European Medicines Agency

EMA/MB/628139/2009/Rev.1/En/Adopted
10 December 2009

Draft Budget for 2010

Background note

Pursuant to Article 66 of Regulation (EC) No 726/2004 and Article 27(6) of the EMEA Financial Regulation, the Board is invited to adopt the 2010 budget together with the establishment plan. It will become final following the adoption of the European Union's budget by the European Parliament (EP) on Thursday, 17 December 2009.

The adopted budget will be sent to the European Parliament in accordance with the Code of Conduct on budgetary matters. The budget 2010 (Annex I and V listed below) will be published in the Official Journal of the European Union in accordance with Article 26 of the EMEA Financial Regulation

This document sets out the changes between the Preliminary Draft Budget 2010, adopted by the Management Board at its meeting on 5 March 2009, and the Draft Budget. The EMEA's draft work programme (EMEA/MB/203131/2009) sets out planned activities and the related objectives with their key initiatives for 2010.

Matters for consideration

The Management Board is invited to review and consider the following:

1. Introductory statement and priorities for 2010
2. Outline of the main changes in the 2009 draft budget compared to the 2010 preliminary draft budget and compared to the 2009 budget as of 31 October 2009
3. Staffing and human resource needs
4. Revenue and expenditure overview 2008 - 2010

The following annexes are enclosed:

Annex I	Detailed draft budget for 2010 (separate document)
Annex II	Staff Policy Plan 2010 (separate document)
Annex III	Activity Based Budget 2009-2010
Annex IV	Justifications for posts requested for 2010 – revised following restructuring of the Agency
Annex V	Establishment plan for 2010
Annex VI	Revision of budget nomenclature
Annex VII	Quarterly Cash-Flow Forecast 2010

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1. Introductory Statement and priorities for 2010

The 2010 Preliminary Draft Budget (PDB) was adopted by the Management Board on 5 March 2009 (EMEA/MB/95645/2009Rev.1), totalling € 211.8 million in line with the draft work programme (EMEA/MB/67958/2008).

The revised 2010 budget has decreased by € 13.6 million to € 198.2 million (-6.43%). The changes take account of the adjustment in the EU contributions of - € 8.883 million, a revision of the estimated fee income of - € 5.54 million as well as adjustments in administrative charges and miscellaneous income of + € 813 000.

The Draft Budget (DB) 2010 represents an increase of 1.95% over the 2009 budget (including Amending Budget (AB) 01-2009).

For details of the adjustments please see point 2 of this document (Outline of the main changes in the 2010 draft budget compared to the 2010 preliminary draft budget and compared to the 2009 budget as of 31 October 2009)

The Agency's key priorities for 2010 are summarised as follows (for full information on the agency's priorities and relating activities, please refer to the EMEA Work Programme 2010):

- Conducing the Agency's core business to the highest quality standards, amidst the increasing volume of activities
- Successful implementation of the tasks vested by new legislation
- Cooperation with the international partners and contribution to international activities
- Ensuring effective safety monitoring of medicinal products
- Further improving communication, provision of information and increasing transparency
- Cooperation and support to the European medicines network

For full information on the agency's priorities and relating activities, please refer to the EMEA Work Programme 2010.

2. Outline of the main changes in the 2010 DB as compared to the 2010 PDB and as compared to 2009 budget as of 31 October 2009

- **Adjustments on the revenue side of the DB**

For 2010 the European Commission proposed contributions of € 26.85 million and the budgeting of € 10.26 million of the Agency's surplus 2008. However, on 7 October 2008 in line with the Committee on Budgets' recommendations for the annual Budget (2010) at the first reading the rapporteur for the Committee on Budgets, Mrs Jutta Haug, reinstated the reserve for the three fee-earning agencies, EMEA, ECHA and EASA. This enables the EMEA to maintain the 2008 surplus at the level of DG Enterprise a buffer for a decline in fee income or for expenditure for other unforeseen events.

Adjustments in revenue in the 2010 DB compared to the 2010 PDB and budget 2009 are summarised as follows:

Chapter/ Article	Difference DB – PDB (€'000)	Remarks	Difference DB 10 – B 09 (€'000)	Remarks
100 - Revised fee revenue from fee-related activities	- 5 540	The estimated fee income was adjusted in line with the updated workload forecast for 2010 and the assumed impact of the implementation of the variations Regulation. The estimates include a 1.8% increase in the level of fees for inflation.	+ 11 814	Increased income for higher level of post-authorisation activity due to the increase in portfolio.
200 EU General Contribution	- 7 883	The total contribution includes • € 8,263 for general Public Health issues; • € 6,705 million for the implementation of the Paediatric legislation' • € 5,726 million for the implementation of the SME legislation • € 1,918 million for the implementation of the Advanced Therapies Regulation • € 10,000 million of the implementation of the Telematics Master Plan.	- 7 478	2009 contributions of €36.39 million + use of surplus 2007 (totaling €4.9 million of which €3.7 million for general contribution + €1.2 million for orphan contribution) with Amending Budget 01-09 of which • € 16.905 million for general Public Health issues; • € 6.669 million for the implementation of the Paediatric legislation • € 4.593 million for the implementation of the SME legislation • € 2.976 million for the implementation of the Advanced Therapies Regulation • € 8.947 million of the implementation of the Telematics Master Plan.

Chapter/ Article	Difference DB – PDB (€'000)	Remarks	Difference DB 10 – B 09 (€'000)	Remarks
201 Decrease in Orphan Contribution	- 1 000	Estimated requirement for orphan contribution amounts to € 5.5 million. Current contribution of € 4.5 million will be complemented by unused amounts from 2009 contribution (estimated at € 1.2 million).	- 2 200	Orphan contribution 2009 was increased from € 5.5 million to € 6.7 million with the use of surplus 2008 (above). Amounts unused of estimated €1.2 million are to be carried-over to support 2010 fee reductions.
300 - Decrease in EEA contribution	- 72	Reduced in line with decrease in contributions calculated on the basis of 2.52% of all EU contributions.	+ 47	Increased in contribution from 2.40% in 2009 to 2.52% in 2010 at a reduced level of contributions.
520 – Revenue from bank interest	- 575	The major drop in interest rates in early 2009 was not foreseen when the PDB was drafted. Current rates are 0.5% for Sterling deposits and 1.00% for EURO deposits.	- 100	Interest to be received for 2010 is estimated to be slightly lower than in 2009.
521 – Administrative charges	+ 1 260	Taking account of the implementation of the Variations Regulation, in line with the current proposal for work sharing administrative fees are to be introduced for work-sharing procedures for centralised products. At the same time the number of Parallel Distributions is now estimated to increase by 26.32% compared to estimates for PDB).	+ 1 465	Effect of introduction of administrative fee for work sharing for variations of centralised products.
600 – Community programmes	- 200	Adjustment in the multi-beneficiary programme for the preparation of the candidate countries Croatia, Turkey, Macedonia and potential candidate countries: Serbia, Albania, Kosovo, Bosnia & Herzegovina and Montenegro.	+ 100	Change in programme as proposed by DG Enlargement.
601 – Joint programmes	+/- 0	A minor contribution for the EMEA is foreseen for the involvement in the Innovative Medicines Initiative (IMI) with the proposed project PROTECT.	+/- 0	
900 - Miscellaneous revenue	+ 400	Income previously budgeted in 2009 for a capital contribution for the 1st floor 7 Westferry Circus from the previous tenant of the floor is now expected in 2010.	+ 150	See remarks on difference PDB-DB.
TOTAL CHANGE	**- 13 610**		**+ 3 798**	

- **Changes on the expenditure side of the budget**

Changes in expenditure in the 2010 DB compared to the 2010 PDB and budget 2009 can be summarised as follows:

Chapter/ Article	Difference DB – PDB (€'000)	Remarks	Difference DB 10 – B 09 (€'000)	Remarks
11 – Salaries and allowances	- 3 023	Major reductions in estimated salary cost were achieved through the revision of the London weighting for the decrease in exchange rate as well as a revised estimated increase in basic salaries. It provides for 37 additional Temporary Agents as per the PDB and 125 Contract Agents (increased from 90 planned with the PDB).	+ 7 622	Increased costs in line with additional staff planned for 2010.
13 – Missions	+ /- 0	As per PDB	+ /- 0	Mission activity in 2010 is anticipated at the same level as for 2009.
14 – Socio-medical infrastructure	- 20	Adjustment for improvement in EUR/GBP exchange rate from the drafting of the PDB to the drafting of the DB only.	+ 90	Overall increase by 16% for the increase in the number of staff.
15 – Exchange of civil servants and experts	+ 94	Adjustment for an extended period for traineeships introduced as of 1 October 2009.	- 1 123	The budget 2009 allowed for a total of 28 FTE National Experts whereas 19 FTE are forecasted for 2010.
16 – Social welfare	+ 20	Effect of moving budget item 1820 to 1620 (see Annex VII – revision of budget nomenclature)	+ 40	Increase in 'nursery allowance' for increase in additional children for staff members as well as effect of change in nomenclature.
17 – Entertainment and representation expenses	- 45	Planned expenditure for the preparation of the 15th anniversary of the Agency (January 2010) was reduced.	+ 12	Impact of preparatory activities for the 15th anniversary of the Agency in 2010 for January 2010.
18 – Staff insurances	- 27	Adjustment (-4.31%) in line with reduction of estimated salary expenditure compared to PDB 2010 as well as the effect of the change in budget nomenclature (see 16-Social welfare above).	+ 266	Adjustment (+10.71%) in line with increased estimated salary expenditure compared to 2009.
Total Title 1	*- 3 001*		*+ 6 907*	

Chapter/ Article	Difference DB – PDB (€'000)	Remarks	Difference DB 09 – B 08 (€'000)	Remarks
20 – Investments in immovable property, renting of building and associated costs	+ 1 050	With the PDB no refurbishment was planned for 2010, whereas in the course of 2009 the Agency identified the need for additional office space. Accommodation has become available in 11 Westferry Circus, with a rent-free period of 24 months, for which miscellaneous refurbishment costs can now be anticipated. In addition, some preparatory activities for a possible relocation of the Agency after the expiry of the lease in 2014 are included. The chapter also takes account of the improvement of the EUR/GBP exchange rate from the drafting of the PDB to the drafting of the DB at an overall cost saving of around 11%.	+ 1 196	Impact of additional fit-out costs and the preparatory activities for a possible relocation of the Agency around 2014.
211 –Computer networks and equipment for the operation of the agency	- 1 946	Reduction of a total of €6.0 million due to the reduction in EC contribution and estimated fee income. For the actual planned activities, please see document EMEA/MB/727972/2009 for details.	- 2 295	For 2010 no purchase of new or replacement hardware and software now is planned. The necessary investments were partly brought forward into 2009 with AB 01-2009 to anticipate the required reductions in the 2010 budget.
212 - Computer networks and equipment for specified projects	- 4 054		- 5 229	Adjustment in projects to be carried out in 2010 due to budgetary restrictions.
22 – Movable property and associated costs	- 134	Adjustment (-8.43%) with including a revision of the requirements for subscriptions in line with the actual 2009 usage.	- 1 384	Budget 2009 included the audio-vision equipment for the 1st floor area as well as for the meeting rooms 4A and 4 B refurbishment.
23 – Current administrative expenditure	+ 145	Impact of allocating the cost for the office concierge within this chapter from 2010 (previously article 241-Telecoms).	- 253	Policy for professional indemnity insurance covers period up to end 2010, therefore no cost for this insurance in 2010.
24 – Postal charges and telecommunications	- 361	Impact of shift of cost for office concierge to chapter 23 (see above) with DB 2010.	- 314	Impact of shift of cost for office concierge to chapter 23 (see above) with DB 2010.
25 –Meetings in general	+ 56	From 2010 the Agency intends to subscribe to additional GARTNER database access for the ICT area	+ 39	Impact of GARTNER subscription.
Total Title 2	*- 5 244*		*- 8 240*	

Chapter/ Article	Difference DB – PDB (€'000)	Remarks	Difference DB 10 – B 09 (€'000)	Remarks
300 - Meetings	- 26	Adjustment in catering for meeting sin line with the actual usage in 2009.	+ 771	Minor adjustment allowing for 2010 the same level of meetings
301 – Evaluation of medicinal products	- 4 542	Payments for rapporteur activities have been adjusted in line with the decreased estimated fee income taking account of the share of fees as per the current Implementing Rules to the Fee Regulation as approved by the Management Board.	+ 4 656	Payments for rapporteur activities have increased in line with additional level of applications estimated in 2010.
302 – Translation expenses	- 560	Initially for 2010 it was planned to carry out the translation of parts of the EMEA website into 21 languages whereas now 4 languages are planned with the costs to be spread over 2010 and 2011.	+ 84	For 2010 it is planned to start with translations of part of the external website into 4 languages.
303- Studies and consultants	+/- 0	As per PDB	+/- 0	As per 2009
304 – Information and publications	- 37	Reduction in estimated cost for the roll-out of the new corporate design for the Agency.	- 122	Budget 2009 also included a provision of €75,000 for a corporate video.
305 – Community programmes	- 200	Adjusted of IPA programme, please see Income 600 for details.	+ 100	Adjustment of IPA programme, please see Income 600 for details.
Total Title 3	*- 5 365*		*+5 489*	
900 – Provisional appropriation	+/- 0	As per PDB	- 358	With AB 01-2009 provisional appropriations were introduced which might not be transferred.
Total Title 3	*+/- 0*		*- 358*	
TOTAL CHANGE	**- 13 610**		**+ 3 798**	

3. Staffing and human resource needs

The establishment plan as adopted by the Management Board in March 2009 contains 37 new posts. Please see annex V for details on the justification of the 37 posts. The post allocation per unit was revised following the implementation of the restructuring of the Agency in September 2009.

In addition to Temporary Agents on established posts, the EMEA employs Contract Agents against financial credits. These Contract Agents are

a) for workload where a post in the establishment plan is available but no suitable Temporary Agent has been recruited yet;
b) for interim cover for Temporary Agents on part-time or on long-term leave, e.g. for maternity or family leave,
c) for project related workload on a short- to medium term assignment and
d) for long-term increases in workload where no post in the establishment plan is provided for yet.

For 2010 the EMEA had to revise its need for Contract Agents and consequently the budgetary provision of initially 90 FTE has been increased to a total of up to 125 FTE.

The additional Contract Agents are required

- to support adult pandemic activities
- to support paediatric pandemic activities
- to work on the Innovative Medicines Initiatives
- to cover staff elected to the Staff Committee working part time for this activity
- to undertake the full implementation of SAP financial due to come into operation by 1 January 2010,
- to carry out increased volumes of workload especially in the area of referrals (veterinary and human), maintenance of EPITTT (tracking of pharmacovigilance using IT tools), EVDAS as well as
- to replace staff for additional maternity and part time cases.

The allocation for staff expenditure includes € 30,000 for exceptional education allowance.

4. Revenue and expenditure overview 2008-2010

		2008[1]		2009[2]		2010 PDB[3]		2010 DB	
		€ '000	%	€ '000	%	€ '000	%	€ '000	%
	Revenue								
100	Fees	132,179	*70.16*	140,966	*72.52*	158,320	*74.75*	152,780	*77.09*
200	General EU contribution	34,408	*18.26*	36,390	*18.72*	40,495	*19.12*	32,612	*16.46*
200	Surplus from previous year (reserve)	7,977	*4.23*	[4]4,900	*2.52*	p.m.	*0.00*	p.m.	*0.00*
201	Special EU contribution for orphan medicinal products	3,755	*1.99*	5,500	*2.83*	5,500	*2.60*	4,500	*2.27*
300	Contribution from EEA	956	*0.51*	888	*0.46*	1,007	*0.48*	935	*0.47*
600	Community programmes	576	*0.31*	360	*0.19*	600	*0.28*	400	*0.20*
500+ 900	Other	8,541	*4.53*	5,385	*2.77*	5,875	*2.77*	6,960	*3.51*
TOTAL REVENUE		**188,392**	*100.00*	**194,389**	*100.00*	**211,797**	*100.00*	**198,187**	*100.00*

Expenditure									
Staff									
11	Staff in active employment	49,200	*28.40*	54,867	*28.23*	65,512	*30.93*	62,489	*31.53*
13	Mission expenses	605	*0.35*	789	*0.41*	789	*0.37*	789	*0.40*
14	Socio-medical infrastructure	429	*0.25*	550	*0.28*	660	*0.31*	640	*0.32*
15	Exchange of civil servants and experts	1,866	*1.08*	3,970	*2.04*	2,753	*1.30*	2,847	*1.44*
16	Social welfare	92	*0.05*	105	*0.05*	125	*0.06*	145	*0.07*
17	Entertainment and representation expenses	33	*0.02*	38	*0.02*	95	*0.04*	50	*0.03*
18	Staff insurances	1,573	*0.91*	1,867	*0.96*	2,160	*1.02*	2,133	*1.08*
	Total Title 1	*53,798*	*31.06*	*62,186*	*31.99*	*72,094*	*34.04*	*69,093*	*34.86*
Building/equipment									
20	Investment in immovable property, renting of building and associated costs	18,641	*10.76*	16,511	*8.49*	16,657	*7.86*	17,707	*8.93*
21	Expenditure on data processing	25,375	*14.65*	29,595	*15.22*	28,071	*13.25*	22,071	*11.14*
22	Movable property and ass costs	1,668	*0.96*	2,840	*1.46*	1,590	*0.75*	1,456	*0.73*
23	Other administrative expenditure	778	*0.45*	1,316	*0.68*	918	*0.43*	1,063	*0.54*
24	Postage and communications	771	*0.45*	978	*0.50*	1,025	*0.48*	664	*0.34*
25	Expenditure on formal and other meetings	63	*0.04*	104	*0.05*	87	*0.04*	143	*0.07*
	Total Title 2	*47,296*	*27.31*	*51,344*	*26.41*	*48,348*	*22.83*	*43,104*	*21.75*
Operational expenditure									
300	Meetings	7,259	*4.19*	8,159	*4.20*	8,956	*4.23*	8,930	*4.51*
301	Evaluations	60,181	*34.74*	67,419	*34.68*	76,617	*36.17*	72,075	*36.37*
302	Translation	3,937	*2.27*	4,245	*2.18*	4,889	*2.31*	4,329	*2.18*
303	Studies and consultants	82	*0.05*	80	*0.04*	80	*0.04*	80	*0.04*
304	Publications	281	*0.16*	298	*0.15*	213	*0.10*	176	*0.09*
305	Community programmes	379	*0.22*	300	*0.15*	600	*0.28*	400	*0.20*
	Total Title 3	*72,120*	*41.64*	*80,501*	*41.41*	*91,355*	*43.13*	*86,175*	*43.48*
Provisional appropriation									
900	Provisional appropriation	0	0.00	358	0.19	0	0.00	0	0.00
	Total Title 9	*0*	*0.00*	*358*	*0.19*	*0*	*0.00*	*0*	*0.00*
TOTAL EXPENDITURE		**173,213**	*100.00*	**194,389**	*100.00*	**211,797**	*100.00*	**198,187**	*100.00*

[1] 2008 as per final accounts;
[2] Budget 2009 as of 31 October 2009 (incl. AB 01-2009)
[3] PDB 2010 as adopted by the Management Board on 5 March 2009
[4] With AB 01-2009 of total reserve €3.7 million were allocated to I200 and €1.2 million to I201

Annex III ACTIVITY BASED BUDGET 2009 – 2010

		DB 2010				
Chapter	**Activity**	**Reference to chapters in Draft Work Programme**	**Human resources**	**Cost per Activity**	**Costs per activity incl. Support Service**	**of total**
			%	**€ '000**	**€ '000**	**%**
01	**Initial Evaluation** – (initial applications for marketing authorisation)	2.3 3.2 and 3.3	10.08	24,637	25,892	13.06
02	**Specific Post Authorisation Activities** (variations, extensions and transfer of marketing authorisation and renewals)	2.4 3.4	9.03	38,486	40,446	20.41
03	**Pharmacovigilance and maintenance Activities –** (Adverse Drug Reaction reports, Periodic Safety Update Reports, follow-up measures, annual re-assessments)	2.6 3.5	13.66	26,972	28,346	14.30
04	**Scientific Advice & Protocol Assistance –** (advice and assistance to sponsors during the phase of research and development of medicinal products)	2.2 3.1	4.22	13,792	14,495	7.31
05	**Arbitration / Referrals**	2.7 3.6	2.56	3,995	4,198	2.12
06	**Inspections** – Good manufacturing practice (GMP) Good Clinical practice (GCP), Good laboratory practice (GLP), Clinical trials directive and testing and sampling of centrally authorised medicinal products	4.1 4.2 and 4.3	3.22	6,348	6,671	3.37
07	**Administrative Charges** – (parallel distribution notifications and certificate of medicinal products)	1.3 2.5	3.00	1,948	2,047	1.03
08	**EU Public Health and Harmonisation Activities**					
08-01	**Orphan medicines** – (support to the COMP in making recommendations to the European Commission for the designation of Orphan medicinal products for rare diseases)	2.1	1.90	2,141	2,250	1.14
08-02	**Medicines for Paediatric use**	2.8	5.85	6,675	7,015	3.54
08-03	**Herbal medicinal products**	2.9	1.42	1,815	1,907	0.96
08-04	**Small and Medium Size Enterprises (SMEs) Office** (provision of a single interface between the applicant SME and the Agency to facilitate communication)	1.5	0.82	1,475	1,551	0.78
08-05	**Coordination group for mutual recognition** and decentralised procedures Human & Vet	1.3 2.12 and 3.8	1.64	1,302	1,368	0.69
08-06	**Specified medicinal areas:** Bio terrorism, clinical trials and Antimicrobial resistance	1.2	3.51	3,523	3,703	1.87
08-07	**EU co-operation** – (Liaison with EU Institutions and national competent authorities)	1.1 1.2	0.72	1,011	1,062	0.54
08-08	**International co-operation** – (scientific contribution to the European Union presence in a number of international fora)	1.3	1.54	2,067	2,172	1.10
08-09	**Advance therapies and other emerging and new therapies**	1.6 2.10	0.63	1,553	1,632	0.82
09	**Project related activities**: (implementation of a number of IT projects linked to the European Union telematics strategy for pharmaceuticals and other corporate IT projects)	1.5 5.1 and 5.2	7.80	8,429	8,859	4.47
10.01	**Corporate governance** – (Management Board, Audit Advisory Committee, Integrated Quality Management)	1.7	11.23	11,297	11,872	5.99
10.02-06	**Support services** - (Executive support, personnel, budget, accounting and infrastructure service)	1.7	11.43	9,604		
10.07	**Product information quality, Quality review document and**	1.4	5.74	5,539	5,821	2.94
11	**Management and organisation of the CPMP, CVMP and Working Parties meetings**	1.1 2.11 and 3.7	0.00	12,454	13,089	6.60
	Total		**100.00**	**198,187**	**198,187**	**100.00**

		2009				
Chapter	**Activity**	**Reference to chapters in Work Programme**	**Human resources**	**Cost per Activity**	**Costs per activity incl. Support Service**	**of total**
			%	**€ '000**	**€ '000**	**%**
01	**Initial Evaluation** – (initial applications for marketing authorisation)	2.3 3.2 and 3.3	8.32	20,822	21,866	11.25
02	**Specific Post Authorisation Activities** (variations, extensions and transfer of marketing authorisation and renewals)	2.4 3.4	9.18	39,357	41,331	21.26
03	**Pharmacovigilance and maintenance Activities -** (Adverse Drug Reaction reports, Periodic Safety Update Reports, follow-up measures, annual re-assessments)	2.6 3.5	13.92	24,926	26,176	13.47
04	**Scientific Advice & Protocol Assistance –** (advice and assistance to sponsors during the phase of research and development of medicinal products)	2.2 3.1	4.28	12,227	12,840	6.61
05	**Arbitration / Referrals**	2.7 and 3.6	2.60	3,470	3,644	1.87
06	**Inspections** - Good manufacturing practice (GMP) Good Clinical practice (GCP), Good laboratory practice (GLP), Clinical trials directive and testing and sampling of centrally authorised medicinal products	4.1 4.2 and 4.3	3.29	6,120	6,427	3.31
07	**Administrative Charges** – (parallel distribution notifications and certificate of medicinal products)	1.3 2.5	3.07	2,056	2,159	1.11
08	**EU Public Health and Harmonisation Activities**	1.5				
08-01	**Orphan medicines** - (support to the COMP in making recommendations to the European Commission for the designation of Orphan medicinal products for rare diseases)	2.1	1.94	2,458	2,581	1.33
08-02	**Medicines for Paediatric use**	2.8	5.98	7,287	7,652	3.94
08-03	**Herbal medicinal products**	2.9	1.45	2,231	2,343	1.21
08-04	**Small and Medium Size Enterprises (SMEs) Office** (provision of a single interface between the applicant SME and the Agency to facilitate communication)	1.5	0.84	1,457	1,530	0.79
08-05	**Coordination group for mutual recognition** and decentralised procedures Human & Vet	1.3 2.13 and 3.8	1.68	1,326	1,393	0.72
08-06	**Specified medicinal areas:** Bio terrorism, clinical trials and Antimicrobial resistance	1.2	3.59	3,720	3,907	2.01
08-07	**EU co-operation** – (Liaison with EU Institutions and national competent authorities)	1.1 1.2	0.74	1,068	1,122	0.58
08-09	**International co-operation** – (scientific contribution to the European Union presence in a number of international fora)	1.3 1.6	1.58	2,181	2,290	1.18
08-10	**Advance therapies and other emerging and new therapies**	2.10	0.64	1,816	1,907	0.98
09	**Product information quality, Quality review document and translation** - (translation, product information and control of quality of regulatory documents)	1.3 2.11 and 2.14	5.82	5,234	5,497	2.83
10	**Project related activities**: (implementation of a number of IT projects linked to the European Union telematics strategy for pharmaceuticals and other corporate IT projects)	5.1 5.2	7.96	19,164	20,125	10.35
11	**Corporate governance** – (Management Board, Audit Advisory Committee, Integrated Quality Management)	1.7	11.49	11,806	12,398	6.38
12	**Support services** - (Executive support, personnel, budget, accounting and infrastructure service)	1.7	11.63	9,283		
13	**Management and organisation of the CHMP, CVMP and Working Parties meetings** - (reimbursement to delegates and management and organisation of scientific meetings)	1.1 2.12 and 3.7	0.00	16,380	17,202	8.85
	Total		**100.00**	**194,389**	**194,389**	**100.00**

Please note that the performance indicators for the main activities listed above are set under the relative chapters in the work programme.

Annex IV JUSTIFICIATION FOR POSTS REQUESTED FOR 2010

<table>
<tr><th>Unit</th><th>Total posts 2009</th><th colspan="3">Posts requested</th><th>Post justifications</th><th>Total posts 2010</th></tr>
<tr><td>D
Directorate</td><td>34</td><td>1</td><td>1</td><td>AD
Office of the Executive Director (D-ED)

10.07 Information and Communication</td><td>The EMEA online strategy places a considerable emphasis on improving content provision on the EMEA website. A web editor is needed to develop and write usable content and work with external suppliers on new ideas to meet user needs. In addition, to the corporate website, the editor will also need to work with C&N project managers on the design and editorial side of Telematics websites.</td><td>35</td></tr>
<tr><td rowspan="2">A
Administration</td><td rowspan="2">82[5]</td><td rowspan="2">4</td><td>1</td><td>AD
HoU support (A-SUP)

10.04 Finance and Budget/Accounting</td><td>Assist the Head of Unit on planning and reporting activities regarding overall resource policies (personnel, finance and accommodation), corporate governance polices and multi-annual forecasts. Support P&B on policy development in specific areas and to take over the organisation and programming of long-tem horizontal projects which fall under the ownership of Administration.</td><td rowspan="2">86</td></tr>
<tr><td>1</td><td>AD
Human Resources (A-HR)

10.03 Personnel & Staff matters</td><td>Management of selection and recruitment, personnel administration is a growing task as staff numbers expand and the steady high rate of external selection procedures needed to recruit specialist scientific staff. An accurate knowledge of the Staff Regulations and their implementing rules is needed and investment must be made to do full research on difficult cases taking account of these rules and there consequences on individual persons. Time consuming procedures need to be followed in great detail to ensure full audit trails, to comply will all procedural elements and to avoid onerous court cases or complaints to the European Ombudsman. Effort is required to provide regular information sessions to staff, in updating management tools and information systems to control complexity.
<table>
<tr><th>Staff members on 31.12.</th><th>2006</th><th>2007</th><th>2008</th><th>2009 (est.)</th><th>2010 (est.)</th></tr>
<tr><td>Temporary Agents</td><td>394</td><td>422</td><td>468</td><td>504</td><td>541</td></tr>
<tr><td>Contract Agents</td><td>37</td><td>56</td><td>66</td><td>85</td><td>90</td></tr>
<tr><td>Other staff</td><td>62</td><td>68</td><td>83</td><td>90</td><td>100</td></tr>
<tr><td>Number of external selection procedures</td><td>16 AT</td><td>13 AT</td><td>21 AT
+ 10 CA</td><td>15 AT
+ 10 CA</td><td>20 AT
+ 10 CA</td></tr>
<tr><td>Number of applicants to external selection procedures</td><td>1 078</td><td>930</td><td>1 957</td><td>1 800</td><td>2 000</td></tr>
<tr><td>Number of absence requests (annual leave special leave and other)</td><td>8 206</td><td>10 056</td><td>11 167</td><td>12 000</td><td>13 000</td></tr>
<tr><td>Number of AD category staff to perform activity</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1+1</td></tr>
</table></td></tr>
</table>

[5] including one post for management position to be re-allocated with the restructuring of the Agency

<table>
<tr><th>Unit</th><th>Total posts 2009</th><th colspan="3">Posts requested</th><th>Post justifications</th><th>Total posts 2010</th></tr>
<tr><td rowspan="2">A
(cont.)</td><td rowspan="2"></td><td rowspan="2"></td><td>1</td><td>AST
Human Resources (A-HR)

10.04 Finance and Budget/Accounting</td><td>For the management of the EMEA budget and financial transactions an additional assistant is required
- to support the existing budget team of two staff with the establishment and implementation of the agency’s budget where the volume and complexity, especially within IT and Telematics area, has increased by 283% over the last 10 years.
- to assist the PROTECT-IMI programme from a financial administrative perspective .
- to assist with the review of the Fee Regulation from a budgetary perspective.

<table><tr><th></th><th>2006</th><th>2007</th><th>2008</th><th>2009</th><th>2010 (est.)</th></tr><tr><td>EMEA Budget (€’000)</td><td>138 676</td><td>163 113</td><td>182 895</td><td>188 689</td><td>211 797</td></tr><tr><td>No. of post for activity</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2+1</td></tr></table></td><td rowspan="2"></td></tr>
<tr><td>1</td><td>AD
Accounting (A-AC)/ Finance and Budget (A-FIN)

10.04 Finance and Budget/Accounting</td><td>The EMEA is in the process of blueprinting its financial processes for an implementation of an Enterprise Resource Planning System – SAP. It is anticipated that this new financial system will go-live in early 2010 where with the go-live phase the establishment of an SAP helpdesk is required.
These are new tasks as the maintenance and development including the helpdesk function of the previous financial system SI2 was carried out by the European Commission and the Common Support Service (CSS). At the same time, it is planned to extend the SAP applications beyond the financial processes to include Personnel administration. As the functioning of the financial and personnel system are critical to the administration of the agency, full user support is required.</td></tr>
<tr><td rowspan="3">ICT
Information and Communication Technology</td><td rowspan="3">53</td><td rowspan="3">5</td><td>1</td><td>AD
ICT Infrastructure (I-IF)

10.06 Information Technology</td><td>In view of the increase in the number of information systems in production and the number of users of such systems and recognising the need for extended and improved service levels and periods the IT Operations must be strengthened. Furthermore following discussions at the Management Board to plan for the replacement of external contractors by allocating post, in line with the emphasis made by the Executive Director on the concept of provision of continuous services and considering that at present there are external contractors assisting with IT Operations activities. Please see also see recommendations made by the Internal Audit Service of the European Commission (EC IAS).</td><td rowspan="3">58</td></tr>
<tr><td>3</td><td>AD
ICT Development (I-DV)

10.06 Information Technology</td><td>Following discussions at the Management Board to plan for the replacement of external contractors by allocating Temporary Agents post, in line with the emphasis made by the Executive Director on the concept of provision of continuous services and considering that at present there are external contractors assisting with IT Development activities. Please see also see recommendations made by EC IAS.</td></tr>
<tr><td>1</td><td>AST
ICT Infrastructure (I-IF)

10.06 Information Technology</td><td>Assistant Administrator for virtual meetings technology. This follows extensive discussions at the EMEA Management Board about the growing number of meetings and increasing number of experts from the National Competent Authorities having to travel to London to attend meetings. Consequently the need for alternative meeting solutions resulted in increased use of virtual meeting services.</td></tr>
</table>

<table>
<tr><th>Unit</th><th>Total posts 2009</th><th colspan="3">Posts requested</th><th>Post justifications</th><th>Total posts 2010</th></tr>
<tr><td>P
Patient Health Protection</td><td>135</td><td>11</td><td>1</td><td>AD
Regulatory, Procedural and Committee Support (P-R)

01 Initial Evaluation</td><td>Administrator to
- improve transparency of the procedures handled by the CHMP by preparing and implementing the publication of meeting agendas and minutes.
- provide organisational support to the monthly CHMP meetings
- improve the co-ordination between the CHMP and the other Scientific Committees, in particular the Paediatric Committee and the Advanced Therapies Committee.
-
<table><tr><th></th><th>2006</th><th>2007</th><th>2008</th><th>2009 (est.)</th><th>2010 (est.)</th></tr><tr><td>Total number of procedures</td><td>986</td><td>1092</td><td>1227</td><td>1233</td><td>1327</td></tr><tr><td>Number of established posts in the CHMP Secretariat (Administrators)</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2+1</td></tr></table></td><td>146</td></tr>
<tr><td></td><td></td><td></td><td>2</td><td>1 AD
1 AST
Regulatory, Procedural and Committee Support (P-R)

05 Referrals</td><td>– Dedicated referrals team responsible for referrals made under Articles 29 and 30 of Directive 2001/83/EC established since 2007 and composed of contract agents recruited for this activity and 2 temporary agents deployed temporarily from other core business activities
– Number of referrals since 2007 has stabilised and the longer term resources required can be determined on the experienced gained
– The complexity of referral procedures involving interaction with several Member States and with both CMD(h) and CHMP and the increasing number of re-examinations necessitates experienced AST staff to support the scientific administrators
– Implementation of a robust control system to ensure the quality of the output and improvements in efficiency of procedures
– Broadening of scope to include HMPC referrals

<table><tr><th></th><th>2007</th><th>2008</th><th>2009 (est.)</th><th>2010 (est.)</th></tr><tr><td>Referrals (Articles 29 and 30)</td><td>26</td><td>28</td><td>24</td><td>24</td></tr><tr><td>Number of posts (AD / AST3 / AST1)</td><td>0</td><td>0</td><td>0</td><td>2+2+2</td></tr></table></td><td></td></tr>
</table>

<table>
<tr><th>Unit</th><th>Total posts 2009</th><th colspan="3">Posts requested</th><th>Post justifications</th><th>Total posts 2010</th></tr>
<tr><td>P
(cont.)</td><td></td><td></td><td>1</td><td>AD
Regulatory, Procedural and Committee Support (P-R)

05 Arbitrations/Referrals</td><td>Administrator to manage the increased workload specifically associated with Referral and other procedures, in particular with regards to Article 31 referrals / Article 20 procedures, the number of which is expected to further grow to provide a regulatory framework for the safety class reviews with subsequent labelling changes generated by the PhVWP
– The Paediatric referrals (Article 29)
– The scientific opinions under Art 5.3.
There will also be an increase in the complexity of the community procedures e.g. parallel procedures including centrally and non-centrally authorised products. In addition, there is an increase in the access to documents requests pertaining to referral procedures.
<table>
<tr><th></th><th>2006</th><th>2007</th><th>2008</th><th>2009 (est.)</th><th>2010 (est.)</th></tr>
<tr><td>Total number of referral procedures</td><td>7</td><td>19</td><td>8</td><td>19</td><td>23</td></tr>
<tr><td>Total number of requests for access to documents</td><td>60</td><td>54</td><td>106</td><td>120</td><td>160</td></tr>
<tr><td>Number of established AD posts in Specialised Groups dealing with referrals</td><td>3</td><td>3</td><td>4</td><td>4</td><td>4+1</td></tr>
</table></td><td></td></tr>
<tr><td></td><td></td><td></td><td>1</td><td>AD PhV – RM

01 Initial Evaluation</td><td>– New work: Risk management relating to Advanced Therapy medicinal products and Paediatric Use Marketing Authorisations.
– Increasing volumes:
o The pipeline monitoring suggests that new applications will remain steady in 2010 at approximately 89 all of which will have a risk management plan for review.
o 85 extensions of indication are anticipated and risk management plans are anticipated for these (in the past these did not routinely include risk management plans needing review).
o Now that risk management plans are established for almost all new centrally authorised products, their maintenance will constitute a major workload in 2010. This needs to be conducted to ensure MAH compliance, scientific consistency and robust protection of public health. Approximately 478 "routine" updates to the risk management plans are anticipated in 2010.</td><td></td></tr>
<tr><td></td><td></td><td></td><td>1</td><td>AST
Pharmacovigilance and Risk Management (P-PV)

03-05 Eudravigilance</td><td>– Increasing work: To deal with NCA requests to perform statistical data analysis using EudraVigilance, SAS and other healthcare databases (e.g. THIN). The work is being piloted in late 2008, will increase in volume in 2009. By 2010 we anticipate 10 complex queries from the NCAs per week.
– New work: Eudravigilance access policy agreed by the EMEA Management Board will be operational in 2010. Additional posts needed:
o all practical aspects in relation to the proactive information disclosure in the frame of the EudraVigilance access policy
o to deal with requests for access to information related to EudraVigilance from third parties (reactive information disclosure) and associated evaluation of data</td><td></td></tr>
</table>

<table>
<tr><th>Unit</th><th>Total posts 2009</th><th colspan="3">Posts requested</th><th>Post justifications</th><th>Total posts 2010</th></tr>
<tr><td>P
(cont.)</td><td></td><td></td><td>2</td><td>AD
Pharmacovigilance and Risk Management (P-PV)

03-02 Signal detection</td><td>New work: EMEA will be coordinating drug safety signals between Rapporteurs, NCAs and EMEA on all authorised products in the Community. This is to be piloted in 2009 and will be in full production before the end of 2009.
Increasing work: Conducting the signal detection activities at the EMEA for centrally authorised medicinal products taking into account the increasing number of centrally authorised medicinal products. The most intensive work is for intensively-monitored (IM) products. The following numbers are forecasted for the year 2010:
Intensively-monitored products:
– N signals: 501
– N signals requiring action: 159 (nearly a doubling of the work in 2010).
For non-intensively monitored products, an important increase in the number of signals is also expected.</td><td></td></tr>
<tr><td></td><td></td><td></td><td>1</td><td>AD
Medical Information (P-MI)

10-07 Information and communication</td><td>– To prepare for the creation of a EU network on medical information in the context of the implementation of the EMEA Road Map
– To develop procedures to facilitate interaction and exchange of information, and to develop performance indicators to measure the efficiency of such a network
– To prepare and implement the integration of current activities in the medical information network
– To continue the implementation of the other EMEA Road Map initiatives in relation to information to stakeholders.</td><td></td></tr>
<tr><td></td><td></td><td></td><td>1</td><td>AD
Medical Information (P-MI)

01-01 Marketing authorisation</td><td>– Developing checking processes in new product information areas with a direct impact to public health, such as switch to OTC and Advanced Therapy products.
– To reinforce the quality checking of product information in cases of Harmonisation of SPC, Labelling and PLs in the context of art 30 Referral procedures.
– To manage the increasing workload in Product Information Quality related activities, including linguistic review coordination and management of financial aspects, as well as and in the area of the checking of mock-ups & specimens; in particular with a view to enhance the checking of latter and minimise the risk of medication errors.
<table>
<tr><th></th><th>2005</th><th>2006</th><th>2007</th><th>2008</th><th>2009 (est.)</th><th>2010 (est.)</th></tr>
<tr><td>No of procedures</td><td>437</td><td>666</td><td>747</td><td>772</td><td>850</td><td>981</td></tr>
<tr><td>New applications</td><td>42</td><td>68</td><td>90</td><td>86</td><td>98</td><td>103</td></tr>
<tr><td>Referrals</td><td>19</td><td>31</td><td>55</td><td>78</td><td>49</td><td>53</td></tr>
<tr><td>No of mock-ups & specimens checked</td><td>N/A</td><td>N/A</td><td>250</td><td>500</td><td>700</td><td>850</td></tr>
<tr><td>No. of established AD posts in Product Information Quality and mock-ups and specimens</td><td>2</td><td>3</td><td>3</td><td>4</td><td>4</td><td>4+1</td></tr>
</table></td><td></td></tr>
</table>

<table>
<tr><th>Unit</th><th>Total posts 2009</th><th colspan="3">Posts requested</th><th>Post justifications</th><th>Total posts 2010</th></tr>
<tr><td>P
(cont.)</td><td></td><td></td><td>1</td><td>AD
Compliance and inspection (P-CI)

06.02 Pharmacovigilance Inspections</td><td>Scientific Administrator to take over GCP validation work to allow experienced staff to focus on the Pharmacovigilance inspections aspects of the new Pharmacovigilance legislation (streamlining of Pharmacovigilance systems, new guidance and policy development, Pharmacovigilance Inspections database development)
Justification: New inspection related tasks in new pharmacovigilance legislation</td><td></td></tr>
<tr><td rowspan="4">H
Human Medicines Development and Evaluation</td><td rowspan="4">173</td><td rowspan="4">11</td><td>1</td><td>AD
Human Medicines Special Areas (H-HM)

04.03 Orphan medicinal products</td><td>One experienced scientific administrator
– 57% increase in designation applications by 2010 since 2001
– Cumulative increase in total number of annual reports for designated products
– Review of market exclusivity at the end of the 5th year from first authorisation (Article 8.2 of Orphans Regulation), consolidation of confirmation of designation at marketing authorisation stage and publication of reports, strengthening of link between orphan designation phase and marketing authorisation phase
<table>
<tr><th></th><th>2005</th><th>2006</th><th>2007</th><th>2008</th><th>2009 (est.)</th><th>2010 (est.)</th></tr>
<tr><td>Requests for orphan designation</td><td>118</td><td>104</td><td>125</td><td>119</td><td>130</td><td>130</td></tr>
<tr><td>Summary opinions</td><td>91</td><td>82</td><td>77</td><td>100</td><td>104</td><td>104</td></tr>
<tr><td>Annual reports</td><td>149</td><td>253</td><td>348</td><td>447</td><td>490</td><td>535</td></tr>
<tr><td>No. of AD posts to perform activity</td><td>4</td><td>4</td><td>4</td><td>4*</td><td>4</td><td>4+1</td></tr>
</table></td><td rowspan="4">184</td></tr>
<tr><td>1</td><td>AD
Human Medicines Special Areas (H-HM)

08.02 Paediatric medicinal products</td><td>Experienced scientific administrators for the continuous increase in applications for PIPs and waivers, modifications to PIPs, compliance checks at the time of submission of marketing authorisation and extension applications, annual reports.
<table>
<tr><th></th><th>2007</th><th>2008</th><th>2009 (est.)</th><th>2010 (est.)</th></tr>
<tr><td>PIP/waiver applications (by no. of indications), compliance checks</td><td>281</td><td>404</td><td>560</td><td>540</td></tr>
<tr><td>No. of AD posts to perform activity</td><td>5</td><td>10</td><td>11</td><td>11+1</td></tr>
</table></td></tr>
<tr><td>1</td><td>AD
Quality of Medicines (H-QM)

08.09 Advanced Therapies</td><td>One scientific administrator
– Activities related to early evaluation and certification of quality and non-clinical data by the Agency, independently of any marketing authorisation application, for SMEs developing advanced therapy medicinal products
– Activities related to classification of advanced therapy medicinal products
– Support for quality aspects of scientific advice, innovation task force activities, SMEs, activities of Committee on Advanced Therapies</td></tr>
<tr><td>1</td><td>AST
Safety and Efficacy of Medicines (H-SE)

08.09 Advanced Therapies</td><td>Support to the Scientific Administrators for activities related to early evaluation and certification of non-clinical data by the Agency classification of Advanced Therapies, Innovation Task Force activities, support to pre-clinical activities. (1 FGII CA in S&E in 2009 to be converted to TA post)</td></tr>
</table>

<table>
<tr><th>Unit</th><th>Total posts 2009</th><th colspan="2">Posts requested</th><th>Post justifications</th><th>Total posts 2010</th></tr>
<tr><td rowspan="3">H
(cont.)</td><td rowspan="3"></td><td>1</td><td>AD
Human Medicines
Special Areas (H-HM)

04 Scientific Advice</td><td>One experienced scientific administrator for activities to strengthen the scientific secretariat in the field of biostatistics and methodology in the context of clinical trials for centralised applications including advanced therapies, Scientific Advice and Paediatrics.</td><td rowspan="3"></td></tr>
<tr><td>2</td><td>1 AD
1 AST
Quality of Medicines (H-QM)

02 Variations</td><td>One scientific administrator
– 142% increase in Type I and Type II (quality) variations since 2005
– Increasing complexity of procedures introduced by New Regulation on Variations, in particular grouping, work-sharing and classification of variations
– Increased demand by marketing authorisation holders for procedural advice
One assistant
– Support to scientific administrators for 142% increase in Type I and Type II (quality) variations since 2005 and new activities related to the New Regulation on Variations, in particular grouping, work sharing and classification.
<table>
<tr><th></th><th>2005</th><th>2006</th><th>2007</th><th>2008</th><th>2009 (est.)</th><th>2010 (est.)</th></tr>
<tr><td>Type I variations</td><td>637</td><td>793</td><td>1160</td><td>1228</td><td>1410</td><td>1540</td></tr>
<tr><td>Type II(Q) variations</td><td>272</td><td>303</td><td>349</td><td>370</td><td>425</td><td>450</td></tr>
<tr><td>No. of AD posts to perform activity</td><td>5</td><td>5</td><td>5</td><td>5</td><td>6</td><td>6+1</td></tr>
<tr><td>No. of AST posts to perform activity</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1+1</td></tr>
</table></td></tr>
<tr><td>1</td><td>1 AD S&E

05 Referrals</td><td>– Dedicated referrals team responsible for referrals made under Articles 29 and 30 of Directive 2001/83/EC established since 2007 and composed of contract agents recruited for this activity and 2 temporary agents deployed temporarily from other core business activities
– Number of referrals since 2007 has stabilised and the longer term resources required can be determined on the experienced gained
– The complexity of referral procedures involving interaction with several Member States and with both CMD(h) and CHMP and the increasing number of re-examinations necessitates experienced AST staff to support the scientific administrators
– Implementation of a robust control system to ensure the quality of the output and improvements in efficiency of procedures
– Broadening of scope to include HMPC referrals
<table>
<tr><th></th><th>2007</th><th>2008</th><th>2009 (est.)</th><th>2010 (est.)</th></tr>
<tr><td>Referrals (Articles 29 and 30)</td><td>26</td><td>28</td><td>24</td><td>24</td></tr>
<tr><td>Number of posts (AD / AST3 / AST1)</td><td>0</td><td>0</td><td>0</td><td>2+2+2</td></tr>
</table></td></tr>
</table>

<table>
<tr><th>Unit</th><th>Total posts 2009</th><th colspan="3">Posts requested</th><th>Post justifications</th><th>Total posts 2010</th></tr>
<tr><td>H
(cont.)</td><td></td><td></td><td>1</td><td>AST
Safety and Efficacy of Medicines (H-SE)

02 Specific Post-Authorisation</td><td>Assistant to manage the increased workload specifically associated with the increasing number of generics/similar biological products related procedures, in particular with regards to:
– The administrative handling of the rapidly increasing number of procedures for these products (volume).
– The full implementation of a tracking system supporting the handling of the above procedures.
<table>
<tr><th></th><th>2006</th><th>2007</th><th>2008</th><th>2009 (est.)</th><th>2010 (est.)</th></tr>
<tr><td>Total number of generic and bio-similar products</td><td>2</td><td>9</td><td>19</td><td>26</td><td>39</td></tr>
<tr><td>Number of established AST3 posts in Specialised Groups</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3+1</td></tr>
</table></td><td></td></tr>
<tr><td></td><td></td><td></td><td>2</td><td>AD
Safety and Efficacy of Medicines (H-SE)

02 Specific Post-Authorisation 50%
03 Pharmacovigilance 50%</td><td>Two Administrators
– to manage the increased workload in terms of maintaining a higher number of products and corresponding increase in the number of post-authorisation procedures for CAPs, both for PTLs and AST. This will include the first procedures for advanced therapy medicinal products and the impact of the new variation regulation (e.g. grouping).
– to manage the increased workload specifically stemming from the further implementation of the Paediatric legislation impacting on post-authorisation activities in particular with regards to:
– Article 8 applications and Article 46 data submission.
– Tracking of newly implemented performance indicators for the monitoring of the paediatric related activities in the Post-authorisation phase.
– to manage the increased number of requests for information and requests for access to documents in line with the further implementation of the Agency’s transparency policy, and the further development of the Agency’s transparency policy.
<table>
<tr><th></th><th>2006</th><th>2007</th><th>2008</th><th>2009 (est.)</th><th>2010 (est.)</th></tr>
<tr><td>Total number of procedures</td><td>550</td><td>570</td><td>694</td><td>641</td><td>692</td></tr>
<tr><td>Number of requests for access to documents</td><td>60</td><td>54</td><td>106</td><td>120</td><td>160</td></tr>
<tr><td>Number of established AD posts in Specialised Groups dealing with post-authorisation procedures</td><td>22</td><td>22</td><td>24</td><td>27</td><td>27+2</td></tr>
</table></td><td></td></tr>
</table>

<table>
<tr><th>Unit</th><th>Total posts 2009</th><th colspan="3">Posts requested</th><th>Post justifications</th><th>Total posts 2010</th></tr>
<tr><td rowspan="5">V
Veterinary Medicines and Product Data Management</td><td rowspan="5">53</td><td rowspan="5">5</td><td>1</td><td>AST
Development and Evaluation of Veterinary Medicines (V-VM-DEM)

02 Specific Post-Authorsiation</td><td>Administrative assistant is required for post-authorisation activities and for the Referrals:

Variations: increased workload expected with the entry into force of the new Variations Regulation at the end of 2009; additional work will be due to the new legislative provisions on grouping of variations and work sharing

<table><tr><th></th><th>2006</th><th>2007</th><th>2008</th><th>2009 (est.)</th><th>2010 (est.)</th></tr><tr><td>Number of referrals submitted to CVMP</td><td>10</td><td>6</td><td>14</td><td>16</td><td>18</td></tr></table></td><td rowspan="5">58</td></tr>
<tr><td>1</td><td>AD
Animal and Public Health (V-VM-APH)

01.01 MRLs</td><td>Scientific Administrator is required for the workload linked to the New MRL Regulation which will result in additional tasks for the Secretariat.</td></tr>
<tr><td>1</td><td>AD Information Management

10.07 Information and Communication</td><td>Scientific administrator for the quality assurance of data in SIAMED: Reviewing, analysing and validating data to ensure consistency, integrity and accuracy, Undertaking accurate data analysis to support the tasks of the EMEA and its scientific committees, Translating regulatory requirements and business needs into data management objectives and system requirements to further the development of SIAMED in liaison with the IT department.</td></tr>
<tr><td>1</td><td>AD Information Management

10.07 Information and Communication</td><td>Administrator to analyse, document and implement systems for the centralisation of functions related to application management within the EMEA. This will involve process analysis, process and IT design engineering and data management of paper and electronic submissions and associated financial transactions.
<table><tr><th></th><th>2005</th><th>2006</th><th>2007</th><th>2008</th><th>2009 (est)</th><th>2010 (est)</th></tr><tr><td>Income recovered (Mio €)</td><td>67</td><td>97.5</td><td>106</td><td>121.5</td><td>129</td><td>139</td></tr><tr><td>Number of pre-submission meetings</td><td>70</td><td>83</td><td>79</td><td>80</td><td>80</td><td>80</td></tr></table></td></tr>
<tr><td>1</td><td>AST
Product Data Management (V-PD)

01 Initial Evaluation</td><td>Assistant to perform the mail management and document handling of the increased number of procedures, including the linked financial transactions, to handle electronic submissions as per the mandatory use of e-CTD by applicants, to maintain the core master files and to organise the pre-submission meetings.
<table><tr><th></th><th>2006</th><th>2007</th><th>2008</th><th>2009 (est.)</th><th>2010 (est.)</th></tr><tr><td>Total number of procedures</td><td>2053</td><td>2254</td><td>2455</td><td>2643</td><td>2866</td></tr><tr><td>Number of pre-submission meetings</td><td>83</td><td>79</td><td>82</td><td>80</td><td>80</td></tr><tr><td>Number of established posts in CIG (Assistants)</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6+1</td></tr></table></td></tr>
<tr><td>TOTAL</td><td>530</td><td>37</td><td colspan="3"></td><td>567</td></tr>
</table>

Annex V EMEA ESTABLISHMENT PLAN 2010

Annex V-I OVERALL EMEA ESTABLISHMENT PLAN 2010

Function group & Grade	Posts 2008				Posts 2009		Posts 2010	
	Authorised		Actual as per 31.12.2008		Authorised		Requested	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	1				1		1
AD 15	-	3		1		3		4
AD 14	-	4		4		4		5
AD 13	-	5		5		6		6
AD 12	-	34		27		36		37
AD 11	-	33		29		34		36
AD 10	-	33		14		34		32
AD 9	-	22		34		35		35
AD 8	-	42		26		40		43
AD 7	-	43		11		38		38
AD 6	-	23		62		34		39
AD 5	-	9		30		17		34
Total grade AD	*0*	*252*	*0*	*243*		*282*		*310*
AST 11	-	-		1		-		2
AST 10	-	6		1		6		4
AST 9	-	2		2		5		8
AST 8	-	11		3		12		13
AST 7	-	14		13		15		18
AST 6	-	33		16		38		35
AST 5	-	34		15		39		35
AST 4	-	56		28		46		46
AST 3	-	26		51		30		36
AST 2	-	21		16		25		40
AST 1	-	26		80		32		20
Total grade AST	*0*	*229*		*226*		*248*		*257*
Grand Total	**0**	**481**	**0**	**469**	**0**	**530**	**0**	**567**

CONTRACT AGENTS	Actual as per 31.12.2008	Planned FTE 2009	Planned FTE PDB 2010	Planned FTE DB 2010
FG IV	27	35	37	51
FG III	8	10	11	15
FG II	30	39	41	57
FG I	1	1	1	2
Total	**66**	**85**	**90**	**125**

NATIONAL EXPERTS	Actual as per 31.12.2008	Planned FTE 2009	Planned FTE PDB 2010	Planned FTE DB 2010
Total	**12**	**28**	**19**	**19**

Annex V-II TABLE OF ADDITIONAL POSTS REQUESTED

Function group & Grade	Additional posts requested	
	Permanent posts	Temporary posts
AD 16	-	-
AD 15	-	-
AD 14	-	-
AD 13	-	-
AD 12	-	-
AD 11	-	-
AD 10	-	-
AD 9	-	-
AD 8	-	6
AD 7	-	
AD 6	-	5
AD 5	-	17
Total grade AD	*0*	*28*
AST 11	-	-
AST 10	-	-
AST 9	-	-
AST 8	-	-
AST 7	-	-
AST 6	-	-
AST 5	-	-
AST 4	-	-
AST 3	-	6
AST 2	-	-
AST 1	-	3
Total grade AST	*0*	*9*
Grand Total	**0**	**37**

Annex V-III CHANGE IN GRADING THROUGH POSTS REQUESTED

FROM Grade	**TO** Grade	**Permanent posts**	**Temporary posts**
AD 15	AD 16	-	-
AD 14	AD 15	-	+ 1
AD 13	AD 14	-	+ 1
AD 12	AD 13	-	
AD 11	AD 12	-	+ 1
AD 10	AD 11	-	+ 2
AD 9	AD 10	-	- 2
AD 8	AD 9	-	
AD 7	AD 8	-	- 3
AD 6	AD 7	-	
AD 5	AD 6	-	
	AD5	-	
Total grade AD		*0*	*0*
AST 10	AST 11	-	+ 2
AST 9	AST 10	-	- 2
AST 8	AST 9	-	+ 3
AST 7	AST 8	-	+ 1
AST 6	AST 7	-	+ 3
AST 5	AST 6	-	- 3
AST 4	AST 5	-	- 4
AST 3	AST 4	-	
AST 2	AST 3	-	
AST 1	AST 2	-	+ 15
	AST 1	-	- 15
Total grade AST		*0*	*0*
Grand Total	-	**0**	**0**

Annex VI REVISION OF BUDGET NOMENCLATURE

With the introduction to the Preliminary Draft Budget 2010 the Board was informed that a revision of the nomenclature to separate Information Technology projects for the operation of the Agency from Information Technology expenditure for Telematics Programmes was anticipated. A draft is currently being discussed internally and a proposal will be made with the introduction to the Preliminary Draft Budget 2011 in March 2010.

In addition to that some further technical adjustments to the nomenclature need to be included:

1120	Further training, language courses and retraining for staff	Staff Regulations of officials of the European Communities, and in particular Art. 24 (a) thereof. This appropriation covers introduction courses for new recruits, staff development courses, retraining, courses on the use of modern techniques, seminars, information sessions on EU matters etc. **The appropriation also covers the travel costs associated with training as well as** ~~It also covers~~ the purchase of equipment, ~~and~~ documentation, **e-learning, pod casts and other new media** and the hiring of organising consultants.

Clarification that travel costs associated with training courses are included in the appropriation for training (budget item 1120) and not in the appropriation for missions, business travel (budget item 1300).

1620	**Social Contacts between staff and other welfare expenditure**	**This appropriation covers the expenditure by the agency for social welfare activities for staff such as the Employee Assistance Programme, subsides to staff clubs and other activities.**
~~1820~~	~~Social Contacts between staff~~	~~This appropriation covers part of the costs of the recreation centre, cultural activities, subsidies to staff clubs, the management of, and extra equipment for, sports centres, and projects to promote social contact between staff of different nationalities.~~

The allocation of costs for 'social contract between staff' should be moved from Chapter 18 'Insurance against sickness, accidents and occupational disease, unemployment insurance and maintenance of pension rights' to the more appropriate Chapter 16 'Social welfare'. The new budget item should then also include an Employee Assistance Programme.

1700	Entertainment and representation expenses	This appropriation covers expenditure on the Agency's obligations in respect of entertainment and representation. This expenditure may be incurred by authorised staff individually in the fulfillment of their duties and as part of the Agency's activities. **It also covers the cost of off-site meetings for staff.**

Internal meetings that had to be held outside the Agency's premises were previously covered by budget item 1300 *'Mission and duty travel'*, as they were accounted for as short-haul missions. However, with the introduction of the revised Guide to Missions as of 1 July 2009 (EMEA/MB/694348/2008) the concept of short-haul missions was abandoned and the consequently the cost should be covered by the above appropriation.

2010	Insurance	This appropriation covers the payment of insurance premiums on the buildings or parts of buildings occupied by the Agency as well as for contents **and** civil liability ~~and professional liability~~.
2350	Miscellaneous insurance	This appropriation covers various types of insurance (mission insurance, insurance for accountant, **professional indemnity** etc.).

Chapter 20 is for 'Investments in immovable property, renting of buildings and associated costs'. Consequently, budget item 2010 'Insurances' in chapter 20 should cover building and content related insurances only. Therefore, the professional indemnity insurance that the Agency has taken out in 2009 should not be charged to building related insurances but to budget item 2350 'Miscellaneous insurances'.

2359	Other operating expenditure	This appropriation covers other administrative expenditure, **including outsourcing**, not separately provided for in other items.

The Agency is currently reviewing its telecommunication systems. As any new system procured will be IT driven, the responsibility for telecommunication services will be assigned to the ICT Unit. Consequently, outsourcing of the office concierge, currently covered by the budget items dealing with telecommunication will need to be covered within 'other operating expenditure'.

Annex VII ESTIMATED QUARTERLY CASH-FLOW FOREACST 2010

(excluding exchange rate variances and VAT payments/receipts)

CASH FLOW FORECAST : TOTAL	Budget 2010	RAL (C8) 2010	Total	Dec (pre-pay)	Jan - Mar	Apr-May	Jul - Sep	Oct - Dec
YEAR 2010	**€ '000**	**€ '000**	**€ '000**	**€ '000**	**€ '000**	**€ '000**	**€ '000**	**€ '000**
Fee income	152,780		152,780		31,113	40,134	38,955	42,578
Commission subsidy (for the operating budget - Tiles 1, 2 and 3 - of the agency)	32,612		32,612		5,787	5,301	11,501	10,023
Orphan contribution	4,500		4,500		0	1,155	0	3,345
Others funds from Commission (assigned revenue - C5 credits)	0	1,200	1,200		1,200	0	0	0
Other Revenue	8,295		8,295		4,232	1,779	1,503	781
A - TOTAL RECEIPTS	**198,187**	**1,200**	**199,387**		**42,333**	**48,369**	**51,958**	**56,727**
Title I : Staff								
Payments expected on C1 credits	69,093		68,393		16,319	17,692	18,802	15,580
RAL (C8)		800	800		674	31	33	62
Tile II : Administrative Expenses								
Payments expected on C1 credits	43,104		25,104	2,800	6,166	4,276	6,491	5,371
RAL (C8)		18,000	18,000		6,224	4,681	2,146	4,949
Title III : Operational expenditure								
Payments expected on C1 credits	85,990		68,990		7,767	18,976	17,829	24,418
RAL (C8)		16,000	16,000		8,595	5,394	1,069	942
B-TOTAL CASH OUT	**198,187**	**34,800**	197,287	2,800	45,745	51,051	46,370	51,321
Starting Balance Cash and Bank Accounts			**40,000**		**40,000**	**36,588**	**33,906**	**39,494**
+ Total Receipts (A)			199,387		42,333	48,369	51,958	56,727
- Total Payments (B)			197,287	2,800	45,745	51,051	46,370	51,321
Closure Balance Cash and Bank Accounts			**42,100**	**- 2,800**	**36,588**	**33,906**	**39,494**	**44,900**
- Total anticipated carry-over - Commitments not paid by year-end (C8-2011)								**35,000**
Closure Balance Cash and Bank Accounts					**36,588**	**33,906**	**39,494**	**9,900**