HMA WGEO – Rapid Alert Form Counterfeit or illegal product found in the illegal supply chain

Reference:			
Date: 09.06.2020 Time: 11:00		Initials:	
Please complete sections 1 to 5 providing as much information as possible.			
1. REPORTING PERSON			
Name: Position			
Address:			
Telephone No:		Ext:	
e-mail address:			
2. PRODUCT DETAILS			
Product name: Remdesivir 100mg IV Injection			
Manufacturer: Gilead			
Supplier: Celtis Healthcare Ltd. (WDA 48425 REVOKED Jan 2020 and no			
longer valid, however still displayed on company website)			
Legal status: Banned ☐ Counterfeit ☑ Unlicensed ☐ Stolen ☐			
Dosage form: Vials			
Strength: 100mg			
Batch / lot no: unknown Yes  No  RD-202004 not a genuine batch no.			
If yes to the above, advise batch destination country: Not applicable			
Expiry date: 2022/04/06			
Language of packaging: English			
Date of discovery: 29/05/2020			
Details of discovery: Celtis Healthcare Ltd offered to supply 5000 vials to a buyer who questioned pack images with regulators.			
Analysed: YES ⊠ NO ☐ Both pack images and certificate of analysis (see			
attached) have been analysed by Gilead, Ireland.			
If yes, result of analysis: The manufacturer has indicated both the carton and an associated Certificate of Analysis are counterfeit. No product available.			

3. DISTRUBUTION METHOD			
Internet: YES ☐ / NO ☒			
Internet:	Non internet, advise full details:		
URL:	Celtis Healthcare offered product for sale on Indian medicines		
Website address:			
https://www.celtishealthcare.com/	trading site.		
Other details:			
Currency of payment: Has product reached patients/consumers?	NO		
4. RISK TO PUBLIC HEALTH	NO		
Adverse reactions: YES / NO	Unknown		
If yes, please advise details:			
Medical assessment details:			
5. NEED FOR PUBLICITY			
Are 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. DISSEMINATION			
Are you content for this Rapid Alert to be shared outside WGEO membership?			
YES $\boxtimes$ / NO $\square$ (please see below)  If yes, please specify which of the below you are content for this to be shared			
with (you may tick more than 1 box)			
Law Enforcement  Industry Security  Trade Associations			
Traders Other Please specify			
7. PHOTOGRAPH			
If possible, please attach a photograph of t	the product.		
in peddisie, prodes attach a priotograph er	The product.		
Bomdosivir <sup>®</sup> 400 m			
Remdesivir® 100 m	9		
Gilea	uct authorization holder : d Sciences International Ltd,		
Powder for Concentrate for dispersion for Infusion Camb	a Park, Abington		
	facturer:		
Carrig	d Sciences Limited, stohill, County Cork, Ireland		
GILEAD			