COMUNICACIÓN DE ALERTA

Santa Tecla, 27 de abril de 2017

LA DIRECCIÓN NACIONAL DE MEDICAMENTOS (DNM) ALERTA SOBRE *PRODUCTO:* Hormotrop 12 UI

Nivel de alerta: 1
Nombre del producto: Hormotrop, somatropina 12 UI
Presentación/Forma Farmacéutica: polvo para solución inyectable
Número de registro sanitario: No presenta
Laboratorio Fabricante: Laboratorio Químico Farmacéutico Bergamo
Lotes: CC40706 y CC30963
Fecha de vencimiento: 04/17 y 08/16 respectivamente cada lote
Entidad emisora de la Alerta: OMS Brasil
País de Origen: Brasil
Fecha de emisión de la Alerta: 26 de abril de 2017

Descripción del problema encontrado: No se encontró registro sanitario alguno ni importaciones del producto, de acuerdo a la investigación realizada por la DNM.

La DNM alerta a toda la población a abstenerse de adquirir y/o suministrar éste producto, en virtud de que su uso representa un riesgo para la salud de la persona que lo consuma. En razón de que el producto Hormotrop 12 UI ha sido falsificado en los dos lotes antes descritos por lo que estos No cumplen con los requerimientos de calidad que avale su seguridad, calidad y eficacia.

La DNM recomienda no adquirir este tipo de producto ya que pueden generar un riesgo a la salud. Así mismo recuerda adquirir los medicamentos en lugares autorizados por la DNM. Cualquier duda puede recurrir a ésta Dirección llamando al teléfono gratuito 136.

Se informa que la DNM continuará las acciones de vigilancia, como el aseguramiento de productos, para evitar la venta de los mismos porque representan un riesgo a la población.

ANEXOS

World Health Organization

Run Date: 26/04/2017 10:11:41 PM

Reporting Person			
Name	Mariana Von Collani		
Position		Organisation	ANVISA
Type of Organisation	National Drug Regulatory Authority	Country	Brazil
Telephone Number	+55 61 3462 5365	Email	mariana.collani@anvisa.gov.br

Discovery Details			
Date discovered	06/Jan/2017	Discovered By	Importer
Address or location of where the suspect product was discovered (geographically)?		Is the suspect product in distribution within your country?	Yes
Countries imported from		Is suspect product available within Regulated or Unregulated Supply-Chain?	Unknown
If available within the regulated supply chain, at what level?		Method of distribution to public	Pharmacy
If available via the Internet, please record the website address			

Suspect Product Details			
Hormotrop			
General			
Suspect Product Name	Hormotrop	Type of Product	Other
Is suspect product registered in reporting country?	Yes	Registration, Product or Marketing Authorisation number shown on suspect product	Unknown
All APIS in Product	Somatropin		
Main intended medical use	Hormone of human growth	Other uses	
Manufacturer	Dong A	Dosage Form	Powder
Container Type	Vial	Dosage Strength	12UI
Batch / Lot number	CC40706	Expiry Date	07/17
Date of Manufacture	07/14	Packaging languages	Portuguese
Method of Administration	Parenteral	Quantity discovered	Unknown

World Health Organization

Run Date: 26/04/2017 10:11:41 PM

Type	Vials	Are photographs of the suspect product available?	Yes
Product Analysis			
Laboratory Analysis undertaken	No	Type of laboratory analysis undertaken	
Email address		Result of Analysis - Dose	
Result of Analysis - Packaging			
Impact on Public Health			
Have adverse reactions been reported?	None Reported	Severity of adverse reactions	
Symptoms		Estimated number of patients affected or at risk	
Communication			
Has any public statement been made?	Yes	Date of public statement	13/Mar/2017
Has any product been withdrawn or recalled?	No	Date of product recall	
Have any other stakeholders been informed?	No	Have the media reported the incident?	Not Known

Hormotrop

General			
Suspect Product Name	Hormotrop	Type of Product	Other
Is suspect product registered in reporting country?	Yes	Registration, Product or Marketing Authorisation number shown on suspect product	1.0646.0137002-5
All APIS in Product	Somatropin		
Main intended medical use	Hormone of human growth	Other uses	
Manufacturer	Dong A	Dosage Form	Powder
Container Type	Vial	Dosage Strength	12IU
Batch / Lot number	CC30963	Expiry Date	08/16
Date of Manufacture	08/14	Packaging languages	Portuguese
Method of Administration	Parenteral	Quantity discovered	Unknown

Type	Vials	Are photographs of the suspect product available?	Yes
Product Analysis			
Laboratory Analysis undertaken	No	Type of laboratory analysis undertaken	
Email address		Result of Analysis - Dose	
Result of Analysis - Packaging			
Impact on Public Health			
Have adverse reactions been reported?	None Reported	Severity of adverse reactions	
Symptoms		Estimated number of patients affected or at risk	
Communication			
Has any public statement been made?	Yes	Date of public statement	13/Mar/2017
Has any product been withdrawn or recalled?	No	Date of product recall	
Have any other stakeholders been informed?	No	Have the media reported the incident?	Not Known

Investigation

Is this incident the subject of Regulatory action regulatory or any other type of investigation?

Comments

Comments. Please record here any other details, including what prompted this report

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The importer detected two different Hormotrop lots falsified in brazilian market.

Lot CC40706: The company Laboratório Químico Farmacêutico Bergamo (the importer) received a question from a customer regarding the lot CC40706. The company confirmed the lot was sold by them, but identified that the bacteriostatical diluent present in the product had a batch number (091196587) and an expire date (04/17) different from the one used in the original product.

The falsified Horrmotrop can be identified based on the product expire date presented in the secondary package. The original one expires in 07/16, but the falsified expires in 07/17.

Lot CC30963: The importer received a contact from a police investigator regarding the lot CC30963. The company confirmed the lot was sold by them. However, the manufacture and expire dates presented in the secondary package of the falsified product (Man: 08/14 Exp: 08/16) don't match with the information presented in the original product (Man: 09.2013 e Exp. 09.2015).

Anvisa is investigating these suspicion, but so far, no product has been recalled or effectively withdrawn.

Do you wish WHO to further disseminate this report? Yes