05 September2013
EMA/516861/2013

# Proposal for European Medicines Agency's involvement in the 9th IMI Call "WEBAE-Leveraging emerging technology for pharmacovigilance"

## 1. Preliminary considerations

EMA considers that development of ADR reporting apps and integration with e-health records, and exploitation of social media sites to monitor the benefits and risks of medicines has great potential benefit for public health. EMA wishes to play a significant role by ensuring that the project remains focused on public health and that reporting tools are compatible with law and systems. EMA is also well placed to facilitate liaison with different stakeholders in the consortium, including patient representatives.

The Agency's involvement will be limited to supporting the project for public health and scientific reasons.

The EMA considers that it can take the leadership of Work Package (WP) 1 suggested in the call, titled "Policy Advancement". A summary of the work involvement of EMA is described below.

The EMA is ready to join any consortium that puts forward a high quality bid likely to achieve the public health deliverables set out in the call and reflecting EMA's proposal for its involvement (as set out in the summary below). On this basis, EMA foresees to be a member of multiple competing consortia. This maximises the chances of the winning consortia having the active participation of EMA and thereby maximises the likelihood of a successful project. Any consortium wishing to collaborate with EMA should contact henry.fitt@ema.europa.eu or victoria.newbould@ema.europa.eu.

## 2. EMA participation

### Work Package 1: Policy Advancement

The EMA proposes to lead work package 1 and therefore provide its most substantial contribution to this area.

Given that the EMA has played a pivotal role in the implementation of the new pharmacovigilance legislation and the development of guidelines and best practices, it is important for the EMA to provide leadership in this work package to ensure compatibility with EU law, EU systems and best practice. This will also ensure consistency with work on-going in other European fora concerning patient reporting and use of emerging technology to report ADRs (for example, the European Commission Joint Action on pharmacovigilance http://ec.europa.eu/eahc/health/JA_2013_pharmacovigilance.html).

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In order to ensure integration with EudraVigilance work flows, the EMA can play an important role in the analysis of compatibility with the format of individual case safety report forms in Eudravigilance (EV) [ICH E2B (R3)] and the EU E2B (R3) Implementation Guide], and also for medicinal product information in accordance with Article 57(2) of Regulation (EC) No. 726/2004 (Identification of Medicinal Products (IDMP)).There may also be specific product or product type considerations such as those under additional monitoring or batch number provision for biologics.

A policy deliverable will be based on the need to be able to track the provenance of the data with respect to identifiability of reporter and patient, which are key principles of a valid safety report as defined in the international scientific community (ICH E2B(R2), ISO ICSR, HL7 patient safety: Identifiable Patient, Identifiable Reporter, Suspect Drug, Adverse Event/reaction. This also has implications for data privacy as the deliverables will need to fully comply with EU data protection legislation. EMA will provide important input to data privacy/protection considerations in liaison with the EMA data protection officer, especially in light of experience gained with Eudravigilance, including review by the European Data Protection Supervisor (EDPS).

One of the critical deliverables for this project is to provide practical guidelines for market authorisation holders on how social media surveillance can be used to identify reliable signals and ensure a balance between the numbers of signals and the follow-up activities. There is a need to inform these guidelines on the results of the study from work package 4.

WEBAE is an ideal opportunity to facilitate reporting of medication errors and also misuse/abuse, off-label use and occupational exposure. Although medication errors without adverse reactions (or near misses) are not required to be reported under EU pharmaceutical law, it is important to create links with responsible national bodies for patient safety, and also to provide guidance on processing of these reports for periodic reporting by Marketing Authorisation Holders. There is also further policy to be defined for processing cases of misuse/abuse, off label use and occupational exposure where there is no associated adverse reaction, and any impact on analysis of Risk Management Plans. The EMA is involved in ongoing work within the EU regulatory network to develop good practice on medication error reporting and will develop this aspect and facilitate collaboration with interested parties.

There may also be other medical insights reported through utilisation of social media where EMA input is important, for example for reports of product quality defects.

Considerations related to communication with stakeholders are of paramount importance to EMA, and policy is required to ensure that best use is made of EMA RSS feeds, allowing those using the app to automatically receive specific regulatory news updates (e.g. safety alerts, EPAR updates, quality issues, product recalls, withdrawal from market, counterfeit warnings, etc). EMA suggests that there should be a related deliverable to monitor the response to the increase in direct communication with stakeholders. This should include not only positive outcomes of increases in safe and effective use of medicines, increased reporting and engaging patients and consumers, but also any detrimental effects, such as where medicines are stopped because of alarm caused by safety alerts, or discouragement in using apps because of large volumes of information which may cause irritation particularly if it is perceived to be of a promotional nature.

It will be important to define the follow-up activities with respect to reporting into EV and possible follow up of the information received.

There is a need to raise awareness of the official routes of ADR reporting and facilitate reporting, which could be achieved through the appropriate interaction with digital media such as internet-based patient support groups. The EMA is well placed to facilitate interactions with stakeholder groups concerned by this project, such as representatives from patients' and healthcare professionals' groups.

**Work Package 3: Mobile platform developments**

EMA can participate in work package 3 by facilitating discussion in technical fora in order to ensure that there is an overview of mapping between business and policy needs and technical functionalities.

Much of the focus for EMA will be on the interface with the EudraVigilance system, and compatibility with medicinal product information in XEVMPD in the context of the implementation of Art 57(2), of the new pharmacovigilance legislation. EMA would like to ensure that reliable information on medicinal products is provided, and has considerable experience in multilingual and multidisciplinary exchange of data and information.

**Work package 4: Research Study**

The Agency considers that a valid estimation of the value of new technologies for signal detection is a critical element for the success of the project as it will help determine the role that these technologies may play in pharmacovigilance. Screening from the social media would add a new dimension to the current sources of information on the benefits and risks of medicines, which may have a considerable impact on human and computer resources of national competent agencies, pharmaceutical companies and the Agency. Therefore, the Agency considers that adequate expertise and resources should be allocated to this work package.

The Agency suggests that the following aspects could be considered in the study:

- number of reports that would/could be identified in a defined time period;
- characteristics of the reports in terms of minimal information required for reporting, availability of data needed for causality assessment, level of medical confirmation allowing to distinguish between adverse events and adverse reactions, demographics of reporters (age and sex), seriousness and listedness of reports;
- added value of screening technologies in terms of number of new safety signals detected;
- potential for negative consequences of increased information provision to patients, for example where medicines are stopped because of alarm caused by safety alerts
- estimation of impact on resources, e.g. in terms of need for follow-up, coding, processing and reporting of reports.

It is suggested that the scope of this work package could be enlarged to the European Medicines Agency and pharmaceutical companies. The Agency proposes that it could participate in this work package to estimate the impact of the new technologies on its operations and on the EudraVigilance system and to assess the added value of any reports received for centrally-authorised products for signal detection. It is assumed that pharmaceutical companies could participate, through their in-kind contribution, in estimating the impact of the new screening technologies on their own systems.

**3. Possible involvement of EMA in other work packages**

EMA would likely have a limited involvement (e.g. participation in an oversight body) in work package 2 Technical Advancement.