



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 October 2010
EMA/MB/603657/2010

Transfers of appropriations in the budget 2010 in accordance with Article 23 (2) of the Financial Regulation

Management Board meeting 7 October 2010

Background note

Article 23(2) of the EMA Financial Regulation specifies that the Executive Director may propose to the Management Board transfers of appropriations from one title to another for transfers beyond the limit of 10 % of the appropriations for the financial year shown on the line from which the transfer is made.

With Amending Budget 01-2010 (EMA/MB/47425/2010) the Management Board was informed that a transfer would be requested if the appropriation on 'Provisional appropriation' could be utilised.

Matters for consideration

With the Budget Monitoring as of 31 August 2010 the Agency has evaluated its budgetary situations. As a result, the Agency is now prepared to release part of the provisional appropriation that was set aside for possible variations in fee income with Amending Budget 01-2010. The focus on projects to be financed was to bring forward agreed ICT projects that might be insufficiently financed in 2011 due to reductions in EU contributions for 2011 as indicated by the Budgetary Authority.

Please see Annex I for the items to be financed with the proposed transfer. Annex II sets out the transfer by budget item.



Area	Amount EUR	Explanation
EudraVigilance Data Analysis System (EVDAS)	438,000	Improved functionality of data analysis of adverse event reports.
New EudraVigilance Human Data Warehouse	1,323,000	Integration and consolidation of current EV human Data Warehouse into Eudra Data Warehouse.
EUTCT - (International Standardisation)	1,324,000	The EU system for controlled terminologies needs to be upgraded to incorporate new international standards (ISO) for the identification of medicinal products, and for electronic submission of adverse event reports.
EudraVigilance Transactional Human v 8.X	644,000	The arrival of international data standards (ISO) for the identification of medicinal products, and for electronic submission of adverse event reports, and the entry into force of new pharmacovigilance legislation in 2012 requires initiation of work on a new version of EudraVigilance.
UPI (Unique Product Identifier)	37,000	Urgent business requirement to harmonise product-related information processing.
Electronic signatures	318,000	Required to complete the transition to all-electronic submission processes.
Regulation (EC) 1049-2001	185,000	The legal requirement for enabling public access to documents has not yet addressed by the Agency and highlighted repeatedly by audits (CoA, IAS).
Contingency for all projects above (+/- 3%)	131,000	
Total	4,400,000	

Decision on transfer of appropriations TFT 07-2010

THE MANAGEMENT BOARD,

Having regard to Council Regulation (EEC) No 726/2004 of 31 March 2004, and in particular Article 68(1) thereof,

Having regard to the Financial Regulation applying to the European Medicines Agency, and in particular Article 23(2) thereof,

Whereas the Executive Director shall implement the Agency's budget,

Whereas the Executive Director may propose to the Management Board transfers of appropriations from one title to another for transfers beyond the limit of 10 % of the appropriations for the financial year shown on the line from which the transfer is made (as referred in Article 23(1)),

Whereas consideration is given to the requirement for appropriations in 2010

HAS DECIDED

Article 1

The following appropriations are transferred between titles of the Agency's 2010 expenditure budget:

Item	Description	Initial appropriation	Current appropriation	Commitment 30/09/2010	Transfer 23(2)	Future appropriation
		EUR	EUR`	EUR	EUR	EUR
Title 2 - Buildings, equipment and miscellaneous operating equipment						
Chapter 21 - Expenditure on data processing						
2115	Analysis, programming and technical assistance for the operation of the Agency	2,674,000	2,621,000	2,605,941	+540,000	3,161,000
2125	Analysis, programming and technical assistance for specified programmes	7,385,000	11,543,000	9,727,965	+3,860,000	15,403,000
Title 9 - Provisional appropriation						
Chapter 90 - Provisional appropriation						
9000	Provisional appropriation	p.m.	5,369,000	0	-4,400,000	969,000
	Total				0	

Article 2

The Executive Director shall implement this decision.

Article 3

The decision shall take effect on 7 October 2010.

Signature on file

Pat O' Mahony

Chairman Management Board