EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Defective Product Report

Medicine Type

Human

Date/Time of Submission

2/9/2022 12:2

1 REPORTER DETAILS

Reporter	Company	Representing
Address	**E-mail**	**Direct Phone Number**

2 PRODUCT DETAILS

+ Product - Product

	Product	INN	MA Type	MA Number	Strength
1	Iclusig	ponatinib	CAP	EU/1/13/839/003	45 mg

Pharmaceutical Form	Route of Administration	Presentation/packaging
Film-coated tablet	Oral use	45 mg / 30 ct

Manufacturer of the Batch		Site of Batch Release		Marketing Authorisation Holder	
Name	N/A	**Name**	N/A	**Name**	N/A
Address	N/A	**Address**	N/A	**Address**	N/A

+ Batch -Batch

	Batch Size	Units Affected	Batch N	Expiry Date	Manufacturing Date	Product Distribution	Pack Language (s)
1.1	Unknown	Unknown	PR084957	09-2023	Unknown	Unknown	German

3 DEFECT DETAILS

Defect Description

Confirmed falsification of Iclusig 45 mg/30 ct German packs in India:

On 16 August 2022, Incyte received an enquiry from India from a patient's brother.
The request was to confirm whether Iclusig 45 mg, batch PR084957, Exp: 09-2023, purchased from a Wholesaler in India (name not disclosed by enquirer), was genuine or not.

After evaluation by Incyte, it can be confirmed that the product (Iclusig 45 mg, batch PR084957, labelled in German, Exp: 09-2023) is a counterfeit.
Indeed, although Batch PR084957 corresponds to an actual batch of Iclusig 45 mg, released by Incyte on 7 August 2019 and distributed in Germany, it is expired since September 2021.
In addition and based solely on pictures provided, the following differences have been noticed between the actual batch PR084957 released by Incyte and the counterfeited batch PR084957 (see attached pictures):
- Different typeface, colors and text positioning and typos
- Wrong MAH (Incyte Biosciences UK instead of Incyte Biosciences Distribution B.V.)
- Wrong expiry date (09-2023 instead of 09/2021 for the actual batch released by Incyte)
- Wrong label artwork reference (20001194-01 instead of 20001106-03)

There is no indication that any pack of the counterfeited batch PR084957 has ever been distributed in Germany or any other EU country.

+ -

Defect Category	Defect Descriptor
3.0 Product label issues	3.1 Physical product label

Site where the defect occurred

Name	Address
Unknown	Unknown

4 INVESTIGATION AND ACTION DETAILS

Summary of the investigation

The investigation includes:

- Retrieval and testing of sample of the counterfeited batch
- Name of distributor(s) and supply chain
- Presence of other counterfeited batches in India

Competent Authority (ies) Contacted

- Indian Authorities
- WHO
- Incyte is also notifying the national Authorities of countries where pack in German is currently supplied: BfArM, Swissmedic

Adverse Reactions/ Events and Reoccurrence Identified (report according to applicable pharmacovigilance requirements for **human medicines** or **veterinary medicines**.

No adverse events have been reported as the product has not been administrated to the patient as per the counterfeit report.

Proposed Action	Justification of the Proposed Action
Other, please specify	Investigation on the supply chain. Samples also needed to conduct analysis on the tablets

Other: Seek support of Indian Authorities to investigate on distributor(s) and to receive some samples of the counterfeited batch

Proposed Depth of the Recall	Consequences of proposed action on market
None	

-> In the event that the agreed action intended to take is leading to disruption in product supply, please verify if a Withdrawn Product Notification is needed.

Description of the Root Cause Identified/Expected	Root Cause Details
Other, please specify	Confirmed falsified product

Other:

+ CAPA - CAPA

	Proposed/Taken CAPA to Prevent Issue Reoccurrence	CAPA Implementation Timeline
1	Serialization and tamper evidency on Iclusig packs (already implemented)	As per FMD implementation timelines

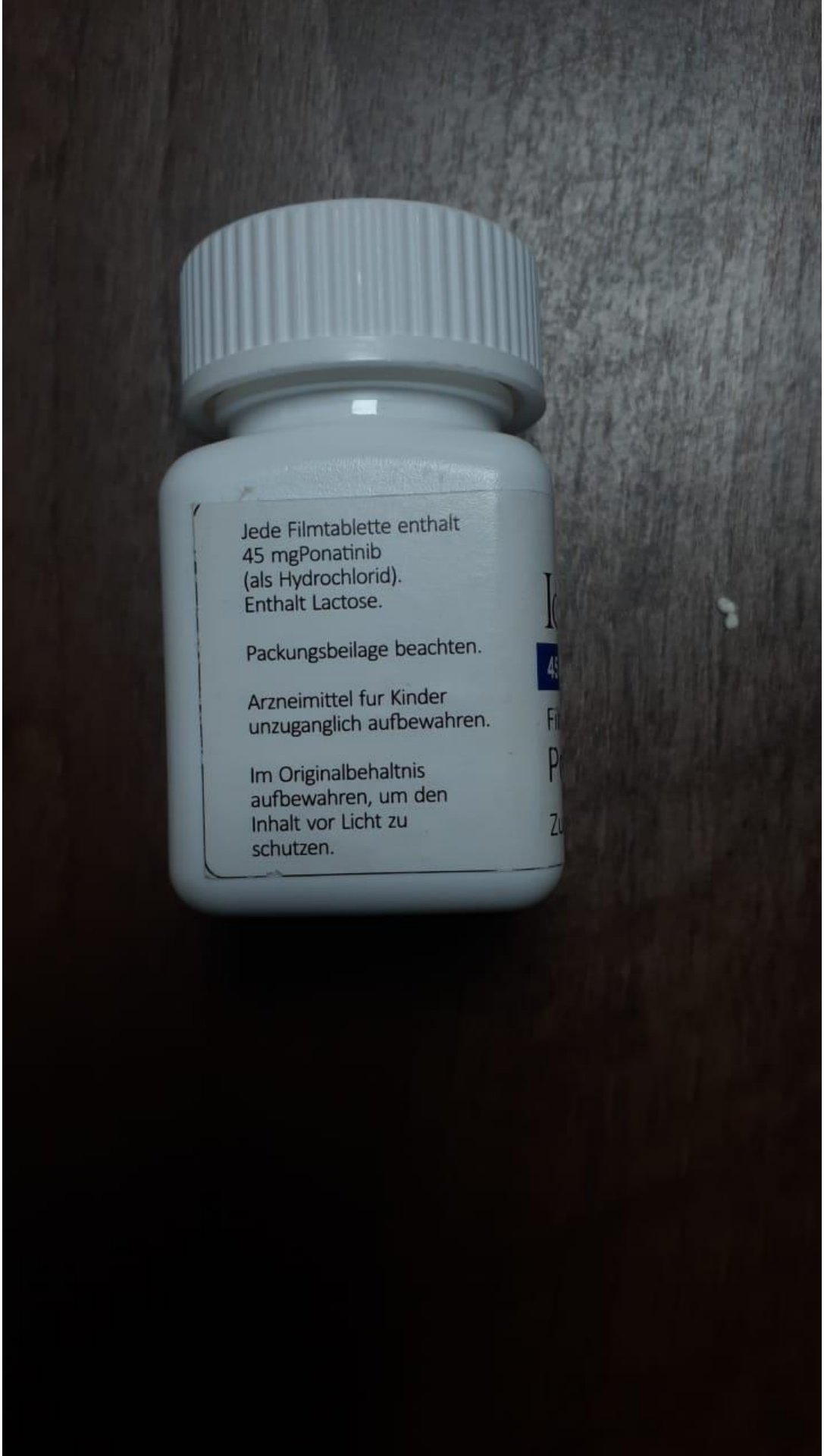
! Please provide in timely fashion: investigation report including CAPAs, health hazard risk assessment report, photos, test results and any other documentation, if needed.

Attach Files

Please attach the investigation and any other relevant documentation.

Submit Notification


30 Tabletten
ICLUSIG®
45 mg
Filmtabletten
Ponatinib
Zum Einnehmen
Incyte Biosciences UK Ltd.
Riverbridge House
Guildford Road, Leatherhead


Jede Filmtablette enthalt
45 mgPonatinib
(als Hydrochlorid).
Enthalt Lactose.
Packungsbeilage beachten.
Arzneimittel fur Kinder
unzuganglich aufbewahren.
Im Originalbehaltnis
aufbewahren, um den
Inhalt vor Licht zu
schutzen.

Surrey Kt22 9AD
Vereinigtes Konigreich

20001194-01
Ch.-B. : PR084957
Verwendbar bis : 09 - 2023
EU/1/13/839/003

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