Medicines and Healthcare products Regulatory Agency

15 December 2017

Update on Patient Safety and Vigilance Strategy (PSVS)

Purpose:

This paper provides the Board with an update on the three-project work-streams which underpin the Patient Safety and Vigilance Strategy (PSVS). The project was discussed at the December CET meeting.

Summary

An update was last given to the Board in September 2017. It is timely to update the Board in advance of the Health Summit that is being held with key partners on 18 January 2018.

The paper provides information on the health summit and highlights the progress made in a number of areas. It also indicates some issues/areas to be considered in more depth by the Steering Group or to be taken forward in conjunction with the Operational Transformation.

Those to highlight up front are:

- Plans are progressing well with other key partners for the Improving the Impact of Safety Messages Health Summit, with key speakers, an impressive list of delegates and agreed agenda.
- The technical providers of our signal detection tools have been helping to develop methodologies for device signal generation and a report was considered at a workshop in early September. A plan to prioritise and take forward the recommendations and next steps has been drafted and will be discussed at the next Steering Group meeting.
- The proposed study on use of CPRD data for devices has been agreed and final revisions to a protocol are being made. The protocol will be submitted to the Independent Scientific Advisory Committee (ISAC) in December 2017.
- A strategy document for uses of CPRD in relation to devices vigilance is being further developed and will be brought to the next Steering Group.
- The joint assessment of paraffin-based topical products and fire risk is in progress and will be used as a case-study/opportunity to learn and build from.
- Restructuring in Devices and the Operational Transformation work have impacted on some deliverable dates which are being monitored and may need to be revised.

The Board is asked to note progress and comments on progress with deliverables are welcomed.

Resource implications:

Resources have already been committed to the activities underway by the project teams and the project management resource is in place.
Timings: The project plans indicate activities will continue beyond 2018.
Action required by Corporate Executive Team: The Board is invited to note and comment on this update on the PSVS.
Links: • VRMM IMD • Devices COMMS • I,E&S
Author(s): Mick Foy, Tony Sant, Louise Loughlin, PT Leads and input from wider co-ordination group
FOI/publication issues:
Can paper be published on INsite? (List any deletions required) Yes
CET sponsors: June Raine, John Wilkinson

Patient Safety and Vigilance Strategy

1. Introduction

1.1 This paper updates on progress in all three PSVS project teams, and, informs the Board on plans for the Improving the Impact of Safety Messages Health Summit.

2. Summary of Project Team Deliverables and Timescales

Project Team 1 incident reporting and signal detection

Project Team 1 is responsible for delivering **Strategic Objective 1** on effective capture of information and **Strategic Objective 2** on improving MHRA's signal detection capability. The deliverables for Project Team 1 are set out below together with an update on progress:

Deliverable	**Progress**	**Delivery Date**
Delivery of mobile reporting for medicines (adverse reactions, counterfeits and defects)	It was agreed that the delivery of mobile reporting for medical devices is considered as part of the Operational Transformation, with the ongoing Devices Transformation project, however PSVS, and in particular the PSVS Steering Group, should remain having oversight of this work. The work has been on hold during the Operational Transformation prioritisation exercise and business case development. Initial discussions with Government Digital Service (GDS) had previously been held in order to obtain early buy-in and collaborative working between ourselves and GDS, but had not progressed further as it will be considered as part of OT. It should be noted however that the OT customer insight work will probably not provide the level of detail required by GDS for this specific piece of work and so discussions with OT at the right point in time will need to be held to progress this. Maintenance of the Yellow Card App through WEB-RADR has been contracted out to a company charged with enhancing and adapting the app and this might provide	Q1 18/19 had been given as an indicative potential date, however this may not be feasible due to the number of decisions to be made and prioritisation of this through the Operational Transformation

	opportunities to make progress in delivering a YC app for all incident reports.	
Device Information Standard for Incident reporting	The final EU format for vigilance reports was agreed in November and the draft standard developed needs to be updated in light of this EU agreement. NHS Digital's Standards Assurance Service has sent documentation to be filled completed.	Target delivery date as NHS Digital Standard Q1, 2018 – this target date is not achievable due to resource issues and a revised target date will need to be agreed.
Implement a formalised signal detection methodology for devices	An outline plan on suggested next steps following the Devices Signal Detection report from the technical provider has been developed and will be considered by the Steering Group at the next meeting.	New delivery date to be agreed. Many dependencies on other work packages e.g. Devices Safety & Surveillance (DSS) risk unit being set up, EU taskforce on a common EU process for Signal Management and OT
Investigate a common signal management process and tools for all healthcare product incident types	To be revisited in light of OT. The work from the technical provider's report and the information from PT2's mapping exercise on handling of safety signals will be used in the discovery.	To be determined following decisions from Operational Transformation

4. Project Team 2 – risk benefit assessment

Project Team 2 is responsible for delivering **Strategic Objective 3** on looking at wider vigilance data pools and **Strategic Objective 4** on improving risk benefit assessment. The deliverables for Project Team 2 are set out below together with an update on progress:

Deliverable	Progress	Delivery Date
Better use of CPRD for information on devices safety to support signal and risk assessment	Preliminary feasibility work has been completed and a full study is now planned to explore the use CPRD with devices. A protocol will be submitted for approval by the Independent Scientific Advisory Committee, on target in Q4 2017. The study will be led by VRMM and will be started in Q1 2018.	Q4 2017
	A strategy document to robustly explore the wider use of CPRD by Devices is needed. The scope for this document was reviewed by the PSVS steering group in September and will continue to be developed in parallel with the above CPRD study.	Q4 2017

Engagement with registries to support better data collection and information sharing	Initial data gathering exercise (to collate details of already established Device and VRMM registry contacts and to identify future potential contacts of value) completed. Prioritisation of most important registries to our work with a view to increased engagement is the next step.	On hold – CPRD and signal/risk assessment work prioritised
Devices specific PSUR	UK is leading a cross EU task Force to develop a devices-specific PSUR and good progress is being made.	2018 – progress dictated by EU process

Better use of CPRD for information on devices safety to support signal and risk assessment

The planned study will be the first analysis of CPRD data conducted by the Agency for supporting devices vigilance. It is being led by VRMM given the expertise required.

This will inform a strategy document to get a broader understanding of where in the spectrum of device types there will be relevant data on exposure captured by the CPRD.

Common approach to post marketing/authorisation risk assessment

In addition to these deliverables, the CET considered the results of a mapping exercise on how post-marketing/post-authorisation safety signals are handled in Devices

Division and in VRMM. As part of this work Project Team 2 had looked at the tools used to support the signal/risk assessment process; the reports that are produced, who they are produced by and the sign-off process; and the criteria for seeking expert advice. For the Devices process, the Team also looked at the relative roles of the notified bodies (NBs) and MHRA in these processes and the mechanisms in place for sharing information on signals between the NBs and MHRA. Following consideration, the CET requested further clarification work to be done, particularly around procedures and processes which are different, to consider why these are different and provide justification as to why these could not be consistent across VRMM and Devices.

VRMM members of PT2 have met to consider current VRMM signal assessment procedures and processes and to discuss how these can be strengthened (in the short, medium and long term) in light of the opportunities afforded by Operational Transformation. The team has devised a framework for these considerations, which ensures there is consistent and systematic discussion of each and every step of the process.

Devices division propose the development of a risk based team which will be led by a G6 manager and will bring additional capacity and capability to understanding of risk.

HPRA visited the agency on 23 November to share their Risk Evaluation procedure for medical device related incidents. This presentation was intended to inform thinking on risk evaluation as part of the further development of devices safety and surveillance risk team and PSVS Project Team 2. The Devices work and VRMM workshops will be brought together by the Project Team so that similarities and differences between the proposed strengthened process can be discussed and a common approach agreed, where appropriate.

VRMM and Devices Divisions are undertaking a joint assessment of paraffin-based topical products and fire risk following receipt of a Coroner's report. The assessment of data relating to this risk will be jointly conducted by a BRMG Scientific Assessor and Device Specialists. A joint VRMM and Devices letter was sent to all marketing authorisation holders / manufacturers of these products requesting submission of all data/queries/complaints relating to this issue. The assessment of this data has begun with medicines and devices committee consideration anticipated in early 2018. It will provide a worked-example insight in to the different processes/procedures used by VRMM and Devices.

5. Project Team 3 – safety messaging and risk communication

Project Team 3 is responsible for delivering Strategic Objective 5 on improving MHRA's ability to deliver and target safety and learning messages.
The deliverables for Project Team 3 are set out below together with an update on progress:

Deliverable	**Progress**	**Delivery Date**
Bring together customer services to create	The appointed PSVS Delivery Manager will now be taking forward	Q4 2017 - Delay

safety hub, pilot joint safety update	this work – due to backfilling of roles this work commenced later than planned. Selected Medical Device Alerts are included in Drug Safety Update. Medicines and Devices will discuss a potential joint safety update in more detail.	Joint safety update Q1 2017
Reduce the number of channels via which information is sent to HCPs	This is connected with the Central Alerting System (CAS) and health summit work. A paper in relation to CAS was brought to the July 17 Regulatory Group.	Develop action plan in light of findings from the Health Summit – Q2 2018 (moved from Q1 2017)
Take over responsibility for sending DHPCs electronically	Plans for a 6 month pilot are still being worked up to test whether Direct Healthcare Professional Communications (DHPCs) sent electronically by MHRA using Gov.Delivery would improve health professional engagement and action compared to DHPCs sent by industry by post, as they are now.	Start pilot by Q1 2018 – delay
Intelligent point of care/prescribing system	This is a long-term project and not yet started.	TBC
Organise summit of health organisations that send safety messages to HCPs	MHRA is working with 13 partners to deliver the health summit which will now be held on 18 January 18. (further detail below).	January 2018

Pilot Joint Safety Update

PT3 is co-ordinating further discussions regarding a pilot for joint safety messages and an update will be given to the Steering Group. Initial concerns have been raised that will need to be considered, for example, many clinicians that sign up to the Drug Safety Update do not necessarily use devices so a MDA is not relevant to them; subscribers to MDA alerts may unsubscribe if they receive duplicate device alerts via Drug Safety Update and duplication runs the risk of being ignored; there is potential to send a mixed message / cause confusion by integrating medicines and device issues; customer preferences should be considered.

Engagement with the Healthcare System

Project Team 3 has been continuing to work with key healthcare partners to organise a **Health Summit** to discuss improving the impact of safety messaging in the healthcare sector. The summit is being held on 18 January at the Royal Society, later than the 31 October date we were originally working towards, but that time was needed to confirm speakers and the agenda.

Interest has also been shown by the National Quality Board,. This is seen as an important step and could be where any actions arising from the event (which are likely to fall to a number of partner organisations as well as ourselves at the Agency) are tracked and followed up.

The 'health summit' has also come to the attention of Ministers.

The Agency and partners have been delighted with the interest in this event from senior individuals. The event is oversubscribed and we have carefully managed the expressions of interest we have received. A number of Chief Executives and Medical Directors have submitted their interest, and we are offering a place to every NHS Trust and every CCG that has expressed an interest.

Over the coming weeks we will be putting the finishing touches to the day; we have a number of upcoming partnership meetings to support this process.

Central Alerting System (CAS)

Work is now underway on the lift and replicate model for the replacement system, due to be housed in the Agency and operational by April 2018. This is not a 'lift and shift' per se, as some components on the current system (Lotus Notes and Oracle Discoverer reporting tool) will not feature in the replacement. We are expecting some incremental improvements to come from replacement functionality, but much of the system will remain as is.
We have established a governance group, which will meet monthly until the new system is live, and will be involved in project oversight, user acceptance testing, and looking at any changes in functionality which may be possible. This group has representation from all organisations which use the current system to send their alerts.

In parallel to this work, we have been engaging with the independent sector to understand their use of CAS, their systems for processing safety alerts and what this might mean for any future changes. We have spoken to the Association of Independent Healthcare Organisations (and through them we have a number of upcoming visits to independent hospitals to look at their systems and processes) and we are speaking at a Hospice UK meeting of clinical leads, in early December. We have approached other Associations with a view to securing other opportunities to engage this diverse sector.

In the longer-term the intention is to use the Health Summit to understand what is needed from any future safety messaging system, which will inform any future business case.

Virtual Hub

Following the opening discussions with Comms, Devices, IE&S and VRMM, a paper was produced and presented to the PSVS Steering Group. A number of comments were made, with a request that management teams in each of the divisions have a chance to discuss and comment. Sessions have been held with Devices and VRMM,

and a date is sought with IE&S. These comments will inform a refreshed paper, which will be resubmitted to the Steering Group for comment and agreement on next steps.

6. Operational Transformation and Budget

There are Operational Transformation (including budgetary) implications for several of the deliverables agreed in this PSVS delivery phase and business cases will need to be developed at the appropriate time. There will continue to be discussions between the PSVS and OT teams in order to progress these as appropriate.

7. Conclusion and questions for the Board

This paper shows progress in a number of areas and highlights areas where there have been no developments due to resource issues or OT implications. In particular the Board is asked to note the Improving the Impact of Safety Messages Health Summit activities.

The Board is are asked to:

- Note the progress and issues highlighted in the report.
- Comments are welcomed

Devices
VRMM

December 2017