DOCUMENT VERIFICATION

Prior to using this document, the user is responsible for verifying that the revision and effective date are current.

REVISION HISTORY

Rev.	Effective Date	Changes Made to Document
1	16-April-2021	First issue

1. Content

2. Introduction

The purpose of this document is to summarise the fortnight post-market surveillance report for LFD where DHSC is distributor or manufacturer. This report covers period from 27-March-2021 to 09-April-2021.

This report includes inputs from Intertek Testing, Product Complaints, Qualtrics survey, Real World Performance Monitoring, CAPA and SCARs.

3. Methodology

The methodology for data collection was established in the PMS plan PMS-0001 Revision 1, dated 24-Feb-2021.

4. Findings /Results

Intertek Testing

A sample size of the 34 lots was tested. Lot quantity for these lots range from 1 million units to 4 million units. Sample size tested varies from 14 to 400 units tested. Samples are tested for performance positive control, Negative control and control line test. All sample tested passed the test. (Refer to Attachment 2 for data)

All tested devices performed as expected.

Product complaints

- A total of 37 reported complaints were registered in the complaints log by DHSC Quality. Out of these, 35 were yellow card complaints forwarded by MHRA and 2 were reported by control tower.

- All 37 reports Complaints were considered: Not reportable following assessment *(A: An even has occurred, B: The MANUFACTURER's device is suspected to be a contributory cause of the INCIDENT, C: The event led, or might have led, to one of the following outcomes: -dead or serious deterioration in state of health).* of the complaints as per MEDDEV 2 12-1 Rev8 section 5.1.1
- 21 yellow card complaints were reported without any batch information.
- 2 complaints (Complaint-21-03-0508, Complaint-21-03-0546) related to false negative result were allocated to the same lot X2101004.Hazard ID allocated to them was HI39, however after investigation it was identified that 1 complaint (Complaint-21-03-0546) was not device related.
- The highest number of complaints was for hazard ID HI10 related to missing components with 11 complaints. Batch number was provided for only 5 complaints out of 11 complaints. There was no trend seen for missing component complaints for the 5 batches number reported.
- A new hazard identified which was not recorded in the current Risk Management File revision 2 was for nose bleeding.

(Refer to Attachment 3 for data)

Qualtrics survey

Qualtrics Survey has been updating during this period. The data is skewed because it was updated mid reporting period, so there are 2 different sets of data

- A total of 656 complaints were recorded through the Qualtrics Survey
- 37 out of 656 complaints reported missing Buffer Sachet or Bottle
- 82 out of 656 complaints received reported injury to user. Survey redirects user to Yellow Card to report injury
- No new hazards have been identified

(Refer to Attachment 3,4 for data)

Real World Performance Monitoring

The performance for Innova 3&7 self-testing for the period is outlined

1. Escalated 1 site ([redacted] as potential incidents to integrator team due to void rate with confidence intervals above our pre-defined threshold
2. Escalate to Private Industry and Public Industry use-case teams that overall Confirmatory PCR testing rates (60.0% and 66.7% respectively) are below threshold (70%) in the self-testing setting which is currently being piloted.
3. Work ongoing to formally model expected device performance relative to prevalence positivity

(Refer to Attachment 5, 6, 7 for data)

CAPA and SCARs

CAPA currently open for LFD

CAPA-21-04-0005 for Latex Allergic this is in Investigation and action planning status

The below is a list of closed (SCARs) Supplier Corrective Actions Records raised previously to address LFD product issues:

SCAR-2021-002 Missing Component –

1. Innova has addressed this issue within the supply chain and has requested our suppliers to undertake more cautious quality checks. Innova is also dedicating additional personnel to conduct additional quality checks at the manufacturing facility.

SCAR-2021-004 Faulty Product –

1. Innova has stopped using split extraction tubes since January, 2021. At the same time, Innova has intensified efforts to find new suppliers, design and develop new mouldings, and eliminate the occurrence of bad problems from the source of product design. Extraction tube suppliers are also ramping up production to avoid the phenomenon of different extraction tubes in batch.

SCAR-2021-008 Labelling/ Identification –

1. Why the outer box does not indicate the lot information ： Because Innova thinks that liquids are shipped in lot as an accessory, and the lot number is fixed, so Innova only adds the name and quantity of the contents in the outer box, ignoring the identification batch information;

2. Why the lot information is ignored: Because the project was produced in the form of a temporary contact list, the label on the outer box was not systematically evaluated, which led to the occurrence of this problem.

SCAR-2021-012 Leaking tube –

1. Improve bottle structure design; The structure of double screw cap is improved into the form of inner plug and single screw cap

2. Improve labelling procedure, and adopt automatic labelling by machine instead of manual labelling;

3. Work with the label supplier to find out if there is a waterproof label with better adhesion;

4. Improve packaging methods if necessary, arrange the bottles neatly to avoid squeezing, or reduce the quantity of the whole box

(Refer to Attachment 8 for data)

5. Conclusion

Batch issues

- Only 16 Reports have lot number information out of 37 reports.
- No trend was seen for any particular batch number reported.
- Qualtrics Survey- 37 out of 656 complaints reported missing Buffer Sachet or Bottle

User incidence

- Qualtrics Survey – 82 out of 656 complaints received reported injury to user. Survey redirects user to Yellow Card to report injury
- Yellow Card – A new hazard was identified for RMF: nose bleeding.

CAPA

- CAPA-21-04-0005 for Latex Allergic this is in Investigation and action planning status

Trends and analysis

- The highest number of complaints was for hazard ID HI10 related to missing components with 11 complaints. Batch number was provided for only 5 complaints out of 11 complaints. There was no trend seen for missing component complaints for the 5 batches number reported.

Clinical Review

- Clinical reviewed requested for event related to Allergies for clarification on the reportability.

Recall

- Non instigated

6. Actions

No	Action	Responsible Name/Email	Due Date
1	Risk management file to be updated with hazard for allergic reaction, latex and bleeding nose, missing components an unable to continue the test.	[redacted]	30-April-2021
2	CAPA to be opened to record Real World Performance monitoring actions	[redacted]	19-April-2021

7. Attachments

Attachment 1: PMS-0001, PMS Plan for the DHSC Covit-19 LFD Devices (3 and 7 kit) Rev1, 24-Feb-2021

Attachment 2: Intertek testing

Attachment 3: DHSC PSR – Complaints & Qualtrics data

Attachment 4: Qualtrics data review summary

Attachment 5: RWPM Innova 25s

Attachment 6: RWPM Innova 3s and 7s

Attachment 7: RWPM Innova Assisted

Attachment 8: CAPAs and SCARs for LFD

Attachment 9: PMS tracker presented previously.