Legal actions & practice against wrongdoers in the Hungarian medicinal market

Dr. Nánay János András
National Institute for Quality and Organizational Development in Healthcare and Medicines
National Institute of Pharmacy Directorate
Head of Legal Department
Supervision of the Medicinal Market

Personal Scope:

- National Institute for Quality and Organizational Development in Healthcare and Medicine (GYEMSZI)
- National Public Health and Medical Offer Service
- Office of Health Authorisation and Administrative Procedures
- National Institute for Food and Nutrition Science
- National Authority of Taxes and Duties
- National Police Office
- Hungarian Authority of Consumer Protection
- Hungarian Competition Authority
Horisontal division of competence

- **Categories on the medicinal market:**
  - Medicinal products subject to medical prescription
  - Medicinal products not subject to medical prescription
  - Medicinal
  - Medical devices
  - Nutrition and food-supplements
  - Others
Vertical division of competence

- **Related to the persons on the medicinal market:**
  - **MAH** (Gytv. 5. §, 52/2005. EüMR)  
    Supervision: GYEMSZI (NIP)
  - **Manufacturers** (Gytv. 4. §, 44/2004 EüMR)  
    Supervision: GYEMSZI (NIP)
  - **Wholesalers** (Gytv. 11. §, 53/2004 ESzCsMR)  
    Supervision: GYEMSZI (NIP)
  - **Pharmacies and medicine retail dealers**, Supervision: National Public Health Service
  - **Marketing medicinal products by entities other than pharmacies**
Authorisation Procedures of NIP

• New applications, variations and renewals of marketing authorisations
• Authorisation of Clinical trials, Genetically modified organisms
• New applications and variations of manufacturer’s licences
• New applications and variations of wholesaler’s licences
• Authorisation of individual medicine import
• Authorisation of duty-free donations of medicines
Supervising activities of NIP

• Inspections (GMP, GLP, GCP, GDP, PhV)
• Pharmacovigilance (spontaneous and clinical adverse effects, PSURs)
• Advertisement control
• Control of the promotion of medicinal products and medical aids
• Counterfeit medicines
  • a) drugs without active ingredients
  • b) medicinal products that contain less active ingredients than it is indicated
  • c) medicinal products that contain other ingredients
  • d) medicines with correct ingredients, but without authorisation
  • e) medicines with correct ingredients, but the manufacturer is different
Supervising activities of NIP

What does NIP do for protecting the patients?

• The most effective and best known approach in fighting against counterfeit drugs is to ensure a closed circuit of distributional system. The quintessence of this is that every member of the distributional system has to dispose of an administrative authorisation issued by medicinal supervisory authority of Hungary, also of all member states of the EU. This activity, validated by the administrative authorisation, is controlled continuously by the authority.

• While any pharmacy in Hungary can only obtain medicine or ingredients from an authorized wholesaler/retailer (executive distributor), then in abroad – because of the liberalization of medicinal retail – the problem of counterfeit drugs within the legal medicinal market has increased. To some extent the situation of internet-pharmacies is a little more favourable. These are never virtual in Hungary, unlike abroad. At us, only real providers can be deliverers, the ones possessing a proper marketing authorisation.
Supervision activities of NIP

What does NIP do for protecting the patients?

- It is significant to highlight that currently in Hungary we do not have information on any counterfeit drugs within this closed distributional chain. The domestic legal medicine-market is strictly controlled. The National Institute of Pharmacy controls the route of the medicine all the way till the pharmacy, meaning the quality of the drugs, their efficacy and safe usage, also the activity of the medicine wholesalers. The National Public Health and Medical Officer Service then checks on the retail-merchandising of the medicines (pharmacies, small retail shops with particular authorisations).

- The ingredients with ambiguous origin can become components of counterfeit drugs, therefore the tracking of the manufacturing of the ingredients has great importance among the wholesalers and/or manufacturers.
Legal actions against wrongdoers

National basis of the legal actions:

• Administrative law actions
  • Act XCV of 2005 on Medical Products for Human Use
  • Act XCVIII of 2006 on Supply Medical products and Medical aids
  • Act XLVII of 2008 on Prohibition of unfair commercial practice against consumers
  • Act LVII of 1996 on Prohibition of the unfair and restrictive market practices

• Civil law actions
  • Act IV of 1959 on the Civil Code of the Republic of Hungary

• Criminal law actions
  • Act IV of 1978 on the Criminal Code of the Republic of Hungary
Legal actions against wrongdoers

- **International basis of the legal actions:**
  - Convention on the counterfeiting of medical products and similar crimes involving threats to public health (so-called Medicrime Convention) (not implemented)
  - Jurisdiction of the ECJ and national courts of MS
  - Legal practice of the European Commission and the European Medicines Agency
  - WHO - global coalition of stakeholders called IMPACT (International Medical Products Anti-Counterfeiting Taskforce)
Act XCV of 2005 on Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products

• (1) The NIP shall be vested with authority to supervise the obligations conferred under this Act or other legislation adopted by authorization of this Act relating to the manufacture, distribution, placing on the market of medicinal products, as well as the public service obligation for the supply of medicinal products, furthermore, to the clinical trial of investigational products and the activities of laboratories contracted for testing medicinal products for reasons of safety, whereas in connection with pharmacies and other medical service providers the same authority shall be conferred upon the government body in charge of the healthcare system.

• The regulations concerning the promotion of medicinal products and for the enforcement of the provisions relating to business-to-consumer commercial practices shall be laid down in specific other legislation, including the provisions for any infringement of these provisions.

• (2) In the control proceedings the NIP shall establish the facts, and shall take the measures consistent with the nature and severity of any discrepancies and irregularities, and shall monitor their implementation.
(3) Where the NIP finds that a marketing authorization holder, or its representative, or a manufacturer of medicinal products or an authorized wholesale distributor of medicinal products, the holder of authorization for the conduct of a clinical trial, or the laboratory contracted for testing medicinal products for reasons of safety is in non-compliance with the requirements set out in this Act or any other legislation adopted by authorization of this Act, or is in breach of the obligations conferred upon it, the NIP shall:

a) order the state of infringement to be terminated;
b) prohibit continuation of the illegal conduct;
c) order the medicinal product or the production batch that is deemed harmful to life, health or physical safety to be removed from the market;
d) order the person affected to eliminate the discrepancies within the prescribed deadline, or to suspend his authorization until the said discrepancies are eliminated;
e) revoke the authorization of repeat offenders.
Act XCV of 2005 on Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products

• The NIP and government body in charge of the healthcare system shall have **powers to impose penalties upon the person having committed the infringement.** In the case of **multiple violations** the **amount of fines imposed may aggregate.**

• (5) The amount of the fine shall be determined with **regard to all applicable circumstances,** in particular, the scope and **gravity of the injury caused to patients and the duration of the illegal conduct.** Repeat offenders shall be penalized accordingly. The fine shall be minimum one hundred thousand forints, or maximum one per cent of the perpetrator's net domestic sales of the product in question in the previous calendar year. Unpaid fines shall be enforced in the same manner as taxes.
Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products

(2) If the promoter of medicinal products, a medical sales representative [...] has infringed upon the provisions of this Act or the Decree pertaining to the promotion of medicinal products or medical aids, the NIP:

a) may contact the competent trade association requesting ethics proceedings, where applicable;

b) may order the infringer to eliminate the discrepancies within the prescribed deadline and may suspend his authorization until the said discrepancies are eliminated;

c) shall declare the fact of infringement, may order the state of infringement to be terminated and prohibit continuation of the illegal conduct;

d) in connection with a repeated or grave infringement, shall ban the promoter of medicinal products governed under Subsection (3) of Section 12, that is held accountable for the infringement, from engaging in promotional activities for a period of between six months and three years;
Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products

• e) may impose a fine of between five hundred thousand and twenty-five million forints;

• f) in connection with a repeated or grave infringement, shall contact the health insurance administration agency that has entered into a financing contract with the infringer, or an agreement granting entitlement for the prescription of subsidized medicinal products and medical aids for the suspension of prescription and distribution rights within the subsidized system.

• The amount of the fine shall be determined with regard to all applicable circumstances, in particular, the scope and gravity of the injury caused to patients and persons qualified to prescribe or supply medicinal products and/or medical aids, and the duration of the illegal conduct. Repeat offenders shall be penalized accordingly. In the case of multiple violations the amount of fines imposed may be cumulative. Unpaid fines shall be enforced in the same manner as taxes.
Other administrative authorities

- Act XLVII of 2008 on Prohibition of unfair commercial practice against consumers

- For the insult of the unfair commercial practice the enterprise is liable, which interested in saling of the product and in sales incentives.

- The consequences defined in the act can be the following: to cease the non-legislative state, or prohibition of continuing this non-legislative state, such as product removal from the market, fine, release of verdict/decree about the suspension of pursuit, withdrawal of marketing authorisation.
Other administrative authorities

• Act LVII of 1996 on Prohibition of the unfair and restrictive market practices
  • The competition council proceeding in the case,
  • d) may establish that the conduct is unlawful,
  • e) may order a situation violating this Act to be eliminated,
  • f) may prohibit the continuation of the conduct which violates the provisions of this Act,
  • g) where it finds that there is an infringement of the law, it may impose obligations […]
• The proceeding competition council may impose a fine on persons violating the provisions of this Act. The maximum fine shall not exceed ten per cent of the net turnover, achieved in the business year preceding that in which the decision establishing the violation is reached, of the undertaking or, where the undertaking is member of a group of undertakings, which is identified in the decision, of that group of undertakings.
Civil and Criminal Actions

• *Act IV of 1959 on the Civil Code of the Republic of Hungary*
  • General rules of compensation - damages
  • Monetary compensation
  • Non monetary compensation (punitive damages)
  • Product liability (Act X of 1993 on Product liability)
  • Brand and Patent Piracy

• Enforce the aggrieved party’s rights: Civil court
Civil and Criminal actions

• Act IV of 1978 on the Criminal Code of the Republic of Hungary
  • Fraud
  • Piracy
  • Abuse of consumer’s goods
  • Marketing of schlock
  • False designation of origin of the product

• Enforce the aggrieved party’s rights: Criminal court
New challenges in the supervision of the medicinal market

- Vertical integration
- Horizontal integration (fusion of wholesalers, chains of pharmacies)
- Ceasing of medicinal products not labelled medicines
- Effective control of promotion and advertising of medicinal products
- Breaking of the quality assurance chain (re-export, intermediate trade of medicines)
- Struggle against counterfeit medicines
- Effective control of the non authorised activities
Thank you for your attention!