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| *March, 13, 2014* | Kenneth C. Frazier  Chairman of the Board,  President and Chief Executive Officer  Merck & Co., Inc.  Paul E Schaper  Executive Director, Global Public Policy  Merck | MSD  601 Pennsylvania Ave NW  North Building, Suite 1200  Washington DC 20004  Tetyana Bilyk  External Affairs Lead Ukraine and CIS  Ildar Seytyagyayev  General Director  MSD Ukraine, LLC  3rd Floor,Horizon Business Park  12 Amosova Street, Kiev,03680  Ukraine |

Dear Sir/Madame,

We are writing this letter on behalf of the Community Advisory Board in Eastern Europe and Central Asia (EECA CAB), established in 2009 by International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPCru) and East Europe and Central Asia Union of people living with HIV (ECUO.

EECA CAB unites treatment access activists from the following countries: Azerbaijan, Armenia, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Russia, Tajikistan, Ukraine, Uzbekistan, and Estonia.

The experience of expanding access to life-saving HIV treatment shows that access to generic competition is critical for obtaining sustainable prices affordable for governments and international donors that run treatment programs in EECA region.

February 24, 2015, Medicines Patent Pool announced a license agreement with Merck Sharp & Dohme Corp. and MSD Italia s.r.l. (collectively "Merck") for pediatric raltegravir. From the EECA region, the following countries were included into the geographical coverage of the license: Ukraine, Armenia, Georgia, Moldova, Tajikistan, Kyrgyzstan, and Uzbekistan. The license allows importation of peadiatric forms of raltegravir sublicensed from the Patent Pool.

On the one hand, EECA CAB welcomes the decision of the company to include our region in the geographic coverage of the license. We appreciate Merck’s taking into consideration the needs of the children for whom treatment options are limited, and for whom access to such drugs as raltegravir is critical.

**However, in practice, the inclusion of these 7 countries in the license will not lead to a real expansion of access to treatment in the near future.**

Below follows a substantiation based on the analysis of the current availability of raltegravir in EECA.

**In Ukraine,** 97 people are receiving raltegravir, among them **5 children**. The required volumes of paediatric formulations are too small to attract generics to the market. It should also be noted that the pediatric formulations of raltegravir (chewable tablets and granules for solution) that were licensed by the agreement are not registered in Ukraine. This makes it difficult to realize the opportunities provided by this license agreement.

**Uzbekistan.** Approximately 4000 children are receiving ART now, and availability of raltegravir regimens would be very important. However, given the high cost of raltegravir, this option was not even considered by the Ministry of Health of the Republic of Uzbekistan. It is difficult to estimate the potential size of the market at the moment, but it is unlikely it will be sufficient to motivate generic companies.

**In Armenia,** **only 1 child is now receiving a regiment with raltegravir (adult form**). In the national guidelines, raltegravir is included as a second-line regimen, and it is also recommended as a first-line option. However, the drug is not registered in the country, and its high cost, even in donor programmes, is a barrier to increasing the number of patients on raltegravir.

**In Tajikistan, Moldova and Georgia**, raltegravir as of now is **neither available nor registered**. Consequently, children do not have access to the drug. Data on the availability of pediatric formulations in Kyrgyzstan is currently not available.

Thus, under the circumstances, we can talk about **some theoretical possibility of expanding access to treatment de facto for 6 children (in Ukraine and Armenia),** and, possibly, for a small number of children in Uzbekistan. In general, the number of children who are receiving or may receive raltegravir in our region is so small that it is unlikely to attract generic companies to the markets of the region.

The situation can change if the agreement is extended to the adult form of RAL.

It is also important to note that last year the region faced a dramatic deterioration of the socio-economic situation; budgets allocated to health care were cut. Withdrawal or limitation of the GF programmes has led to stock-outs of treatment. Under these conditions, such an expensive medicine as raltegravir is unlikely to be included in the national treatment programmes funded by the state. Consequently, a significant price decrease will be critical to improve access.

**We call on Merck Sharp & Dohme Corp. and MSD Italia s.r.l. ("Merck") to extend the terms of the license agreement covering EECA countries to the adult forms of raltegravir. Also, we urge Merck to take steps to ensure registration of the medicine in countries where it is still not registered, and, given the difficult social and economical situation the region is currently facing, decrease prices for raltegravir in the countries where it is used.** These actions will prove the commitment of Merck to the idea of providing access to all who are in need of treatment and will demonstrate social responsibility of the company.

We are ready to provide an additional justification based on epidemiological, economical and political data to build a productive dialogue on the inclusion of EECA in the list of countries to be covered by the voluntary license for adult forms of raltegravir. We are also ready to ensure a productive trilateral dialogue between the community of patients, the pharmaceutical sector and the governments of our countries in order to provide an opportunity for prompt voluntary licensing of raltegravir to make it available for all who are in need of the drug in the region of EECA.

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| President  East Europe & Central Asia Union of PLHIV  unnamed | Regional coordinator of the ITPCru |