

# PRODUCT SECURITY IN RUSSIA AND CIS – GENERAL OVERVIEW & KEY CHALLENGES

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# AGENDA

- INTRODUCTION
- PRODUCT SECURITY OVERVIEW & CHALLENGES

# INTRODUCTION

PRODUCT SECURITY (a.k.a. BRAND INTEGRITY, ANTI ILLICIT TRADE, BRAND PROTECTION, etc.) - IS BASICALLY ALL ABOUT PREVENTING AND RESISTING COUNTERFEITING, ILLEGAL DIVERSION AND THEFT OF MEDICINES.

# INTRODUCTION

- COUNTERFEIT - Medicine which was deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product. Counterfeit products may contain less than or more than the actual amount of active ingredient in the authentic version. The product may even be authentic, but be repackaged in counterfeited packaging.
- DIVERSION - Legitimate pharmaceutical is approved and intended for sale in one market, but then illegally intercepted and sold in another market. The criminal nature of such operations exposes patients to potentially harmful drugs due to the questionable handling and storage of these products while outside the normal distribution channel.
- THEFT - Illegal taking of pharmaceuticals: burglary, robbery, embezzlement etc. The location of the theft could include thefts from anywhere in the supply chain: sight of manufacture, freight forwarder, distribution centers, warehouses, pharmacies, or hospitals.

# PRODUCT SECURITY OVERVIEW & CHALLENGES

Roszdravnadzor – top government structure which controls the turnover of pharmaceutical products - has limited capabilities:

- Can not conduct checks of the pharmacies during the first 3 (three) years from initial registration of the pharmacy.
- Can not conduct unexpected checks of any pharmacies, all checks are planned annually and this plan is published on the chief prosecutor's office website.
- Complaints submitted through Roszdravnadzor – how does it work?
- In 2013 – few officially filed cases of falsified or counterfeited pharmaceutical products (according to Roszdravnadzor info).

# PRODUCT SECURITY OVERVIEW & CHALLENGES

- Typical Information Flow:
  - Discovery of a product (by patients, field force, authorities)
  - Test Purchase
  - Preliminary Sample Analysis
  - Full Scale Expertise (Production Site and/ or Scientific Campus)
  - Report to the State Authorities - Roszdravnadzor/ Gosselkhoznadzor
  - Product Recall, Law Enforcement Action or Litigation...

...3 out of 20 cases investigated in 2013 led to some tangible results.

- App. 20% of medicines in Russia & CIS is either counterfeit or diverted.  
There is no reliable statistics though.

# PRODUCT SECURITY OVERVIEW & CHALLENGES

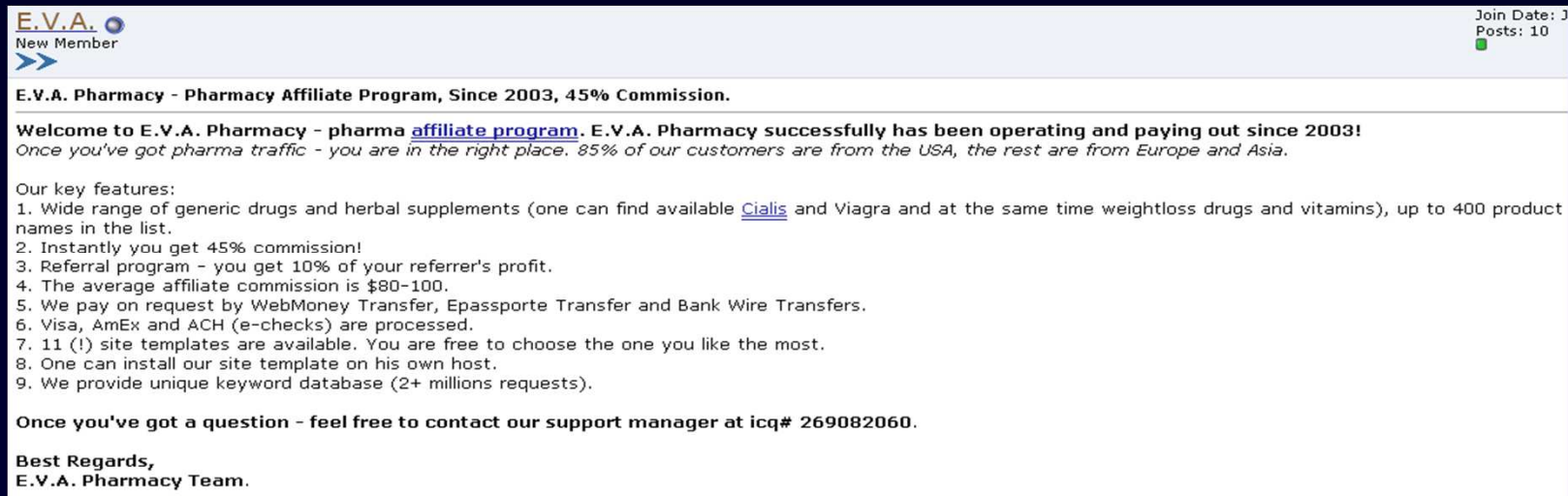
## Possible Legal Actions

- No relative juridical practice exists in Russia & CIS countries.
- Complicated process, involving notary in the test purchase, etc.
- Administrative penalties are against a pharmacy employee (not the owner).
- Complaint can be submitted to the host owner (internet pharmacy) in .SU .RU .PФ domain zones.
- Penalty (administrative - not criminal) for selling pharmaceutical products without proper license – 2,000-2,500 RUR (40-50 EURO).
- Penalty for violating existing legislation in retail – 1,000 – 50,000 RUR (20-1,000 EURO), etc.

# PRODUCT SECURITY OVERVIEW & CHALLENGES

## Global Internet Pharmacy

- Over 36,000 online pharmacies are currently active globally: around 2000 appear to be legitimate and 34,000 are reported to conduct illegal activities (sales of counterfeit/ diverted/ stolen drugs).
- EvaPharmacy is a huge network of internet pharmacies owned by the Ukrainian citizen Alex Polyakov (alias name) generates turnover of around USD 1,8 bln annually. Network is built on recruiting spammers and hackers through Undernet websites & blogs.



The screenshot shows an email header with the logo 'E.V.A.' and 'New Member' status. The main body of the email contains a welcome message and a list of features for their pharmacy affiliate program.

**E.V.A. Pharmacy - Pharmacy Affiliate Program, Since 2003, 45% Commission.**

Welcome to E.V.A. Pharmacy - pharma [affiliate program](#). E.V.A. Pharmacy successfully has been operating and paying out since 2003!  
*Once you've got pharma traffic - you are in the right place. 85% of our customers are from the USA, the rest are from Europe and Asia.*

Our key features:

1. Wide range of generic drugs and herbal supplements (one can find available [Cialis](#) and Viagra and at the same time weightloss drugs and vitamins), up to 400 product names in the list.
2. Instantly you get 45% commission!
3. Referral program - you get 10% of your referrer's profit.
4. The average affiliate commission is \$80-100.
5. We pay on request by WebMoney Transfer, Epassporte Transfer and Bank Wire Transfers.
6. Visa, AmEx and ACH (e-checks) are processed.
7. 11 (!) site templates are available. You are free to choose the one you like the most.
8. One can install our site template on his own host.
9. We provide unique keyword database (2+ millions requests).

Once you've got a question - feel free to contact our support manager at icq# 269082060.

Best Regards,  
E.V.A. Pharmacy Team.



# PRODUCT SECURITY OVERVIEW & CHALLENGES

## Internet Pharmacies in Russia & CIS

- Volume of suspicious products increases (more expensive “but better quality”, make delivery, convenient, taking orders to bring medicine from abroad).
- Presenting fake documents (invoices, incorrect addresses, etc.).
- Hard to control and administer especially if registered in .COM or .ORG domain zones.
- Any official actions should be notarized.
- State authorities are not interested to file official cases and conduct investigations – key focus on other internet related issues (movies, pornography, drugs, etc.).

# PRODUCT SECURITY OVERVIEW & CHALLENGES

## MediCrime Convention

- Initiated by Russia in 2006, when chaired in EU Council, signed in 2011 and still not ratified. Forecast: ratification of the convention will lead to changes in Administrative and Criminal Codes of the Russian Federation – offenders involved in diversion/falsification/counterfeiting are subjects to higher penalties and imprisonment.

## FAS initiative (Legalization of Parallel Import)

- Draft project of the respective law submitted to the government. It is not clear whether pharmaceutical industry will be included in the scope or not. Currently on hold until 2016-2018 with strong potential to be considered earlier.

## Customs Union

- IPR treaty signed by the Custom Union countries (Russia, Belarus, Kazakhstan) is likely to include new members (Uzbekistan, Kyrgyzstan, others).

Legislation environment requires major improvements and is generally quite similar across former Soviet Union countries

THANK YOU. QUESTIONS?

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