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RESTREINT UE

NOTE FOR THE ATTENTION OF THE 133 COMMITTEE

SUBJECT: ***EU-India FTA negotiations: Latest texts on goods, SPS and IPR***

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OBJECTIVE: For information

REMARKS: Member States will find attached for information (and comments if they wish) the following negotiating texts for the FTA negotiations with India:

1) Trade in goods: Consolidated text following discussions held at the 5th round of negotiations (Member States already received an earlier version).

2) SPS: EC textual proposal (Member States were already consulted on the text via the Potsdam Group).

3) IPR:
(a) Consolidated text of 9 September 2008 prepared by EC following the 5th round of negotiations (Member States already received an earlier version of the text).
(b) Indian comments on the consolidated text of 9 September which considerably lower the overall level of ambition; this will be addressed at the next round.

These texts will be discussed at the next round of negotiations to be held from 17-19 March in Delhi. Further oral information about the preparations of the round will be presented in the 133 Committee of 27 February.

Please note that the documents are labelled as "RESTREINT UE" and should be treated accordingly.

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Article 10

[**EC** to provide a revised text]

[***Protection of Data Submitted to Obtain a Marketing Authorisation***

1. The Parties will implement a comprehensive system to guarantee the confidentiality, undisclosed and non-reliance of data submitted for registration purpose of medicinal products.

2. The Parties will enact and implement legislation ensuring that any information submitted to obtain marketing approval, i.e., registration, of pharmaceutical products will remain undisclosed to third parties and benefit from a period of [...] years of protection against unfair commercial use starting from the date of grant of marketing approval in the Parties, i.e. that during this period of protection, no person or entity (public or private), other than the person or entity who submitted such undisclosed data, will without the explicit consent of the person or entity who submitted this data, rely directly or indirectly on such data in support of an application for medicinal product approval/registration.

3. During this [...]-year period, any subsequent application for marketing approval or registration would not be granted, unless the subsequent applicant submitted his/her own data (or data used with authorization of the right holder) meeting the same requirements as the first applicant. Products registered without submission of such data would be removed from the market until the requirements were met.

4. In addition, the [...]-year period referred shall be extended to a maximum of [...]years if, during the first [...] years after obtaining the registration in the Parties, the registration

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holder obtains an authorisation for one or more new therapeutic indications which are considered of significant clinical benefit in comparison with easting therapies.]

[EU Note: Similar provision on data protection for chemical products will be inserted]

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