Human Medicines Division
EMA/222433/2024

Business process description

Title: Quality defect and non-compliance management		
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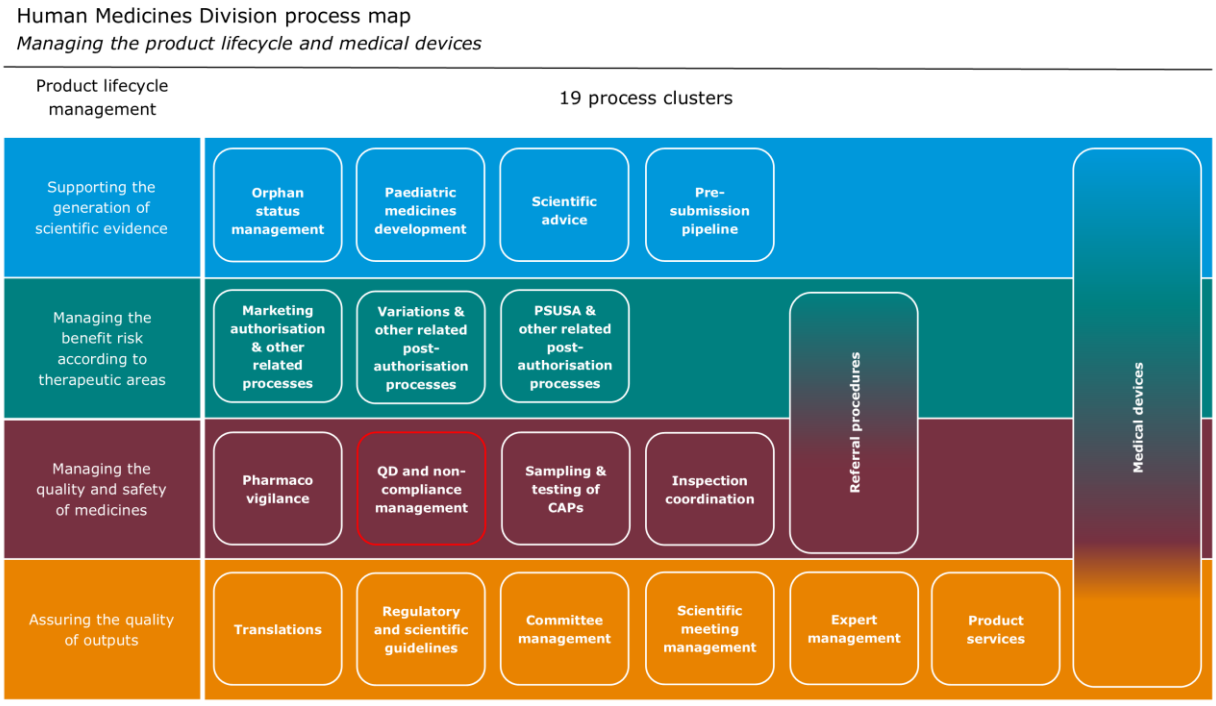
1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for the quality defect and non-compliance process, which involves the coordination of the investigation, evaluation, and follow-up in cases of suspected quality defects.

This process is part of the Human Medicines Division's process map (image below) which provides a high-level overview of the 19 process clusters within the operating model of the Human Medicines Division.



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Quality defect and non-compliance management process:

The quality defect and non-compliance management process encompasses both human and veterinary products/activities.

It describes the actions and responsibilities for the handling of:

- notifications of (suspected) quality defects, rapid alerts, non-compliance statements and (suspected) falsifications of centrally authorised human and veterinary medicinal products;
- pharmacovigilance non-compliance notifications of centrally and nationally authorised human and veterinary medicinal products,

received by EMA, and which may require immediate action. These notifications may concern all or some batches placed on the market for commercial use or batches that are due to be released.

With respect to quality defects, rapid alerts, GMP non-compliance statements and (suspected) falsifications, this process can also apply to products authorised through the mutual recognition, decentralised or national procedures but only when such cases are considered to have a broader impact to several markets and where a Member State has requested a central co-ordination of the issue.

2. Changes since last revision

New business process description

3. Related documents

Procedure documents:

- Procedure for dealing with serious GMP non-compliance requiring co-ordinated measures to protect public or animal health
- Procedure for dealing with serious GMP non-compliance information originating from third country authorities or international organisations
- Procedure for managing rapid alerts arising from quality defects risk assessment

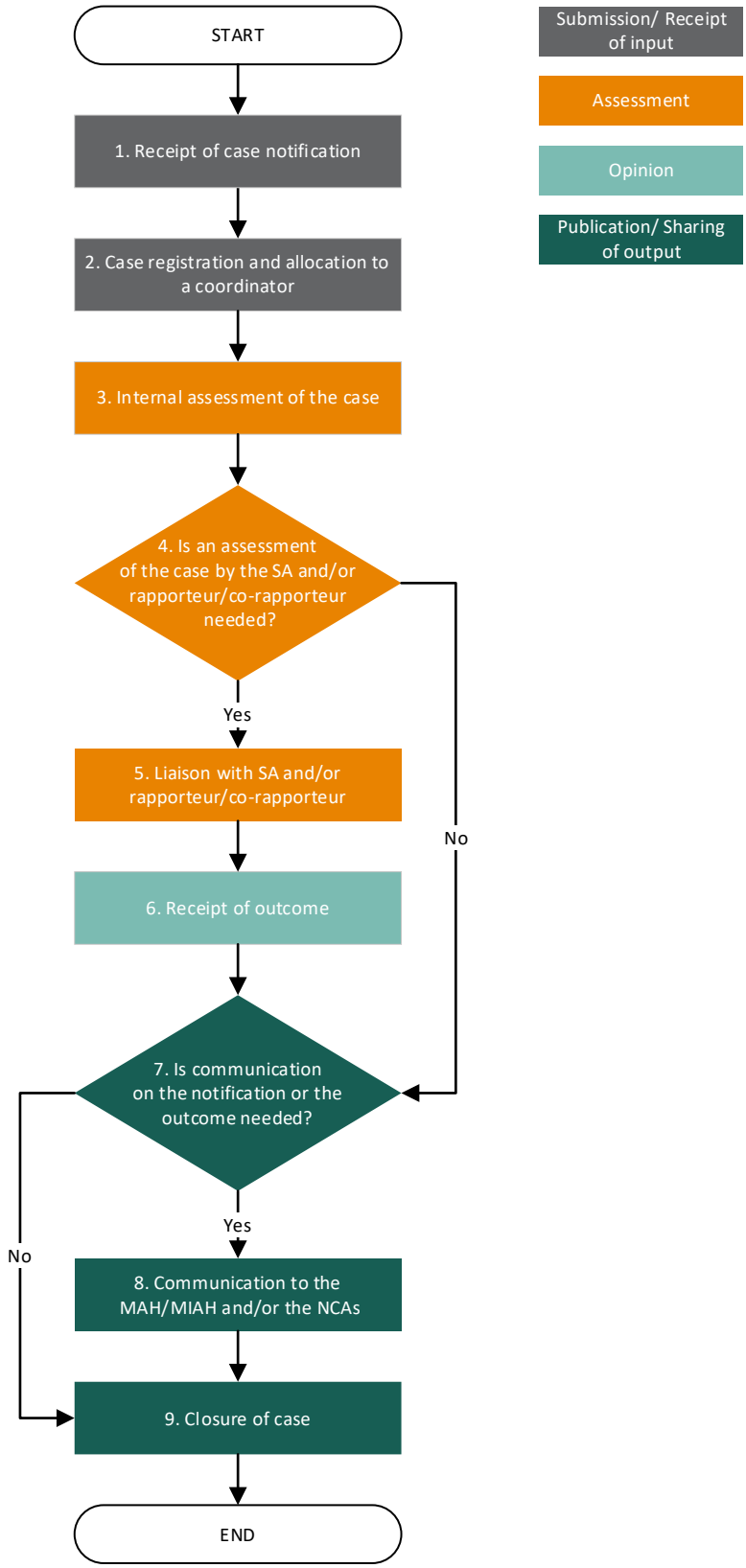
Relevant information:

- Falsified medicines: reporting obligations
- Good manufacturing practice
- Notification of serious GMP non-compliance information originating from third country authorities or international organisations
- Management and classification of reports of suspected quality defects in medicinal products and risk-based decision-making
- Reporting a quality defect to EMA

4. Abbreviations/Definitions

CAPs	Centrally authorised products
EMA	European Medicines Agency
GMP	Good Manufacturing Practice
MAH	Marketing authorisation holder
MIAH	Manufacturing and importation authorisation holder
NCA	National competent authority
PSUSA	Periodic safety update report single assessment
QD	Quality defect
SA	Supervisory authority

5. Process map(s)



6. Procedure

Step	Description
1.	**Receipt of case notification** • The case notification is received through the applicable functional mailbox
2.	**Case registration and allocation to a coordinator**
3.	**Internal assessment of the case** • The case is assessed by the coordinator to verify which actions are required
4.	**Is an assessment of the case by the SA and/or rapporteur/co-rapporteur needed?** • If yes, go to step 5 • If no, go to step 7
5.	**Liaison with SA and/or rapporteur/co-rapporteur**
6.	**Receipt of outcome** • The outcome of the assessment performed by the SA and/or rapporteur/co-rapporteur is received
7.	**Is communication on the notification or the outcome needed?** • If yes, go to step 8 • If no, go to step 9
8.	**Communication to the MAH/MIAH and/or the NCAs** • The notification or the outcome, including regulatory action(s) if applicable, is communicated to the MAH/MIAH and/or the NCAs
9.	**Closure of case** • The case is closed, and the records are updated