|  |
| --- |
| **Неофициальный перевод** DRAFTMemorandumOn timely registration of manufacturer's limit selling prices for medicines Minsk «\_\_\_»\_\_\_\_\_\_\_\_2018 |
| The Ministry of Health of the Republic of Belarus represented by the Minister Valery Malashko, on the one hand, and legal entities and individual entrepreneurs engaged in pharmaceutical activities (industrial production of medicines, wholesale and retail sale of medicines), representative offices of foreign pharmaceutical manufacturers operating in the territory of the Republic of Belarus, non-commercial organizations representing professional and business interests of foreign pharmaceutical manufacturers, legal entities of the Republic of Belarus representing the interests of Belarusian manufacturers of medicines (hereinafter all together – pharmaceutical manufacturers), represented by managers, on the other hand, hereinafter referred to as the Parties, guided by Articles 4 and 5 of the Law of the Republic of Belarus “On medicines” of 20 July 2006, according to which the state guarantees the right to health protection and ensures the availability of medicines as a necessary condition for providing the population with timely medical care and, taking into account the effectiveness of the state regulation of the turnover of medicines, have agreed as follows:1. The Memorandum is the basis for the implementation of urgent measures aimed at the registration of manufacturer's limit selling prices for medicines registered in the Republic of Belarus, the list of international nonproprietary names of which is approved by the President’s Decree of the Republic of Belarus No. 345 “On registration of prices for medicines” of 22August 2018 (hereinafter – medicines), and is aimed to preventing the reduction of the nomenclature of listed medicines in the Republic of Belarus.In order to achieve the goals of guaranteeing the constitutional rights of citizens to health protection, **the Parties will ensure**: |
| **1.** **The Ministry of Health of the Republic of Belarus**:post of all necessary information relating to registration of manufacturer's limit selling prices for medicines on the website of RUE “Center for examinations and tests in health service” ([www.rceth.by](http://www.rceth.by));acceptance of documents for registration of manufacturer's limit selling prices for medicines in accordance with the Regulations on the procedure for registration of manufacturer's limit selling prices for medicines, approved by the Resolution of the Council of Ministers of the Republic of Belarus No. 776 “On registration of manufacturer's limit selling prices for medicines” of 31 October 2018 on working days, weekends and holidays in December 2018 in RUE “Center for examinations and tests in health service” from 8.30 p.m. to 12.30 a.m., from 1.15 a.m. to 4.30 a.m.;timely decision on registration of manufacturer's limit selling prices in accordance with the terms established by the legislation;maintenance of the state register of manufacturer's limit selling prices for medicines;operational interaction with the Ministry of Antimonopoly Regulation and Trade of the Republic of Belarus, other national authorities to obtain the necessary information in order to the fastest possible realization of registration of manufacturer's limit selling prices for medicines;operational interaction with distributors of medicines and retail chains engaged in wholesale and retail sale of medicines;consulting within the competence of interested pharmaceutical manufacturers on the procedure and terms of registration of manufacturer's limit selling prices for medicines;consideration of proposals of pharmaceutical manufacturers and other interested parties to improve the procedure for registration of manufacturer's limit selling prices for medicines in the Republic of Belarus. |
| **2. The pharmaceutical manufacturers:**timely (up to 24 December, 2018) appeal to the Ministry of Health of the Republic of Belarus in accordance with the established procedure for registration of manufacturer's limit selling prices for medicines and provision of documents, provided by the Resolution of the Council of Ministers of the Republic of Belarus No. 776 “On registration of manufacturer's limit selling prices for medicines” 31 October 2018 and the Resolution of the Ministry of Antimonopoly Regulation and Trade of the Republic of Belarus No. 83 “On approval of the Instruction on the method of manufacturer's limit selling prices for medicines calculation” 19November 2018; providing the necessary information to the Ministry of Health of the Republic of Belarus and the Ministry of Antimonopoly Regulation and Trade of the Republic of Belarus in accordance with the requirements of normative legal acts regulating the registration of manufacturer's limit selling prices for medicines;taking actions to prevent the disappearance of medicines;prompt informing of the Ministry of Health of the Republic of Belarus on critical cases of the possibility of disappearance of medicines from the market of the Republic of Belarus, the limit selling prices for which are subject to registration;submission of proposals to improve the procedure for registration of manufacturer's limit selling prices for medicines in the Republic of Belarus to the Ministry of Health of the Republic of Belarus. |
| **3. Final remarks**3.1. The Parties will be guided by the current legislation of the Republic of Belarus when signing the Memorandum.3.2. The Memorandum is concluded for a period of up to 2019 and will enter into force on the date of its signing.3.3. The assessment of the terms of the Memorandum is carried out on quarterly basis. |

|  |  |  |
| --- | --- | --- |
| **The Ministry of Health of the Republic of Belarus** | Valery Malashko Minister |  |
| **The pharmaceutical manufacturers** |
| *Name of legal entity**(individual entrepreneur)* | *First name and last name* | *Signature* |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |