



Asunto: Suspensión de autorización de las entidades de distribución Schmidt Logistics y Apobutik
Ref: SOFM/MJA/as/167
Fecha: 15/09/2016

La Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) informa de la suspensión de la autorización por parte de la Danish Medicines Agency, de dos entidades de distribución ubicadas en Dinamarca:

- Almacén de distribución: **Schmidt Logistics A/S**
- Número de autorización: 30206
- Dirección: Brydehusvej 30A, Ballerup, 2750, Denmark

- Almacén de distribución: **Apobutik ApS**
- Número de autorización: 30207
- Dirección: Brydehusvej 30 A, Ballerup, 2750, Denmark

El motivo de la suspensión de la autorización es el incumplimiento de las Buenas Prácticas de Distribución (BPD). Las declaraciones de incumplimiento de BPD de estas entidades, están publicadas en EudraGMDP.

Según ha informado Dinamarca, ambas compañías operan únicamente en territorio danés. No obstante, se recuerda que no se podrá establecer relación comercial alguna con las entidades de distribución no autorizadas.

En Logroño, a 15 de septiembre de 2016.

Dra. M.J. Aza Pascual Salcedo
Jefa del Servicio de Ordenación Farmacéutica y Medicamentos.



**Gobierno
de La Rioja**
Salud

Prestaciones y Farmacia



Danish Medicines Agency

Report Number : DK GDP 00079016

STATEMENT OF NON-COMPLIANCE WITH GDP MEDICINAL PRODUCTS FOR HUMAN USE

**Exchange of information between National Competent Authorities (NCAs) of the EEA
following the discovery of serious GDP non-compliance at a wholesale distributor**

Part 1

Issued following an inspection in accordance with Art. 111(7) of Directive 2001/83/EC as amended

The competent authority of Denmark confirms the following:

The wholesale distributor: Schmidt Logistics A/S

Authorisation number : 30206

Site address: Brydehusvej 30A, Ballerup, 2750, Denmark

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2016-05-31, it is considered that **it does not comply with the Good Distribution Practice** requirements referred to in Article 84 of Directive 2001/83/EC.

Part 2

Wholesale distribution activity affected : Procuring, holding and supplying medicine.

Part 3

1. Nature of non-compliance: The company has in general failed to comply with good distribution practice as they did not use the described quality system. The company has written procedures but was not able to show documentation for acting according to the procedures. Further the company does not have documentation for storage under correct temperature, a system for ensuring that they only obtain their supplies of medicine from companies with a valid WDA/MIA or a system for ensuring that they only supply medicines to companies with a valid WDA or a valid license to supply medicine to the public.

2. Action taken/proposed by the NCA: Suspension of the Wholesale Dealers Authorisation no 30206 from 15th of July 2016.

3. Additional comments: Based on the information gained during the latest inspection the company only obtain medicine from and supply medicine to companies in Denmark.

2016-09-09

Name and signature of the authorised person of the
Competent Authority of Denmark

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Danish Medicines Agency

Report Number : DK GDP 00079116

STATEMENT OF NON-COMPLIANCE WITH GDP MEDICINAL PRODUCTS FOR HUMAN USE

Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GDP non-compliance at a wholesale distributor

Part 1

Issued following an inspection in accordance with Art. 111(7) of Directive 2001/83/EC as amended

The competent authority of Denmark confirms the following:

The wholesale distributor: Apobutik ApS

Authorisation number : 30207

Site address: Brydehusvej 30 A, Ballerup, 2750, Denmark

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2016-05-31, it is considered that **it does not comply with the Good Distribution Practice** requirements referred to in Article 84 of Directive 2001/83/EC.

Part 2

Wholesale distribution activity affected : Procuring and supplying medicine. Storage of medicine outsourced.

Part 3

1. Nature of non-compliance: The company has in general failed to comply with good distribution practice as they did not use the described quality system. The company has written procedures but was not able to show documentation for acting according to the procedures. Further the company does not have a system for ensuring that they only obtain their supplies of medicine from companies with a valid WDA/MIA or a system for ensuring that they only supply medicines to companies with a valid WDA or a valid license to supply medicine to the public.

2. Action taken/proposed by the NCA: Suspension of the Wholesale Dealers Authorisation no 30207 from 15th of July 2016.

3. Additional comments: Based on the information gained during the latest inspection the company only obtain medicine from and supply medicine to companies in Denmark.

2016-09-09

Name and signature of the authorised person of the
Competent Authority of Denmark

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