# IP, Treatment Access and Community Response Case of Russia



#### Why do patient organizations work with IP?

- 1. We understand the link between lack of medicines and patent monopolies
- We recognize the IP system does not act in our benefit
- We believe that the civil society have the right and the obligation to interfere when things go wrong



# Step 1 – Access Problems

- Stock-outs of drugs
- Regimen change due to non-medical reasons
- Treatment deficit (25% treatment coverage currently in Russia, 150,000 may need treatment urgently)

## Step 1 – How Do We Know

- Research conducted on the ground by focal points
- Specialized websites (pereboi.ru)
- Messages from service organizations



### Step 2 – Understanding the Causes

- Logistics?
- Procurement process?
- Planning?
- Budget deficit?



## Step 2 – How Do We Know

- Continuous drug procurement monitoring system:
  - Several thousand tenders analyzed on a continuous basis each year (procurement in Russia is decentralized)
  - Data compiled and analyzed by means of special software
  - Results are presented in regular reports and submitted to authorities



# Step 3 – Data Analysis

- Drug choice we can compare with the recommendations and see whether we are buying adequate drugs
- Volume we can use specialized formula to understand how many patients can be treated
- Prices we can see the price dynamics, compare with prices at other markets and with estimated manufacturing prices, such as the Andrew Hill data)

## **Step 4 – Drawing Conclusions**

- We have a treatment deficit! (approximately 200,000 receive treatment, at least 150,000 need treatment urgently)
- 2. Some drugs occupy a huge portion of the budget (LPV/r, RAL, ATV)
- Some drugs cost a lot and are almost unavailable to patients despite the fact that they are highly recommended (TDF/3TC, TDF/3TC/EFV)
- 4. All of these drugs have no generics



Then we go and check if the drug is protected by patent, and the link between lack of access and patent monopolies is completed!



#### Step 5 – Options to Eliminate IP Barriers

- Direct negotiations aiming for price decrease
- Voluntary licenses to local producers
- Compulsory license issued by the government/by court
- Patent oppositions generic industry or CS



#### What Can We Do?

- Mediator between companies and government – keeping the high price issue on the agenda
- In some cases can be a negotiator
- Patent oppositions can be done directly ITPCru is taking the case of SOF patent to court



## Compulsory license

- Both government use and a CL issued by court are in the Russian law
- Campaign for a CL for ARVs started in 2014
- Preparing and submitting an analysis based on our research (prices, patents, budget share)
- Choice of drugs: LPV/r, TDF/FTC, RAL; SOF and DCV as the next line
- Supported open letters by CS organizations
- Awareness-raising about the CL among the key stakeholders and the media – interviews, policy briefs



# 5 Common Myths We Fight

- 1. CL is basically a robbery
- 2. You get bad drugs if you issue a CL
- 3. You still get high prices if you issue a CL
- 4. You damage your investment climate, the companies will leave your market
- 5. CL is for "third-world" countries



# Who is For and Against?

FOR: some governments agencies, some patient groups, some politicians, some experts, some local producers

AGAINST: some governments agencies, some patient groups, some politicians, some experts, some local producers + the brand companies

# Ways to Avoid CL

- Decrease prices (dramatic decrease in prices for tenofovir could partly be due to pressure to issue CL for TDF/FTC)
- 2. Give a voluntary license
- Localize manufacturing (similar to VL) for SOF, there are currently negotiations
  about localizing the manufacturing of the
  drug

#### **Our Ultimate Goal**

- CLs, price decreases and other <u>market</u> <u>characteristics</u> are sort of "surrogate endpoints" in terms of the patient benefit
- The ultimate goal is to have as many people as possible receiving quality treatment which meets the current standards

#### **THANK YOU**

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