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

Reference:							
Date:	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: Soladek solucion oral; Soladek N solucion oral							
Manufacturer: Indo Pharma, Santo Domingo, Dominican Republic							
Supplier:							
Legal status: Banned ☐ Counterfeit ☐ Unlicensed ☒ Stolen ☐							
Dosage form: oral solution							
Strength: N/A							
Batch / lot no: 2010017C Is batch number genuine: Yes No							
If yes to the above, advise batch destination country:							
Expiry date: 03-2023							
Language of packaging: Spanish							
Date of discovery: 29-04-2020							
Details of discovery: The product was discovered in a parcel during a customs							
check.							
Analysed: YES ☐ NO ⊠							
If yes, result of analysis:							
A DISTRIBUTION METHOD							
3. DISTRUBUTION METHOD							
Internet: YES / NO							
Internet: N/A		Non internet, advise full details:					

URL: N/A						
Website address:						
Other details: N/A						
Currency of payment:						
Has product reached patients/consumers?	No.					
4. RISK TO PUBLIC HEALTH						
Adverse reactions: YES ⊠/ NO ☐ unknown ☐						
If yes, please advise details:						
In 2011 the Food and Drug Administration (FDA) has issued a warning to stop						
taking Soladek vitamin solution because Soladek contains levels of vitamin A						
and vitamin D that were many times the recommended daily allowances for						
these vitamins. According to the manufacturer's label, each 5-ml vial of						
Soladek contains vitamin D (600,000 IU), vitamin A (120,000 IU), and vitamin						
E (5 mg). Soladek N is the lower dose for children.						
Medical assessment details:						
Lowe et al. Vitamin D Toxicity due to a Commonly Available "Over the						
Counter" Remedy from the Dominican Republic. J Clin Endocrinol Metab,						
February 2011, 96(2):291–295.						
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 ⊠ / NO □ (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						



