SBMISSION OF COMMENTS ON LEGISLATIVE PROPOSALS TO STRENGTHEN AND RATIONALISE THE EU SYSTEM OF PHARMACOVIGILANCE (5 DECEMBER 2007)

COMMENTS FROM EUROPEAN VACCINE MANUFACTURERS (EVM)

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GENERAL COMMENTS

EVM welcomes the initiative of the Commission to further strengthen and rationalise EU system of Pharmacovigilance and recognises improvements made in order to simplify current processes and requirements. In general, EVM agrees with EFPIA comments.

However, EVM would like to draw the attention of the Commission on the specificity of vaccines and on its implications in terms of pharmacovigilance:

a. Considering the very nature of vaccination (e.g. prevention), that distinguish vaccines from other medicinal products,
b. Considering the political sensitiveness concerning vaccination issues and the higher sensitivity of the general public to adverse reactions regarding vaccines
c. Considering the importance of paediatric vaccination in EU countries in terms of the total paediatric population exposure
d. Considering the introduction of the proposal (p7) that acknowledges the principle of proportionality in reporting Adverse Reactions,
e. Considering the introduction of the proposal (p7), considering Art 22, Art 101(e), 101 (i) of the revised Dir 2001/83/EC, on Adverse Reaction reports including by patients

EVM acknowledges the necessity to empower patients and to make it possible to self-report side effects of their own medications. Most patients undergoing pharmacological therapy should hopefully also be able to notice a relief or a benefit ("response") to counterbalance experienced side effects. However, for preventive therapies (e.g., vaccines) the situation is different. The benefit will not be immediately obvious to the vaccinated individual (or the parents of a vaccinated child) since it consists of a future or potential protection against disease.

EVM fears that self-reporting of adverse events could easily lead to an accumulation of unrelated observations (cf. like frequent childhood infections) thus generating a false perception of risk in general public. If, or when, a system of self-reporting (and parent reporting) is put in place, it will be crucial to ensure that the report includes necessary information elements (e.g., name and contact details of a family physician) to allow for validation. While this applies generally, to all medicines, it may be particularly relevant to preventive therapies.
Due consideration has to be given by the legislator as to where and by whom the medical evaluation will be made.

COMMENTS ON TEXT		
Precise Reference and page of consultation document	**Comment and Rationale**	**Proposed change**
Article 101e(1) P22	EVM considers that it is unclear whether patient reports are required to be confirmed by a health care professional. Defining causal assessment is also unclear: MAHs are requested to report cases where 'a causal relationship is at least a reasonable possibility', without defining what this means.	To clarify whether the patients report needs a health care professional confirmation. The evaluation of "reasonable possibility" needs to be defined for vaccines.
Article 101e(4) P23		EVM believes that giving patients the opportunity to insert reports into Eudravigilance needs medical filter/triage to ensure that the quality of the data in the Eudravigilance meets high quality standards.

Please feel free to add more rows if needed.