The State Commission for the Protection of Economic Competition of the Republic of Armenia

General competition issues in parallel import of drugs

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Motives, goals and objectives of the study

- ➤ In 2017 The Commission received a statement from economic entities involved in the import and distribution of medicinal products on the territory of the Republic of Armenia.
- According to the position of economic entities the Ministry of Health (Ministry) refused to allow certain medicines to be imported into the Republic of Armenia, which helped to restrict competition in the pharmaceutical market.
- According to the position of the Ministry the aforementioned refusals are due to the fact that some differences were detected between registered and imported medicines, so they were considered unregistered.
- As a result of the Commission's studies conducted in 2013-2015, a number of provisions restricting competition have been identified in legal acts regulating the import and registration of medicines.
- > To solve the identified problems, the Commission provided relevant information to the Government of Armenia, proposing amendments to these acts, finalizing and introducing a full-fledged procedure for parallel importation of medicines.
- ➤ As a result, the new drug law, adopted in 2016, finalized and introduced the parallel import procedure.
- > Currently, there are problems with the full operation of the parallel import system, as existing legal regulations require that imported and registered drugs are identical, while pharmaceutical companies provide the same drug to different countries with some differences.





Example 1. Difference with respect to primary packaging (form of release) Tirozol 10 mg N50

- > Producer of the drug Merck KGaA (Germany).
- Form issued in the Republic of Armenia $(2 \times 25, 2 \text{ blisters with } 25 \text{ tablets each})$.
- \triangleright The form of release of the imported preparation (5 × 10, 5 blisters with 10 tablets each).
- ➤ As a result of the study, it was found out before March 27, 2017 that the drug was registered in the Republic of Armenia with a package of 5 × 10, and then the above change was made

Registered drug



Imported drug



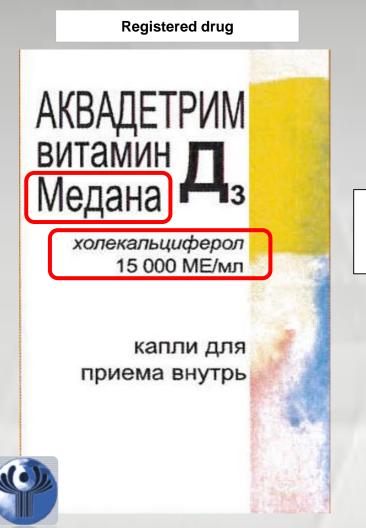
Price difference-



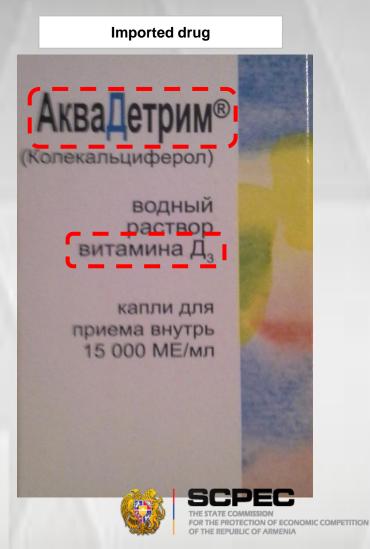


Example 2. Difference with respect to secondary packaging (design) Aquadetrim Vitamin D3

- > Производитель лекарства Medana Pharma (Польша).
- > В Армении препарат был зарегистрирован под торговым наименованием Аквадетрим витамин Медана.



Price difference – 71%



Example 4. Difference regarding instructions Thrombopol 75 mg

Manufacturer; Polpharma (Poland).

Registered drug



Price difference-206%

Imported drug





Упаковка

По 10 таблеток в контурную ячейковую упаковку (блистер) из пленки поливинилхлоридной и фольги алюминиевой. По 3 или 6 контурных ячейковых упаковок вместе с инструкцией по применению вкладывают в картонную пачку.



Форма выпуска

Таблетки кишечнорастворимые, покрытые оболочкой, 75 мг или 150 мг. По 10 таблеток в блистер из фольги Ал/ПВХ/ПВДХ.

По 3, 5 или 6 олистеров вместе с инструкцией по применению помещают в картонную пачку.



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Example 3. Difference in storage conditions MIG 400 N 10

> Manufacturer: Berlin-Chemie AG (Germany).

Price difference– 88%

Registered drug

Imported drug





Условия хранения

Данный лекарственный препарат не требует специальных условий хранения.

Условия хранения

<u>Хранить при температуре не выше 30 °C.</u> Лекарственное средство хранить в недоступном для детей месте!







Thank you!

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