Code of Good Practice in the Pharmaceuticals Industry

Work on development and implementation of compliance procedures is currently being conducted all over the world. In Russia the history of this question has begun approximately since 2011, and 2013 of the Russian Federal Antimonopoly Service (hereinafter – the "**FAS**") has included antitrust compliance in the long-term strategy as the independent direction of further work of the authority and has accurately designated it as a priority for development of the antitrust legislation and law enforcement practice because the main objective of the authorities is not only suppression of violations committed, but also their prevention.

Any measures aimed at prevention of antitrust violations are encouraged and approved by the antimonopoly service. Compliance procedures such as development of codes of conducts and policies in the industry are exactly directed to the prevention of committing such offenses. Implementation of compliance procedures is not a coercion, it is a "soft" instrument of implementation of the state competition policy. Adoption of various codes of conducts, policies are efficient mechanisms of suppression of offenses as establishing correct behavior models and those provisions to which the antimonopoly authority pays close attention. The FAS has also recently suggested involving more actively the companies of member states of the Eurasian Economic Union (EAEU) in development of rules of self-regulation in those markets where now a large number of violations of the antitrust law could be observed.

On April 19, 2016 Association of European Business (hereinafter – "**AEB**") presented the Code of Good Practice in the Pharmaceuticals Industry (hereinafter – the "**Code**"). The full text of the Code (both in Russian and English) is available on the official web-site of the antimonopoly authority (http://fas.gov.ru/documents/documentdetails.html?id=14513).

The Code continues new trend in Russian antitrust legislation aimed at creation of rules of conduct by industry associations and unions in collaboration with the FAS and trend aimed at creation of compliance procedures by the companies and industries.

Among the most interesting examples of the conducts already elaborated are the Code of Good Practice between Retail Chains and Suppliers of Consumer Goods and the Code of Conduct between Vehicle Manufacturers and Auto-Distributors on the Markets of Sale of New Vehicles and Spare Parts to them.

Codes of Conducts developed in different industries are important in law enforcemen. Often they are created when the antimonopoly authority is particularly active in the market and adoption of codes is the result of the reached compromise: players in a particular market change their behavior according to such rules while the FAS decreases the level of its supervision over them.

Historically, the pharmaceutical market remains under the close supervision of the FAS for a long time. The basis for the Code of pharmaceutical manufacturers is a big experience gained by the FAS in the course of interaction with market participants. In general, the Code establishes the approaches already formed in practice of the FAS and of courts, in particular, that the dominant players on the market should develop a policy on interaction with their customers.

Major aims of the Code are as follows:

- creation of effective self-regulation system in the pharmaceutical industry in Russia; *AND*
- creation of transparent and fair rules of competitive interaction in this sector.

The Code regulates such aspects as:

1. Selection of distributors

The Code states that the participants shall endeavor to ensure the implementing **effective system for monitoring** compliance with legislation, including anti-corruption legislation and the law on the protection of competition, in particular through **adoption of a commercial policy** governing the work with customers and incorporating the provisions stipulated by the Code.

The Code provides for criteria of economic and technological justification, compliance with the Russian legislation (and the EAEU legislation) as well as with foreign legislation, if applicable to the participant, for selection of distributors by manufacturers .

The Code introduces the requirements of **clear, transparent and measurable, objectively justified and nondiscriminatory selection criteria for distributors**. Commercial policy should include regulatory procedure and timeframes of selection process, standard contract terms and conditions, discount/bonus procedures and mechanisms, general payment terms and procedure for informing the existing distributors of the commercial terms and any changes (and be available on the official web site of the participant).

The Code provides for **approximate (not exhaustive) criteria** that may be taken into consideration during the selection procedure. Apart from standard criteria such as absence of tax arrears, necessity to have licenses and some other, there is a criterion stating that there are no documented violations of legislation on combating corruption including foreign legislation if it is applicable to the participant.

It is also interesting that the Code states that for audit purposes the participants apart from Russian legislation may take into account **the FCPA and the UK Bribery Act**.

One more interesting provision relates to possibility by the participants independently determine in the commercial policy **a number of distributors** which is economically and technologically justified. This provision would allow manufacturers without violation of the Russian competition legislation to establish their own business model and not to enter into agreements with all potential distributors if this is not economically justified.

2. Termination of cooperation with distributors and setting discriminatory conditions

The Code lists samples of **grounds for termination of cooperation** with distributors such as being in the process of liquidation, absence of necessary licenses, establishment of the fact of involvement into corruption offences, arrears under the contract. The list is also not exhaustive and the participants may introduce other grounds in their commercial policies.

The Code introduces provisions making difference between definitions of **discriminatory conditions** in contracts and different conditions that are not deemed to be discriminatory. Conditions that differ in contracts with several distributors are not deemed to be discriminatory, if products being subject matter of contracts relate to different markets, and if products are traded on the same market, provided that the parameters of transactions are not of equal value, which makes the application of a variety of terms and conditions economically justified (for example, the price per unit may be lower for large product purchases in natural terms or if payment includes advance payment rather than commercial loan).

3. Transparency and validity of bonus models

The Code sets forth that the participants may offer bonuses and discounts; however, they should apply on a non-discriminatory basis (for example, for achievement of certain value or volume of purchases or conclusion of a contract with a state customer).

4. Minimum amount of purchases

Based on the economic and technological capabilities, a member of the Code has a right to establish in a commercial policy the minimum amount of one-time shipping and the minimum amount of purchases in a certain period, both in quantity and in value terms. If the buyer fails to comply with these conditions, the participant will be entitled to terminate the contract and not to enter into an agreement with the purchaser for the next period.

5. Credit limits

The Code establishes the criteria for setting credit limits for distributors. Such limits may be stipulated in the local acts and calculated on the basis of objective criteria listed in the Code. In case of exceeding the credit limit party to the Code shall have the right to suspend the delivery of products to the distributor.

6. Exclusive agreement

As a general rule, the Code does not allow the conclusion of exclusive agreements between the party and the contractor if a party dominates on the market. The Code provides some exceptions that can be applied when there is the localization of production in Russia

Such exceptions are seemed to be reasonable due to the fact that localization projects require large investments, from both foreign and Russian partners. In order to ensure that the Russian partner will return its investment, you should give him the opportunity to determine the policy and give the exclusive right to carry out sales on the territory of the Russian Federation.

7. Other provisions

In order to adhere to the Code, potential participant should sign the **special accession declaration** attached to the Code, send it to AEB and publish on its official web site. AEB further also publishes the information on accession to the Code by the participant and send this information to the FAS.

After 1 year of application of the Code, the participants will analyze the respective results and consider possibility of creation special collegial body for resolution of disputes under the Code.

We believe that the Code introduces a number of important rules not provided for by the current legislation that would influence further activity of the players in the pharmaceuticals market. We expect that the Code will influence the manufacturers' conduct in Russia in part of compliance with its rules for mitigation of risks of violation of the Russian competition legislation. Although the Code is not obligatory, it is likely that the pharmaceutical companies will have to review their existing commercial policies (or adopt them in case of absence) and standard distribution contracts to prevent the risks of conflicting with antimonopoly legislation in day-to-day business and excessive attention from the FAS side.

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