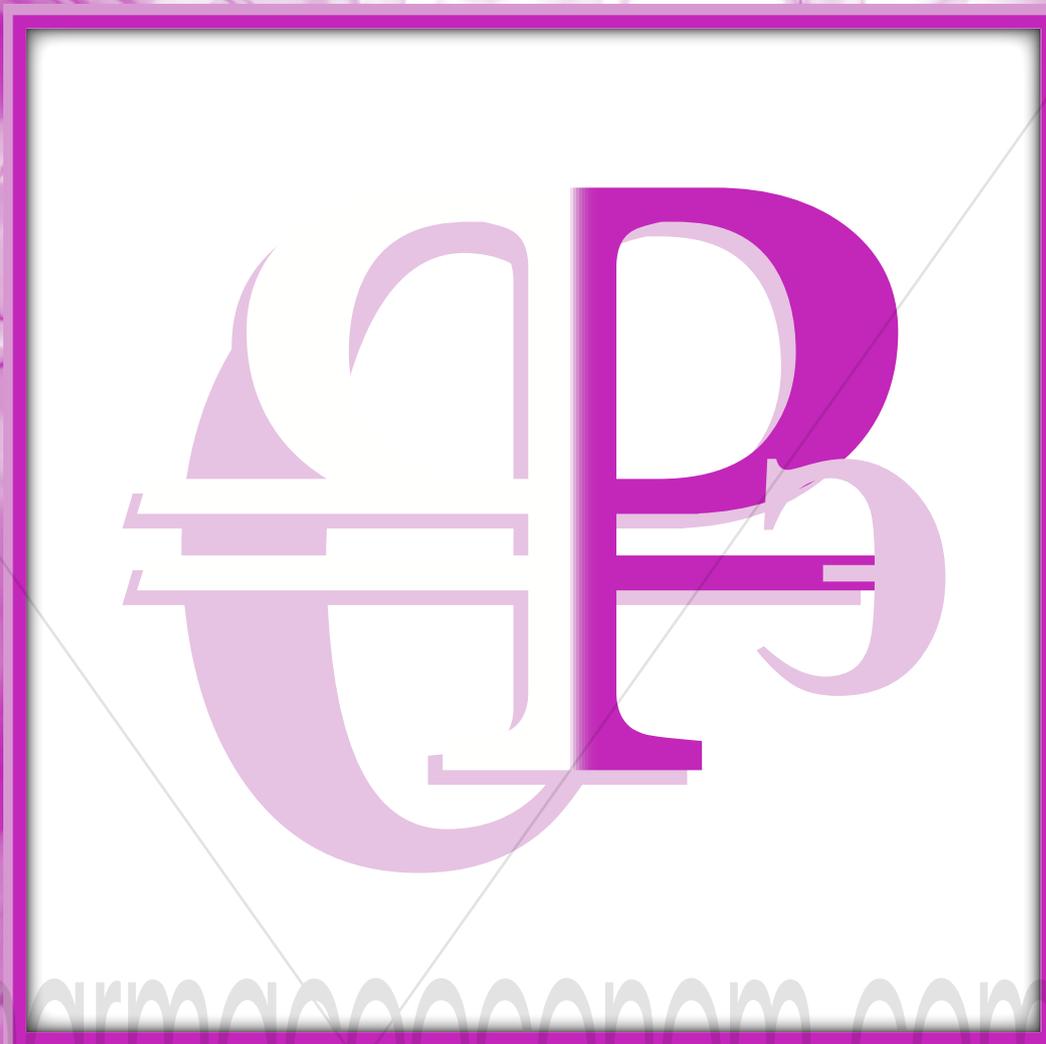


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- **IX НАЦИОНАЛЬНЫЙ КОНГРЕСС С МЕЖДУНАРОДНЫМ УЧАСТИЕМ «РАЗВИТИЕ ФАРМАКОЭКОНОМИКИ И ФАРМАКОЭПИДЕМИОЛОГИИ В РОССИЙСКОЙ ФЕДЕРАЦИИ»**  
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- **ОРИГИНАЛЬНЫЕ РОССИЙСКИЕ ФАРМАКОЭКОНОМИЧЕСКИЕ ИССЛЕДОВАНИЯ**

## VALIDATION OF THE PHARMACOECONOMIC MODEL OF EMTRICITABIN/ RILPIVIRINE/ TENOFOVIR (EVIPLERA) INCLUSION IN HIGHLY ACTIVE ANTIRETROVIRAL THERAPY OF HIV/AIDS IN THE RUSSIAN FEDERATION

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**Abstract:** *The article deals with the results of validation of the pharmacoeconomic model of emtricitabin/ rilpivirine/ tenofovir (Eviplera) inclusion in highly active antiretroviral therapy of HIV/AIDS in the Russian Federation.*

**Key words:** *human immunodeficiency virus (HIV), highly active antiretroviral therapy (HAART), modeling, validation, budget impact analysis.*

The purpose of this work was to validate the pharmacoeconomic model of inclusion of emtricitabin/ rilpivirine/ tenofovir (Eviplera) in highly active antiretroviral therapy of HIV/AIDS in the Russian Federation

### **Description of model**

The pharmacoeconomic model provided by Janssen (Johnson & Johnson LLC) for analysis was built in Microsoft Office Excel.

The model was developed to find possible ways to include new medicinal products, namely the combination medicinal product Eviplera (emtricitabin/ rilpivirine/ tenofovir), in the structure of government procurement in 2015-2018. Budget impact analysis is used in the model.

The modeling horizon covered 4 years (2015-2018). The financial capabilities of the budget over that period was based on the budget noted in Federal Law dated 01.12.2014 No. 384-FZ On the Federal Budget for 2015 and for the Planning Period of 2016 and 2017. It should be mentioned that the budget for 2015-2017 is fixed, while the budget for 2018 was increased by 10%.

Data for 2013-2014 was used to determine the structure and size of patient population administered such kind of treatment. The cohort size was based on average consumption of the medicinal product (baseline therapy) by a patient and on data about the number of product packages procured. It should be noted that the following assumption was used: the number of patients entitled to benefits related to medicinal product supply would increase by 10% annually (this assumption was justified by the budget growth and previous cohort size dynamics).

Data showing the budget spent on antiretroviral medicinal products and the budget cost structure were based on government procurement statistics published on-line at: [www.zakupki.gov.ru](http://www.zakupki.gov.ru). Based on these data, medicinal products of the following groups were procured: non-nucleoside reverse-transcriptase inhibitors, integrase inhibitors and protease inhibitors.

The prices for medicinal products were also based on government procurement statistics for 2013-2014. It was determined that INN prices will decrease annually, which will be driven by decreasing prices for the originator medicinal products and also by the launch of generics. Data related to the launch of generics were taken from the web-site at <http://grls.rosminzdrav.ru/>.

The model took into account that the state lists include certain innovative medicinal products, such as dolutegravir, tenofovir + emtricitabin, tenofovir + emtricitabin + elvitegravir, tenofovir + emtricitabin + rilpivirine, which are characterized by a better safety profile, a more convenient dosing scheme (frequency of administration reduced to one tablet daily) and the availability of a combination dosage form (except for dolutegravir); and the model also took into account that medicinal products with a safety profile worse than that of analogous products already available in the Russian market were excluded from procurement. Certain medicinal products were excluded from procurement since their safety and tolerability profile did not satisfy the current requirements to HAART.

### **Evaluation of the methodology used**

The software selected to build the model is a generally accepted one for pharmacoeconomic evaluation, since it offers an appropriate level of availability and transparency of the mathematical mechanisms, and, in case any changes are needed, it does not require many special skills from the end user (decision maker).

In terms of modern pharmacoeconomic evaluation methodology, this model is based on the optimization approach, i.e. a way to include an innovative medicinal product to treat HIV patients within the approved HAART budget was proposed.

The model took into account possible changes in the procurement structure, in particular a shift to treatment schemes with a better safety profile and a higher level of compliance. In addition, it also took into account the consequences of emergence of generic antiretroviral medicinal products that will be cheaper than the originator medicinal products. It should be noted that, based on the proposed model, expected savings resulting from the use of antiretroviral generics will enable the procurement of emtricitabin/ rilpivirine/ tenofovir (Eviplera) therapy within the approved budget. The results of study demonstrate potential increasing in number of patients who can received HAART with another innovation drugs (table 1).

Although this model does not include sensitivity analysis, the possibility

of introduction of innovative therapy is very likely to be affected most of all by the inclusion of generics in the structure of government procurement.

**Table 1.** Budget impact analysis results generated by the model.

Parameter	2015	2016	2017	2018
Antiretroviral therapy budget, RUB billion	19,3	19,3	19,3	21,2
Budget savings from the use of generics, RUB billion	0,5	2,3	3,4	5,2
RPV/FTC/TDF, RUB billion		1,5	2,9	3,8
Percent of budget allocated for innovative medicinal products	34	45	53	57
Percent of patients on antiretroviral treatment schemes based on innovative medicinal products	33	35	36	41

#### Evaluation of the data used

This model takes into account only costs for procurement of antiretroviral medicinal products. However, medicinal products can differ in terms of safety, efficacy and convenience of administration, and such differences can have an impact on the amount and structure of costs during HIV treatment.

Modeling of the government procurement structure for the planning period of 2016-2018 was based on published government budget data and public procurement statistics. Such approach is acceptable from the point of view of the pharmacoeconomic evaluation methodology.

#### Conclusions

The analysis of the pharmacoeconomic model of inclusion of emtricitabin/rilpivirine/ tenofovir (Eviplera) in highly active antiretroviral therapy of HIV/AIDS in the Russian Federation showed that the approach used is consistent with the international guidelines on pharmacoeconomic studies.

The pharmacoeconomic model demonstrates that if generics will be included in the Russian national program «Healthcare Development» to the extent of financing of antiretroviral medicine procurement for prophylaxis and treatment of patients with HIV, and hepatitis B or C in 2016-2018 (subprogram

«Improvement Secondary Care Improvement, Including High-Tech Medical Care») than it is possible to include emtricitabin/ rilpivirine/ tenofovir (Eviplera) in antiretroviral therapy of HIV/AIDS without increasing of the program budget.

Moreover, releasing a budget for innovative medicinal products after wide use of generics leads to increase in patients receiving HAART regimens with innovative drugs which are already on market or going to be registered.

In addition, for future model development, it is recommended to add a sensitivity analysis to the existing model, take into account all types of costs for HIV treatment, and also take into account the discounting effect in order to understand the consequences as much as possible and gain insights into potential risks that may arise during the use of the results provided by this model to design government medicinal product procurement programs for HIV patients.

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