গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
মহাখালী, ঢাকা-১২১২
www.dgda.gov.bd
DGDA-PV/BD/III/02/002/2019

নং-ডিজিডিএ/এলার্ট-নোটিশ-০১/২০১৭/১৬ তারিখঃ ২৪/০২/২০১৯

বরাবর

1. DG, Directorate General of Health Services (Attention: Director, Hospital & Clinical Service)
2. Dr. Md. Rafiqul Islalm, Associate Professor, Department of Medical Oncology, National Institute of Cancer Research & Hospital (NICRH), Mohakhali, Dhaka.
3. Secretary General, Bangladesh Medical Association (BMA), BMA Vaban, 15/2 Topkhana Road, Dhaka.
4. Secretary General, Bangladesh Society of Medicine, Dept. of Medicine, Dhaka Medical College, Dhaka.
5. Secretary General, Bangladesh Pediatric Association (BPA), Plot#7/3C, Barabag. sec#2, Mirpur, Dhaka-1216.
6. Secretary General, BAPI.
7. President, Bangladesh Importers Association.

বিষয়ঃ বিশ্ব স্বাস্থ্য সংস্থা (WHO) মেডিক্যাল প্রোডাক্ট এলার্ট N° 3/2019 প্রসঙ্গে।

বিশ্ব স্বাস্থ্য সংস্থা (WHO) সম্প্রতি মেডিক্যাল প্রোডাক্ট এলার্ট N° 3/2019- এ এই মর্মে সতর্ক করেছে যে, INCYTE Biosciences UK Ltd. কর্তৃক উৎপাদিত ICLUSIG 45mg (30 Tablets) এর ২টি ব্যাচ (Batch No: PR072875 এবং Batch No: PR0834170) মালয়েশিয়ার বাজারে নকল (Falsified) হিসেবে পাওয়া গেছে। নকলের কারণ হিসেবে ল্যাবরেটরীর ফলাফল অনুযায়ী উক্ত দুইটি ব্যাচের ঔষধে Ponatinib ছিল না, যার পরিবর্তে Paracetamol পাওয়া গেছে। ঔষধ প্রশাসন অধিদপ্তর কর্তৃক ঔষধটি আমদানি ও বাজারজাতকরণের জন্য কোন রেজিস্ট্রেশন প্রদান করা হয়নি বিধায় বাংলাদেশের জন্য ঔষধটি অবৈধ।
(সংযুক্ত কপিতে রঙ্গিন ছবি সহ টেব্যুলেটেড ফর্মে বিস্তারিত উল্লেখ করা আছে)।

Lot/Batch No	Language on Packaging	Expiary Date
PR072875	English	Dec, 2019
PR0834170	German	June, 2020

এমতাবস্থায়, উপরোল্লিখিত INCYTE Biosciences UK Ltd. কর্তৃক উৎপাদিত ০২ (দুই) টি ব্যাচের ICLUSIG 45mg (30 Tablets) নামীয় ঔষধ ব্যবহার থেকে বিরত থাকার জন্য এবং এতদ্বসংক্রান্ত বিষয়ে প্রয়োজনীয় ব্যবস্থা গ্রহণের জন্য অনুরোধ করা হল।

সংযুক্তিঃ ০৩ (তিন) পাতা।

২৪/২/২০১৯
পরিচালক (চঃদাঃ)
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Ref. EMP/SAV/Alert N°3.2019 21 February 2019

Medical Product Alert N° 3 / 2019

Falsified ICLUSIG available at patient level in Asia and traded globally

This Medical Product Alert relates to confirmed falsified versions of ICLUSIG 45mg circulating in the WHO Region of the Western Pacific. This is linked to the WHO Medical Product Alert N°2/2019 issued on 31 January 2019 regarding falsified ICLUSIG traded globally. Genuine ICLUSIG, the active pharmaceutical ingredient of which is Ponatinib Hydrochloride, is used to treat different forms of leukaemia.

On 18 February 2019, WHO was informed that a wholesaler based in Malaysia had purchased the product ICLUSIG 45mg with batch number PR072875, presented in English language packaging. This specific product is referenced in the previous WHO Medical Product Alert N°2/2019 and is confirmed falsified.

The same wholesaler had also purchased ICLUSIG 45mg with batch number PR0834170, presented in German language packaging. Upon verification, the stated manufacturer confirmed that this specific product is also falsified.

Details of the two falsified products detected in Malaysia are summarized in the below table:

Table 1: Details of falsified ICLUSIG products and subject of the WHO Medical Product Alert N°3/2019

Product Name	ICLUSIG 45mg (30 tablets)	ICLUSIG 45mg (30 Tabletten)
Stated manufacturer	INCYTE Biosciences UK Ltd.	INCYTE Biosciences UK Ltd
Lot / Batch Number	PR072875	PR0834170
Expiry Date	12/2019	06/2020
Language on packaging	*English*	*German*

At this stage, laboratory analysis has not yet been conducted on the samples from Malaysia. Both products were made available at patient level.

Samples of the two falsified ICLUSIG products which are referenced in the previous WHO Medical Product Alert N°2/2019 have been analyzed (ICLUSIG 45mg with batch number PR072875 and ICLUSIG 15mg with batch number 25A19E09). Both laboratory results show that the expected active ingredient, ponatinib, is absent, and, instead, paracetamol is present.

ICLUSIG is commercialized by different stakeholders in different parts of the world. The pharmaceutical companies TAKEDA and INCYTE are the genuine manufacturers of ICLUSIG and they have both confirmed to WHO that:

- They did not manufacture or supply the above products;
- The batch number PR0834170 does not correspond to genuine manufacturing records;
- The batch number PR072875 combined with English language packaging does not correspond to genuine manufacturing records.

Photographs are available on the following page.

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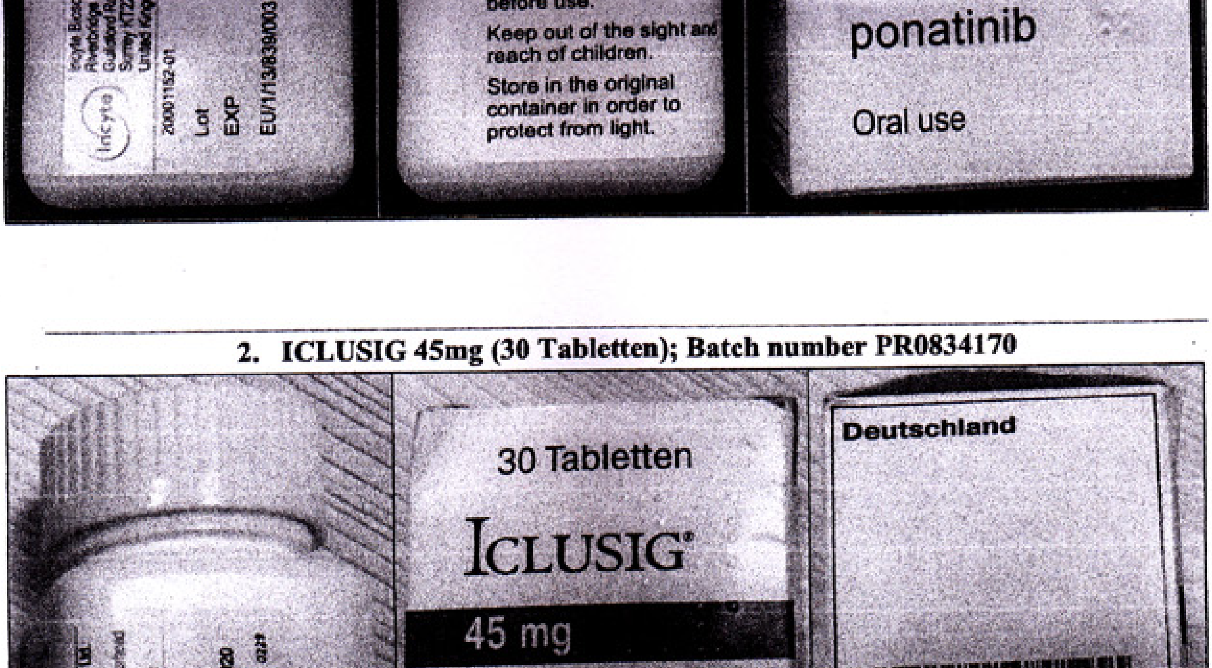
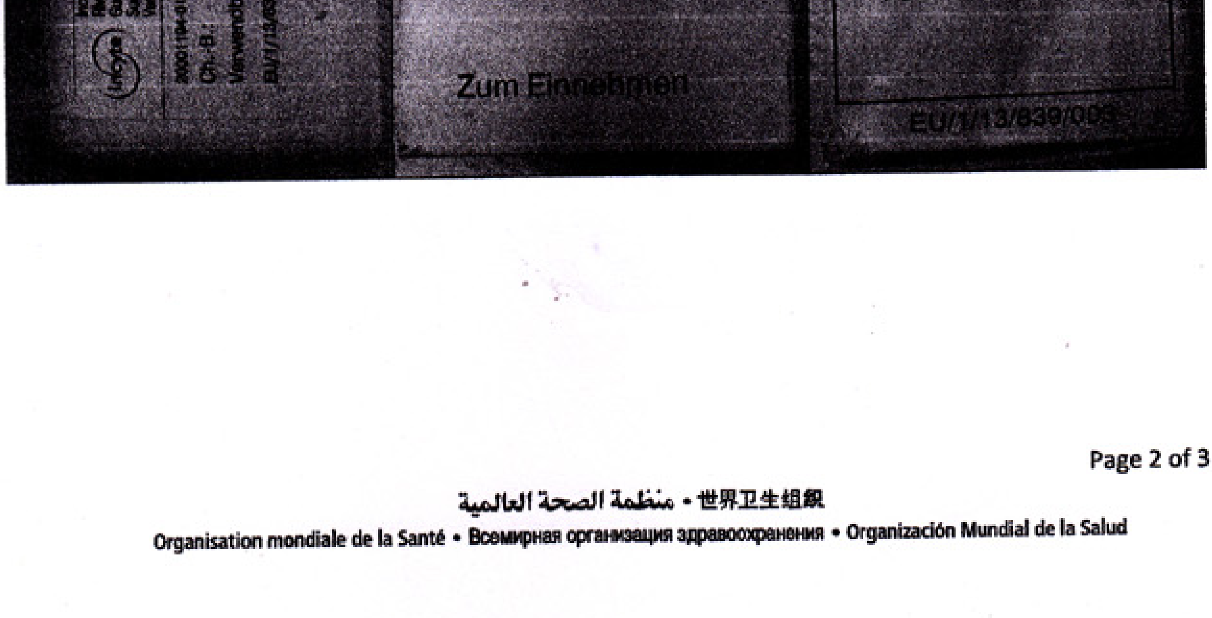
PHOTOGRAPHS OF CONFIRMED FALSIFIED ICLUSIG PRODUCTS

1. **ICLUSIG 45mg (30 tablets); Batch number PR072875**



2. **ICLUSIG 45mg (30 Tabletten); Batch number PR0834170**



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WHO requests increased vigilance within the supply chains of countries likely to be affected by these falsified products. Increased vigilance should include hospitals, clinics, health centers, wholesalers, distributors, pharmacies and any other suppliers of medical products.

If you are in possession of the above products, please do not use. If you have taken this falsified product, or if you suffer an adverse event or an unexpected lack of efficacy, please seek immediate advice from a qualified healthcare professional, and ensure they report the incident to your local Ministry of Health/National Medicines Regulatory Authorities/National Pharmacovigilance Centre.

All medical products must be obtained from authentic and reliable sources. Their authenticity and condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.

National health authorities are asked to immediately notify WHO if these falsified products are discovered in their country. If you have any information concerning the manufacture, distribution, or supply of these products, please contact rapidalert@who.int .

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products
For further information, please visit our website: www.who.int/medicines/regulation/ssffc/en/

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