Public Consultation Paper
Review of Commission Regulation (EC) n° 1234/2008

(European Vaccine Manufacturers comments)

General comments

Company	**General comment** (if any)	**Outcome** (if applicable)
	The EVM members welcome the opportunity to provide feedback to this Consultation regarding vaccine-specific topics and overall support the response provided by EFPIA	

Consultation item n° 5

Do you agree to extend the current system that allows holders to implement certain variations prior to the adoption of the Commission Decision (to the exclusion of those changes with most impact for public health)?

Company	**General comment** (if any)	**Outcome** (if applicable)
	The EVM members agree with the response provided by EFPIA in which it is highlighted that for products typically placed on the market in tender environments, such as vaccines, it is important that the EMA promptly makes the revised product information publicly available on their website following the committee Opinion. Indeed, calls for tender occur only at fixed moments in time, and certain product characteristics that appear in the SmPC, even if they may seem less important for public health, can be crucial as they may be part of the tender specifications (e.g. shelf life, time that a product can be kept out of the fridge).	

Consultation item n° 7

More stable summary of product characteristics. Do you agree with the analysis?

Company	**General comment** (if any)	**Outcome** (if applicable)
	The EVM members agree with the response provided by EFPIA and would like to make some additional vaccine-specific comments. Indeed, it is important to clarify what is meant in the public consultation paper with 'small changes', as there is a risk for subjective interpretation. In the case of vaccines there are regular changes to the section 5.1 Pharmacodynamic properties. These are not to be considered as small changes since in general these concern: • Variations that are imposed on the Company through the follow-up measures that are laid down in the Letter of Undertaking; • Variations that are submitted by the Company upon availability of new results that are considered to be important for the prescriber, for example data on persistence of the immune responses, data on effectiveness, additional data in specific age groups or populations. In addition, as already stressed under consultation item n°5, a system where changes that are considered less important for public health would be implemented less frequently in the "Summary of the Product Characteristics" (SmPC) – and be subject to	

Company	**General comment** (if any)	**Outcome** (if applicable)
	less frequent updates of Commission Decisions - may create a disadvantage for EU based manufacturers: - First, with respect to registration in non-EU countries, in many of which a CPP (Certificate of Pharmaceutical Product) is required based on the SmPC authorised in the EU. - Second, with respect to products which are placed on the market in tender environments, which is often the case for vaccines.	

Consultation item n° 9

Do you think that changes to the procedure in Article 21 of the Variations Regulation are necessary?

Company	**General comment** (if any)	**Outcome** (if applicable)
	In the light of the experience and lessons learnt from the recent H1N1 pandemic, the legal framework provided by Art.21 proved to be flexible enough to allow prompt authorisation of vaccines in an emergency situation. We therefore believe that **no changes are needed to the text of Commission Regulation (EC) No 1234/2008.** It may however be necessary to reconsider some detailed aspects of the practical regulatory procedures for the submission, assessment and authorisation of vaccines in a pandemic setting, as they are today described in EMA guidelines. But we understand that this currently being looked at by the EMA and its relevant scientific committees, and we are looking forward to the opportunity of discussing the revision of these guidelines in joint industry-authority workshops and meetings in the light of the experience of the various stakeholders concerned.	