Document 05.05

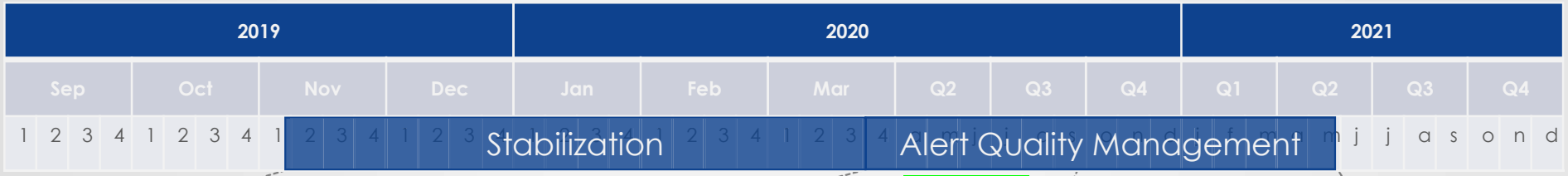
OPERATIONS UPDATE

FMD WORKSHOP
04/12/2019

EMVO AGENDA

- Hub Release Roadmap
- Hub Release 1.6
- Hub Release 1.7
- Alert Quality Management (Stabilization)
- NCA Reports
- Incidents

EU Hub Roadmap & scope



EU HUB
R 1.6

Completed Successful

Features

- CR0047_NCA Reports
- CR0059_Sample Management v2
- CR0060_Change Request - Reviewed Randomization Test
- CR0062_Update PMD Report
- CR0064_CR EU Hub – Change
- GTIN-ownership – Tool
- CR0072_Change Request - National Code Mandatory on per market basis
- CR0102_O1 Error Message Text refinement
- CR0112_ Add location of OBP Verifying Packs
- CR0113_Address API for End Users
- CR0114_Link between OBP and MAH
- CR0129_EU Hub R1.6
- Data lake solution (no data loss)

EU HUB
R 1.7

Planned

Features

- CR0092_Consistent routing IMT requests
- CR0100_Supervision Repackaging Reports
- Data Lake SSOT (Single Source Of Truth)
- PDR report in Datalake (stabilization)

EU HUB
R 1.8

In Governance

- CR56_Pack State "Clinical Trials"
- CR85_Call Back
- CR0103_PPSU Status Determination
- CR108_Update Alert propagation configuration

EU HUB
R 1.9

In Governance

Scope and Defect fixes to be assigned

Exact date to be confirmed

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HUB RELEASE 1.6 STATUS

- ***The Scope (reminder):***
- Several features for the NCA Reports are enabled.
- Pack Status updates for FREE SAMPLE and SAMPLE are possible in bulk.
- Serial Number Randomisation for the EU Hub is simplified.
- Product Master Data Report structure is updated.
- For Product Master Data uploads, the National Code is now a mandatory field for Portugal, Austria, Germany and Spain.
- Additional context description for O1 error messages is provided.

HUB RELEASE 1.6 STATUS

- ***What has been achieved?:***
- The system went live as planned on the 1st of November.
- No major issues have been found.
- ***What are the next steps?:***
- Lessons learned/retrospective sessions at EMVO & SSR.
- Combined findings :
  - Avoid multiple releases (HUB vs National)
  - Improve Communication planning & crisis management
  - Improve document quality and timing
  - IOT planning well in advance (automate where possible)
- Action plan under preparation with SSR

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HUB RELEASE 1.7 STATUS

- ***The Scope :***
- Due to a dependency (CR0100)of the 6.2 release of the SSR national system(planned for April 2020), Release 1.7 of the Hub must be finalised at the latest by end of March 2020.
- Release 6.2 of the SSR national system contains the next set of NCA reports.
- This has modified the intended scope, so release 1.7 will include
  - CR0092 Consistent routing of IMT requests (details next slide)
  - CR0100 Supervision Repacking Reports (details next slide)
  - PDR report in Datalake (stabilization)
  - Datalake as (SSOT) single source of truth.

1.7 CHANGE REQUESTS

Change Number	CR0092_Consistent routing of IMT requests
Description	The proposed change is to ensure that for a given pack, all intermarket requests are always routed to the same market
Advantage	Guarantees a consistent responses of IMT request
Risk	No risk identified
System Impacted	EU-Hub
Status	Scoped to the Hub release 1.7
Dependencies	No dependencies

1.7 CHANGE REQUESTS

Change Number	CR0100_Supervision Repackaging Reports
Description	This change will allow NCAs to request reports which relate with parallel distributor activities, as agreed with the EU-Commission to be delivered in April 2020.
Advantage	Permits NCAs to request two reports as per the requirements
Risk if not done	No risk identified
System Impacted	EU-Hub
Status	Scoped to the Hub release 1.7
Dependencies	No dependencies

HUB RELEASE 1.7 STATUS

- ***What has been achieved?:***
- Scope finalised
- Release date fixed (end March 2020)
- ***What are the next steps?:***
- Finalise detailed plan
- Review with TEAG at next F2F meeting (16/01/2020)
- Document approval
- Commence development

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ALERT QUALITY MANAGEMENT (STABILIZATION)

- We have started a project at EMVO to improve the quality of alerts.
- Project has been named SEA (Stabilize EMVS Alerts) by the technical team.
- We have singled out existing CRs that will have a direct impact on alert quality.

CR Number	Description	HUB	NMVS
EMVS_CR_011	Whitelisting for Products and Batches		X
EMVS_CR_XXXX	PSUM by the same Organisation Id and Alerts raising rules		X
EMVS_CR_XXXX (CR0138)	IMT Timeouts	X	X
EMVS_CR_XXXX	IMT and MMP Sync		X
CR0092 (Release 1.7)	Consistent routing of IMT requests	X	
EMVS_CR_012	IMTs - Initiating National system to raise alert		X
EMVS_CR_0013 (CR0134)	Expiry Date Data Elements Check	X	X
CR0135	Parameters and Potencial Incident Falsication Store	X	
EMVS_CR_XXXX	Manual Data Entry Harmonisation		X

PROJECT SEA

Change Number	EMVS_CR_0011_Whitelisting for Products and Batches
Description	Allows National Systems to whitelist Product Codes and Batches that are out of scope of the FMD, so that no alerts are raised for packs associated with these Products and Batches.
Ranking	1
Advantage	No alerts raised for packs that are out of scope of FMD
Risk	Risk of potential misuse of the whitelist
System Impacted	National System
Status	Scoped (Arvato 1.06) Solidsoft (Not started)
Dependencies	No dependencies

PROJECT SEA

Change Number	EMVS_CR_XXXX_PSUM by the same Organisation Id and Alerts raising rules
Description	In case the same OBP requests twice (or more times) the same pack status update in a defined period, the National System shall not respond with an alert, but with an error message informing the user that the same request has been already submitted
Ranking	2
Advantage	No unnecessary alerts are raised. A single request can raise up to 250k alerts
Risk	No risk identified
System Impacted	National System
Status	CR ready for CAB approval
Dependencies	No dependencies

PROJECT SEA

Change Number	EMVS_CR_XXXX_IMT Timeouts CR0138_IMT Timeouts
Description	Allows that packs can still be decommissioned if an IMT times-out. No alerts will be raised in this scenario anymore
Ranking	3
Advantage	No packs are rendered unsellable. No unnecessary alerts raised.
Risk	No risk identified
System Impacted	EU-Hub and National System
Status	Pre-Design
Dependencies	CR0092 EMVS_CR_XXXX_IMT and MMP Sync

PROJECT SEA

Change Number	EMVS_CR_XXXX_IMT and MMP Sync
Description	If a National System receives an IMT Status Update or Multiple Market Pack Synchronisation that was initiated by the same organisation and at the same time as a previously received request, then this should be considered as a repeated request and no alert should be raised
Ranking	3
Advantage	No unnecessary alerts are raised in case a National System has timed-out during an IMT transaction.
Risk	No risk identified
System Impacted	National System
Status	Pre-Design
Dependencies	No dependencies

PROJECT SEA

Change Number	EMVS_CR_012_IMTs - Initiating National system to raise alert
Description	If an alert needs to be raised in an IMT process, then it shall be raised by the initial National System of the requests - where the pack is locally scanned.
Ranking	4
Advantage	Enforces that National Systems raise only one alert in this scenario
Risk	No risk identified
System Impacted	National System
Status	Ready for CAB's approval
Dependencies	No dependencies

PROJECT SEA

Change Number	EMVS_CR_0013_Expiry Date Data Elements Check CR0134_Expiry Date Data Elements Check
Description	If a pack is verified or decommissioned the system shall no longer raise an alert in case there is a mismatch in the day of the expiry date. Month and Year shall still be checked and raise an alert if necessary
Ranking	4
Advantage	Harmonize the scenarios that raise an Expiry Date Mismatch alert between National Systems
Risk	No risk identified
System Impacted	EU-Hub and National System
Status	Draft (Available in the EU Cab Folder)
Dependencies	No dependencies

PROJECT SEA

Change Number	CR0135_Parameters and Potencial Incident Falsication Store
Description	Guarantees that the pack disclosure report contains all information about the pack audit trail
Ranking	5
Advantage	Although it does not reduce number of alerts, it will guarantee that an accurate information is in the pack disclosure report
Risk	No risk identified
System Impacted	EU-Hub
Status	CR ready for SSR
Dependencies	No dependencies

PROJECT SEA

Change Number	EMVS_CR_XXXX_Manual Data Entry Harmonisation
Description	This change describes how manual entry of data should be handled by the different National Blue-Print Systems
Ranking	5
Advantage	Avoid that human errors provoke an alert when an IMT is requested
Risk	No risk identified
System Impacted	National System
Status	Pre-Design
Dependencies	No dependencies

PROJECT SEA

- ***What are the next steps?:***
- Document change requests
- Liaise with NMVOs on national system modifications
- Review with TEAG
- Create detailed plan and release dates for each change request.

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NCA REPORTS NATIONAL SYSTEMS

Ref	Title	Delivery	Delivery Date	Arvato countries delivered or on track YES/NO	SSR countries delivered or on track YES/NO
S.2.1	General Activity Report (Wholesaler)	1	25-Oct-19	Partially?	YES
S.2.2	Sepcific Report for a Medicinal Product (Wholesaler)	1	25-Oct-19	Partially?	YES
S.3.1	General Activity Report (Local Organisation)	1	25-Oct-19	Partially?	YES
S.3.2	Specific Report for a Medicinal Product (Local Organisation)	1	25-Oct-19	Partially?	YES
I.1	Audit trail of a suscpected medicinal product pack	1	25-Oct-19	Partially?	YES
I.2	Specific Report for operations with other packs of a suspected medicinal product	1	25-Oct-19	Partially?	YES
S.1.1	General Activity Report (MAH)	2	13-Dec-19	Postponed to 09-Mar-20	YES - except Sweden (mid-January TBD)
S.1.3	List of the manufacturers/MAH and their ID	2	13-Dec-19	Postponed to 09-Mar-20	YES - except Sweden (mid-January TBD)
S.2.3	Specific Report Verified Packs	2	13-Dec-19	Postponed to 09-Mar-20	YES - except Sweden (mid-January TBD)
S.2.4	Specific Report Decommissioned/Reverted Decommissioned packs (Wholesaler)	2	13-Dec-19	Postponed to 09-Mar-20	YES - except Sweden (mid-January TBD)
S.2.5	List of the wholesalers and their ID	2	13-Dec-19	Postponed to 09-Mar-20	YES - except Sweden (mid-January TBD)
S.3.3	Specific Report Decommissioned/Reverted Decommissioned Packs (Local Orgnaisation)	2	13-Dec-19	Postponed to 09-Mar-20	YES - except Sweden (mid-January TBD)
S.3.4	Auxilliary report: List of persons authorised or entitled to supply medicinal products	2	13-Dec-19	Postponed to 09-Mar-20	YES - except Sweden (mid-January TBD)
R.4	Auxilliary Report: List of persons entitled to supply medicinal products to the public	2	13-Dec-19	Postponed to 09-Mar-20	YES - except Sweden (mid-January TBD)
R.1	Number of product packs decommissioned as supplied in a market or post code	2	13-Dec-19	Postponed to 09-Mar-20	YES - except Sweden (mid-January TBD)
R.2	Number of product packs decommissioned (supplied) by a person entitled to supply medicinal products to the public	2	13-Dec-19	Postponed to 09-Mar-20	YES - except Sweden (mid-January TBD)
I.3	Similar operations with other medicial products by the same agent	2	13-Dec-19	Postponed to 09-Mar-20	YES - except Sweden (mid-January TBD)
I.4	Falsified packs/batch situation report	2	13-Dec-19	Postponed to 09-Mar-20	YES - except Sweden (mid-January TBD)
I.5	Number of products packs intended for other markets and verified in a specific market	2	13-Dec-19	Postponed to 09-Mar-20	YES - except Sweden (mid-January TBD)
S.1.2	Decommissioned/Reverted Packs Report	3	24-Apr-20	Expected delay in delivery	YES
S.2.6	Auxilliart report: Designated wholesalers	3	24-Apr-20	Expected delay in delivery	YES
S.4.1	No activity Report for MIA/MAH	3	24-Apr-20	Expected delay in delivery	YES
S.4.2	No Activity Report for Wholesalers	3	24-Apr-20	Expected delay in delivery	YES
S.4.3	No activity Report for entities supplying to the public	3	24-Apr-20	Expected delay in delivery	YES
R.3	Product pack Unique Identifiers decommissioned (supplied) by a person entitled to supply medicinal products to the public	3	24-Apr-20	Expected delay in delivery	YES
R.5	Master data - Product code to National code	3	24-Apr-20	Expected delay in delivery	YES
Ph.1	Number of products decommissioned in a specific market	3	24-Apr-20	Expected delay in delivery	YES
Ph.2	Batch Destination Report	3	24-Apr-20	Expected delay in delivery	YES
Ph.3	Active Packs Available Report	3	24-Apr-20	Expected delay in delivery	YES

- Priority 1: Mainly delivered (Arvato?)
- Priority 2:
  - Arvato delayed until 09/03/2020
  - SSR on track (except Sweden)
- Priority 3:
  - Arvato countries expected delay due to priority 2 postponement
  - SSR on track
- Germany:
  - Same set of reports as specified by EMVO/WG II
  - Content of NCA reports as specified by EMVO/COM WG II except
  - I.1 "Audit trail of a suspected medicinal product pack" adapted to the differing requirements of the German market
  - Lay-out and language of the reports/GUI still to be decided

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INCIDENTS

- **Audit log queues overload**
  - **Description**
    - Due to the number of alerts, the component that writes the alerts audits has been overwhelmed
    - Alert messages are delivered with no delays, but this audit points need to be written for reporting purposes. (e.g. request a Pack Disclosure Report)
    - There is a limitation in this queues to store messages for only 7 days, so when the audit writer falls behind, there is the risk that the event drops off the queue before being processed
    - Any occurrence since the incident of mid-July
  - **Actions**
    - Daily monitoring by Solidsoft Reply to evaluate the state within the audit store
    - Monitoring is communicated to the EMVO Operations team
  - **Fixing plan**
    - First Stage: Avoid data loss by starting to write the audit points in Data Lake – Release 1.6 - Done
    - Second Stage: Full fix PDR with the implementation of Data Lake solution – Release 1.7

INCIDENTS

- **Alerts**
  - **Description**
    - Propagation of alerts from the Hub to be extended to include all L5 alerts in the configuration
    - Content and raising conditions different between the two suppliers
  - **Actions**
    - CR0108 approved and in scope for the EU-Hub release 1.8 **(Sep 2020)**
  - **Alert Harmonisation Workgroup weekly sessions**
    - The group is working on a to-be document to be shared within the EMVS community
    - A plan from both Arvato and Solidsoft will be done to achieve the harmonisation
    - No impact is expected on OBPs' side.
    - The group is aiming to have the document ready by the **31st of December 2019**

INCIDENTS

- **IMT issues**
  - **Description**
    - IMT requests being routed to the wrong fulfilment market Fixed as 1.6 is deployed
    - Time out transaction in the fulfilling National systems is returned to the initiating one, however the pack status is done
    - As the initial end-user receives a failed confirmation but the pack needs to be supplied, a retry action is re-initiated
    - Alerts are raised in the fulfilling National System

  - **Actions**
    - Fulfilment bug fixed in release 1.6 (Done)
    - EMVO Operations team is currently discussing this issue with the EMVS architect to find the best solution to this problem
    - Change to be defined and follow the usual change control process
    - We have already a concept for two change to fix this:
      - **Change 1:** In case an IMT timeout, then the EU Hub shall respond with a more specific error code to the initiating National System
      - **Change 2:** If a National System receives an IMT Status Update or Multiple Market Pack Sync requests where the end-user location, timestamp and status change matches a previous transaction, then the response back to the EU Hub shall be that the pack is successfully updated.
      - There is a dependency with CR0092 routing of IMT requests.

QUESTIONS ?