

16 December 2010
EMA/MB/784261/2010 Adopted

Introduction to the draft budget 2011

Management Board meeting 16 December 2010

Background note

Pursuant to Article 66 of Regulation (EC) No 726/2004 and Article 27(6) of the Agency's Financial Regulation, the Board adopted the 2011 budget together with the establishment plan. It takes account of the budget for the European Union (EU) for 2011 as adopted by the Budgetary Authority on 15 December 2010.

The adopted budget will be sent to the European Parliament in accordance with the Code of Conduct on budgetary matters. The budget 2011 (Annex I and IV listed below) will be published in the Official Journal of the European Union in accordance with Article 26 of the Financial Regulation

This document sets out the changes between the Preliminary Draft Budget 2011, adopted by the Management Board at its meeting on 18 March 2010, and the Draft Budget. The Agency's draft work programme (EMA/MB/482208/2010) sets out planned activities and the related objectives with their key initiatives for 2011.

Matters for consideration

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

1. Introductory statement and priorities for 2011
2. Outline of the main changes in the 2011 draft budget as compared to 2011 preliminary draft budget and 2010 actual budget
3. Staffing and human resource needs
4. Revenue and expenditure overview 2009 – 2011

The following annexes are enclosed:

Annex I Detailed draft budget for 2011 [separate document]

Annex II Activity Based Budget

~~Annex III Justifications for posts requested for 2011 [not applicable]~~

Annex IV Establishment plan for 2011

Annex V Revised Staff Policy Plan 2011 [separate document, updated for no new posts in 2011]

Annex VI Revision of budget nomenclature

Annex VII Quarterly Cash-Flow Forecast 2011

1. Introductory Statement and priorities for 2011

The 2011 Preliminary Draft Budget (PDB) was adopted by the Management Board on 18 March 2010 (EMA/MB/68936/2010), totalling EUR 218.9 million in line with the draft work programme (EMA/MB/6505/2010).

The revised 2011 budget has decreased by EUR 10.1 million to EUR 208.9 million (-4.60%) compared to the PDB. The changes take account of the adjustment in the EU contributions of - EUR 14.11 million, the budgeting of the Agency's surplus from 2009 of + EUR 5.48 million, a revision of the estimated fee income of - EUR 1.96 million as well as adjustments in administrative charges and miscellaneous income of + EUR 524 000.

The Draft Budget (DB) 2011 represents a minor increase of +0.23% over the 2010 budget (including Amending Budget (AB) 01-2010).

For details of the adjustments please see point 2 of this document (Outline of the main changes in the 2011 draft budget compared to the 2011 preliminary draft budget and compared to the 2010 budget as of 31 October 2010)

The Agency's key priorities for 2011 are summarised as follows (for full information on the agency's priorities and relating activities, please refer to the Work Programme 2011):

- Effective and efficient management of the core business;
- Successful implementation of new legislation, with the pharmacovigilance legislation being most relevant for 2011;
- Effective monitoring of the balance of benefits and risks of medicines while contributing to a more rational use of medicines;
- Communicating and engaging with stakeholders, empowering patients and enabling their participation in healthcare decisions, as well as increasing transparency of the Agency's activities;
- Contributing to international activities and responding to globalisation of pharmaceutical research, development and manufacturing;
- Responding to public health needs, including availability of medicines;
- Fostering the European regulatory network.

2. Outline of the main changes in the 2011 Draft Budget

2.1. Adjustments in revenue

Adjustments in revenue in the 2011 DB compared to the 2011 PDB and budget 2010 are summarised as follows:

Chapter/Article	Difference DB 2011 – PDB 2011 EUR '000	Remarks	Difference DB 2011 – B 2010 EUR '000	Remarks
100 - Revised fee revenue from fee-related activities	-1,959	The estimated fee income was adjusted in line with the updated workload forecast including the revised impact of the variations Regulation. The estimates now include a 1.5% increase in the level of fees for inflation.	+8,261	Increased income for higher level of post-authorisation activity due to the increase in portfolio.
200 EU General Contribution	-6,537	<p>The total contribution of EUR 28.0 million + use of surplus 2009 resulting in</p> <ul style="list-style-type: none"> • EUR 6.1 for general Public Health issues; • EUR 7.9 million for the implementation of the Paediatric legislation; • EUR 5.2 million for the implementation of the SME legislation; • EUR 2.3 million for the implementation of the Advanced Therapies Regulation, • EUR 12.0 million of the implementation of the Telematics Master Plan. • EUR 5.5 million of the Agency's 2009 surplus. 	-5,593	<p>2010 contributions of EUR 28.3 million + use of surplus 2008 resulting in</p> <ul style="list-style-type: none"> • EUR 3.9 million for general Public Health issues; • EUR 7.9 million for the implementation of the Paediatric legislation; • EUR 5.2 million for the implementation of the SME legislation; • EUR 1.3 million for the implementation of the Advanced Therapies Regulation, • EUR 10.0 million of the implementation of the Telematics Master Plan. • EUR 10.8 million of the Agency's surplus 2008 (+ EUR 3.7 million of the surplus allocated to orphan contribution below).

Chapter/Article	Difference DB 2011 – PDB 2011 EUR '000	Remarks	Difference DB 2011 – B 2010 EUR '000	Remarks
201 Orphan Contribution	-2,099	Estimated requirement for orphan contribution amounts to EUR 7.0 million. Current contribution of EUR 4.9 million will need to be reinforced in the course of 2011.	-3,299	Orphan contribution 2009 was increased from EUR 4.5 million to EUR 8.2 million with the use of surplus 2008 (above).
300 - Decrease in EEA contribution	-402	Reduced in line with decrease in contributions calculated on the basis of 2.38% of all EU contributions.	-151	Decrease in contribution from 2.52% in 2010 to 2.38% in 2011 at a reduced level of contributions.
520 – Revenue from bank interest	-140	The estimated interest rates are adjusted in line with the actual rates 2011 and the policy on cash management.	-40	Interest to be received for 2011 is estimated to be slightly lower than in 2010 due to estimated lower cash deposits.
521 – Administrative charges	+766	Adjustment for the experience gained with the implementation of the Variations Regulation and the administrative fees for centralised products for work sharing. At the same time the income from Parallel Distributions is now estimated to increase by 28.4% compared to PDB).	+1,298	Expected increase in notifications for Parallel Distributions.
600 – Community programmes	+/-0	No change compared to PDB.	+100	The multi-beneficiary programme 2010/11 for the preparation of the candidate countries and potential candidate of EUR 900,000 was split into EUR 400,000 for 2010 and EUR 500,000 for 2011.

Chapter/Article	Difference DB 2011 – PDB 2011 EUR '000	Remarks	Difference DB 2011 – B 2010 EUR '000	Remarks
601 – Joint programmes	+/-0	A minor contribution is foreseen for the involvement in the Innovative Medicines Initiative (IMI) with the proposed project PROTECT.	+/-0	Same level of contribution in 2011 as in 2010.
900 - Miscellaneous revenue	+300	Capital contribution for the 1 st floor 7 Westferry Circus from the previous tenant of the floor is now expected in 2011.	-100	Miscellaneous adjustments and effect of shift in capital contribution (see remarks on difference PDB-DB).
TOTAL CHANGE	-10,071		+476	

2.2. Adjustments in expenditure

Chapter/ Article	Difference DB 2011 – PDB 2011 EUR '000	Remarks	Difference DB 2011 – B 2010 EUR '000	Remarks
11 – Salaries and allowances	-453	Reductions in estimated salary cost as no additional posts are foreseen for 2011. This saving is used to finance additional Contract Agents as well as to compensate for an expected increase in weighting costs for exchange rate variances.	+4,717	Increased costs mainly due to exchange rate adjustments resulting into an increase in the London weighting.
13 – Missions	+/-0	As per PDB	+11	Mission activity in 2011 is anticipated to increase by 1.4%.
14 – Socio-medical infrastructure	+37	Adjustment for negative effect EUR/GBP exchange rate from the drafting of the PDB to the drafting of the DB only.	+7	Estimated increase in staff for use of restaurant and attending annual medical examination.
15 – Exchange of civil servants and experts	+1,094	Due to the restrictions in recruiting temporary agents, the allocation for National Experts was increased from 10 FTE in PDB to 20 FTE.	+152	Budget 2010 allowed for a total of 19 FTE National Experts whereas for 2011 20 FTE are now assumed.
16 – Social welfare	-3	Minor adjustment (-1.9%).	+7	Increase in 'nursery allowance' for additional children for staff members.
17 – Entertainment and representation expenses	-6	Scaling down of planned expenditure for entertainment and representation.	-35	2010 included expenditure for 15 th anniversary of the Agency (Jan 2010).
18 – Staff insurances	-220	Adjustment (-9.4%) in line with reduction of estimated expenditure in basic salaries.	-3	Adjustment (-0.1%) in line with shift from Temporary Agents to Contract Agents for which the sickness insurance is accounted for separately.

Chapter/ Article	Difference DB 2011 – PDB 2011 EUR '000	Remarks	Difference DB 2011 – B 2010 EUR '000	Remarks
<i>Subtotal Title 1</i>	<i>+449</i>		<i>+4,856</i>	
20 – Investments in immovable property, renting of building and associated costs	-991	<p>With the PDB the refurbishment of two floors in 11 Westferry Circus was planned. This additional floor space is no longer required resulting in a cost saving.</p> <p>Please note that for a possible relocation of the Agency after the expiry of the lease no provisions are so far included, pending a final decision.</p> <p>The chapter also takes account of the decline in EUR/GBP exchange rate from the drafting of the PDB to the drafting of the DB at an overall cost of around 7%.</p>	-1,152	2010 provides for the start-up costs for preparatory activities for a possible relocation of the Agency in 2013/2014, whereas in 2011 only a token amount is provided so far.
211 – Computer networks and equipment for the operation of the agency	+754	Reduction of a total of EUR 6.6 million split between chapters 21 and 31 due to the reduction in EU contribution. For the actual planned activities, please see document EMA/MB/691944/2010 for details.	-2,645	For 2011 only minor or considerably reduced purchases of hard- and software is planned and ICT consultancy for maintenance is now reduced compared to 2010.
212 - Computer networks and equipment for specified projects	+/-0	Article is no longer in use (see justification DB 2011 B 2010).	-20,456	Article 212 was moved to articles 310 and 311 from PDB 2011.
22 – Movable property and associated costs	+93	Adjustment for exchange rate (6.2%) including a revision of the requirements for subscriptions.	+113	Effect of anticipated purchases of miscellaneous technical equipment and additional subscriptions in 2011.

Chapter/ Article	Difference DB 2011 – PDB 2011 EUR '000	Remarks	Difference DB 2011 – B 2010 EUR '000	Remarks
23 – Current administrative expenditure	+13	Overall impact of miscellaneous adjustments (1.06%)	+153	Impact of expiry of contract with archiving provider in 2011 plus cost for moving archiving boxes to different provider or deep-storage.
24 – Postal charges and telecommunications	+87	Change in express postal service provider in 2010 at higher costs as provider assumed with PDB as well as telecommunication charges increase.	+245	Estimate for initial investment for change telephony.
25 –Meetings in general	-5	Minor adjustment.	-15	With the change in financial IT system in 2011, a subscription related to the phased-outs system is no longer required.
Subtotal Title 2	-49		-23,757	<i>Major decrease due to change in ICT nomenclature; see also subtotal Title 3.</i>
300 - Meetings	-107	Adjustment in catering for meetings in line with the actual usage in 2010.	-429	Revision in line with actual 2010 meeting expenditure excluding the effect of the cancellation of meetings for the ash-cloud (increase in virtual meetings at lower cost).
301 – Evaluation of medicinal products	-2,000	Payments for rapporteur activities have been adjusted in line with the decreased estimated fee income and taking account of the share of fees as per the Implementing Rules to the Fee Regulation. Allocation also provides for costs of Testing & sampling programme as well as contracting of ENCePP studies.	+2,850	Estimated increase in line with additional level of applications estimated in 2011.

Chapter/ Article	Difference DB 2011 – PDB 2011 EUR '000	Remarks	Difference DB 2011 – B 2010 EUR '000	Remarks
302 – Translation expenses	-462	PDB 2011 included the translation of the Agency's new website into 4 languages. This project is now postponed to allow the evaluation of the technical requirements.	+67	Taking account of estimated price increase for Translation Centre Luxembourg.
303- Studies and consultants	-542	PDB 2011 initially included consultancy for EVDAS which is now no longer provided for.	+100	In 2011 audits for IMI programme and general ICT will need to be contracted.
304 – Information and publications	-6	Adjustment in line with 2010 actual expenditure.	-31	Budget 2010 included promotional material for the 15 th anniversary.
305 – Community programmes	+/- 0	As per PDB.	+100	Adjustment of IPA programme, please see Income 600 for details.
310 – Expenditure on data processing related to the lifecycle of a product	+133	Reduction of a total of EUR 6.6 million split between chapters 21 and 31 due to the reduction in EU contribution. For the actual planned activities, please see document EMA/MB/691944/2010 for details.	+5,792	Change in budget nomenclature in 2011; expenditure was previously included in chapter 21.
311 - Expenditure on data processing for special programmes	-7,487		+11,897	
Total Title 3	-10,471		+20,346	<i>Major increase due to change in ICT nomenclature; see also subtotal Title 2.</i>
900 – Provisional appropriation	+/- 0	As per PDB	-969	Amount currently remaining on provisional appropriation.
Total Title 9	+/- 0		- 969	
TOTAL	-10,071		+476	

3. Staffing and human resource needs

The establishment plan as adopted by the Management Board in March 2010 contained 48 new posts. However, the European Commission, in forwarding the Agency's request to the Budgetary Authority, did not support the Agency's request for posts. Consequently, currently the Budgetary Authority will not authorise the 48 positions requested by the Agency.

However, the European Parliament in its instructions to the Commission for Budget 2011 had highlighted that posts, that are not to be financed by the Unions contribution but by fees, should be supported. Consequently, the European Parliament might initiate an Amending Budget for the 48 posts in the course of 2011. The budget as presented to the Board does not yet include such provisions.

In order to compensate for the Temporary Agents, counted against posts, that the Agency will not be able to recruit in 2011, the level of Contract Agents, counted against financial credits, as well as the level of National Experts for 2011 needed to be increased. For 2011 the Agency had to increase its budgetary provision for Contract Agents from 90 to 150 FTE (Full Time Equivalent) and for National Experts from 10 to 20 FTE.

This adjustment in staffing results in possible 22 additional staff in 2011 compared to PDB 2011 and 26 additional staff compared to 2010 provisions. This takes account of the originally very low provisions for additional staff in 2011 which had to be corrected to reflect the workload in the Agency.

	2010	PDB 2011	DB 2011
Posts for Temporary Agents	567	615	567
Provisions for Contract Agents (FTE)	125	90	150
Provisions for National Experts (FTE)	19	10	20
Total staffing	711	715	737
Additional staffing provisions originally planned 2010 - PDB 2011			+4
Additional staffing provisions DB - PDB 2011			+22
Additional staffing provisions DB 2011 - 2010			+26

The Contract Agents and National Experts are for

- workload where a post in the establishment plan is not available due to the cut in additional posts for 2011;
- workload where a post in the establishment plan is available but no suitable Temporary Agent could be recruited yet;
- interim cover for Temporary Agents on part-time or on long-term leave, e.g. for maternity or family leave,
- project related workload on a short- to medium term assignment and
- increases in workload where no post in the establishment plan could be provided for yet.

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

4. Revenue and expenditure overview 2009-2011

		2009 ¹		2010 ²		2011 PDB ³		2011 DB	
		€ '000	%	€ '000	%	€ '000	%	€ '000	%
Revenue									
100	Fees	141,023	71.9	152,780	73.3	163,000	74.4	161,041	77.1
200	General EU contribution	36,320	18.5	28,280	13.6	40,056	18.3	28,042	13.4
200	Surplus from previous year	4,900	2.5	⁴ 14,532	7.0	p.m.	0.00	5,477	2.6
201	Special EU contribution for orphan medicinal products	5,632	2.9	4,500	2.2	7,000	3.2	4,901	2.3
300	Contribution from EEA	873	0.4	935	0.4	1,186	0.5	784	0.4
600	Community programmes	103	0.1	460	0.2	560	0.3	560	0.3
5+9	Other	7,283	3.7	6,900	3.3	7,132	3.3	8,058	3.9
TOTAL REVENUE		196,135	100.0	208,387	100.0	218,934	100.0	208,863	100.0
Expenditure									
Staff									
11	Staff in active employment	51,988	27.8	62,489	30.0	67,639	30.9	67,186	32.2
13	Mission expenses	663	0.4	789	0.4	800	0.4	800	0.4
14	Socio-medical infrastructure	535	0.3	640	0.3	610	0.3	647	0.3
15	Exchange of civil servants and experts	2,636	1.4	2,847	1.4	1,905	0.9	2,999	1.4
16	Social welfare	97	0.1	145	0.1	155	0.1	152	0.1
17	Entertainment and representation expenses	37	0.0	50	0.0	41	0.0	35	0.0
18	Staff insurances	1,786	1.0	2,133	1.0	2,350	1.1	2,130	1.0
	<i>Total Title 1</i>	<i>57,741</i>	<i>30.9</i>	<i>69,093</i>	<i>33.2</i>	<i>73,500</i>	<i>33.6</i>	<i>73,949</i>	<i>35.4</i>
Building/equipment									
20	Investment in immovable property, renting of building and associated costs	16,056	8.6	18,207	8.7	17,936	8.2	16,945	8.1
21	Expenditure on data processing	29,589	15.8	30,802	14.8	6,947	3.2	7,701	3.7
22	Movable property [...]	2,598	1.4	1,456	0.7	1,506	0.7	1,599	0.8
23	Other admin. expenditure	1,128	0.6	1,063	0.5	1,223	0.6	1,236	0.6
24	Postage and communication	818	0.4	664	0.3	872	0.4	959	0.5
25	Expenditure on other meetings	92	0.0	143	0.1	143	0.1	138	0.1
	<i>Total Title 2</i>	<i>50,281</i>	<i>26.9</i>	<i>52,335</i>	<i>25.1</i>	<i>28,627</i>	<i>13.1</i>	<i>28,578</i>	<i>13.7</i>
Operational expenditure									
300	Meetings	7,660	4.1	8,930	4.3	8,578	3.9	8,471	4.1
301	Evaluation of medicines	66,487	35.6	72,075	34.6	76,925	35.1	74,925	35.9
302-304	Translations, studies and consultants, publications	4,251	2.2	4,585	2.2	5,761	2.6	4,751	2.4
305	Community programmes	272	0.1	400	0.2	500	0.2	500	0.2
310	Expenditure on data processing related to product lifecycle					5,659	2.6	5,792	2.8
311	Expenditure on data processing for special programmes					19,384	8.9	11,897	5.7
	<i>Total Title 3</i>	<i>78,670</i>	<i>42.1</i>	<i>85,990</i>	<i>41.3</i>	<i>116,807</i>	<i>53.4</i>	<i>106,336</i>	<i>50.9</i>
Provisional appropriation									
900	Provisional appropriation	0	0.0	969	0.5	0	0.0	0	0.0
	<i>Total Title 9</i>	<i>0</i>	<i>0.0</i>	<i>969</i>	<i>0.5</i>	<i>0</i>	<i>0.0</i>	<i>0</i>	<i>0.0</i>
TOTAL EXPENDITURE		186,693	100.0	208,387	100.0	218,934	100.0	208,863	100.0

¹ 2009 as per final accounts;

² Budget 2010 as of 31 October 2010 (incl. AB 01-2010)

³ PDB 2011 as adopted by the Management Board on 18 March 2010

⁴ EUR 3.7 million of surplus are used to compensate for orphan medicines fee reductions (AB 01-2010)

Annex II Activity based budget 2010 – 2011

Chapter	Activity	Reference to Draft Work Programme	Human resources	Cost per Activity	Costs per activity incl. Support	of total
	DB 2011			EUR '000	EUR '000	
01.00	Initial Evaluation – (initial applications for marketing authorisation)	2.3, 3.2 and 3.3	6.76%	21,138	22,194	10.63%
02.00	Specific Post Authorisation Activities (variations, extensions, renewals transfer of marketing authorisation,)	2.4 and 3.4	8.96%	42,917	45,062	21.57%
03.00	Pharmacovigilance and maintenance Activities	2.5 and 3.5	14.04%	28,413	29,833	14.28%
04.00	Scientific Advice & Protocol Assistance	2.2 and 3.1	4.34%	17,507	18,382	8.80%
05.00	Arbitration / Referrals	2.6 and 3.6	3.41%	4,875	5,118	2.45%
06.00	Inspections - and testing and sampling of centrally authorised medicinal products	4.1, 4.2 and 4.3	3.77%	8,606	9,036	4.33%
07.00	Administrative Charges – (parallel distribution notifications, certificate of medicinal products and variations work-sharing)	4.4 and 4.5	3.40%	2,514	2,639	1.26%
08.00	EU Public Health and Harmonisation Activities					
08.01	Support to orphan designation process	2.1	1.65%	2,311	2,427	1.16%
08.02	Medicines for Paediatric use	2.7	7.08%	8,046	8,448	4.04%
08.03	Herbal medicinal products	2.8	1.16%	1,881	1,975	0.95%
08.04	Small and Medium Size Enterprises (SMEs) Office	1.5	0.74%	1,198	1,258	0.60%
08.05	Coordination group for mutual recognition and decentralised procedures Human & Vet	2.11 and 3.8	1.21%	1,072	1,125	0.54%
08.06	Specified medicinal areas: Bio terrorism, clinical trials and Antimicrobial resistance	1.2	2.47%	2,713	2,849	1.36%
08.07	EU co-operation – (Liaison with EU Institutions and national competent authorities)	1.1 and 1.2	0.87%	1,300	1,365	0.65%
08.08	International co-operation – (scientific contribution to the European Union presence in a number of international fora)	1.3	1.55%	2,324	2,440	1.17%
08.09	Advance therapies and other emerging and new therapies	1.6 and 2.9	0.49%	1,215	1,276	0.61%
09.00	Project related activities: (implementation of a IT projects linked to the EU telematics strategy and other IT projects)	1.5, 5.1 and 5.2	9.17%	23,305	24,470	11.72%
10.00	Corporate governance – (Management Board, Audit Advisory Committee, Integrated Quality Management)	1.7	11.15%	12,322	12,938	6.19%
10.01	Support services - (Executive support and Administration)	1.7	11.42%	9,941		
10.02	Product information quality, Quality review document and translation	1.4 and 1.7	6.36%	6,558	6,885	3.30%
11.00	Management and organisation of the CHMP, CVMP and Working Parties meetings (including reimbursement to delegates)	1.1, 2.10 and 3.7		8,708	9,143	4.38%
	Total		100.00%	208,864	208,863	100.00%

Chapter	Activity	Reference to Draft Work Programme	Human resources	Cost per Activity	Costs per activity incl. Support	of total
	2010			EUR '000	EUR '000	
01.00	Initial Evaluation – (initial applications for marketing authorisation)	2.3, 3.2 and 3.3	6.75%	19,366	20,287	9.78%
02.00	Specific Post Authorisation Activities (variations, extensions, renewals transfer of marketing authorisation)	2.4 and 3.4	9.13%	40,769	42,709	20.59%
03.00	Pharmacovigilance and maintenance Activities	2.5 and 3.5	14.12%	27,320	28,621	13.80%
04.00	Scientific Advice & Protocol Assistance	2.2 and 3.1	4.57%	15,385	16,117	7.77%
05.00	Arbitration / Referrals	2.6 and 3.6	2.95%	4,502	4,717	2.27%
06.00	Inspections - and testing and sampling of centrally authorised medicinal products	4.1, 4.2 and 4.3	3.43%	7,794	8,165	3.94%
07.00	Administrative Charges – (parallel distribution notifications, certificate of medicinal products and variations work-sharing)	4.4 and 4.5	2.98%	2,184	2,288	1.10%
08.00	EU Public Health and Harmonisation Activities					
08.01	Support to orphan designation process	2.1	1.87%	2,601	2,725	1.31%
08.02	Medicines for Paediatric use	2.7	7.19%	7,949	8,328	4.01%
08.03	Herbal medicinal products	2.8	1.32%	2,019	2,115	1.02%
08.04	Small and Medium Size Enterprises (SMEs) Office	1.5	0.84%	1,165	1,220	0.59%
08.05	Coordination group for mutual recognition and decentralised procedures Human & Vet	2.11 and 3.8	1.35%	1,149	1,204	0.58%
08.06	Specified medicinal areas: Bio terrorism, clinical trials and Antimicrobial resistance	1.2	2.42%	2,739	2,870	1.38%
08.07	EU co-operation – (Liaison with EU Institutions and national competent authorities)	1.1 and 1.2	0.90%	1,360	1,425	0.69%
08.08	International co-operation – (scientific contribution to the European Union presence in a number of international fora)	1.3	1.76%	2,529	2,649	1.28%
08.09	Advance therapies and other emerging and new therapies	1.6 and 2.9	0.46%	1,165	1,221	0.59%
09.00	Project related activities: (implementation of a IT projects linked to the EU telematics strategy and other IT projects)	1.5, 5.1 and 5.2	8.52%	24,988	26,177	12.62%
10.00	Corporate governance – (Management Board, Audit Advisory Committee, Integrated Quality Management)	1.7	12.20%	13,002	13,621	6.57%
10.01	Support services - (Executive support and Administration)	1.7	10.91%	9,425		
10.02	Product information quality, Quality review document and translation	1.4 and 1.7	6.34%	6,216	6,512	3.14%
11.00	Management and organisation of the CHMP, CVMP and Working Parties meetings (including reimbursement to delegates)	1.1, 2.10 and 3.7		13,791	14,447	6.97%
	Total		100.00%	207,418	207,418	100.00%
	Provisional appropriation			969	969	
	Grand Total			208,387	208,387	

Annex IV Establishment plan for 2011

Function Group & Grade	Authorised for 2009		Occupied as at 31.12.2009			Authorised for 2010		Requested for 2011 ⁵	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts	Permanent posts	Temporary posts
				Grade filled	Actual grade				
AD 16	-	1	-	1	-	-	1	-	1
AD 15	-	3	-	3	1	-	4	-	4
AD 14	-	4	-	4	4	-	5	-	5
AD 13	-	6	-	6	6	-	6	-	7
AD 12	-	36	-	36	27	-	37	-	37
AD 11	-	34	-	34	28	-	36	-	36
AD 10	-	34	-	34	15	-	32	-	32
AD 9	-	35	-	32	37	-	35	-	38
AD 8	-	40	-	34	26	-	43	-	43
AD 7	-	38	-	38	19	-	38	-	42
AD 6	-	34	-	32	68	-	39	-	32
AD 5	-	17	-	15	36	-	34	-	33
Total AD	0	282	0	269	267	0	310	0	310
AST 11	-	-	-	-	1	-	2	-	2
AST 10	-	6	-	5	1	-	4	-	4
AST 9	-	5	-	5	2	-	8	-	8
AST 8	-	12	-	12	3	-	13	-	13
AST 7	-	15	-	14	13	-	18	-	19
AST 6	-	38	-	38	16	-	35	-	35
AST 5	-	39	-	39	16	-	35	-	35
AST 4	-	46	-	46	34	-	46	-	49
AST 3	-	30	-	28	50	-	36	-	36
AST 2	-	25	-	24	21	-	40	-	40
AST 1	-	32	-	31	87	-	20	-	16
Total AST	0	248	0	242	244	0	257	0	257
Total	0	530	0	511	511	0	567	0	567

⁵ As revised for draft Establishment Plan endorsed by the Budgetary Authority

Contract Agents	2009 Actual FTE used	2009 Actual as at 31.12.2009	2010 Planned FTE	PDB 2011 Planned FTE	DB 2011 Planned FTE
FG IV	31	40	51	36	68
FG III	9	11	15	10	15
FG II	43	39	57	43	64
FG I	2	2	2	1	3
Total	85	92	125	90	150

National Experts	2009 Actual FTE used	2009 Actual as at 31.12.2009	2010 Planned FTE	PDB 2011 Planned FTE	DB 2011 Planned FTE
Total	19	20	19	10	20

Annex VI REVISION OF BUDGET NOMENCLATURE

(deletions are marked in strikethrough, additions are marked in bold)

With the introduction to the Preliminary Draft Budget 2011 the Board was informed of a revision of the nomenclature for various activities. To this regard the Board is invited to note a correction in the numbering of the budget items:

CHAPTER 31 Expenditure on operational data processing	
Announced numbering	Actual numbering
3110 Purchase of new hardware related to the lifecycle of medicinal products	3100
3111 Purchase of new software related to the lifecycle of medicinal products	3101
3112 Replacement of hardware and software related to the lifecycle of medicinal products	3102
3113 Hire of hardware and software related to the lifecycle of medicinal products	3103
3114 Maintenance and repair of hardware and software related to the lifecycle of medicinal products	3104
3115 Analysis, programming and technical assistance related to the lifecycle of medicinal products	3105
3120 Purchase of new hardware for special programmes	3110
3121 Purchase of new software for special programmes	3111
3122 Replacement of hardware and software for special programmes	3112
3123 Hire of hardware and software for special programmes	3113
3124 Maintenance and repair of hardware and software for special programmes	3114
3125 Analysis, programming and technical assistance for special programmes	3115

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

CHAPTER 11 Staff in active employment		
1149	Other allowances and repayments	Staff Regulations of officials of the European Communities, and in particular Art 34 thereof and Annex X reimbursement of expenses . This appropriation covers allowances in the event of dismissal of a probationary official for obvious inadequacy (Art 34), allowances in the event of cancellation by the Agency of the contract of a relevant staff member (Art 34) and any expenses to be reimbursed according to Annex X.

With the detachment of a temporary agent to the US Food and Drug Administration (FDA) the expenses according to Annex X of the Staff Regulations (Special and exceptional provisions applicable to officials serving in a third country) need to be accommodated in the budget remarks.

CHAPTER 20 Investment in immovable property, renting of building and associated costs		
2090	Other expenditure on buildings	This appropriation covers expenditure on service charges for multiple-tenanted buildings, estate service charges and local taxes on buildings. It also covers expenditure on buildings not specifically provided for in the other articles of this chapter in particular management fees for multiple-tenanted buildings, costs of surveys of premises and charges for utilities (refuse collection etc.). It also covers the cost of technical assistance.

Appropriation on budget item 2090 amounts to around 30% of the total chapter. Consequently the type of expenditure covered by the item needs to be clarified further as the title 'other expenditure on buildings' might imply only minor miscellaneous expenditure. Please note that the items paid from this budget item relate to service charges payable to the landlord, estate charges payable to Canary Wharf Ltd. and business rates payable to the local council.

Annex VII DRAFT CASH FLOW FORECAST (excluding exchange rate variances and VAT payments/receipts)

CASH FLOW FORECAST : TOTAL	Approved	Estimated	Total	Dec (pre-pay)	Jan - Mar	Apr-Jun	Jul - Sep	Oct - Dec
	Budget 2011	RAL (C8) 2011	Annual	estimated	estimated	estimated	estimated	estimated
YEAR 2011	€ '000	€ '000	€ '000	€ '000	€ '000	€ '000	€ '000	€ '000
Fee income	161,041		161,041		30,859	40,152	45,466	44,564
European Union contribution (for the operating budget - Titles 1, 2 and 3 of the agency)	28,042		28,042		0	0	13,036	15,006
Orphan contribution	4,901		4,901		0	3,008	1,055	838
Surplus of previous year	5,477		5,477		5,477			
Other Revenue	9,402		9,402		1,179	2,039	2,052	4,132
A - TOTAL RECEIPTS	208,863	0	208,863		37,515	45,199	61,609	64,540
Title I : Staff								
Payments expected on C1 credits	73,949		73,149		16,710	17,530	19,547	19,362
RAL (C8)		800	800		562	108	59	71
Title II : Administrative Expenses								
Payments expected on C1 credits	28,578		10,578	2,800	1,808	1,248	1,812	2,910
RAL (C8)		18,000	18,000		6,312	4,865	5,745	1,078
Title III : Operational expenditure								
Payments expected on C1 credits	106,336		88,336		12,121	21,565	23,377	31,273
RAL (C8)		18,000	18,000		9,395	5,437	1,526	1,641
B-TOTAL CASH OUT	208,863	36,800	208,863	2,800	46,908	50,753	52,068	56,335
Starting Balance Cash and Bank Accounts			50,000		50,000	40,607	35,054	44,595
+ Total Receipts (A)			208,863		37,515	45,199	61,609	64,540
- Total Payments (B)			208,863	2,800	46,908	50,753	52,068	56,335
Closure Balance Cash and Bank Accounts			50,000	-2,800	40,607	35,054	44,595	52,800
- Total anticipated carry-over - Commitments not paid by year-end (C8-2011)								36,800
Closure Balance					40,607	35,054	44,595	16,000