EUROPEAN PARLIAMENT

2004 *2009*

Committee on the Environment, Public Health and Food Safety

2008/2262(DEC)

12.2.2009

OPINION

of the Committee on the Environment, Public Health and Food Safety

for the Committee on Budgetary Control

on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2007
(SEC(2008)2359 - C6-0435/2008 - 2008/2262(DEC))

Rapporteur: Péter Olajos

PA_NonLeg

SUGGESTIONS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on Budgetary Control, as the committee responsible, to incorporate the following suggestions in its motion for a resolution:

1. Underlines that the European Medicines Agency's (EMEA's) budget is financed both from the EU Budget and mainly by fees paid by pharmaceutical industry applicants for obtaining or maintaining a Community marketing authorisation. However notes that the EC general contribution increased by 24,48 % from 2006 to 2007 and represents 24,13 % of the total 2007 revenue; is aware in this context of newly assigned tasks arising from the new Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and an increase in the orphan drugs budget line;

2. Welcomes the efforts of the EMEA to provide more scientific advice at early stages of the development of new medicines as well as the introduction of measures to accelerate the assessment of medicines that are of critical importance to public health and to accelerate the development and implementation of Telematics programmes;

3. Considers the EMEA as a source of important scientific advice, science-based recommendations, best practice for medicines evaluation and supervision in Europe and welcomes the contributions to the Commission and the Member States towards the harmonisation of regulatory standards at international level;

4. Encourages the EMEA to continue its action in the Orphan Medicines field; discourages, however, the decrease in the Orphan Medicines contribution, mainly due to a change in the policy for orphan fee reductions resulting from the flexibility provided by the Council Regulation (EC) No 1905/2005 on fees, which nonetheless results in (generates) a reduction of 26,25 % in 2007 compared to 2006;

5. Emphasises the role of the EMEA to monitoring the safety of medicines through the pharmacovigilance network; calls, however, for constant improvement of the vigilance level;

6. On the basis of the data available, is of the opinion that the Executive Director of the European Medicines Agency can be granted discharge in respect of the implementation of the budget of the EMEA for the financial year 2007.

RESULT OF FINAL VOTE IN COMMITTEE

Date adopted	10.2.2009
Result of final vote	+: 44 –: 0 0: 1
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Pilar Ayuso, Irena Belohorská, Maria Berger, Johannes Blokland, John Bowis, Martin Callanan, Magor Imre Csibi, Chris Davies, Avril Doyle, Mojca Drčar Murko, Elisabetta Gardini, Matthias Groote, Françoise Grossetête, Satu Hassi, Gyula Hegyi, Marie Anne Isler Béguin, Christa Klaß, Eija-Riitta Korhola, Holger Krahmer, Urszula Krupa, Peter Liese, Linda McAvan, Péter Olajos, Miroslav Ouzký, Vladko Todorov Panayotov, Vittorio Prodi, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Amalia Sartori, Carl Schlyter, Horst Schnellhardt, Richard Seeber, María Sornosa Martínez, Antonios Trakatellis, Thomas Ulmer, Åsa Westlund
Substitute(s) present for the final vote	Iles Braghetto, Jutta Haug, Hartmut Nassauer, Bart Staes, Andres Tarand
Substitute(s) under Rule 178(2) present for the final vote	Emanuel Jardim Fernandes