EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

GVP MODULE IV- PHARMACOVIGILANCE AUDIT

PUBLIC CONSULTATION

Edit Weidlich Dr, CA, CGAP- Head of Internal Audit, EMA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

All industries face...

unprecedented change

TASKS AHEAD

EMA's, NCA's and HMA's Mission, should we choose to accept, it is to **build, deliver and put in place an audit team** which adopts a strategic mind-set to respond to risk and ready **to deliver audit reports in line with the legislative requirements** (EMA-REG Art 28f, NCAs- Art 101(2) IR Art 8, 14,15,16,17(1) and 17(2), MAH-DIR Art 104(2), IR Art 8,10,11,12,13).

All of this must be conducted within tight affordability constraints and in line with the professional auditing standards.

FIRST AUDIT reports of the pharmacovigilance system audit **needs to be ready** (EMA- IV Q.2013, NCA's-21 September 2013).

EC shall make public a report on the performance :
-EMA-by 2 January 2014
- NCA's -21 July 2015

The **PRAG shall have due regard to the design and evaluation of the pharmacovigilance audit** (REG Art 61

- **Interlink with GVPs on Quality System, PSMF, Inspe Modules.**

Positive feedbacks received

We very much appreciate the **risk-based approach** to pharmacovigilance audits.	AESGP
In principle a **risk-based approach** to pharmacovigilance audits is welcomed.	BPI
The **module is well structured and the content appropriately describes the basics for such audits.** We particularly welcome the development of the risk-based approach requested in the Implementing Measures. **Overall this document provides clear guidance on planning and conducting audits which will help promote standards and harmonisation throughout the European network**. It is well written and thus comments of the companies are minimal.	EFPIA
The module is well structured and therefore our comments are very few and focus on a small number of areas in the text where further clarity could be given.	NOVARTIS
Overall, this draft **module (GVP Module IV – Pharmacovigilance audits) is very comprehensive and provides detailed and helpful guidance on expectations regarding pharmacovigilance audits**. We thank the Agency for efforts to provide comprehensive guidance. Further, we appreciate the opportunity to review this document and provide the following comments with the goal of improving, and thereby strengthening, the final guidance.	PFIZER

Comments received

1. TERMINOLOGY(Clarification was requested for some elements of terminology, and these have been addressed by additional explanation and additional entries in the glossary, like audit strategy, audit programme, objective evidence, recommendations, internal control, upper management, audit)

2. THE POSITION OF AUDITORS TO MAKE RECOMMENDATIONS

   (The position of the auditor to make recommendations was highlighted as a new concept in some submissions, however we draw attention to internationally accepted auditing standards that address the proficiency requirements for auditors and the criteria for audit communication that includes, along with the scope and objectives of the audit, but also applicable conclusions, recommendations and action plans(see IIA Standards 2410 Criteria for communicating audit results).

3. GRADING OF FINDINGS/RECOMMENDATIONS (risk based approach)

COMMENTS RECEIVED

4. RISK BASED APROACH ON THREE LEVELS (strategical, tactical and operational level)

5. REPORTING LINES (legislation requires some specific reporting lines, internal reporting lines- upper management)

6. DOCUMENTATION (in line with GVM Module II B.2.2, GVP Module I section I B.10)

8. INDEPENDENCE (legal requirement, see auditing standards-"The freedom from conditions that threaten objectivity or the appearance of objectivity. Such treats to objectivity must be managed at the individual auditor, engagement, functional and organisational level")

9. TRAINING AND QUALIFICATIONS (In line with Module I- I.B.7)

10. EVALUATION OF AUDIT WORK (quality assessment of the auditors work is a professional requirement)

Comments received

11. AUDIT STRATEGY/PROGRAMME (see Glossary- strategy for 2-5 years/include in the annual audit program the outline of the scope and objectives of the audits to be performed during the year)

12. DETAILED HOW-TO GUIDANCE (**There was a general request for more detailed 'how-to' guidance, which we found was a positive sign.**

A)The difficulties of providing a detailed guidance to be applicable to a number of organisations with vast differences in size and complexity was considered by the drafting group, who endeavoured to provide a generic structure without imposing prescriptive elements, see detailed guidance in recommended internationally accepted auditing stand.

B)The role and responsibilities of the QPPV in relation to the preparation of the audit strategy, audit programme as well as the planning and conduct of individual audits was queried- as QPPV playing a key role in the pharmacovigilance systems of the organisations and as independence in audit is crucial- QPPV cannot be the one who would prepare audit strategy or plans, however QPPV will be involved in the discussion and will receive all information from reports and about implementation of the IAPs.


A
partnership
approach

NEXT STEPS

Comments to be discussed with AUDIT/INSPECTION Project Team members and BEMA SG

FINALISATION OF THE GVP Module IV

Publication on 15 December 2012

Further methodologies and harmonization tasks-

Pharmacovigilance Audit Facilitation Group

THANK YOU FOR YOUR KIND COMMENTS AND ATTENTION

QUESTIONS?