REPUBLIC OF BULGARIA

Ministry of Health

Minister of Health

**ORDER**

No РД-01-185 of 7 April 2020

**supplementing Order No РД-01-200 of 9 July 2019, previously amended and supplemented by Order No РД-01-247 of 23 August 2019, Order No РД-01-262 of 16 September 2019, Order No РД-01-282 of 8 October 2019, Order No РД-01-303 of 28 October 2019, Order No РД-01-334 of 22 November 2019, Order No РД-01-341 of 27 November 2019, Order No РД-01-365 of 10 December2019, Order No РД-01-6 of 9 January 2020, Order No РД-01-48 of 5 February 2020, Order No РД-01-50 of 7 February 2020, Order No РД-01-92 of 17 February 2020, Order No РД-01-151 of 25 March 2020 and Order No РД-01-164 of 27 March 2020**

Pursuant to Article 25(4) of the Administration Act, Article 266a(2) of the Medicinal Products in Human Medicine Act, Article 16(4) and (6) of Regulation No 10/2011 on the Conditions and Procedure for Treatment with Medicinal Products Unauthorised in the Republic of Bulgaria and Compassionate Use Medicinal Products and the Conditions and Procedure for Including, Varying, Excluding and Supplying Medicinal Products Included on the List Referred to in Article 266a(2) of the Medicinal Products in Human Medicine Act and in relation to letters with incoming ref. No 33-18-18 of 28 February 2020 by the University Multiprofile Hospital for Active Treatment Aleksandrovska EAD and incoming ref. No 33-15-8 of 11 February 2020 of the Saint Ekaterina University Multiprofile Hospital for Active Treatment, opinions with incoming ref. No 33-18-18 of 11 March 2020 and incoming ref. No 33-15-8 of 31 March 2020 by the Bulgarian Medicine Agency and opinions with incoming ref. No 33-08-24 of 28 March 2020 by the Expert Allergology Council and incoming ref. No 33-15-8 of 13 March 2020 by the Expert Nephrology Council,

I hereby ORDER:

1. Lines 77 through 80 shall be added to the Annex entitled ‘List of medicinal products referred to in Article 266a(2) of the Medicinal Products in Human Medicine Act’, which forms part of Order No РД-01-200 of 9 July 2019, previously amended and supplemented by Order No РД-01-247 of 23 August 2019, Order No РД-01-262 of 16 September 2019, Order No РД-01-282 of 8 October 2019, Order No РД-01-303 of 28 October 2019, Order No РД-01-334 of 22 November 2019, Order No РД-01-341 of 27 November 2019, Order No РД-01-365 of 10 December 2019, Order No РД-01-6 of 9 January 2020, Order No РД-01-48 of 5 February 2020, Order No РД-01-50 of 7 February 2020, Order No РД-01-92 of 17 February 2020, Order No РД-01-151 of 25 March 2020 and Order No РД-01-164 of 27 March 2020:

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| --- | --- | --- | --- | --- | --- | --- | --- |
| No | | АТС code | | International Non-proprietary Name under which the product is listed (INN) | Pharmaceutical form and active substance amount | Disease under the International Classification of Diseases | Additional information |
| 77 | | В06АС05 | | Lanadelumab | 300 mg/2ml solution for injection | D84.1 | Including hereditary angioedema |
| 78 | | B05ZB | | Haemofiltrates | Potassium solution for haemofiltration 2mmol/l | N17.0; N17.1; N17.2; N17.8; N17.9; N18.0 |  |
| 79 | B05ZB | | Haemofiltrates | | Potassium solution for haemofiltration 4mmol/l | N17.0; N17.1; N17.2; N17.8; N17.10; N18.0 |  |
| 80 | B05ZB | | Haemofiltrates | | Solution for haemofiltration without potassium | N17.0; N17.1; N17.2; N17.8; N17.9; N18.0 |  |

1. This Order shall be published on the website of the Ministry of Health.

*[Signature]*

*[Round stamp reading ‘Ministry of Health, Sofia, Republic of Bulgaria, 2’]*

**Kiril Ananiev**

*Minister of Health*