Pharmaceutical Market in Azerbaijan:
Regulatory base, practical problems and opportunities

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– Total land area of 86,600 sq km. Sharing borders with Russia, Georgia, Turkey, Iran, and Armenia.

– Population is 9.15 million (31 percent of the population between 14 and 29 years old and only 9.3 percent of retirement age).

– Baku population – around 4 million.
Some figures

— For 2011, gross domestic product (GDP) was USD 63 billion and GDP per capita was USD 4,283.80.

— Expected GDP for the year 2012 is USD 67.7 billion; per capita – USD 6,000.

— Healthcare expenses in 2012 – USD 595 mln (includes everything).

— Per capita expenses – USD 45-50.
Main legal acts

— Regulation of Cabinet of Ministers on State Registration and Maintenance of the Register of Medical Products, dated July 13, 2007.
— Order of the Minister of Health No 130 on broadening the list of the Most Important Medical Products and Medical Equipment, dated December 22, 2011.
Statistics

- Market volume: Local information – around USD 500 mln.
- International companies info: 250-300 mln euro (import prices)
- Business monitor – USD 0.4 billion
- Growth – 10% per year (could be more - 10+ x percent)
- Between 2010 and 2015, BMI projected a compound annual growth rate (CAGR) of 15.64% in local currency terms and 17.16% in US dollar terms. That would mean USD 1 billion in 2015.
- The Government is considering introducing obligatory mandatory insurance which should boost up the market to USD 1.5 billion (realistic?)
**Major Players**

- Generally – **Major players are either already here or about to enter**
- Active – Turkish companies
- Indian companies (in 2005 – market share 60%, in 2011 – 15%); declined due to various reasons
- From CIS – Ukraine, Russia, Belarus
- Joint activity is not welcomed for some reason
- Major tender players and distributors – Centrus-Pharma, Avromed, Riad-Far, Azermed, Velga
Local Production

— Small and undeveloped
— Just over USD 1 mln
— Local producer: “Azerfarm Ltd” (produces around 150 medicines)
— 99% of medicines are imported

Reasons:
— High production costs
— Lack of technically trained workers
— Dollar flow into the country which makes it easy to buy
— Government is not flexible
— State purchases – USD 100 million including equipment
— Ministry of Health purchase for hospital drugs – USD 60-70 mln.
— Market is slowly developing where the “branded generics” play important role. Around 200 local companies are engaged into active marketing of branded generics from Eastern and Western Europe, South America and South Korea, Egypt.
Health Insurance

- People still spend out of pocket.
- Draft law on compulsory insurance is discussed (Fee would be split between employer and employee. Healthcare services are meant to be covered)
- Proposal: on particular areas of treatment, the Government provides certain budget for such insurance (oncology, hemophilia). Some developments in this direction are expected.
Health insurance (cont’d)

- Around 5% are covered by private insurance companies. It is a developing parallel area.

- Azerbaijani drug-store chain Zəfəran (Saffron) has entered a cooperation deal with insurance company Azsigorta for voluntary health insurance. The deal will enable Azsigorta customers to purchase free-of-cost medicines at Zəfəran stores in the 25 cities the network covers. The customers will be provided with free medication on the basis of their prescription and insurance policy. The programme includes more than 3,000 drugs (Businessmonitor, February 2012)
— Tendency – demand for more quality and efficacy (people switch to higher quality products)

— This may one of the reasons market in Azerbaijan tends to grow more in value than in volume
Problems with price control (market volume)

The prices are various because:

1. Medicines are produced in different countries with implementation of different technologies;

2. Drug store owners artificially increase prices by entering into deals with distributors;

3. Drug store owners artificially increase prices taking the opportunity of absence of state regulation over prices on medicines;

4. The Ministry of Health is not competent in price control over medicinal products, limiting its functions to quality control.

In 2012, it is expected that the Government will introduce price limits for INN.
Registration and Certification of Medicines

Which medicinal products should be registered?

1. Originator medical products;
2. Generic medicines;
3. New combinations of the registered medicines;
4. Medicines which term of registration expired;
5. Medical substances (used in production as active substances).
Procedure of Registration

1. **Application** to the Ministry of Health should be provided in line with certain documents and samples of the medicines and active substances claimed to be registered.

2. During preliminary expertise the Ministry of Health verifies the expedience of the registration and completeness of documents submitted. Once the medicine passed this stage the producer is notified in this regard and the medicine is presented for expertise.

3. **Specialized Expertise** evaluates the results of laboratory test, normative technical documents and clinical-pharmatoxicological tests.

4. **Additional Specialized Expertise** is charged by Expert Board on Pharmacologic and Pharmacopeia under the Ministry of Health while the results of the above mentioned expertise are insufficient. Additional Specialized Expertise is consists of expertise of the reports of the Specialized Expertise and (or) laboratorial analysis of medicinal products.

   **All kinds of expertise are payable by the producer and are to be provided within prescribed time limits.**

5. Should the medicine get a positive decision from the above mentioned stages the producer is granted a **Registration Certificate** which is valid within 5 years. After the 5 year period expires the producer should claim for the state registration again.
– From March 2008, importation of medicines without proper state registration is prohibited.

– Registration procedure is very complicated. Very tough attitude. 210 days. Bioequivalence of drug with the original is required.

– From the one hand such a complicated system protects from distribution of sporadic, fake and harmful medicines. But it also bans important and vital medicines than can be brought to Azerbaijan.

– Requires user manual in state Azerbaijani language. Used for registration but not for distribution/sale.

– Not enforced yet due to various reasons: (small population; small market; make no economic sense for companies to print it; some medical products are of great demand even if the manual is not in Azerbaijan).
Drug Stores and Pharmacy

– Medicines are distributed among the population only through drug stores. Drug stores are prohibited to treat patients unless first medical aid is necessary to save patient’s life.

Medicines which necessarily should be in each drug store:

– Medical products that are vitally important and used in emergency. Pursuant to Order No 130 issued by the Minister of Health the list of the most important medicinal products and equipments was broadened. (Whether the Order was triggered by objective necessity or other side reasons.)
c. Advertisement and E-Commerce.

It is prohibited to advertise medical products in the Republic of Azerbaijan—this provision was excluded from the Law on Pharmaceutical Products.

For now it is wholly prohibited to advertise drugs that are issued only under prescription. With regard to advertisement of other drugs it is prohibited to:

1. refer to minors;
2. refer to specific circumstances of improvement and rehabilitation of diseases;
3. express gratitude of natural persons who used the advertised medicines;
4. create an imagination of necessity to use the advertised medicines for healthy person;
5. create an imagination that there is no need to refer to doctors;
6. guarantee positive reaction, safety, efficacy of the medicine and the absence of adverse reactions;
7. perform medicinal products as biologically active substance and food additions or any product other than medicine (However in practice namely this norm is violated very frequently);
8. disseminate the information which guarantees that advertised product has natural source, is safe and effective.
According to the Regulations dated December 24, 2010, advertisement of medicines issued without prescription may only take place if positive opinion of the Ministry of Health obtained. To get that opinion legal entity (manufacturer or whole seller) should apply to the Ministry in writing with relevant application form.

**Note:** Law on E-commerce fails to provide any special rules for distribution of medicines through Internet or other means of electronic communication. In practice it triggers a question: given that only drug stores are entitled to distribute medicinal products may we allege that distribution by e-commerce is importation medicines for personal use in certain dosages (when getting from foreign country)? What about the sale within Azerbaijan?
QUESTIONS?

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