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To:	Delegations
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Subject:	Proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC <i>- Examination of the Presidency compromise text</i>

In document ST 13503/23 INIT, on page 13, Article 3(22) should read as follows:

- (22) ‘clinical outcome **monitoring** ~~monitoring~~ **registration**’ means **evaluation of the health of a SoHO recipient for the purpose of following-up the results of a SoHO preparation application, maintaining care and demonstrating safety and effectiveness** ~~recording information on results from clinical outcome monitoring as referred in Article 41, including transferring such information to other registries~~ evaluation of the health of a SoHO recipient for the purpose of monitoring the results of a SoHO preparation application, maintaining care and demonstrating safety and efficacy];