TAG
Treatment Action Group

Mr. Arseniy Yatsenyuk, Prime Minister of Ukraine
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Cabinet of Ministers of Ukraine
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Dmytro Sherembey, Head of CF "Patients of Ukraine"

November 27, 2014

Your Excellency:

Treatment Action Group (TAG), a US-based non-governmental HIV/AIDS advocacy organization, strongly supports our colleagues in Ukraine, who are advocating for their rightful place at the table to inform the national drug development and regulatory processes. We hope you will strongly consider their demands.

The benefits of involving patients and community advocates in local, national and international research, program and policymaking in the area of HIV/AIDS are well documented, and endorsed by the United Nations.

Community participation is particularly relevant when confronting HIV and hepatitis C virus (HCV), two diseases that are highly prevalent among marginalized, criminalized, impoverished and disenfranchised communities such as people who inject drugs (PWID) and men who have sex with men (MSM). Ensuring community representation promotes the likelihood of effective policies and programs that improve,the health and lives of marginalized groups.

Globally, community advisory boards (CABs) --or patient boards --have a long history of helping government regulators, researchers and the pharmaceutical industry to influence clinical trial design, policy, drug pricing and access to safe and effective treatments.

The majority of European governments and leading pharmaceutical industry representatives rely on patient boards to:

- Provide critical and relevant information about their products;
- Ensure a transparent process of decision-making on access to medicines on national and regional level; and,
- Demonstrate a good working model of civil society involvement in the governance system.

Therefore, we are deeply concerned that Valartin Pharma Co., a Ukrainian national manufacturer of HCV medication, has avoided open dialogue with community experts, neglected concerns raised by the National Expert Committee of the Ministry of Health, and attacked patient organizations in the media. The registration of medications for the national market must take place in accordance with best practise and international standards, which include soliciting regular expert feedback from patient groups.

Our organization fully supports policies in favor of building national pharmaceutical capacity and ensuring open competition from generic manufacturers to effectively reduce drug prices. Such policies are crucial in the context of HIV and viral hepatitis, where national governments quote price barriers as the most significant in hampering their attempts to effectively address local epidemics.

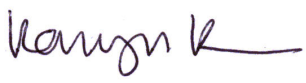
Patients and their civil society representatives must be involved in all national policy decisions that affect their lives. Discussions concerning originator and generic medications should take place in a transparent and inclusive manner, with the meaningful participation of individuals and communities in which HCV is most prevalent.

TAG has years of experience of working to promote access to safe and effective of medicines. In support of our colleagues, **we ask that you urgently establish a transparent and effective process for the approval of new medicines for the Ukrainian market, and encourage the active participation of the HCV patient community in this process.**

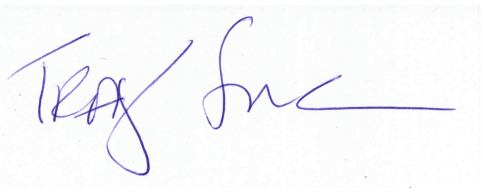
We hope you will demonstrate appropriate leadership by inviting the three key stakeholder groups --patient community representatives, Valartin Pharma Co., and Ukraine's Ministry of Health experts -- to engage in an open and constructive dialogue and ongoing consultation, regarding the safety and efficacy of HCV medications for your country.

Thank you for your consideration.

Yours sincerely,



Karyn Kaplan, Director
International Hepatitis/HIV Policy & Advocacy



Tracy Swan, Director
Hepatitis/HIV Project