Dear Sir/Madam,

I have directed this email to:

1. Eudravigilance
2. EMA
3. Division looking at the revision of the new variations guideline 1234/2008

We are looking at introducing the new PVMF across all European licenses. We have 3 queries we would gratefully appreciate clarification/recommendation on. We appreciate some of the guidance is still draft at this stage. I have included full details and background information below but in summary the queries are:

Summary of questions

- **Can our PVMF be allocated a PSMF number. Is it available? How do we obtain this?**
- **Whilst we appreciate 1234/2008 update is still draft we would like some guidance from the EMA weather to include such a reference statement to article 57 database in our Summary of Pharmacovigilance System document in 1.8.1?**
- **XEVMPD database should be updated with details concerning location of the PVMF before we submit the variations. Please confirm**

Kind regards

Nick

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Background information for queries

Background:
In the new draft legislation guidance 1234/2008
http://ec.europa.eu/health/files/betterreg/2012_06_11_public_consultation_en.pdf on page 80 there is a comment referring to a 'PSMF number'(a unique provided to each DMF).
In the EMA Guideline on Good Pharmacovigilance practives (GVP) 22 June 2012 EMA/816573/2011 http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129133.pdf at the bottom of page 5/top of page 6 & additionally in II.B.6.1 on page 16 references are also made to 'the unique number assigned by the EV System to the pharmacovigilance system master file when the XEVPRM is processed in the XEVMPD'. We assume both documents are discussing the same number.
It appears that the number will be allocated via processing of the PVMF through the XEVMPD database. But we are not sure of the process?

Query 1

- **Can our PVMF be allocated a PSMF number. Is it available? How do we obtain this?**

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Background:

In the new draft legislation guidance 1234/2008
http://ec.europa.eu/health/files/betterreg/2012_06_11_public_consultation_en.pdf on page 80 there is a paragraph referring to proposed category C.I.8b)

Once the Article 57 database is functional, changes in QPPV, including contact details (telephone and fax numbers, postal address and email address) and changes to the address of the PSMF (street, city, postcode, country) may be updated in the Article 57 database only, without the need for a variation, provided that this is done immediately. Where reference is made to Article 57 database, Applicants/MAH are requested, at the time of introducing/varying the summary of the pharmacovigilance system, to include a reference for future updates to 'current version of the information, as included in the Article 57 database' in addition to providing the QPPV information and the PSMF location

Query 2

- **Whilst we appreciate the guidance is still draft (and thus intend to submit under C.I.z CMDH article 5 recommendation) we would like some guidance from the EMA weather to include such a statement referenced above in our Summary of Pharmacovigilance System document in 1.8.1?**

Rationale
This would negate the need for future variations (assuming all changes are made immediately to the article 57 database) to the PVMF
This would save us having to resubmit the Summary of Pharmacovigilance System with this statement in at a later date for all products.

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Background
In the EMA Guideline on Good Pharmacovigilance practives (GVP) 22 June 2012 EMA/816573/2011 http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129133.pdf on page 19 under section II.B.2.3 Registration there is guidance: All pharmacovigilance system master files must be registered in XEVMPD. The MAH shall update the database with the location of the pharmacovigilance system master file for each product, and update the information immediately upon change, as XEVMPD must be correctly populated with the pharmacovigilance system master file location. There are fields in the XEVMPD article 57 database that we can and should update these database fields for all products before submitting the variations.

Query 3

- **XEVMPD database should be updated with details concerning location of the PVMF before we submit the variations. Please**

Thank you for your help with the above

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