Abstract

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Moving towards a global replacement of the animal test for human rabies vaccines by an ELISA: an international collaborative study (BSP148)

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Regulatory texts for human rabies vaccines require that the potency of each final lot is estimated by a mouse challenge assay (NIH test). The NIH test is, among the remaining compendial in vivo assays, one of the most challenging to replace. It is a painful, scientifically disputable, highly variable and costly test that is contrary to the 3R strategy of the European Pharmacopoeia (Ph. Eur.). Despite many efforts, the global replacement of the NIH test by an in vitro assay is hindered by the absence of a common standardised method. One of the latest initiatives is the international study run by the European Partnership for Alternative Approaches to Animal Testing (EPAA). The project identified the currently most promising ELISA method [1]. It is a method which uses highly-characterised monoclonal antibodies, is specific to conformational epitopes responsible for the protection conferred by the vaccines, recognises most virus strains used for vaccine production and discriminates test sub-potent vaccines produced by various methods. With a view to proposing a global replacement of the NIH test, an international collaborative study was set up to evaluate the large-scale transferability and robustness of the selected method. The coordination of the study is ensured by the European Directorate for the Quality of Medicines & HealthCare (EDQM, Council of Europe) in the frame of the Biological Standardisation Programme (BSP) financed by the Council of Europe and the European Union Commission.
The study will include 3 phases: a preparatory Phase 1, a collaborative Phase 2 involving laboratories worldwide testing a common set of samples with various virus strains and potencies with a standardised protocol. Data will be centrally analysed at the EDQM. The Phase 3 of the study will aim at collecting data from commercial batches tested with the standardised protocol. These data will support the evaluation of the applicability of the method to routine testing and of the potency requirements in view of the revision of compendial texts.

[1] Replacement of in vivo human rabies vaccine potency testing by in vitro glycoprotein quantification using ELISA - Results of an international collaborative study. Morgeaux S, Poirier B, Ragan I, Wilkinson D, Arabin U, Guinet-Morlot F, Levis R, Meyer H, Riou P, Shaid S, Volokhov D, Tordo N, Chapsal JM. Vaccine, 2017, 40(5):369-81

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