Med Safety Newsletter, July 2020: Issue 2

We are delighted to present the second Med Safety newsletter. This second issue provides updates on recent developments to improve the stability of the mobile applications (apps) and enhance user experience. It also contains information about recent publications and the updated WEB-RADR website which holds all the information you need to know about the Med Safety App platform.

Through collaboration between the Medicines and Healthcare products Regulatory Agency (MHRA), the World Health Organization (WHO), Uppsala Monitoring Centre (UMC) - WHO Collaborating Centre for International Drug Monitoring, and National Regulatory Authorities, the Med Safety App has been adopted by countries across the globe.

Since the first newsletter, App development has been supported in:
- Ethiopia
- Botswana
- Cote d'Ivoire
- Uganda
- DRC
- Kyrgyzstan
- Pakistan
- Nigeria

Information about country launches can be found on the WEB-RADR website. The website has a dedicated Med Safety section with sub-pages on launch events and features and functionalities, and there is a Vigilance Hub section.

A number of exciting technical developments have progressed and brought new benefits to users of the platform.

1.   Report configuration (RC)

This significant piece of work will enable the ability to configure reporting forms through the Vigilance Hub. RC was released in late April 2020 and made available to Med Safety Apps in June. New functionality includes the ability to:
- Add new questions, with answers mapping to the narrative
- Change the wording of existing questions
- Change which questions are mandatory (note that questions which are mandatory for key validations must remain mandatory)
- Add additional questions related to pregnancy into the reporting forms building on work initially added to the Yellow Card App by MHRA
- Allow company (Marketing Authorisation Holder) representatives to report through the App if desired; this was previously only available in the UAE RADR App
- Add multiple reporting forms, for example if a partner wants to have a reporting form for medicines and a separate reporting form for vaccines.

Using some of the functionality offered by RC, the MHRA has also developed a dedicated coronavirus Yellow Card reporting site, which uses the Yellow Card Vigilance Hub as it's back-end. More information on this can be found below. As part of the development of this

site, we have introduced further enhancements to the reporting form in Apps which had been requested by partners:

- Ability to report as a guest with either email address or postal address
- Reporter must provide any one of patient sex, patient age or patient initials. Previously, date of birth was always mandatory even if not known.

2. E2B ICH R3

Work undertaken has enabled the creation of reporting forms in E2B ICH R3 format. This is focused primarily for industry users at this stage. However, a healthcare professional and patient-friendly version has also been created. This work is in testing phase and is expected to be delivered in the coming months.

3. Coronavirus (COVID-19) reporting

Work completed through report configuration (RC) has enabled the MHRA to create a dedicated reporting form for medicines and medical devices used to treat coronavirus symptoms. This form is currently available to patients and healthcare professionals in a separate coronavirus Yellow Card reporting site.

The COVID-19 specific questions created by the MHRA are available to partners to adopt in their Apps within existing reporting forms, or as a separate reporting form. MHRA, WHO and UMC have been discussing how best to support Med Safety countries in their response to the pandemic and interested partners are encouraged contact the MHRA for further information. We will also be reaching out by email about this topic separately.

4. Vigilance Hub

This is the back-end system used to manage the App. The WEB-RADR website has a dedicated page on the Vigilance Hub with further information: https://web-radr.eu/mobile-apps/med-safety/vigilance-hub/.

5. Vigilance Hub training materials

To support adoption of the Vigilance Hub, training materials have been created and are available on the WEB-RADR website. Videos have been created to support different functionalities of the Vigilance Hub. This includes:

- Overview of all functionality available on the Vigilance Hub
- How to add App branding - changing colours for the Vigilance Hub and App, uploading icons, adding logos
- How to create a news feature - the creation of news articles and association to RSS feeds

6. Med Safety introductory video

An introductory video on the Med Safety App has been created and is available on YouTube.

7. Article published in WHO Pharmaceuticals Newsletter

A feature article about the Med Safety App has been published in the WHO Pharmaceuticals Newsletter - No. 6, 2019: Med Safety App: an international mobile tool for drug safety. The article includes information on the App development, downloads and usage, recent launches, and international collaborative efforts.

8. Article published in Uppsala Reports

A Med Safety App article has been published in Uppsala Reports: https://www.uppsalareports.org/articles/med-safety-app-an-international-mobile-tool-for-drug-safety. Botswana and Ghana are two case-study examples presented in this article.

Coming soon:
- WEB-RADR 2 project AbbVie app pilot
- Future Med Safety App launches
- Additional training materials for the Vigilance Hub