





## Med Safety Newsletter, November 2020: Issue 3

The third issue of the Med Safety newsletter provides updates on developments since July 2020. Enhancements implemented have increased the use of branding as well as strengthened the security of the 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 second newsletter, the Med Safety App has been officially launched in Nigeria and Pakistan during the Med Safety Week campaign, 2-6 November.

Seventy-six countries took part in Med Safety Week and preliminary analysis of the reach of the #MedSafetyWeek hashtag indicates that content reached more than 140 million people and generated over 100,000 engagements during the week.

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

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

## 1. WEB-RADR 2 project AbbVie app pilot

AbbVie piloted the WEBRADR app which was customized to their reporting needs and branded as "e-PV" at their South African Affiliate during May and June 2020. It was piloted in a Patient Support Program with 5 patient support program (PSP) nurses using the App to report adverse events (AEs) to the Affiliate PV team.

The pilot aimed to determine the following objectives;

- Technical feasibility
- User experience
- Efficiency measures
- Assess quality and completeness of reporting using e-PV vs. traditional methods of reporting

A total of 100 AE reports were submitted using e-PV. The data collected are currently under review but the overall user experience was very positive with most PSP nurses feeling that the app added value to their role. They also felt that reporting AEs using the app was much faster and easier than traditional reporting methods. A summary of the pilot was covered at the WEB-RADR 2 Webinar in June 2020. The team intends to publish results in 2021.







# 2. Adoption of the coronavirus (COVID-19) reporting form

The COVID-19 reporting form has been specifically designed for the reporting of medicines used to treat coronavirus symptoms. Since being made available in the Med Safety App, a number of countries have implemented the form. This includes Armenia, Botswana, Burkina Faso, Ethiopia, Uganda, Zambia, Pakistan and Nigeria. Countries interested in adopting the COVID-19 form are encouraged contact the MHRA for further information.

## 3. Customisable email acknowledgments

Customisable email acknowledgments are a new feature of the Med Safety App. Previously, adopters were limited to embedding just email addresses and phone numbers within a standard acknowledgment email. The acknowledgment email can now be fully edited, and different acknowledgements can be sent for different reporting forms. The WEB-RADR team can support any adopter in making use of this enhanced functionality.

## 4. Improved branding on PDFs and emails

Med Safety PDFs and emails have not previously been branded. PDFs and emails are now branded and are automatically linked with the adopters' set up; banner, logo, name. This new functionality gives brand identity to the PDFs and emails generated and allows them to be easily recognisable.

## 5. COVID-19 coding

COVID-19 additional questions such as test results previously populated into the report narrative. This information has now been successfully mapped to the XML structure. This is particularly important for coding consistency and reduces the manual burden of classifying from a free-text narrative.

## 6. Tailoring ADR report World Wide Reference Number

It is possible to tailor the World Wide Reference Number (WWRN) of adverse drug reaction (ADR) reports submitted in the Med Safety App. This new functionality will assist in the differentiation of reports and can be applied separately for each report configuration. For example, a different WWRN can be used for a medicines form and a COVID-19 form.







## 7. Units conversion - weight

It is now possible to have unit conversion for weight within the Med Safety app. Weight can now either be reported in metric (e.g. kilogram) or imperial (e.g. pounds) units. The units selected to be used within the ADR report by the reporter are converted to the units selected by the adopter and converted during XML population. The conversion of units for height is currently being worked on and will be available soon.

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#### Coming soon:

- Additional training materials for the Vigilance Hub
- Pop-up notification functionality

#### Acknowledgement

The mobile application was initially developed within the WEB-RADR project.

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