

DECISION
No. 32/18.11.2010

**on approval of amendment of Scientific Council Decision No. 22/03.09.2010
on approval of the Detailed guideline on the request to the competent
authorities for authorisation of a clinical trial on a medicinal product for
human use, notification of substantial amendments and declaration of the
end of the clinical trial in Romania**

The Scientific Council of the National Agency for Medicines and Medical Devices, established based on Minister of Health Order No. 1123/18.08.2010, in accordance with Art. 12(5) of Government Ordinance No. 734/2010 regarding the organisation and operation of the National Agency for Medicines and Medical Devices and with Art. 8 of the Regulation on the organisation and operation of the Scientific Council, hereby adopts, through written procedure, the following

DECISION

Sole article. – The amendment of Scientific Council Decision No. 22/03.09.2010 on approval of the Detailed guideline on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, notification of substantial amendments and declaration of the end of the clinical trial in Romania is approved, as follows:

- under Chapter II, Art. 16, (2) is amended and shall read as follows:
“Day 0 is the day of receipt of the request”;

- under Chapter II, Art. 95, (5) is amended and shall read as follows:
“confirmation of fee payment according to the fee for assessment of documentation for authorisation of conduct of clinical trials on medicinal products for human use, in line with provisions of Order of the Minister of Public Health No. 716/11.06.2009 and with the payment order”.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim