Medicines & Healthcare products Regulatory Agency

Board Meeting

Update on the Innovative Medicines Initiative WEB-RADR Project

15 April 2019

Issue/ Purpose:

To provide the board with an update on the WEB-RADR (Recognising Adverse Drug Reactions) project, and to summarise the future opportunities associated with the programme of work.

Summary:

The MHRA is leading an innovative programme of work funded by the European Commission's Innovative Medicines Initiative that is delivering enhanced tools for safety and surveillance of medicinal products. This will enable integration of incident reporting into third party services including the recently announced NHS App.

Resource implications:

Within existing resource although activities funded through the work undertaken

EU Referendum implications:

Important Brexit priority to demonstrate international expertise and leadership. Participation in Horizon2020 programme projects is covered by a Government funding guarantee.

Implications for patients and the public:

The project is delivering enhanced vigilance systems which will improve access to reporting systems and subsequent information from the MHRA for both patients and healthcare professionals.

Timings:

The WEB-RADR Exploitation project began in September 2019 and will conclude in March 2020

Action required by Board:

The Board is requested to note the update on the project and associated activities and comment on the future roadmap.

Links:

VRMM, Finance, OT

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Which of the themes in the Corporate Plan 2018/2023 does the paper support?

- We will enhance our public health impact through building stronger partnerships, collaboration and engagement including through further development of our international strategy
- We will deliver robust proactive surveillance for medicines and medical devices including improved use of real-world data and enhanced information sharing

If relevant, which Business Plan strategic activity does it support?

- We will enhance our public health impact through building stronger partnerships, collaboration and engagement including through further development of our international strategy

CET Sponsor:

June Raine, Director VRMM

Update on the Innovative Medicines Initiative WEB-RADR Project

Background

1. The original MHRA led WEB-RADR project ran from 2014 to 2017 and was designed to evaluate the value of mobile apps and social media data for pharmacovigilance. The project, funded by the European Commission's (EC) Innovative Medicines Initiative (IMI) successfully delivered mobile applications to five countries (UK, Netherlands, Croatia, Burkina Faso and Zambia) and initiated collaboration with the World Health Organisation to maximise the value and sustainability of the tools.

2. In 2018, the MHRA successfully bid for and initiated a further 19-month IMI project known as WEB-RADR2 under the EC Horizon 2020 programme, designed to increase the reach and impact of the original project. This paper describes the progress with this work and its value for UK public health.

3. The work delivered through the IMI WEB-RADR Project dovetails with the MHRA Yellow Card Strategy principles around enhancing access to reporting systems and safety information, with the technology delivered forming an important component of the MHRA's strategy to increase healthcare system engagement with regulatory information. This has included enhancement of the Yellow Card app to collect additional information on possible exposures during pregnancy.

WEB-RADR2

4. The WEB-RADR2 project is intended to take the outputs of the original work and make them more widely accessible to stakeholders. Included in the workplan are features that will enable the mobile platform to be more attractive to prospective adopters and technology that will enable others to benefit from the information and functionality of the mobile platform even if they do not specifically download it to their own devices.

5. The current apps are supported by several Application Programming Interfaces (APIs) which will be developed under the WEB-RADR2 project to enable integration with other services. This will enable, in the UK setting for instance, the ADR reporting function to be embedded into other services such as the recently announced NHS app, or those offered by health charities or NHS trusts to support specific diseases or populations. Equally the platform will facilitate delivery of regulatory news, such as Drug Safety Update into clinical systems or health information portals, thus extending the reach and impact of safety communications.

6. In a global context this development has the potential to make information about medicines and ADR reporting available in rural settings in low-middle income countries where previously such provision has not been possible. This is particularly relevant as new/ novel products are launched in these settings

to address emergency public health issues prior to adoption in more developed settings.

7. To maximise impact, under the leadership of the MHRA, the project is conducting a two-way mapping activity between core medical terminologies; SNOMED CT and the Medical Dictionary for Regulatory Activities (MedDRA). The MedDRA terminology, originally developed by the MHRA is a statutory requirement of regulatory systems, while SNOMED CT is the terminology mandated in the UK healthcare system. The WEB-RADR project will deliver a validated mapping between the two sets, which for the project will facilitate two-way exchange of information between regulatory and healthcare systems, but more broadly will be valuable in analysis of healthcare data for regulatory purposes, including the conduct of epidemiological studies.

International collaboration

8. The MHRA invited the World Health Organisation to participate in the external advisory board to the WEB-RADR Project. Through this collaboration, the project had opportunity to test the roll out of the mobile application to two LMICs; Zambia and Burkina Faso. As a result of this pilot significant changes were made to the platform to facilitate rapid roll out of the technology to new settings with flexibility to easily add new regions and languages at low cost. As a result, the platform now supports safety data collection in multiple languages and the ability to onboard new countries in a matter of weeks, meaning that it is well placed to support collection and provision of information in emerging health crises.

9. There has been significant international interest in the platform as a result of the initial pilots. As a result of the initial success, the WHO funded adoption of the platform by ten countries by the end of 2019, with a number of other countries and regions interested in different components.

10. The Agency's work with the Bill and Melinda Gates Foundation to strengthen pharmacovigilance capacity in low and middle income countries is also providing an important platform to provide these tools to countries with a low level of reporting.

Future activities

11. The MHRA has been in contact with colleagues at NHS Digital with regard to addition of the Yellow Card app to the NHS app library, and subsequently integration of the underlying APIs into the NHS App. Following completion of its roll out (anticipated May 2019) the NHS app will be used by patients for access to primary care services including booking GP appointments and access to individuals primary care record. Government discussion has emphasised the importance of inclusion of ADR reporting and information provision to this platform, and the MHRA team has had positive engagement with NHS Digital about integration of features following their initial

deployment. This fits well with WEB-RADR2 project delivery, which will have the relevant APIs available around the same time.

12. Through the Operational Transformation programme the Agency is planning to add Medical Device, Defective Medicines and Counterfeit reporting to the platform by the end of 2019. This will be through the same platform as the existing ADR reporting functionality, meaning that all areas will benefit from the ability to be integrated to other services though APIs. In due course it is intended that this will enable a much smarter entry into Agency reporting systems, with a single form presented to users using intelligent questions to gather the required information for safety monitoring irrespective of the type of incident.

13. The MHRA has agreed a charter with the WEB-RADR external advisory group committing to principles of transparency, impartiality and sustainability. The external advisory board has agreed that use of the platform must be non-promotional, and that it should be operated on a not-for-profit basis.

14. In due course it is intended that the suite of tools offered by the platform replaces the existing Yellow Card website, delivering a fully integrated experience between app, website and third-party channels.

15. It is anticipated that the enhanced vigilance capability offered by the platform internationally will also indirectly benefit UK public health, with improved international data, meaning that potential safety issues for new medicines and technologies can be identified more quickly than would otherwise be possible.

Action required

16. The Board is requested to note the update on the project and associated activities and comment on the future roadmap.