

HMA WGEO – Rapid Alert Form

Counterfeit or illegal product found in the illegal supply chain

Shaded area to be completed by the secretariat

Reference:	
Date: 05 March 2020	Time: Initials:
Please complete sections 1 to 5 providing as much information as possible.	
1. REPORTING PERSON	
Name:	Position:
Organisation:	
Address:	
Telephone No:	Ext:
e-mail address:	
2. PRODUCT DETAILS	
Product name: Keytruda	
Manufacturer:	
Supplier:	
Legal status: Banned <input type="checkbox"/> Counterfeit <input checked="" type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input type="checkbox"/>	
Dosage form:	
Strength: 100 mg	
Batch / lot no: 8303605A12	
Is batch number genuine: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
If yes to the above, advise batch destination country:	
Expiry date:	
Language of packaging: Italian	
Date of discovery: December 2019	
Details of discovery:	
MSD Global Security Group has identified counterfeit Keytruda offered for sale on illegitimate, internet-based distribution channels. The lot and expiry combinations are invalid for authentic Keytruda 100mg manufactured by MSD. The carton, the vial label and the tamper evidence seal are counterfeited. The patient leaflet (PIL) is consistent with the authentic artwork file. The counterfeit specimen has only been found in illegitimate internet-based	

distribution channels. There is no indication of any compromise to MSD's manufacturing or distribution systems.

The bollino sticker is authentic and matches with one of the theft of Keytruda batch 8302605B11, on January 2019 (WGEO Alert of 31st January 2019); it could be possible that the stolen vials of Keytruda have been repackaged into the falsified packages using the authentic stolen bollino stickers (range 000135001 – 000149999).

Analysed: YES ☒ NO ☐

If yes, result of analysis:

The product contained within the vials was chemically consistent with authentic Keytruda. However, as the product has been manipulated outside of the legitimate supply chain, the efficacy of the product could be impacted due to the broken cold chain (Keytruda needs to be stored between 2 and 8°C).

3. DISTRIBUTION METHODInternet: YES ☒ / NO ☐

Internet:	Non internet, advise full details:
URL:	
Website address:	
Other details:	

Currency of payment:

Has product reached patients/consumers?

The medicines could be illegally marketed in internet.

4. RISK TO PUBLIC HEALTHAdverse reactions: YES ☐ / NO ☐

If yes, please advise details:

Medical assessment details:

5. NEED FOR PUBLICITYAre you making a public statement? YES ☐ / NO ☒Are you issuing a press release? YES ☐ / NO ☒Are you recalling product? YES ☐ / NO ☒

If yes to any of the above, when do you intend to take action?

6. PHOTOGRAPH

If possible, please attach a photograph of the product: