Article 8(2) of Regulation (EC) No 141/2000 with respect to the review of the period of market exclusivity of orphan medicinal products has started and the procedure outline is expected by the end of the 3rd quarter.

Performance indicator	Target	Outcome	Outcome the same period 2008
✓ Percentage of applications evaluated within the 90-day timeline	100% of applications	100%	100%
✓ Percentage of summaries of opinions published within 1 month of the European Commission's decision on designation	70%	100% (also all 2000-2009 backlog has been addressed)	100%

2.2 Scientific advice and protocol assistance

Core activity

- Applications for protocol assistance (PA) are **in line** with forecast.
33 applications were received (2008: 31).

- Number of applications for scientific advice (SA) is **in line** with forecast.
  The agency received 157 applications for scientific advice in (2008: 148). Based on expected applications for the 2nd half of the year, the forecast is reduced by 20 applications from 318 to 300.
  55% of marketing authorisation applications received scientific advice. SMEs requested 20% of scientific advice and 29% of protocol assistance.

Think-tank report activities (biomarkers, urgent and minor scientific advice)

✓ The scientific advice procedure on **biomarkers** has been completed.

- The development of the procedure for **urgent and minor scientific-advice follow-up** is ongoing and will be completed by the end of 2009.

✓ A workshop with stakeholders on statistics in clinical trials has been organised on 2 April 2009. A report is in preparation.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
✓ Scientific advice and protocol assistance requests evaluated within the procedural timelines	100% of requests	98.4%	98.5%
× External experts involved in procedures	50% of scientific advice and protocol assistance requests	39% (revised composition of SAWP and appointment of alternates for all members necessitates involvement of fewer external experts)	49%

2.3 Initial evaluation

Core activities

- Overall number of applications is similar to forecast. However, of note is that the number of new applications has decreased compared to 2008 and the number of generic applications has significantly increased.

  Estimates for applications in 2009 have been revised and the overall number will increase by around 16.5% due to the number of generic applications.

Type of procedure	Applications received 2008 (1st half)	Applications received 2009 (1st half)	Applications originally planned for 2009	Revised 2009 forecast, if applicable
⇩ Initial evaluation (non-orphan medicinal products)	26	14	61	-11
▪ Initial evaluation (orphan medicinal products)	6	4	11	+4

Type of procedure	Applications received 2008 (1st half)	Applications received 2009 (1st half)	Applications originally planned for 2009	Revised 2009 forecast, if applicable
⇩ Similar-biological-product applications	0	1	8	-6
⇧ Generic applications	3	31	20	+35
⇩ Hybrid and abridged applications	7	1	6	-3
▪ PUMA	0	0	2	No change
▪ Article 58 (WHO-related) applications	0	0	1	-1
▪ Total number of applications	42	51	109	+18 (16.5% increase due to generic applications)

Type of procedure	Applications received 2008 (1st half)	Applications received 2009 (1st half)	Applications originally planned for 2009	Revised 2009 forecast, if applicable
▪ Requests for compassionate use	0	0	1	No change
▪ Plasma-master-file applications	8	7	18	+2
▪ Vaccine-antigen-master-file applications	0	0	1	-1

Quality control

✓ Additional quality-control tools have been developed and are being piloted. After completion of the pilot in the 3rd quarter, the process will be formalised and extended further .

▪ Work ongoing to implement quality control elements or application validation, advanced therapies and clinical trials compliance with ethical standards. Checks implemented for PIP compliance at validation. A pilot is ongoing.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
✓ Percentage of applications or accelerated assessment applications evaluated within the	100% of applications	100% (no accelerated assessment applications	100% (no accelerated assessment applications

	regulatory timeline of 210 days or 150 days respectively		were concluded)	were concluded)
✓	Percentage of plasma master file applications evaluated within the regulatory timeline	100% of applications	100%	100%
✓	Percentage of opinions sent to the European Commission within the regulatory timeline of 15 days	100% of applications	100%	100%
✓	Percentage of marketing authorisation applications including risk-management plans (RMPs) peer reviewed by the EMEA as part of the assessment of the initial marketing authorisation application	80% of applications that include an RMP	100%	100%

2.4 Post-authorisation activities

Core activity

- Majority of post-authorisation applications are largely **close to target**.
  Type IA variations are below target but close to 2008 figures, while **line extensions** are below target and 2008 figures. Forecasts are revised accordingly.

Type of procedure	Applications received 2008 (1st half)	Applications received 2009 (1st half)	Applications originally planned for 2009	Revised forecast, if applicable
▪ Type-IA variations	419	412	990	-140
⇧ Type-IB variations	242	218	420	No change
▪ Type-II quality variations	167	179	425	-25
▪ Type-II clinical variations	225	285	557	+17
⇧ Line extensions	20	11	25	-6

× Delays in the circulation of the (Co)-Rapporteurs' assessment reports for post-authorisation activities continued to occur in the first half year.
This required additional work to ensure that the legal timelines were met. The issue will be analysed and presented to the CHMP in the third quarter of 2009.

× Delays have occurred as regards the post-opinion processing time (i.e. the transmission of the Annexes of Opinions to the European Commission on Day 27 after the Opinions). There was 81% adherence to the timelines (2008: 55%). However, only 8% were sent with delays exceeding 3 days.
The main reasons for the delays appear to be the very short timeframe foreseen by the timetable to finalise Annexes, and the clash between Day 27 and the CHMP week. The inconsistent quality of the Annexes provided by the MAHs is another cause as well as the late circulation of the Annexes by the MAHs. The situation is being closely monitored.

Strengthen the regulatory and scientific consistency

- The introduction of the peer-review system will be considered following the re-organisation.

Implement the revised variations regulation

- The implementation of the revised variations regulation constitutes a major additional work for the agency in the post-authorisation field. Activities are ongoing in the areas of -
    - **New procedures** and **guidelines** for grouping, work sharing, classification and recommendations: **procedures are in preparation**, relevant guidelines provided to the European Commission. Procedures to be adapted following the outcome of public consultation and subsequent European Commission decision. Revision of standard operating procedures for variations is taking place.
    - Re-development and drafting of guideline on **variation classification**. To be **adopted later in the year**.
    - Finalisation of **financial impact analysis**. Ongoing revision of EMEA fee implementing rules for submission to the European Commission.
    - Staff training held and will continue.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
✓ Percentage of applications for post-authorisation procedures evaluated within the regulatory timelines	100% of applications (95% for extensions)	Type IA - 95% Type IB – 100% Type II quality – 100% Type II clinical – 100% Extensions – 100%	Type IA - 100% Type IB – 100% Type II quality – 100% Type II clinical – 100% Extensions – 100%
× Percentage of applications meeting the legal timeline of 27 days for the linguistic post-opinion check	100% of applications	81%	55%

Parallel distribution

Core activities

⇧ The number of **initial parallel** distribution notifications is **higher** than forecasted (1,020 compared to the forecasted 713) (2008: 792). The figure for the whole of 2009 has been revised accordingly.

- The number of notifications of a change is close to forecast (2,398 compared to the forecasted 2,500 for the first half of 2009) (2008: 2,457).

✓ The timelines for **initial notifications** have improved compared to 2008 due to priority for this type of notifications.

× However, a backlog has developed for the handling of **notifications of a change**.
The average time was 56 working days (regulatory timeline 5 working days). Remedial action has been taken to address the backlog.

Verifying compliance

- The Agency awaits the outcome of the study on parallel trade before starting verification of compliance with the mandatory notification procedure.
- Only 1 parallel distributed product was sampled in the EMEA-EDQM sampling and testing programme due to a limited or no availability of the selected products in the sampling Member State. The EMEA performed the check of the product.
  A voluntary sampling of parallel distributed products by GMP/GDP inspectors was proposed.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
✓ Percentage of notifications checked for compliance within the regulatory timelines of 35 working days	70% of applications	78% (the average handling time is 27 working days)	65% (the average time - 44 days).

2.5 Pharmacovigilance and maintenance activities

Core activity

- 384,697 individual case safety reports were received and processed in EudraVigilance.
- 13,266 medicinal product reports were processes in the EVMPD.

Implementation of ERMS (incident management plan, communication strategy, pandemic influenza)

✓ The **pilot** phase of the EU Regulatory system **incident management** plan was launched. The incident review network was tested.
Training on the incident management plan was provided to EMEA staff.

- In the area of EU Regulatory system **communication strategy on emerging safety related issues**, the concept of pharmacovigilance working party monthly reports was further developed and presented at HMA level.

✓ In the area of pandemic influenza preparedness, the antiviral plans were reviewed and adopted in June 2009.
Revised core risk management plans for vaccines were adopted.

Strengthening the EU EudraVigilance system

- Improvements in the area of spontaneous reporting of adverse drug reactions focussed on initiatives to improve the **quality of the submitted data**. The EudraVigilance Phase IIb project has been initiated in January 2009. The next milestone will be the user acceptance testing of the **duplicate detection** and management tools. The EudraVigilance Support Programme was initiated end of January 2009 to support Member States in their signal detection and evaluation activities

✓ A protocol for creating a structured **database of labelled adverse reactions to centrally authorised products** to support signal detection has been developed. Data entry is underway.

✓ The **key principles**, including roles and responsibilities for **signal management** for products authorised by different regulatory procedures have been agreed (CHMP, PhVWP, HMA). A pilot phase for **signal management** in the EU was conducted successfully. The pilot phase confirmed the viability of those principles. The recommendations stemming from the pilot will now be implemented

- EPITT (European Pharmacovigilance Issues Tracking Tool) is routinely used to support the signal management process. All Member States are connected.

Implementation of ENCePPP

- Work undertaken during the first half of the year focused on topics such as the **ENCePP Code of Conduct**, the inventory(ies) of research resources and post-authorisation safety studies.

IMI and 7th framework programme

✓ The EMEA led **project PROTECT** to address IMI call No 6 has been **successful** in the second round of IMI calls.
The evaluation graded the research proposal as excellent. The project will address the development and testing of new quantitative signal detection methods.

- Input was provided to DG Research on important health safety issues to be considered for research funding through the 7th Framework Programme.

Legislative proposal on revision of the EU pharmacovigilance system

- EMEA provided necessary support to the European Commission in relation to the Council Working Party discussions on the new Pharmacovigilance legislation. These efforts will continue and will probably be strengthened over the next 6 months, also in view of the start of the preparatory work at the level of the European Parliament.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
▪ Percentage of RMPs that are peer reviewed by the EMEA as part of the assessment of variations and line extensions that result in a significant change to a marketing authorisation	80% of RMPs.	47% for line extensions and 52% for extension of inductions (all significant changes to a marketing authorisation for products with a risk management plan are reviewed. Due to resource constraints and unforeseen challenges there has been a need to prioritise those	78.6% for line extensions and 100% for extension of indication applications

		products considered high risk).	
▪ Submission of outcome reports for PACs to applicants/MAHs within 2 weeks of the CHMP meeting	100% of reports.	94%	97.8 %

2.6 Arbitration and Community referrals

Core activity

- 20 referrals were received (2008: 18).
  The forecast of 43 referrals for the year will be maintained.
- ✓ All procedures were finalised within the legal timelines.
- For some referrals, it remains difficult to ensure compliance with the **post-opinion processing time**, mainly because of the complexity of the procedures (i.e. the number of medicinal products and MAHs involved).

Streamlining the procedures

- Preparation of **public recommendations** on the handing of Article 29 and 30 referral procedures is **ongoing**.
- Preparation of the guidance on Article 29 paediatric procedures will be delayed as only 1 procedure was completed.

Increasing transparency

- Publication of the outcome of the scientific review progressed as planned. A further increase in transparency will be undertaken following the Agency's restructuring.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
✓ Percentage of arbitration and referral procedures managed within the legal timeline	100%	100%	100%
✓ Publication of question-and-answer documents for Community interest referral procedures (Articles 31, 36 and 107(2))	100%	100%	N/A
✓ Publication of the CHMP opinion and assessment report for Article 5(3) procedures at the time of the CHMP opinion	100%	100%	N/A

2.7 Herbal medicinal products

Core activities

- × 4 Community monographs finalised (2008: 5).
  It is expected that in the second half of 2009 more Community monographs will be drafted and finalised with a revised estimate of 18 Monographs being finalised by the end of 2009.
  No list entries finalised (2008: 4).

Cooperation of HMPC with other bodies

- A joint meeting with EFSA took place in June 2009 to discuss the modalities of cooperation between the Agencies and their respective scientific groups on **health claims** and **medical indications for herbal medicines**. The objective of this cooperation is to avoid the release of divergent positions in this field. Interaction on these aspects will continue during the second half of 2009.
- The committee agreed to mutual participation in meetings with the EDQM (group of experts in Photochemistry and the chairs of the certain groups of experts).

Extension of the scope of the simplified registration procedure

- No action is anticipated in 2009.

Informing interested parties

- The HMPC agreed on a new policy for the organisation of hearings with interested parties.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
× Number of Community herbal monographs (finalised)	20 (10 first half)	4	5
× Number of Community list entries (finalised)	5 (2 first half)	0	4

2.8 Paediatric medicines

Core activity

- ⇩ 179 paediatric investigation plans and paediatric waiver applications by clinical indication were received (2008: 194).
  The forecast of 450 applications (by clinical indication) remains unchanged.

Streamlining the assessment of paediatric investigation plans

✓ The work is progressing in line with plans:
Review of procedures for assessment of paediatric investigation plans and waivers finalised.
Review of procedure for paediatric scientific advice started.
Core SOP on PIP/waiver procedure finalised.
Paediatric learned societies identified and invited to participate in EMEA research network.

Process for compliance check

- A new procedure prepared and undergoing **internal consultation**. Amendments in collaboration with Member States planned.

Inventory of paediatric therapeutic needs

✓ Survey of **existing uses of medicinal products** in the paediatric population **completed** and outcomes compiled.
Reply received from 20 Member States. Work to prepare the inventory continues.

Establishing the Paediatric Research Network

✓ **List of existing networks published**. A workshop with the networks held in February.
Two working groups were created with members from identified networks to define recognition criteria and operation of the network.

Influenza A/H1N1 Pandemic

- Intensive paediatric-related activities for PIPs for novel influenza vaccines and anti-virals integrated in the work of the EMEA Task Force.

Risk management and pharmacovigilance

✓ An **Action plan** on Paediatric Pharmacovigilance based on EudraVigilance data has been **adopted**.
The plan includes the organisation of a brainstorming meeting on research on the safety of drugs in children.

✓ Similarly, an action plan on the **sharing of information regarding paediatric safety** issues and RMP related aspects has been adopted.

Possible collaboration with DG research and US authorities

- Priority list adopted. Work will continue.

Performance indicators	**Target**	**Outcome in 2009**	**Outcome in 2008**
✓ Number of paediatric investigation plans or waiver opinions and decisions within legal timelines	100%	100%	100%
▪ Number of paediatric clinical trials entered in EudraCT database	100% of paediatric trials conducted	No paediatric data available from the EudraCT database	N/A

2.9 Advanced therapies and other emerging therapies and new technologies

Core activity

- ✓ In January 2009, a major milestone in the implementation of the Advanced Therapies Regulation was reached with the composition and **start of the CAT** secretariat and with the kick-off for the CAT meetings and CAT activities.
  The majority of the documents required for the CAT and its activities has been prepared and approved.
- ✓ **First CHMP opinion** in June on cell-based product adopted **following CAT draft opinion**.
  Another 2 initial evaluation procedures are ongoing.
- ▪ No applications for **re-registration** or variations received.
- ▪ **Certification** of quality and non-clinical data and issue of certificates:
  Procedure not yet in operation. Procedural guideline published.
  Scientific guideline currently under discussion with CHMP, CAT and relevant working parties.
- ✓ One **classification** request was finalised and 4 further requests are ongoing.
- ✓ **Scientific advice procedure updated** in January to take into account systematic consultation of CAT on all advanced therapy scientific advice requests.
  A pilot procedure for the CAT-SAWP interaction has been agreed.
- ✓ **Training** to Committee for Advanced Therapies members and experts on new procedures has been **provided**.
  A workshop with industry has taken place.

Extending expertise on emerging therapies and technologies

- ▪ 1st meeting of an informal group of experts on **nanotechnologies in life sciences** held.
  Review of experience on nanomedicines in the centralised procedure will be organised.
- × Work on **translational medicines** development was re-prioritised to other areas.
  Activity on modelling and simulation was kept at low level due to other priorities.

Performance indicators	Target	Outcome in 2009	Outcome in 2008
✓ Percentage of applications handled by the CAT within the procedural timelines (allowing adoption of the opinion by the CHMP within the legal timeline of 210 days)	100% of applications	On target (1 evaluation completed)	N/A
✓ Scientific recommendations on advanced therapy classification provided within the legal timeline	100% of requests	On target (1 request finalised)	N/A
▪ Certification of quality and non-clinical data issued within the	100% of requests	N/A	N/A

procedural timelines			
✓ Innovation task force briefing meetings organised within 60 days from receipt of a request	80% of meetings	100%	92%
▪ Regulatory-advice and ITF regulatory advice on new, emerging and borderline medicinal products (excluding ATMPs) given within 60 days	80% of requests	N/A	88%

2.10 Working with patients and healthcare professionals

Core activities

✓ Currently 91% (410 of 452) **EPARs** are up-to-date. (2008: 94% (369 of 392)).

× Delays remain in meeting a 2-week deadline for **publication of EPARs** following the Commission Decision.

Implementation of the road map in the area of provision of information

- A draft proposal for the EU network in the field of medical information was presented for the June 2009 meeting of the Management Board. The proposal will be further revised following the guidance received from the Management Board.
- For progress on the project regarding the EMEA website please refer to the section on Communication and Transparency.

Integrating stakeholders in the EMEA activities

✓ The Agency completed the analysis of achievement of 2008 performance indicators in the area of **satisfaction of patients and consumers**. The document will be presented to the Management Board in October.

- Some delays were experienced in the implementation of the recommendations of the working group with **healthcare professionals**. The Agency aims to finalise the framework of interaction by the end of the year. The related performance indicators will be prepared following the adoption of the framework.

Quality and consistency of user consultation

- **User consultation** has been monitored through an analysis of all user testing reports submitted between 2007-2008. The report was presented at the June 2009 QRD plenary meeting and follow-up on the outcome of the analysis is being undertaken.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
✓ Percentage of summaries of opinions published at the time of the CHMP press release	90% of Summaries of Opinion.	100%	100%.

×	Percentage of initial European Public Assessment Reports (EPARs) published within 2 weeks of the Commission decision	80 % of Marketing Authorisations granted.	28%	23%
✓	Percentage of EPAR summaries in a language understandable to the public, published together with the EPAR	90% of EPARs.	100%	100%
×	Percentage of assessment reports published within 2 months of withdrawal of a marketing authorisation application	70% of assessment reports.	39%	42%
×	Percentage of refusal assessment reports published within 2 weeks of the Commission decision	70% of assessment reports.	0% (only 1 refusal during the reference period not published on time)	50%

2.11 Coordination group

Core activities

- 9 (2008:27) mutual recognition procedure (MRP) applications and 8 (2008:19) decentralised procedure (DCP) applications have been **referred to the CMD(h)** in the first half of 2009.
- **Agreement was reached** for 6 (2008:16) MRP and 11 (2008:12) DCP applications.
- 1 (2008:3) MRP and 4 (2008:2) DCP applications have been **referred to the CHMP** according to Article 29(4), Directive 2001/83/EC.
- The CMD(h) is preparing the 2009 list of medicinal products for which a harmonised **SPC** should be drawn up.

Activities arising from the Paediatric regulation

✓ The sub-group on paediatric regulation agreed on the **list of active substances** to be included in the second, third and fourth wave of the work sharing procedure. This information is published on the CMD(h) website.

Improving the functioning of the CMD(h)

✓ An **outcome of the questionnaire** to CMD(h) members and interested parties on the functioning of the CMD(h) and related action plan have been published. The finalised actions include improvements to the CMD(h) website, the publication of presentation given in meetings with interested parties and action plans from meetings.

3 Medicines for veterinary use

Highlights

- Core activities with respect to authorisation and maintenance of veterinary medicines remains largely on track with only minor modification necessary to the forecasts set at the beginning of the year
- The number and complexity of referrals constituted the major challenge for veterinary medicines. Some class referrals concerned in total several hundred products.
- With the new MRL Regulation in force, good progress has been made according to the time plan developed in early 2009 to implement the new provisions in a timely manner
- The release of EudraVigilance Veterinary Data Warehouse, the recoding application and the duplicate detection engine now provide the Agency with the necessary tools to optimise signal detection and surveillance of the data with emphasis on centrally authorised products.
- Much effort was expended in the area of antimicrobial resistance.
- Incentives for the Minor uses and minor species products have become operational

3.1 Scientific advice

Core activity

✓ Four scientific advice applications were received (2008: 2).
The original forecast for 2009 of 11 applications is maintained.

- **No applications for parallel advice** with the FDA/USDA have as yet been submitted.

Performance indicator	Target	Outcome in 2008	Outcome in 2008
✓ Scientific advice requests evaluated within the procedural timelines	90% of applications	100%	100%

3.2 Initial evaluation

Cores business

⇩ 5 applications for new medicinal products were received (2008: 12).
No applications for generics were received (2008: 5).
The total forecast of 17 applications was revised to 15.

Quality assurance system

✓ The pilot phase for the peer review initiative has been reviewed following 6 months of operation and outcome presented to the CVMP.
Revised procedure and templates were adopted.

Performance indicator	Target	Outcome in 2008	Outcome in 2008
✓ Percentage of products evaluated within the regulatory timeline of 210 days	100% of applications	100%	100%

3.3 Establishment of maximum residue limits

Core activities

- **Two new** and 1 **extension/modification** MRL applications were received (2008: 1 of each).
  The forecast for the new applications was increased from 2 to 4, and for extensions/modifications remains unchanged at 2 applications for 2009.
- No MRL **extrapolation** applications were received (2008: 5).
  The forecast of 3 applications remains unchanged.

⇩ No MRL for use of **cascades or biocides** were received.
The annual forecast for MRL for biocides reduced from 4 to 2.

Strengthening the review process

- Peer review of MRL assessments by CVMP members is part of the pilot phase.

New MRL regulation

✓ Good progress has been made with the implementation according to the time plan developed in early 2009 to complete the work by the end of 2009: the first 2 proposals contained within the plan were delivered.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
✓ Percentage of applications evaluated within the 120-day timeline	100% of applications	100%	100%

3.4 Post-authorisation activities

Core activity

- Post-authorisation applications are largely in line with forecasts:
  There is a significant increase in line extension applications.

Type of procedure	Applications received 2008 (1st half)	Applications received 2009 (1st half)	Applications planned for 2009	Revised forecast, if applicable
▪ Type-I variations	22	36	55	No change
▪ Type-II variations	13	17	42	-2
▪ Line-extensions	1	8	5	+5

Strengthening quality assurance process and implementation of variations regulation

- Work to strengthen the quality and consistency of the review process is ongoing.
- The Agency is preparing for the implementation of the revised variations regulation.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
✓ Percentage of applications for type-I and II variations and line extensions evaluated within the regulatory timelines	100% of applications	100%	100%

3.5 Pharmacovigilance and maintenance activities

Core activity

- The expected continued increase (around 40% each year) of the number of serious adverse reaction and human reaction reports has been confirmed so far.
  The forecast of around 3,000 reports for 2009 remains possible.

EU collaboration in veterinary pharmacovigilance

- The Agency continued its contribution to the European Surveillance Strategy (ESS).

✓ Pharmacovigilance **training programme** was developed for the 4 year period.
The programme was endorsed by CVMP and ESS, and approved by HMA.

Processing of pharmacovigilance information

- The release of EudraVigilance Veterinary Data Warehouse, the recoding application and the **duplicate detection** engine now provide the Agency with the necessary tools to optimise signal detection and surveillance of the data with emphasis on centrally authorised products.
- The optimal integration of the EU product data into the Adverse Events database, necessary for the analysis, remains a challenge due to the lack of a single validated product dictionary for EU authorised Veterinary Medicinal Product.

Implementation of risk management plans concept

- A draft paper has been prepared. Public consultation should be initiated by the end of the year.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
✓ Percentage of PSURs and SARs evaluated within the established timelines	80% of PSURs; 100% of SARs	100% (40 PSURs) 100% (1481 SARs)	92% of PSURs assessed 100% of SARs

3.6 Arbitration and Community referrals

Core activity

- Four referrals were started (2008: 5). Two further referral notifications were received which were not started due to a lack of a legal base
The number and complexity of referrals constituted the major challenge for veterinary medicines. Three of these were class referrals, concerning in total several hundred products. The forecast has been revised from 16 to 10 referrals.
- The CVMP concluded the evaluation and issued opinions for 9 referrals that were initiated in 2008/2007.
- Much effort is currently being expended by the CVMP and the secretariat in amending procedures, developing guidance and exploring other possibilities to ensure that the current 'voluntary' system for triggering and processing referrals can continue.

Harmonising approach to avoid inappropriate referrals

- Mutual reporting takes place on all relevant decisions by the CVMP and CMDv. The CMDv reviews the CVMP opinions on referrals and takes these into consideration in future procedures. CVMP is reviewing and documenting its experience gained in handling referrals.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
✓ Percentage of arbitration and referral procedures managed within the legal timeline	100% of procedures	100%	100%

3.7 Coordination group (veterinary)

Core activities

- 6 (2008:9) mutual recognition procedure (MRP) applications and 7 (2008:9) decentralised procedure (DCP) applications have been **referred to the CMD(v)** in the first half of 2009.
- **Agreement was reached** for 5 (2008:4) MRP and 7 (2008:5) DCP applications, of which 3 were referred to CMDv in 2008 and reached Day 60 in 2009. 1 application which was also referred to CMDv in 2008 was withdrawn after reaching Day 60 in 2009.
- 1 (2008:5) MRP and 3 (2008:4) DCP applications have been **referred to the CVMP** according to Article 33, Directive 2001/82/EC.
- The secretariat is assisting a CMD(v) working group aiming to develop a scheme for voluntary **harmonisation of SPCs** for veterinary medicinal products which it is hoped will reduce the number of referrals in the future.

Improving the functioning of the CMD(v)

✓ The secretariat is assisting the CMD(v) with development of procedures related to worksharing within the context of the revised **variations regulation.**

4 Inspections

Highlights

- Requests for GCP, PhV and GMP inspections have exceeded forecasts in the first half of the year with a particular increase noted in relation to GCP inspections
- Public access to EudraGMP is planned for July.
- International inspection cooperation activities are progressing significantly and involving increasing resource for coordination and information exchange activities.
- An EMEA working group on third country clinical trials has been established.
- A report describing the distribution of the number of patients, investigator sites and pivotal clinical trials in third countries versus EU/EE/EFTA has been completed.

4.1 Inspections

Core activities

⇧ 120 **GMP** inspection requests received (2008: 105), representing 57% of the forecast for 2009.

⇧ 39 **GCP/PhV** inspection requests received (2008: 48), representing 78% of the yearlong forecast.
This level may not be sustained in the second half of the year due to limitations on available inspection resource in the Member States, and the greater time needed for inspection in third countries.

- No **GLP** inspection (2008: 4) has yet been requested forecast (2).
- There have been fewer **quality defects** than in 2008 so far, and those received have overall not reached the complexity of some (e.g. Heparin, Viracept) that occurred in 2008. There is a likely cooperation with FDA on a site inspection for one product.

✓ The first Annual Reports of the activities performed by the GCP and Ad Hoc PhV IWGs have been published.

✓ An EMEA working group on third country clinical trials has been established and has commenced work on preparing proposals on additional practical steps to be undertaken to reinforce the framework for conduct and verification of clinical trials carried out in third countries. A public workshop is foreseen in 2010 during the consultation period on these proposals.

✓ Pharmacovigilance inspection procedures in the area of veterinary pharmacovigilance inspections are now publicly available.

- The first risk-based programme for routine pharmacovigilance inspections of marketing authorisation holders connected with veterinary Centrally Authorised Products is being implemented this year with the first pharmacovigilance inspection adopted by the CVMP in April 2009.

✓ A report describing the distribution in third countries versus EU/EE/EFTA of the number of patients, investigator sites and pivotal clinical trials included in the marketing authorizations applications (MAA) submitted to EMEA during the period from January 2005 to December 2008 has been prepared and will be published.

Joint inspections with FDA and other international collaboration

- International inspection **cooperation activities** are **progressing significantly** and involving increasing resource for coordination and information exchange activities. Initiatives include ongoing successful cooperation on joint inspection with FDA on dosage form manufacturers and increasing activity in the realm of active pharmaceutical ingredient inspection.
- One **joint inspection** has been performed. Six are planned later in the year.
- The GMP/GDP inspectors working group **will provide support** allowing Chinese inspectors to join inspections performed by EU Member States and to observe inspections performed by Chinese inspectors.
- It is expected, that Canada and Switzerland will have **access to EudraGMP** by the end of the year.

EudraGMP database

✓ **Public access to EudraGMP** is planned in July 2009 and non-compliance features expected to be operational in the second half of the year.

Impact of advanced therapies regulation

- A revised GCP guideline specific to advanced therapies based on the comments from the public consultation has been prepared on behalf of the Commission.

Performance indicator	Target	Outcome in 2009	Outcome in 2008
✓ Management of inspections within legislative timelines	100% of inspections	100% for GMP, GCP and pharmacovigilance inspections	100%
▪ Successful completion of collaborative inspections with the FDA	1 GMP by end of 2009	On target	NA

4.2 Sampling and testing

✓ The programme for 2008 has been successfully concluded and the 2009 programme is on schedule. The list of products for testing in 2010 has been adopted and preparative steps have begun. A risk-based approach for the 2010 programme has been fully implemented for products used in humans. CVMP has adopted a risk-based approach tailored to veterinary products which will be implemented in the next programme cycle.

Performance indicator	Target	Outcome in 2009
▪ Percentage of planned products (42) actually tested.	95% of planned products	Not applicable at this stage

4.4 Implementation of the clinical trials directives

Clinical trials directive

- ✓ The **EudraCT** version 7 came into production in June 2009 and includes functionalities relating to **validation of clinical trials** application, comparison of information and clinical trials application package.
- ▪ **Further improvements** of the database will concern: the information on **clinical trials** conducted in the third countries that are part of a paediatric investigation plans and the provision of information on clinical trials to the public.
- ✓ A number of **guidelines and reflection papers** have been **developed**, including exchange of GCP inspection reports, coordination of GCP inspections in the context of mutual recognition and decentralised procedures,

5. EU Telematics strategy and corporate IT

5.1 EU Telematics

For more detailed update on the Telematics projects, please refer to the document 'Update on the implementation of the EU telematics strategy' which is listed under the 'for information' section of the Management Board meeting documents.

The following development work has been undertaken:

- EudraCT (EU database on clinical trials)
  Version 7, originally scheduled for December 2008 delivery, delivered in 2009.
- EudraVigilance v7 Human
  Work on Iteration IIb undertaken.
- Product information management (PIM)
  Releases of the system components (PRS, LAT and PDVE) held back as they are dependent upon release of DES v2.7 (work is complete) which is delayed due to delay in finalisation of the new SPC Guideline. The project has been re-planned as the migration exercise (PIM Information project) will require at least two years to ensure proper control, and that industry has the time to implement the necessary systems and process changes.
- EUTCT
  Version 2.1 was released on schedule, but without the BPEL element.
  Work on the maintenance process has been ongoing, but is proving difficult to finalise.
- Eudra data warehouse
  Iteration 4 was closed at the beginning of March 2009 instead of the end of December 2008. Iteration 12 was swapped in the development order with iteration 6.
  Work on the EudraCT Proof of Concept (Business Intelligence) continued, having been delayed from a December 2008 delivery.
- Electronic Application Form
  Updates of the forms published as part of the NtA on the Commission website were completed; Work on the framework DES, as well as requirements gathering and analysis for the software components (authoring tool, receiving tool, validator) was taken forward.
- EudraVigilance Data Management
  Work on the tender delayed due to insufficient resources within the unit to resource the required procurement procedures adequately.
- Incorporation of Human medicinal products pharmacovigilance into Eudra data warehouse
  Work did not commence in 2008, as planned, but only in March 2009. The plan has been drafted and approved, and considerable progress made on design work.

- EudraVigilance v2 Veterinary
  Iteration 4 delivered for UAT.
- EudraGMP
  Version 2 delivered to operations for transition into production
- Further Telematics projects
  Ongoing development projects delivering in line with requirements, though a number are running substantially late.

Performance indicator	Target	Outcome
✓ Percentage of system downtime	Max. 2%	1%
▪ Percentage of user satisfaction	Min. 80%	Not measured
▪ Delivery of project against plan and budget	Min. 90%	75%
▪ Effective transition to production/operation	Min. 95%	85%
✓ Availability of services (excluding planned maintenance downtime)	Min. 98%	99%
✓ Response time to 80% of EU telematics service-desk requests	Max. 2 Hours	91%
✓ Response time to 15% of EU telematics service desk requests	Max. 1 day	99.4%

Corporate IT

- Implementation of the electronic records management system
  Elaboration Phase (part of technical implementation) deferred due to EDMS upgrade being postponed.
  Business Classification Scheme (BCS) & high-level Retention Plan (RP) endorsed.
- Phase 1: Complete Enterprise Information Architecture (EIA) Phase 1 by defining Phased requirement of EIA programme and Selecting Expertise to assist EMEA.
  Action Completed
  Completion of Phase 2, namely derive First-Cut EIA Plan

- EMEA Resource Planning
  Blueprinting completed, late, and ultimately to a satisfactory level of quality. In the interest of project quality, a project review exercise has been initiated extending consequently the project duration.
- WCMS (public facing online information project)
  Design and development activities on track for December go-live
- SIAMED
  Project team composition and planning re-assessed. Development approach changed to deliver modules supporting parts of the process, beginning with pre-submission. Tightly controlled iterative development undertaken.
- Corporate GxP
  Refinement of the requirements took longer than anticipated. GMP prototype produced and demonstrated
- BCP Infrastructure
  Infrastructure installation, application migration and procedures approximately two thirds complete, in line with expectations. Two rehearsals successfully completed.

Performance indicator	**Target**	**Outcome in 2009**
✓ Percentage of system downtime	Max. 2%	1%
▪ Percentage of user satisfaction	Min. 80%	Not measured
▪ Delivery of project against plan and budget	Min. 90%	75%
▪ Effective transition to production/operation	Min. 95%	85%
✓ Availability of services (excluding planned maintenance downtime)	Min. 98%	99%
✓ Max 2 hour response time to corporate IT service desk requests	80%	91%
✓ Max 1 day response time to corporate IT service desk requests	95%	99.4%