



Friday, September 15, 2017

Dmytro Sherembey
All-Ukrainian Network of PLWHA
87-B Mezhyhirska Str., Kyiv, 02000
Ukraine

Dear Dmytro,

Thank you for your letter. We are pleased that you welcome the recent news that Gilead is expanding our voluntary licensing program to include Ukraine, Belarus, Malaysia, Thailand, and Philippines. This is to enable the availability of generic versions of our medicines, to help address the unmet needs of patients who are living with hepatitis C, hepatitis B and HIV in these countries. Please note that despite any reports you may have heard to the contrary since our announcement, our plans to extend our program remain unchanged, and we are writing to you now to ensure you are well-informed on the details of the approach we intend to take.

At Gilead, we are committed to enabling broad access to our lifesaving medicines in order to address unmet health needs, and we therefore regularly review our access approach. We made the decision to increase the scope of our access program following a number of discussions over time with government officials, non-governmental organizations (NGOs) and groups such as the All-Ukrainian Network of People Living with HIV/AIDS, regarding the issues these countries have experienced in their efforts to expand access to hepatitis C, hepatitis B and HIV therapies.

We are confident that including these countries in our direct license agreements, as well as our indirect license for our HIV medicines through the Medicines Patent Pool (MPP), will help these governments to reach patients in need of such life-saving treatments.

We would like to bring to your attention some specific terms which we intend to apply to products sold in these countries, which will be subject to the terms and conditions of the applicable license agreement:

Gilead HCV voluntary license:

- **Licensed Territories:** Addition of **Ukraine, Belarus, Malaysia and Thailand** - for a total of 105 countries within the HCV voluntary license territory.
- **Licensed Gilead Compounds:** *sofosbuvir, ledipasvir, velpatasvir and voxilaprevir.*
- **In-country Manufacturing:** Gilead HCV licensees will have the right to have licensed finished product and/or other combination products manufactured in each country within the territory for sale in such country via contract manufacturing arrangements or by issuing a sub-license and using licensed API manufactured in India.
- **Royalties:**
 - For **Ukraine, Malaysia and Thailand**, a royalty rate of 12% (under negotiation) will apply on net sales of licensed finished product and net sales attributable to licensed API in other combination products.

- For **Belarus** and for all other countries in the licensed territory, royalty rates on net sales of licensed finished product and net sales attributable to licensed API in other combination products will remain at 7%.
- **Reduction of Royalties:** Following a licensee's receipt of WHO pre-qualification approval for a product, such licensee's royalty rate with respect to such product will be reduced to 9% for **Ukraine, Malaysia, and Thailand** and to 4% for all other countries within the licensed territory (under negotiation).

Gilead HIV voluntary license:

- **Licensed Territories :** Addition of **Ukraine, Belarus, Malaysia and Philippines** – for a total of 116 countries within the HIV voluntary license territory (note: Thailand has been included in the HIV voluntary licensed territory since 2006).
- **Licensed Gilead Compounds:** *tenofovir alafenamide, elvitegravir, cobicistat and bictegravir*
- **Royalties :** For **Ukraine, Belarus, Malaysia and Philippines** and for all other countries in the licensed territory, royalty rates on net sales of licensed finished product and net sales attributable to licensed API in other combination products will remain at 5%.

Furthermore, there will be additional changes proposed to certain terms relating to product diversion in connection with the recent *Impression Products, Inc. v. Lexmark International, Inc.* Supreme Court case.

A list of Gilead's HIV, HBV and HCV license partners is attached to this letter.

Thank you for your continued interest in our efforts to enable access to our lifesaving medicines and please do let us know if you require any further information or clarification on the matters outlined in this letter.

Best regards,



Gregg Alton
Executive Vice President, Corporate & Medical Affairs

Attachment 1:

Gilead HIV and HBV License Partners

- Anhui Biochem Pharmaceutical* (China)
- Alkem Laboratories Ltd.
- Aspen Pharmacare (South Africa)
- Aurobindo Pharma Ltd.*
- Cadila Healthcare Ltd.
- Cipla Ltd.*
- Shanghai Desano Pharmaceuticals Ltd* (China)
- Dr Reddy's Laboratories Ltd.*
- Emcure Pharmaceuticals Ltd.*
- Hetero Labs Ltd.*
- Zhejiang Huahai Pharmaceutical Co. Ltd* (China)
- Laurus Labs Ltd.*
- Lupin Limited*
- Macleods Pharmaceuticals Ltd*
- Mcneil & Argus Pharmaceuticals Ltd.
- Micro Labs Ltd.*
- Mylan Laboratories Ltd.
- Natco Pharma Ltd*
- SeQuent Scientific Ltd.
- Strides Shasun Ltd.
- Sun Pharmaceuticals Industries Ltd
- Unimark Remedies Ltd.

*Licensed via Medicines Patent Pool

Gilead HCV License Partners

- Aurobindo Pharma Ltd.
- Biocon Limited
- Cadila Healthcare Ltd.
- Cipla Ltd.
- Hetero Labs Ltd.
- Laurus Labs Pvt. Ltd.
- Mylan Laboratories Ltd.
- Natco Pharma Ltd.
- SeQuent Scientific Ltd.
- Strides Shasun Ltd.
- Sun Pharmaceuticals Industries Ltd