COUNCIL OF
THE EUROPEAN UNION

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(OR. fr)

Interinstitutional file:
2008/0045 (COD)

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SAN 103
AGRILEG 62
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ENT 104

"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
Directive 2001/82/EC and Directive 2001/83/EC as regards variations to the terms
of marketing authorisations for medicinal products [first reading]
– Adoption of the legislative act (LA)

1. On 6 March 2008 the Commission sent the Council the above proposal ¹, based on Article 95
of the EC Treaty.

2. The European Economic and Social Committee delivered its opinion on 9 July 2008 ².

3. In accordance with the joint declaration on practical arrangements for the codecision
procedure ³, informal talks were held between the Council, the European Parliament and the
Commission with a view to reaching agreement at first reading.

¹ 7529/08.
4. The European Parliament delivered its first-reading opinion on 22 October 2008, passing 18 amendments to the Commission proposal. The outcome of voting in the European Parliament \(^1\) reflects the compromise agreement reached between the institutions and should thus be acceptable to the Council.

5. The Permanent Representatives Committee is therefore asked to confirm agreement and advise the Council to adopt the Directive, as set out in PE-CONS 3713/08, as an "A" item at a forthcoming meeting.

After being signed by the President of the European Parliament, the President of the Council and the Secretaries-General of the two institutions, the legislative act will be published in the Official Journal of the European Union.

\(^1\) 14662/08.