ADDENDUM TO "I/A" ITEM NOTE
from: General Secretariat of the Council
to: COREPER /COUNCIL
No Cion prop.: 7529/08 MI 94 SAN 44 AGRILEG 40 ECO 39 ENT 53 CODEC 356
– Adoption of the legislative act (LA + S)


We note with regret that there are shortcomings in the German translation of the legal text prepared by the Council Legal Service, which does not take sufficient account of the requirements of specialist and legal usage in German-speaking countries; these shortcomings have already been pointed out in connection with Regulation (EC) No 1394/2007 of the European Parliament and of the Council on advanced therapy medicinal products. In particular, the translation of the English term "Marketing Authorisation" as "Genehmigung für das Inverkehrbringen" is not customary in German specialist and legal usage and might sometimes even give rise to misunderstandings.
"Zulassung" is the only accurate translation of this English term which would be properly understood by all those working in the sector. This term will therefore continue to be used in Germany in future, even in matters covered by the Directive.

Given that the translation we recommend has been used in Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, which is based on Directive 2001/83/EC, the terminology chosen for this Directive makes the rules on variations in marketing authorisations for medicinal products even more confusing.

Germany will continue to urge that terms reflecting German legal usage be used in the German language versions of future proposals establishing or revising European law on medicinal products and again calls on the Council to take this into account when preparing future legislation.