Civil society struggle for affordable sofosbuvir in Ukraine

Background:

Ukraine is experiencing a severe hepatitis C epidemic and serious lack of access to HCV treatment. According to WHO statistics more than 1,300,000 people are infected with HCV in Ukraine. The state hepatitis treatment program on 2013 – 2016 years covers only about 2,000 people while more than 44,000 Ukrainian citizens urgently needs HCV treatment.

As access to hepatitis C treatment is restricted in Ukraine due to high pricing of existing interferon-based treatment, thus, there is hope on new most promising direct acting antiviral (DAA) medicines such as sofosbuvir. It has similar mechanisms of action and chemical structures to antiretrovirals for HIV infection treatment, which are currently manufactured at relevantly low prices. Furthermore, sofosbuvir-based treatment is pangenotypic (creating savings on diagnostics) with much higher rates for treatment success and fewer side effects.

However, considering that Gilead set exorbitant prices for its blockbaster sofosbuvir in USA, France and many other countries all over the world it becomes clear that affordable price for sofosbuvir in Ukraine may become possible only in case of generic competition.

It should also be noted, that most of the Indian generic manufacturers negotiated voluntary license with Gilead regarding sofosbuvir which do not cover Ukraine. That is why basically only Egyptian or local manufacturers are considered as possible suppliers of generic sofosbuvir.

Patent opposition as hope for a broad access to hepatitis C treatment in Ukraine:

Fortunately Gilead have not submitted to Ukraine its main sofosbuvir patent applications on Modified fluorinated nucleoside analogues (WO2005003147A2) and on Nucleoside phosphoramidate prodrugs (WO2008121634A2). Nevertheless, several blocking sofosbuvir-related patent applications were submitted.

In an effort to prevent sofosbuvir patent monopoly in Ukraine All-Ukrainian Network of People Living with HIV/AIDS on April 30, 2015 submitted to the Ukrainian Patent and Trademark Office patent opposition against patent on Nucleosidephosphoramidates (WO2011123645). This patent application covers process of sofosbuvir preparation as an active ingredient, as well as nucleosidephosphoramidates crystalline form used for HCV infection treatment. Patent opposition was substantiated with legal and scientific arguments regarding inconsistency of patent application with inventive step and novelty requirements. As a result on May 25, 2015 Ukrainian Patent and Trademark Office issued a preliminary rejection in patent granting.

On July 24, 2015 Gilead submitted amended Nucleosidephosphoramidates patent claim. However, it did not stop Ukrainian patient's community from its intentions to prevent patent monopoly in relation to sofosbuvir and in August 2015 All-Ukrainian Network of People Living with HIV/AIDS submitted additional patent opposition taking into consideration amendments to the patent claim made by Gilead. After consideration of additional patent opposition Ukrainian Patent and Trademark Office issued new preliminary rejection of Gilead patent application. On May 25, 2016 Gilead submitted to Ukrainian Patent and Trademark Office new and sufficiently narrowed patent claim on Nucleosidephosphoramidates in a desperate effort to obtain a patent. To ascertain prevention of granting patent All-Ukrainian Network of People Living with

HIV/AIDS on June, 2016 submitted new additional patent opposition considering new narrowed patent claim. Final Patent and Trademark Office decision regarding this patent opposition is expected at August-September 2016.

In February-March, 2016 All-Ukrainian Network of People Living with HIV/AIDS also submitted two patent oppositions against blocking Gilead sofosbuvir-related patent applications on Methods for the preparation of diasteromerically pure phosphoramidate prodrugs (WO2012012465) and Methods for treating HCV (WO2013040492). So even if patent office rejects Gilead Nucleosidephosphoramidates patent application struggle for prevention of sofosbuvir patent monopoly in Ukraine will continue.

Not only patent opposition matters

Another important issue in creating conditions for generics entry to Ukrainian market was inclusion of sofosbuvir in procurement list of medicines for HCV treatment in Ukraine. It is obvious that sofosbuvir has a lot of advantages of usually used for HCV treatment pegylated interferons such as low cost, weaker side effects, higher efficiency etc. Despite that fact, initially health authorities were not very interested in inclusion of sofosbuvir in procurement list for HCV treatment that may be explained by the pressure from local suppliers who still have a lot of pegylated interferons on their stockpiles and want to sell them. Only under a huge pressure from patient groups, Ukrainian health authorities included sofosbuvir to procurement list of HCV medicines. In the last quarter of 2015, the Ukrainian FDA first registered sofosbuvir from Gilead followed by registration of sofusbuvir manufacturered by Pharco. Sofsbuvir was procured in 2016 for the first time by UNDP for MoH Ukraine for almost 2000 patients with significant savings in comparison to old treatment regimen.

Gilead strikes back

On June 2016 Gilead submitted court claim against Europharma International LLC (Pharco Pharmaceuticals distributor in Ukraine), Ukrainian Drug Regulation Authority and Ministry of Health. This claim is based on data exclusivity protection – parallel to patent protection legal mechanism that prohibits registration of generics within 5 years after registration of an originator medicine. Gilead claims cancellation of Europharma International LLC sofosbuvir registration and by that lawsuit tries to remove sofosbuvir generics from Ukrainian market. On the first court hearing on July 25, 2016 court decided to postpone consideration of the case until September 12, 2016 due to procedural issues. Ukrainian civil society raises concerns regarding possibility of cancellation of generic competitors' registrations.

«Competition is crucially important for affordable prices on medicines while creation of monopoly regarding sofosbuvir may lead to increase or freeze its price for many years» says Sergiy Kondratyuk, Legal Specialist on IP and Access to Medicines at All-Ukrainian Network of People Living with HIV/AIDS.

Conclusion

At the present time, prices for state procurements of sofosbuvir in Ukraine are low in comparison with other middle-income countries where Gilead monopoly for this medicine exists (approx.

750 USD per treatment course of Sovaldi). Prices in pharmacies are significantly higher – even generic version is sold at 2800 USD per treatment course of Grateziano. Now it is hard to predict what price for sofosbuvir will be if Gilead succeeds in obtaining monopoly for sofosbuvir on Ukrainian market. However, as it was shown in Andrew Hill research the manufacturing cost of sofosbuvir treatment course could be as low as 86 USD.

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