October 2017

Implementation measures by the Commission in the context of Regulation (EU) No 536/2014 – overview and state of play

	Article in Regulation (EU) 536/2014	Type of Commission measure	Title	Target date for adoption/Publication	State of play/Comments
1.	Article 78(7)	Implementing act	Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 *on the detailed arrangements for good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council*	Adopted on 24 March 2017.	Available: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32017R0556
2.	Article 63	Delegated act	Commission Delegated Regulation (EU) 2017/1569 of 23 May 2017 *supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by specifying principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections*	Adopted on 23 May 2017. Published on 16 September 2017.	Available: http://eur-lex.europa.eu/eli/reg_del/2017/1569/oj

3.	Article 63(1)	Commission guidelines	Detailed guidelines on good manufacturing practice for investigational medicinal products	Adopted on 8 December 2017	https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guideline_adopted_1_en_act_part1_v3.pdf
4.	Article 37(4)	Commission guidelines	Commission guidelines on voluntary sharing of raw data	Target date of adoption - end 2018	Inception phase
5.	Article 97	Report	Report to the European Parliament and to the Council on the application of the Regulation	5 years from the day of entry into application of the Regulation	-
6.	Article 44(2)	Implementing act (may provision)	Implementing act on the rules of cooperation of the Member States in the assessment of safety reporting information	-	The Commission will consider, in consultation with Member States, the necessity of an Implementing Act once the Regulation becomes applicable.