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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Amendment of the financial statement accompanying Regulation (EC) No 297/95

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Amendment of the financial statement accompanying Regulation (EC) No 297/95

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004[1] laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, set up the European Medicines Agency, repealing Council Regulation (EEC) No 2309/93[2]. Article 67(3) of this regulation establishes that the revenue of the Agency shall consist of a contribution from the European Union, and the fees paid by the undertaking for obtaining and maintaining a Community marketing authorisation and for other services provided by the Agency.

Council Regulation (EC) No 297/95 of 10 February 1995[3] on fees payable to the European Medicines Agency ('EMA') sets out the different types of fees payable for services provided, including the possibility for waivers and reductions of certain fees.

For neither the establishment of Regulation (EC) No 297/95 nor its amendments in 1998[4], 2003[5] and 2005[6] the corresponding financial statements (if applicable) provided for the human resource element required to handle fee-related applications.

The Budgetary Authority agreed to additional staff for fee-related activities in 2010. For 2011 and 2012 no additional fee-financed staffing was provided; the additional posts agreed for 2012 correspond to the implementation of the new pharmacovigilance activities only. In DB2013 the Commission agreed on an increase of the EMA establishment plan with 21 additional posts, to be financed by fees from the industry. With this Communication, the Commission wants to address the justification of this increase. In fact, the fee-related activities of EMA have developed substantially since 2010, with the consequential expansion of the workload for the Agency, yet with no corresponding increase in staff.

To provide for the evaluation of medicines, the Agency needs to hire highly specialised administrators, who are to follow a lengthy and costly on-the-job training. As a consequence, for long-term increases in workload, the Agency has to recruit temporary agents rather than contract agents. The latter are recruited for short-term increases in workload as well as for project related work. As the Agency is scaling down project-related work, the number of contract agents can be reduced. At the same time, fee-related income of the Agency, based on Recovery Orders/invoices sent[7], increased from EUR 171,9 million in 2010 to EUR 179,8 million in 2011 and is estimated to further increase to EUR 200,8 million in 2013. This

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1 OJ L 136, 30.4.2004, p. 1, as last amended by Regulation No 1235/2010 (OJ L 348, 15.12.2010).
2 OJ L 214, 24.8.1993, p. 1.
3 OJ L 35, 15.2.1995, p. 1.
4 OJ L 345, 19.12.1998, p. 3.
5 OJ L 73, 19.3.2003, p. 6.
6 OJ L 304, 23.11.2005, p. 1.
7 As opposed to the amount of Recovery Orders cashed, which is important to determine the level of revenues for budgetary purposes.

corresponds to a 5.9% increase for the period 2010-12 and a 16.8% increase over the period 2010-13, which translates into the corresponding increase in workload.

These recent developments in fee-related activities are of a long-term nature and the Agency requires 21 additional temporary agents as of 2013. While asking for this increase, the Agency has taken into account, in accordance with the Commission proposal, to reduce its staff with 5% over 5 years as from 2013 and also considered all means of redeployment and process improvement.

It needs to be highlighted as well that the current fee-financed increase in staffing is not linked to the implementation of the new pharmacovigilance legislation, applicable as of July 2012. It is currently estimated that the Agency will be in a position to charge fees for pharmacovigilance activities, as foreseen in the legislation, in 2014 at the earliest. Related staff covered by the anticipated fee income will only be requested as and when pharmacovigilance fees are estimated to be received.

On the basis of the elements mentioned above, it is necessary to update the legislative financial statement. The new statement is attached herewith.

REVISED LEGISLATIVE FINANCIAL STATEMENT

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1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Medicines Agency – amendment of the financial statement.

1.2. Policy area(s) concerned in the ABM/ABB structure[8]

Policy Area(s) concerned: Heading 1a – Competitiveness for Growth and Employment

1.3. Nature of the proposal/initiative

☐ The proposal/initiative relates to a **new action**

☐ The proposal/initiative relates to a **new action following a pilot project/preparatory action**[9]

☑ The proposal/initiative relates to the **extension of an existing action**

☐ The proposal/initiative relates to an **action redirected towards a new action**

1.4. Objectives

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

To harness European economic integration (the "single market") to the broader goal of sustainable growth by mobilizing economic, social and environmental policies.

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

Specific objective

The EMA shall levy fees to the pharmaceutical industry for obtaining and maintaining an EU market authorisation for medicinal products for human use and for other services rendered by the Agency.

ABM/ABB activities concerned

Heading 1A – Competitiveness for Growth and Employment

17 03 10: EUROPEAN MEDICINES AGENCY

[8] ABM: Activity Based Management – ABB: Activity Based Budgeting.

[9] As referred to in Article 49(6)(a) or (b) of the Financial Regulation.

Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

In light of the continous increase in the activities of the Agency, notably the number of applications in the pre- and post-authorisation phase of the lifecycle of a medicinal product, the number of staff dealing with these applications which are also increasingly complex, needs to increase at a proportional level. The initial financial statement should therefore be revised to adapt to the reality of the agency's staffing needs. The extra staff will be funded by the fee income generated through these activities and is therefore neutral for the EU budget.

a) Increase in activities e.g. numbers of applications/workload

	2009	**2010**	**2011**	**2012 est.**	**2013 est.**
Applications for designation of orphan medicinal products (input)	164	174	166	180	185
Applications for designation of MUMS	4	18	18	18	18
PIP applications including waivers and deferrals	273	326	187	220	220
Clinical indications in PIP applications	364	403	220	258	226
Modification of agreed PIPs		110	177	225	280
Scientific advice and follow-up requests (HUM)	311	332	354	413	454
Protocol assistance and follow-up requests (HUM)	77	68	79	80	89
Scientific Advice (VET)	11	21	26	26	26
New medicinal products (non-orphan) (HUM)	36	34	47	52	56
New medicinal products (orphan) (HUM)	11	12	14	13	13
Similar biological products (HUM)	1	1	3	5	3
Generic, hybrid products, etc. (HUM)	48	42	33	39	38
Scientific opinions for non-EU markets (HUM)	0	1	1	1	0
Paediatric use market. authorisat. (HUM)	0	1	1	0	2
Advanced therapy re-registration * (HUM)		0	1	2	
Applications for new medicinal products (VET)	14	16	8	9	10
Generic applications (VET)	1	2	3	3	3
Type-IA variations (HUM)	897	2.057	2.875	3.300	3.700
Type-IB variations (HUM)	470	1.093	1.260	1.350	1.400
Type-II variations (HUM)	1.186	966	873	870	870
Line extensions (HUM)	24	29	31	25	25
Type-I variation applications (VET)	73	134	241	275	310
Type-II variation applications (VET)	40	28	46	52	65
Line-extension applications (VET)	12	3	7	7	7
Certificates requested	2.144	2.396	3.104	3.200	3.400
New MRL applications	4	3	1	3	2
MRL ext./mod. applications	2	4	8	4	5
MRL extrapolations	0	0	5	2	3
MRL for use under the 'cascade'		4		1	1
Art. 9, Biocides				3	3
Review of draft Codex MRLs	6	6		5	2

Art. 13 of Reg. (EC) No 1234/2008 (HUM)		0	1	1	
Art. 6(12) of Reg. (EC) No 1084/2003 (HUM)	5	0	2		
Art. 6(13) of Reg. (EC) No 1084/2003 (HUM)	1	0	0		
Art. 31 of Dir. 2001/83/EC (HUM)	4	6	10	5	
Art. 36 of Dir. 2001/83/EC (HUM)	0	0	5	1	5
Art. 5(3) of Dir. 2001/83/EC (HUM)	2	3	7	5	
Art. 107(2) of Dir. 2001/838/EC (HUM)	5	3	2	2	
Art. 29(4) of Dir. 2001/83/EC (HUM)	13	6	2	5	5
Art. 30 of Dir. 2001/83/EC (HUM)	10	8	6	3	3
Art. 29 of Reg. (EC) No 1901/2006 (HUM)	6	1	0		
Art. 20 of Reg. (EC) No 726/2004 (HUM)		28	42	8	
Art. 20 foll. Art. 20 proc. of Reg (EU) 1235/2010 (HUM)	-	-	-	6	11
Art. 20 foll. Art. 107j(2) proc. of Dir. 2010/84/EU (HUM)	-	-	-	2	5
Art. 20 foll. Art. 107i proc. of Dir 2010/84/EU (HUM)	-	-	-	6	10
Art. 31 foll. Art. 32-34 of Dir. 2001/83/EC (HUM)	-	-	-	1	2
Art. 31 foll. Art. 107j(2) proc. of Dir. 2010/84/EU (HUM)	-	-	-	4	11
Art. 107i of Dir. 2010/84/EU (HUM)	-	-	-	3	7
Arbitration and Community referral procedures (VET)	9	12	12	12	12
GMP inspections (including PMF)	175	229	375	330	360
GCP inspections	58	62	65	65	70
Pharmacovigilance inspections	-	5	9	9	10
GLP inspections	0	4	1	2	2
Parallel-distribution Initial notifications	2.247	2.599	2.551	2.600	2.800
Parallel-distribution Notifications of change	5.527	4.590	2.150	2.000	1.600
Number of quality defects reported	80	111	154	177	218

b) Increase in revenue from fees and charges (based on Recovery Orders/Invoiced amounts) compared to posts:

	2010 Outturn	2011 Outturn	2012	2013 PDB	Total increase 2010-2011	Total increase 2010-2012	Total increase 2010-2013
Revenue							
Fees+charges **(Recovery Orders)**	171.972.868	179.791.829	182.155.000	200.797.000	7.818.961	10.182.132	28.824.132
Increase n/n-1		**4,55%**	**1,31%**	**10,23%**	**4,55%**	**5,92%**	**16,76%**

Posts	**567**	**567**	**590**	**611**	**0**	**23**	**44**
- of which for fee related activities	457	457	457	479	0	0	22
- of which for general public health policies	110	110	110	109	0	0	-1
- of which for pharmacovigilance legislation	0	0	23	23	0	23	23
= net increase fee related tasks n/n-1		**0,00%**	**0,00%**	**4,81%**	**0,00%**	**0,00%**	**4,81%**

Please note that the amounts for fees and charges mentioned in the table above are based upon the recovery orders/invoices sent. For budgetary purposes, the amount of the recovery orders cashed is taken into account.

1.4.3. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

N/A

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

In accordance with Article 27 (6) of the EMA Financial Regulation (based on the Framework Financial Regulation), the budgetary authority shall adopt the establishment plan of the Agency. The Agency informs its partner DG (DG SANCO) of its budgetary and staffing needs for n+2 with its annual financial statement.

The EMA is financed at 80-85% by fees from the pharmaceutical industry and at 15-20% by an EU balancing contribution. The Agency must be enabled to recruit sufficient staff, financed by fee income, to process the applications for which fees are paid.

1.5.2. Added value of EU involvement

As indicated in recital 21 of Regulation (EC) No 726/2004, the Agency's budget should be composed of fees paid by the private sector and contributions paid out of the Community budget to implement Community procedures.

1.5.3. Lessons learned from similar experiences in the past

N/A

1.5.4. Coherence and possible synergy with other financial instruments

N/A

1.6. Duration and financial impact

☑ Proposal/initiative of **unlimited duration**

– Implementation from 2013

– followed by full-scale operation.

1.7. Management mode(s) envisaged[10]

☐ **Centralised direct management** by the Commission

☑ **Centralised indirect management** with the delegation of implementation tasks to:

– ☐ executive Agencies

– ☑ bodies set up by the Communities[11]

– ☐ national public-sector bodies/bodies with public-service mission

– ☐ persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

☐ **Shared management** with the Member States

☐ **Decentralised management** with third countries

☐ **Joint management** with international organisations (**to be specified**)

If more than one management mode is indicated, please provide details in the 'Comments' section.

Comments

[10] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

[11] As referred to in Article 185 of the Financial Regulation.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

N/A

2.2. Administration and controls

2.2.1. Risk(s) identified

N/A

2.2.2. Control method(s) envisaged

The Agency's accounts will be submitted for the opinion of the Court of Auditors, and subject to the discharge procedure. The Commission's Internal Audit Service will be the agency's internal auditor.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

The Agency is subject to monitoring by the Anti-Fraud Office.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

The increase in the EMA budget expenditure to finance 21 additional posts for the establishment plan as of 2013 will be fully covered by the fees paid by the industry.[12]

[12] For more information, see Annex 1.

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line Number [Description…..….]	Type of expenditure Differentiated/Non-differentiated appropriations [13]	Contribution from EFTA countries [14]	from candidate countries[15]	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
1a	17 03 10 01 – Title 1 and 2 European Medicines Agency (EMA) – Expenditure on administrative management	NDA	YES	No	No	No

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

The appropriations required for budget line 17.03 10 01/02/03 European Medicines Agency (EMA) remain unchanged.

EUR million (to three decimal places)

Heading of multiannual financial framework:	Number 1a	Competitiveness for growth and employment				
DG SANCO			Year 2013[16]	Year 2014	Year 2015	TOTAL
TOTAL appropriations under HEADING 1a of the multiannual financial framework	Commitments	=4+ 6	N.A	N.A	N.A	N.A
	Payments	=5+ 6	N.A	N.A	N.A	N.A

3.2.2. Estimated impact on operational appropriations

– ☑ The proposal/initiative does not require the use of operational appropriations

[13] DA= Differentiated appropriations / NDA= Non-differentiated appropriations.
[14] EFTA: European Free Trade Association.
[15] Candidate countries and, if applicable, the western Balkan potential candidate countries.
[16] Year N is the year in which implementation of the proposal/initiative starts.

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

– ☑ The proposal/initiative does not require the use of administrative appropriations

3.2.3.2. Estimated human resources requirements

– ☑ The proposal/initiative does not require the use of human resources

No additional human and administrative resources will be needed in DG SANCO as a result of this Legislative Financial Statement.

3.2.4. Compatibility with the current multiannual financial framework

– ☑ Proposal is compatible with the current multiannual financial framework.

No change in appropriations for the agency's contribution on budget line 17.0310. Additional staffing will be financed by Agency's own resources financed by fees from pharmaceutical industry.

3.2.5. Third-party contributions

– ☑ Proposal/initiative does not provide for cofinancing by third parties

EFTA contribution is due on the EU subsidy to the EMA, which is not impacted by the current proposal

– The proposal/initiative provides for the co-financing estimated below:

3.3. Estimated impact on revenue

– ☑ Proposal has no financial impact on revenue.

Annex 1: Indicative Budget, detailed description of additional posts and staffing forecast

1. Indicative Budget

The agency's indicative budget can be summed up as follows:

Income	**2012**	**2013**	**Expenditure**	**2012**	**2013**
Fees+Charges	182.255	190.370	Title 1	75.046	80.662
EU subsidies	38.841	39.230	Title 2	32.700	36.199
Other	1.393	1.474	Title 3	114.743	114.213
Total income	**222.489**	**231.074**	**Total Cost**	**222.489**	**231.074**

Expenditure titles 1 and 2 correspond to a revised total number of staff of 611 temporary agents (TAs), 125 contract agents (CAs) and 15 seconded national experts (SNEs) for 2013.

2. Summary of the number of staff requested

While asking for the increase of the staff requests for 2013, EMA has taken account of the fact that 2013 is the first year of application of the 5% staff reductions over five years as per the current proposal for the revised Staff Regulations (=1%/year).

As a consequence of the above, for 2013 EMA requests 21 additional posts with the following justification:

***Maximum** staffing in FTE*	**2012**	**Reduction 1% as per instruction**	**Increase in fee activities 5.9%**	**2013**	**Difference 2013-2012**
Fee related posts	457	-5	27	479	22
Non-fee related posts	133	-1		132	-1
Total Posts	**590**	**-6**	**27**	**611**	**21**
Contract Agents (by year-end)	132			125	-7
National Experts (by year-end)	15			15	0
Total staffing	**737**			**751**	**14**

EMA has applied the required 1% reduction in posts to both fee-related and non-fee related activities and has also reduced the number of Contract Agents.

EMA has not received any new posts for increases in fee-related activities in 2011 and 2012. For 2012 only 23 posts were agreed for the implementation of the Pharmacovigilance legislation.

In calculating staffing requirements for 2013, despite an estimated increase in fee related workload over 16% (compared to 2010) only the average fee–related workload increase between 2010 and 2012 (5.9%) has been taken into account (as shown in the table in point 1.4.3. b/). Estimated workload increases for the DB will have to be covered by internal staff re-allocation and process improvements, and by using Contact Agents when necessary and possible.

3. Detailed description of additional posts

EMA is financed at 80-85% from fees from the pharmaceutical industry for services provided and at 15-20% by a balancing subsidy from the European Union. Increases in fee-related workload need to be reflected with increases in staff if these increases are not just temporary but long-term.

The detailed description of the additional posts requested as well as the justification for each of the posts is shown below. For information purposes, the annual average costs, including overheads, of an AD and AST staff member are estimated at 173.000 and 110.000 EUR respectively. As the EMA staff

is increased with 17 AD posts and 4 AST posts (this split is built on the actual EPP of the agency, adapted with 10% flexibility), the total additional annual cost is estimated at 3 381 000 EUR. However, the number of contract agents is decreased by 7. At an average cost of 105 000 EUR per contract agent, the decrease represents 735 000 EUR. The net impact of the staff changes is thus 2 646 000 EUR, fully financed by fees.

Of the total 21 posts requested 15 are for the direct operational units, Patient Health Protection (P), Human Medicines Development and Evaluation (H) and Veterinary Medicines and Product Data Management (V). Two posts are for the Information and Communications Technology (I) unit, directly dealing with product related databases.

Further four posts are for Administration (A) and Directorate (D). In this context it needs to be noted that support staff at the Agency is split for fee-related and non-fee related support as per the proportion given by the activity-based time recording system in the Agency and the staff requests for additional support staff is linked to the increases in fee-related activities.

Unit	2012 Total Posts	Posts requested			Post Justifications
P	**161**	**6**	1	AD6	To provide scientific and procedural support in the management of Community referrals and Opinions on scientific matters, in particular with regard to: • implementation of a robust control system to ensure the quality of the output and improvements in efficiency of procedures • increase in the number of referrals in view of the effect of the Mediator case in France • increase in the number of safety referrals, as a result of the revised legislative proposals from the European Commission for art. 107i procedures which foresee in a widening of the scope.
			1	AD5	To prepare the replies to the increasing number of requests for access to documents relating to referral procedures, mainly in relation to the identification of documents concerned and identification of content to be redacted in each document. This has become a permanent task in 2011, not only because of the number of requests, but also the amount/size of documents being requested (i.e. clinical trials reports) and because of the high public impact of the procedures. Access to documents — **2009**: Not tracked; **2010**: 16; **2011**: 38; **2012 est.**: 40; **2013 est.**: 42 Request — **2009**: Not tracked; **2010**: 1,421; **2011**: 15,325; **2012 est.**: 16,000; **2013 est.**: 18,000 Pages released — **2009**: Not tracked; **2010**: -; **2011**: > 800h; **2012 est.**: > 800h; **2013 est.**: > 900h Hours spent by Section
			1	AD5	To provide regulatory and procedural advice in relation to the high and increasing number of core activities for products and projects where an increase in the range and complexity of the procedures and project involvement is seen, in particular for the quality of opinions exercise, the increasing number of referrals where a high level of regulatory support needs to be provided.
			1	AD8	To support procedural work related to the coordination of mainly GCP inspections. Number of inspections — **2009**: 58; **2010**: 62; **2011**: 64; **2012 est.**: 65; **2013 est.**: 70 GCP — **2009**: -; **2010**: 5; **2011**: 9; **2012 est.**: 9; **2013 est.**: 10 PhV — **2009**: 0; **2010**: 4; **2011**: 2; **2012 est.**: 2; **2013 est.**: 5 GLP

<table>
<tr><th>Unit</th><th>2012 Total Posts</th><th colspan="3">Posts requested</th><th>Post Justifications</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>To improve triggering of GCP inspections, in particular in relation to clinical trials conducted in third countries but also based on better evaluation of inspection intelligence and of information received from applicants in the application dossier.
• To improve follow-up of serious inspection findings with CHMP and with NCAs/inspectors and to the sponsor/applicant.
• To contribute to maintenance of information in scientific memory and corporate GXP inspection findings database.
• To contribute to capacity building for inspectors.
• To support potential use of penalties regulation in relation to PhV inspection findings.</td></tr>
<tr><td></td><td></td><td></td><td>1</td><td>AST1</td><td>To address the following tasks:
• Potential increase of PD notifications due to new parallel distributors: there is a significant increase in the number of new parallel distributors submitting notifications to the Agency (20 in 2011) due to the process improvements. Even though that the "traditional" parallel distributors are submitting a similar number of notifications, it is expected that the new ones will increase the figures around 10-15% in 2013.
• Annual update for PD: there are currently no fees for notifications of a change. A new procedure involving an annual update with a "Do&Tell" system will be introduced in 2013 with a fee. Every annual update will be more complex and will attract a fee (currently changes don't attract fees)
• Increased workload in financial transactions: due to the above points it is necessary for the high level of business and financial transactions of the Sector and integration of the business and financial systems to reduce or where possible eliminate manual transactions and reprocessing of information.
<table><tr><th></th><th>2009</th><th>2010</th><th>2011</th><th>2012 est.</th><th>2013 est.</th></tr><tr><td>PD (initial notifications)</td><td>2,247</td><td>2,599</td><td>2,551</td><td>2,600</td><td>2,800</td></tr><tr><td>Certificate</td><td>2,144</td><td>2,396</td><td>3,104</td><td>3,200</td><td>3,400</td></tr></table>The increased workload in both PD and Certificates and the potential new fees (i.e. Annual update for PD and Urgent Certificates) will multiply by 2 the financial transactions. However, the estimated revenue for both activities in 2013 compared with 2010 will be:
• PD: 2010 (5.4M Euros). 2013 (7.8M Euros)
• Certificates: 2010 (1.2M Euros). 2013 (2.2M Euros)
Total in 2013=10M Euros (vs 6.6M in 2010, 50% increase)</td></tr>
<tr><td></td><td></td><td></td><td>1</td><td>AD5</td><td>Cooperation in the coordination of inspections in third countries (Art. 111.1). Due to the continuing increase in globalisation of manufacturing and its departure from EU to third countries such as Singapore, Malaysia, Indonesia, Korea, India and China (and others can be expected to increase such as Brazil, and perhaps Russia) there will be a greater need for EU inspection of non-EU manufacturing sites. There is also a strong need to ensure best use of available inspection resource in the Community, to avoid duplication and to improve risk based selection and prioritisation of inspection targets. The EU Regulatory Network seeks the assistance of EMA in achieving this.</td></tr>
<tr><td>H</td><td>184</td><td>6</td><td>2</td><td>AD5</td><td>Two scientific administrators
• For increased complexity and number of procedures, including IMI-related activities and biomarker qualification
<table><tr><th></th><th>2009</th><th>2010</th><th>2011</th><th>2012 est.</th><th>2013 est.</th></tr><tr><td>Scientific advice and protocol assistance requests</td><td>388</td><td>400</td><td>433</td><td>493</td><td>543</td></tr></table></td></tr>
<tr><td></td><td></td><td></td><td>2</td><td>AD5</td><td>Two scientific administrators
• For increase in maintenance procedures and clinical/non-clinical post-authorisation activities.</td></tr>
</table>

Unit	2012 Total Posts	Posts requested			Post Justifications
					• For increasing number of PSUR assessments • Change in compilation, format, submission and assessment of PSURs and increased CHMP-PRAC interactions • Qualitative and quantitative increase in workload related to variation procedures following the entry into force of Variations Regulation (EC) No 1234/2008 **2009 2010 2011 2012 est. 2013 est.** CAPs (maintenance) 442 520 569 640 730 Type IB (C/NC) - 233 235 337 387 Type II (C/NC) 708 618 530 522 522
		1	AST1		One assistant • For coordination of maintenance procedures (e.g. Article 61(3) notifications, transfer of MAs, etc) and support to clinical/non-clinical post-authorisation activities (29% increase in CAPs from 2009 to 2011). • For increased capacity of procedures management to transfer administrative workload from AD to AST staff **2009 2010 2011 2012 est. 2013 est.** CAPS (maintenance) 442 520 569 649 730
			1	AD8	One experienced scientific administrator • Activities to strengthen the scientific secretariat and to support the committees (CHMP, CAT, PDCO, SAWP) in the field of biostatistics and methodology in the context of clinical trials for initial marketing authorisation applications, post-authorisation extensions, and paediatric procedures • Peer review of biostatistical aspects in assessment reports; pilot activity for assessment of raw biostatistical data **2009 2010 2011 2012 est. 2013 est.** New initial MAAs 96 91 100 112 112
V	**61**	**3**	1	AD6	One Scientific Administrator will be required due to the increased number of requests for scientific advice (ca. 150% increase since 2009), requests for MUMS classification, higher demands to support increasing numbers of initial applications from SME companies or for MUMS products. To be able to cope with the increasing number of applications for new technology products, which are expected in the areas cell and tissue products, nanotechnology medicinal products also for veterinary applications, other innovative products are certain immunologicals developed for food-producing animals, it is considered necessary to recruit one scientific administrator with experience in dealing with such new technology products. **2009 2010 2011 2012 est. 2013 est.** Scientific Advice 11 21 26 26 26 MUMS/Limited markets classification 8** 23 21 24 (tbc) Initial Applications 15 18 11 12 14 Type I/II 113 150 282 327 tbc Referrals submitted (of which class referrals) 9 (4) 12 (1) 12 (3) 12 (tbc) 14 (tbc)

Unit	2012 Total Posts	Posts requested			Post Justifications
			1	AD5	One Scientific Administrator for providing input regarding safety issues (Part 3, consumer safety – withdrawal periods, user safety, environmental safety and resistance development of antimicrobials) for applications related to: scientific advice, marketing authorisation and referrals (the majority of referrals relate to safety issues). **2009 2010 2011 2012 est. 2013 est.** Full MRL applications 4 4 1 3 2 Extensions/Modifications 2 4 7 4 4 Extrapolations 0 2 5 2 4 Moreover, the workload in this area is also related to increasing demand on providing technical input and advice for the EU in international fora in particular Codex Alimentarius, and due to increasing demand for MRL reviews/extensions for old substances to adjust to modern requirements for residue control and international trade.
			1	AST1	Financial initiating agent and workflow manager, to support the volume of registration and distribution of incoming electronic applications registration distribution and financial initiation activities. Integration of processes into SIAMED and SAP. **2009 2010 2011 2012 est. 2013 est.** Scientific Advice and Protocol Assistance 365 409 433 493 543 Initial evaluation + Line extensions 124 116 131 132 134 Re-registration of ATMPs 0 2 6 2 tbc Variations 2227 2598 5008 4920 5170 Arbitration, Referrals and Opinions on scientific matters 43 46 28 50 52 Transfers 20 20 26 15 10 Renewals 58 61 67 48 46 Scientific Services (incl. PMF, VAMF & ATMP certification; excl. Art. 58 opinions) 26 32 33 27 28 Annual Fees 431 520 570 650 731
A	**86**	**2**	1	AD5	The Budget Section deals with the establishment and monitoring of the Agency's long- and short-term budgets as well as project budgets; activity based budgeting and costing and the coordination of financial transactions and support to of financial actors throughout the Agency. - Strengthening the financial planning, reporting and control environment within the Agency will require the Budget section to play an increasingly pro-active role in working in partnership with the operational units in the effective, efficient and economic management of our financial resources. The potential savings generated by these activities is difficult to quantify in advance but will far outweigh the cost of ensuring the Budget section is properly resourced to provide this service effectively. - With the implementation of various pieces of pharmaceutical legislation the EMA Fee Regulation and its Implementing Rules need continuous monitoring and revision to ensure the financing of the Agency. - With the implementation of SAP_FIN maintenance business support is required. Therefore in 2012 one post was dedicated to this task with the effect that the Budget section is unable to progress with important initiatives, such as Activity Based Costing, within existing resources. **2009 2010 2011 2012 est. 2013 est.** Budget (EUR'000) 194 389 208 387 208 863 222 489 240 316
			1	AST3	Increased workload in recruitment and Personnel Administration due to staff increases and changes in procedures. One AST is required to:

<table>
<tr><th>Unit</th><th>2012 Total Posts</th><th colspan="3">Posts requested</th><th>Post Justifications</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>
• Handle workload for family allowance processing, performance/probation report administration and contract agent examinations. The larger number of TA and CA staff increases administrative workload in Personnel.
• Probation Reports: EMA is planning to introduce a Long-term Contract Agency Policy, foreseeing that every long-term Contract Agent will have to absolve a probation period, and this will affect the number of probation reports in 2012 and 2013 in addition.
• In addition required as Assistant to the 2 Personnel Administrator, increase of workload due to the following:.
- Increase in difficult staff cases, problematic performance management staff cases and need to closely support managers. (10 such cases in 2011 all very time consuming)
- Follow up for Art 16 issues for separated staff and subsequent employment linked to conflict of interests.
- Secretary to Joint Committee for Art 16 and Disciplinary Committee.
<table>
<tr><th></th><th>2009</th><th>2010</th><th>2011</th><th>2012 est.</th><th>2013 est.</th></tr>
<tr><td>Nursery Allowance</td><td>64</td><td>89</td><td>100</td><td>120</td><td>140</td></tr>
<tr><td>Education allowance applications (B+C)</td><td>210</td><td>180</td><td>200</td><td>230</td><td>250</td></tr>
<tr><td>Education contribution payments</td><td>276</td><td>323</td><td>357</td><td>440</td><td>480</td></tr>
<tr><td>PER + 360° reports</td><td>186</td><td>234</td><td>261</td><td>380</td><td>450</td></tr>
<tr><td>Probation reports</td><td>109</td><td>116</td><td>75</td><td>90</td><td>120</td></tr>
<tr><td>CA testing procedures</td><td>48</td><td>47</td><td>70</td><td>85</td><td>95</td></tr>
</table>
</td></tr>
<tr><td rowspan="2">D</td><td rowspan="2">38</td><td rowspan="2">2</td><td>1</td><td>AD5</td><td>A lawyer to address:
• new responsibilities assigned by various new pieces of legislation.
• likely increase in litigation in the core business and in the field of transparency/ access to documents, and procurement and contracts.
• implementation of the penalties regulation which assigns the task to conduct investigation.</td></tr>
<tr><td>1</td><td>AD6</td><td>A Press Officer is needed to support crisis communication activities; including crisis communication plans and coordination with the European medicines network, drafting relevant communication material, and responding to queries from journalists and other stakeholders in writing and orally, coordination of interviews and press briefings. The post will carry out new tasks: increased volume of safety communications (more referrals, more safety information on nationally authorised products), support to national authorities with rapid communication and coordinating safety announcement, etc.</td></tr>
<tr><td>I</td><td>60</td><td>2</td><td>2</td><td>AD5</td><td>As projects for the development of new information systems are completed, the information systems must be quality and performance tested then operated, maintained and supported. 2 AD posts are required:
1 AD to provide support for an increasing number of applications, in particular with regards to:

SIAMED II, Since SIAMED II will be finalised, the development team could be dismantled, requiring new skills from the support team (Flex3)

• Central Repository
• eAF
• eudraGMP 4
• Eudralink
• Records Management

1 AD as 15 Applications to be added in the portfolio of tested applications

The tables below show a number of key workload metrics. It should be noted that the requested increases in staff numbers would help reduce the risk of</td></tr>
</table>

Unit	2012 Total Posts	Posts requested			Post Justifications
					dependency on external contractors whilst also saving money.

	2009	2010	2011	2012 est.	2013 est.
New Application Releases	N/A*	12	11	10	8
Maintenance releases	N/A*	79	89	100	112
“green light” requests	N/A*	91	100	110	120
Internal users	845	850	900	923	946
External users	17000	19,000	22,000	25,000	29,000
CAST analyses	N/A*	17	18	22	25
functional tests	5*	41	42	50	60
Performance tests	1*	37	44	49	55
INFRA Tickets (user support)	13236**	79,000	82,425	87,000	92,000

* These figures are either not available or reflect Q4 2009 only as these started to be captured, by the relevant sections, following the Agency’s organisation re-structure effective from Sept-2009;
** Only collected from 1-March-2009

4. Staffing forecasts

Staffing forecasts are as follows :

Function group and grade	Posts					
	2013		2012			
	Authorised under the Union budget		Actually filled as at 31 December 2011		Authorised under the Union budget[17]	
	Permanent	Temporary	Permanent	Temporary	Permanent	Temporary
AD 16				1		1
AD 15		4		4		4
AD 14		6		5		6
AD 13		8		7		7
AD 12		38		36		36
AD 11		38		35		36
AD 10		36		30		32
AD 9		40		37		38
AD 8		47		43		46
AD 7		45		39		49
AD 6		42		35		36
AD 5		42		32		35
AD total		*346*		*304*		326
AST 11		2		2		2
AST 10		5		4		5
AST 9		7		8		7
AST 8		13		13		13
AST 7		20		19		20
AST 6		33		34		34
AST 5		35		34		35
AST 4		51		48		51
AST 3		39		32		39
AST 2		40		37		40
AST 1		20		16		18
AST total		*265*		*247*		264
Grand total		**611**		**551**		**590**
Total staff	**611**		**551**		**590**	

[17] The Establishment plan 2012 has been revised as allowed by the Art.32 of the Commission Regulation 2343/2002 of 19 November 2002 and the actual establishment plan for 2012 consists of 329 AD and 261 AST. The distribution between the new AD and AST grades is related to the actual establishment plan of the agency which takes into account the 10% flexibility rule.

Grade	New posts (per grade)		
	Perm	Temp - LT	Temp - ST
AD8	0	2	
AD6	0	3	
AD5	0	12	
Total AD	**0**	**17**	**0**
AST3	0	1	
AST1	0	3	
Total AST	0	**4**	**0**
Overall Total	0	**21**	**0**