Message 201

Communication from the Commission - TRIS/(2024) 1855

Directive (EU) 2015/1535

Notification: 2024/0370/BG

Forwarding of the response of the Member State notifying a draft (Bulgaria) to request for supplementary information (INFOSUP) of European Commission.

MSG: 20241855.EN

1. MSG 201 IND 2024 0370 BG EN 09-07-2024 BG ANSWER

2. Bulgaria

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4. 2024/0370/BG - C10P - Pharmaceuticals

5.

6. Due to the presence of tables and graphs in the additional information submitted, the reply is also attached to the notification as a file in the ‘Texts’ section – ‘Other text’.

Additional information from the Ministry of Health in connection with a request from the European Commission services to Bulgaria received on 5.7.2024 via the point of contact of the Ministry of Economy and Industry under Directive (EU) 2015/1535 inquiry by e-mail from the services of the European Commission to the Republic of Bulgaria regarding notification 2024/370/BG (3.7.2024) of the draft Order of the Minister of Health of the Republic of Bulgaria introducing a temporary ban on the export of certain medicinal products to meet the health needs of the population

Upon carrying out an analysis on the occasion of signals for shortages in the pharmacy network of medicinal products classified according to an anatomical therapeutic chemical classification in accordance with the requirements of the World Health Organisation in pharmacological groups:
1. A10A “Insulins and analogues” – all medicinal products in the group;
2. A10B “Blood sugar lowering medicines excluding insulins” – a medicinal product with Anatomical Therapeutic Chemical (ATC) code A10BJ06 in injection dosage form;
3. J01 “Anti-infectious medicinal products for systemic use” – all medicinal products in the group in pharmaceutical dosage forms “powder for oral suspension” and “granules for oral suspension”.
checks were ordered by the Regional Health Inspectorates (RHI) in the country in community pharmacies on the availability of medicinal products and the possibilities for their supply by a wholesaler.
The inspections in pharmacies were on a sample basis – they covered pharmacies in both large and smaller settlements in Bulgaria.

Regional Health Inspectorate (RHI) Percentage of inspected pharmacies
Razgrad 22 %
Targovishte 22 %
Montana 21 %
Pleven 17 %
Sliven 17 %
Vratsa 16 %
Veliko Tarnovo 15 %
Kardzhali 13 %
Shumen 13 %
Dobrich 12 %
Kyustendil 12 %
Lovech 12 %
Ruse 12 %
Gabrovo 11 %
Pernik 11 %
Plovdiv 11 %
Silistra 11 %
Sofia Region 11 %
Yambol 11 %
Burgas 10 %
Varna 10 %
Vidin 10 %
Pazardzhik 10 %
Smolyan 10 %
Stara Zagora 10 %
Sofia City 10 %
Haskovo 10 %
Blagoevgrad 9 %

According to the information received from the RHI on inspections carried out in pharmacies between 17.06 and 26.6.2024, it is obvious that a total of 347 inspections were carried out in community pharmacies throughout the country. Compared to the total number of pharmacies opened in the country, it can be concluded that inspections were carried out in about 13% of all pharmacies in Bulgaria.

Figure: Percentage of inspected pharmacies by provinces compared to the total number of pharmacies disclosed in the province.
In the figure presented above, it is noticeable that in a large number of the provinces, inspections have been carried out, representing about 13% of the pharmacies disclosed for the respective province, as in some provinces Razgrad, Targovishte and Montana, inspections have been carried out in more than 20% of the pharmacies disclosed in the relevant province.
With regard to the question raised by the European Commission to provide specific data on the reasons for the inclusion of the group 'Anti-infectious medicinal products for systemic use' in the pharmaceutical forms 'powder for oral suspension' and 'granules for oral suspension, it can be noted that as a result of the checks carried out, the following levels of shortages of quantities of medicinal products have been identified:
Commercial name Percentage of provinces in the country experiencing a shortage
Augmentin ES 600 mg/42.9 mg/5 ml – 100 ml 61 %
Augmentin 400 mg/57 mg/5 ml 46 %
Foxero 40 mg/5ml – 100 ml 29 %
Zinnat 250 mg/5 ml – 50 ml 29 %
AZATRIL 200 mg/5 ml – 20 ml 29 %
Amoksiklav 400 mg/57 mg/5 ml – 70 ml 25 %

Ospamox 500 mg/5 ml 100 ml 21 %
Amoksiklav ES 600 mg/42.9 mg/5 ml – 100 ml 21 %
Ximebac 40 mg/5ml 21 %
Zinnat 125 mg/5 ml – 50 ml 21 %
Augmentin 250 mg/62.5 mg/5ml – 100 ml 18 %
Augmentin 125 mg/31.25 mg/5 ml – 100 ml 18 %
AZATRIL 100 mg/5ml 18 %
Medoclav Forte 250 mg/62.5 mg/5 ml – 100 ml 14 %
Medoclav Bis 400 mg/57mg/5ml-140 ml 14 %
Klacid 125 mg/5ml – 100 ml 14 %
Ospamox 250 mg/5 ml 11 %
Klacid 125 mg/5ml – 60 ml 11 %
MEDOCLOR 250 mg/5 ml 7 %
MEDOCLOR 125 mg/5 ml 7 %
MEDOCLAV 125/31.25 mg 7 %
Sumamed 100 mg/5 ml – 20 ml 7 %
PROFIX Suspension 125/5 7 %
ZETRUM Suspension 200/5 7%
PROFIX Suspension 250/5 7 %

61 % of the provinces in the country reported refusal and/or irregular supply of the medicinal product under the commercial name: Augmentin ES 600 mg/42.9 mg/5 ml – 100 ml. In 46 % of the provinces, there is a shortage of supply or refusal of the medicinal product bearing the commercial name: Augmentin 400 mg/57 mg/5 ml. In 29 % of the provinces, respectively, there were irregular supplies or denial of medicinal products with INN Cefpodoxime, Cefuroxime and Azithromycin.
In general, it can be concluded that there have been delays, irregularity in supply, including refusal from the warehouses of wholesalers of medicinal products for the supply of 10 medicinal products with different INN from the therapeutic group "Anti-infectious medicinal products for systemic use" in dosage forms "powder for oral suspension".
Finally, the Ministry of Health considers it necessary to point out that in recent months the Medicines Executive Agency has received notifications of suspension of sales for the following medicinal products: Augmentin ES 600mg/42.9mg/5ml powder for oral suspension 100ml x 1 bottle, Augmentin 125mg/31.25mg/5ml powder for oral suspension 100ml x 1 bottle, Augmentin 400mg/57mg/5ml powder for oral suspension 70ml x 1, Medoclor 125 mg/5 ml granules for oral suspension 100 ml x 1 bottle, Medoclor Forte 250 mg/5 ml granules for oral suspension 100 ml x 1 bottle, Amoxiclav 400 mg/57 mg/5 ml powder for oral suspension 140 ml x 1, Amoxiclav ES 600mg/42, 9mg/5 ml powder for oral suspension 100 ml x 1 bottle, Augmentin 250 mg/62.5 mg/5 ml powder for oral suspension 100 ml x 1 bottle, Amoksiklav 125 mg/31.25 mg/5 ml powder for oral suspension 100 ml x 1 bottle, Amoksiklav 250 mg/62, 5 mg/5 ml powder for oral suspension 100 ml x 1 bottle, Lekoklar 250 mg/5 ml granules for oral suspension 60 ml x 1, Klacid 125 mg/5 ml granules for oral suspension 100 ml x 1 bottle, MEDOCLAV BIS 400 mg/57 mg/5 ml powder for oral suspension 200 ml x 1 bottle.

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European Commission
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