Answers to questions on consequences of EMA's postponement of certain PhV activities on national implementation

1. Do you postpone the implementation of certain provisions in the new PhV legislation due to EMA's postponements?
2. If yes, please describe which provision(s)?
3. If no, why not? And how would you enforce provisions where the underlying procedures are not functioning?

Country	Postponing, yes or no?	If Yes, please describe which provision(s)	If No, why not?
Finland	No		The Finnish national legislation does not detail the European procedures described in articles 107 e, 107 g and 107 n – 107 q.
France	No		The French national legislation does not detail the Europeans procedures of evaluation (procedures described in Articles 107e and 107g regarding the single assessment of PSURs and the parts of Articles 107n to 107q regarding the participation of PRAC); it is regarded as institutional obligations which imposed *de facto* to our Agency. Indeed, for example, only the obligations to submit to the EMA PSURs and their content are implemented. Moreover, according to the article 2 (7) of the Directive 2010/84/EU, our law provides that these new provisions shall enter into force from 12 month after the functionalities of the repository have been established and have been announced by the EMA. Until the EMA can ensure the functionalities agreed for the repository of the PSURs, the MAH shall submit the PSURs to the French Agency.
Germany	No (as far as Jan Farzan knows)		Because the Member States are legally obliged to implement all provisions in time. In case the underlying European procedures are not functioning, we (PEI) may do the work ourselves (cannot tell you in detail at the moment).
Greece	Yes, we intend to postpone the activities/procedures in co-ordination with EMA	We will postpone all the activities that EMA is postponing (i.e. procedures described in Articles 107e and 107g regarding the single assessment of PSURs and parts of Articles 107n to 107q regarding the participation of PRAC in the non-interventional PASS assessment). EMA's active participation is considered necessary for	

		the implementation of the above-mentioned procedures.	
Hungary	No		No, Hungary will not postpone the implementation of the provisions of the Directive due to postponements of EMA. As a Member State, we are legally obliged to implement all provisions in time. Postponing implementation of the Directive by Hungary could be regarded as an infringement of the European legislation. However active participation of EMA is considered necessary for the implementation of mentioned procedures, where the provisions are worked out, we will execute and enforce relevant provisions according to relevant national legislation. Implementation in Hungarian legislation covers obligations for MAH, not the procedures of PRAC or the co-ordination group. If there is a cross-reference to the PRAC or to the coordination group, obligations of the MAH will be supervised and controlled by the National Institute of Pharmacy of National Institute for Quality- and Organizational Development in Healthcare and Medicines (GYEMSZI OGYI) as the competent authority within its scope of authority, according to the relevant national legislation in force, until EMA can ensure the functionalities agreed for the repository of the PSURs. For practical purposes - until EMA announces the functionality of its repository is established - we will receive PSURs directly. Our intent only was to transpose those aspects those directly relate to the obligations of the MAH and the competent authority, towards to make clear to MAH its tasks with respect to submission of PSURs, draft protocols, protocol amendments and etc.
Italy	No		AIFA doesn't believe it is legally possible not to implement the procedures described in Articles 107e and 107g regarding the single assessment of PSURs

			and the parts of Articles 107n to 107q regarding the participation of PRAC (endorsement of protocols, amendments thereof and results management for NAPs) taking into account the EMA's postponement. In the last meeting held in December, the MB decided the deadline of the implementation of the provisions of the Directive 2010/84/EU. The decision was published on February the 2°. Apart from EMA's decision to postpone certain PhV activities due to the lack of fund, we are aware to be obliged to adopt PhV activities since the entry in force of the Directive 2010/84/EU. Directives, in fact, are binding for the Member States to which they refer. Member States shall adopt all the activities for their implementation in the form and at the time indicated. By the way, the postponement of certain activities by the MS, could be regarded as an infringement of the European legislation.
Latvia	No		Our legislation will transpose the Directive.
Liechtenstein	No(?)		The new pharmacovigilance regulation and directive are still in the process of being included into the EEA legislation. As they are still not part of the EEA acquis, the question of postponement does not arise at the moment.
Netherlands	No(?)		The conversion from directive into national law is undiminished in progress and will be round up accordingly. In due course, when the provisions are worked out, they will be executed and enforced.
Spain	No		Our legislation will transpose the Directive. We will issue a document with transitional arrangements.
Sweden	No		Sweden will not postpone the implementation of the provisions of the directive due to EMAs postponements. The implementation in Swedish legislation covers obligations for MAH and the MPA, not the procedures of PRAC or the co-ordination group.

United Kingdom	No, we do not intend to postpone implementation of the provisions relating to the PSUR single assessment or the provisions relating to the post-authorisation safety studies.		Our approach to transposition into national legislation has been to only transpose those aspects that directly relate to the obligations of the MAH and the competent authority. Although the single PSUR assessment will not fully come in to force in July 2012, the current worksharing scheme will still continue for those products already subject to this scheme and for all other national products these PSURs will be assessed at a national level. We therefore envisage that the approach to assessment of PSURS for nationally authorised products will in the interim remain unchanged from what currently happens. The transitional measures will mean that we will receive PSURs directly and this will continue until 12 months after the EMA has announced the functionality of its repository have been established. We do believe that this postpone of implementation will cause any major difficulties but we will need to make clear to MAHs our expectations with respect to submission of PSURs. The new procedures for submission and assessment of PASS protocol, substantial amendments and final study results as provided for in Articles 107n to 107q of Directive 2011/83/EC only apply to PASS studies which have been imposed after 21 July 2012 as a condition of the marketing authorisation. Therefore we do not believe that there will be large numbers of these studies and if it is not possible for them to be considered by PRAC we would imagine that these would be handled through a written procedure with the Reference Member State taking the responsibility for the assessment. The most recent Q&A documents on the implementation of the pharmacovigilance legislation issued by the EMA (dated 23rd May 2012) do not provide clarity on whether they expect study protocols to be submitted to them. Nevertheless it

			will be important that we provide clear information to MAHs about what our expectation are with respect to submission of draft protocols, protocols amendments and final study reports.