

ANNEX III

SAFETY REPORTING

3. ANNUAL SAFETY REPORTING BY THE SPONSOR

23. The report shall contain, in an appendix, the RSI in effect at the start of the reporting period.
24. The RSI in effect at the start of the reporting period shall serve as RSI during the reporting period.
25. If there are significant changes to the RSI during the reporting period they shall be listed in the annual safety report. Moreover, in this case the revised RSI shall be submitted as an appendix to the report, in addition to the RSI in effect at the start of the reporting period. Despite the change to the RSI, the RSI in effect at the start of the reporting period serves as RSI during the reporting period.

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EU) No 536/2014 of the European Parliament and of the Council, Division 3..