

*State Institute for Drug Control,  
Kvetná 11, 825 08, Bratislava,  
the Slovak Republic*

Bratislava, 16 May 2023  
Decision No: 2023/12377  
Reg. No: D-110/2023

## DECISION

The State Institute for Drug Control as the competent state administration authority for proceedings pursuant to Section 5 of Act No 71/1967 Coll. on Administrative Procedure as amended (hereinafter referred to as the “Administrative Procedure Code”) and Section 129 (2) (e-6) of Act No 362/2011 Coll. on medicinal products and medical devices as amended (hereinafter referred to as the “Act”), in accordance with the provisions of Section 7(1)(b-3) of the Act in the administrative procedure on the application for the issue of an authorisation for handling of medicinal products in the wholesale distribution of medicinal products for human use pursuant to Section 7(6) of the Act and in accordance with the provisions of Sections 46 et seq., of the applicant BIODRUG s. r. o. (registered office at Boženy Nemcovej 8, 811 04 Bratislava, company ID 47 964 324) that has submitted the necessary documents, has decided

### as follows:

The application for the issue of the authorisation of the applicant **BIODRUG s. r. o.** (registered office at Boženy Nemcovej 8, 811 04 Bratislava, company ID 47 964 324) **is granted** and the applicant is authorised to handle medicinal products in the following type of activity: **wholesale distribution of medicinal products for human use.**

#### Statutory body:

MVDr. Milan Fišera, DOB: , residing at: Žilina  
PharmDr. Darina Adamečková, DOB: , residing at: Bratislava.

#### The professional representative for wholesale distribution:

PharmDr. Darina Adamečková, DOB: , residing at: Bratislava.

#### Place of practice:

Rožňavská 4380/2, 821 01 Bratislava.

#### Effective date:

The date of commencement of activities shall be the date following the day on which this decision becomes final.

**Justification:**

Having examined the application of the applicant BIODRUG s. r. o., Boženy Nemcovej 8, 811 04 Bratislava, company ID 47 964 324, dated 4 April 2023, supplemented on 5 May 2023 and 11 May 2023, for the issue of an authorisation for handling of medicinal products in the wholesale distribution of medicinal products for human use, registered with ŠÚKL under No: 8242/2023/621, the administrative authority finds that the applicant has fulfilled the statutory conditions for the issue of an authorisation pursuant to the provisions of Sections 3, 4, 5, 6 and 8(3) of the Act.

In the light of the above, the administrative authority has decided as set out in the operative part of this decision.

The conditions and obligations of the authorisation holder for the wholesale distribution of medicinal products for human use are laid down in the provisions of Sections 17, 18 and 74a of the Act.

**Advice:**

An appeal may be lodged against this decision pursuant to Sections 53 et seq. of the Administrative Procedure Code. Pursuant to Section 54 of the Administrative Procedure Code, an appeal shall be lodged with the administrative authority which issued the decision being appealed. The appeal shall be lodged within 15 days of the date of notification of this decision with the State Institute for Drug Control.

This decision is liable to judicial review after it has become final as a result of the exercise of a proper remedy in accordance with Act No 162/2015 Coll., the Administrative Procedure Code.

**PharmDr. Peter Potúček, PhD., MSc.**  
Executive Director