



## Declaring medicines

Since 1 January 2007, mandatory certification of medicaments has been replaced by declaration of compliance. Participants on the pharmaceutical market are transferring to declaration of medicaments in accordance with Resolution of the Government of the Russian Federation and methodological recommendations of the Ministry for Industry and Power of Russia. On 1 April, 2007, in accordance with Resolution of the Government of the Russian Federation dated 28 December, 2006, "On Introduction of Amendments into Resolution No. 72 of the Government of the Russian Federation, dated 10 February, 2004", the period expired during which the declare could (was entitled to) choose independently the form of mandatory confirmation of compliance – mandatory certification or declaration of compliance.

### What exactly is declaration of compliance and what is it needed for?

The declaration system has been in place in the Russian Federation since 1999. The format of the declaration of compliance, the procedure for its acceptance and the list of products subject to declaration were approved. The list of goods subject to declaration has been consistently growing. Since 1 January, medicaments have been added to this list.

Under the system for quality certification of medicines previously in effect, the certifying authority issued the manufacturer with a document confirming the quality of the medicines, thereby assuming some of the responsibility itself.

The change in the system affects manufacturers and sellers, as well as the bodies authorised to register a declaration of compliance.

The declaration system is a unified one for both imported and domestically manufactured medicaments.

Declaration simplifies, for the manufacturer (seller) of the medicaments, the process of mandatory confirmation of compliance with the established requirements, and also makes it considerably more responsible for the output released on to the Russian market. At the same time, a special laboratory for monitoring the quality of medicaments will continue to participate in this process. Currently, the Federal Agency for Technical Regulation and Metrology has accredited, in the established manner, 8 authorities for certifying medicaments and registering a declaration of compliance, and 65 technically competent, independent test laboratories, accredited to perform tests of medicaments for the purposes of a declaration of compliance.

A registered declaration of compliance of a medicament is necessary:

- for presentation to the customs authorities for placing products subject to mandatory confirmation of compliance under customs regimes envisaging the possibility of their disposal or use in accordance with their purpose on the customs territory of the Russian Federation;
- on sale of the products, at the demand of the consumer, the seller is required to provide the purchaser with information about confirmation of the products' compliance with the established requirements.



## What is subject to declaration?

According to the Methodological recommendations on acceptance and registration of a declaration of compliance of medicaments, medicaments registered in the established manner and consisting of mixed or unmixed products for treatment purposes, packed in retail sale packaging (codes 931000-937000 of the All-Russia Product Classification OK 005-93) are subject to confirmation of compliance in the form of a declaration of compliance.

The Methodological recommendations do not apply to medicaments made up in chemists' shops on the basis of doctors' prescriptions, according to the requirements of healthcare institutions, to preparation and packaging carried out by chemists' shops, medicaments intended for performance of clinical tests or registration of medicaments in the established manner. Medicaments without individual packaging (in bulk) are not subject to declaration of compliance or to mandatory certification.

It should be noted that medicaments in circulation as of 1 January, 2007, and covered by a certificate of compliance, issued in the established manner are not subject to declaration.

## Declaration procedure

A declaration of compliance of a medicament can be accepted by a legal entity or an individual, registered in accordance with the legislation of the Russian Federation and on its territory as an individual entrepreneur, which is a manufacturer (seller) or fulfils the functions of a foreign manufacturer on the basis of an agreement with the latter with respect to ensuring compliance by the products supplied with the established requirements and with respect to non-compliance by the products supplied with the established requirements (hereinafter referred to as the declarant).

The declaration of compliance is made according to one of the following systems:

- acceptance of a declaration of compliance on the basis of the manufacturer's own evidence;
- acceptance of a declaration of compliance on the basis of tests performed by an accredited test laboratory.

The manufacturer's own evidence is understood as such documents as the manufacturer's passport (for domestically produced medicines) or a firm's quality certificate (for foreign-made medicaments), a document confirming the origin of the medicine, medicine quality control test reports, certificates for raw and other materials used in producing the medicament, etc.

Reports on tests performed by an accredited test laboratory are accepted as proof received with the participation of a third party in consideration of the requirements of regulatory documents governing specific medicaments.

Each series (batch) of a medicament released into circulation is subject to declaration. The term of validity of a declaration of compliance is set by the declarant. At the same time, the term of validity of the declaration of compliance for a series (batch) of a medicine shall not exceed its shelf life.

The declaration form of compliance by products with the requirements of the technical regulations, as well as recommendations for completing this form, have been approved by Order No. 54 of the Ministry for Industry and Power of the Russian Federation, dated

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22 March, 2006, "On Approval of the Declaration Form for Compliance by Products with the Requirements of the Technical regulations".

A declaration of compliance is signed by the head of the manufacturing (sales) organisation, the authorised representative or individual entrepreneur.

### **Registration of a declaration of compliance**

A declaration of compliance is subject to registration by the certification authority responsible for the sphere of state accreditation including medicaments. Registration of a declaration of compliance of medicaments is performed on the basis of an application by the declarant for registration of the declaration and a specific list of documents. These documents include state registration documents relating to the medicaments, documents confirming the origins of the medicaments, reports on tests performed by an accredited test laboratory and other documents confirming compliance by the products with the established requirements. Within a period of seven days, the certification authority verifies the following:

- inclusion of the medicaments on the List of products subject to declaration of compliance;
- complete and correct indication of the regulatory documents establishing the requirements on the medicaments;
- existence of the required documents;
- correct completion of the declaration of compliance.

Providing the requirements are observed, a registration number is allocated that includes the identifying code of the certification authority and the number of the declaration in the register maintained by the certification authority. The declaration is deemed to have been registered and to have legal force once it is entered into the certification authority's register.

The registered declaration of compliance of the medicaments, together with the documents on the basis of which it was accepted, shall be kept by the declarant for a period of at least three years after its expiry. In addition, copies of the registered declaration of compliance of the medicaments and the other documents submitted by the declarant are kept by the certification authority, also for a period of at least three years after termination of its validity.

In the event that the Federal Service for supervision in the sphere of healthcare and social development identifies cases of non-compliance with the established requirements by medicaments for which a declaration of compliance has been accepted and registered, the declarant shall, within a period of three days, notify the certification authority that registered the given declaration of termination thereof.

Re-acceptance of a declaration of compliance for the given medicaments is possible only after the non-compliances identified by the state supervisory authority have been remedied and the state supervisory authority and the registration authority have been notified to this effect. In this case, the declaration of compliance shall be re-registered by the same certification authority that performed the initial registration of the declaration of compliance.



In conclusion, it should be noted that the system of declaration of compliance broadly implemented in the countries of the European Union increases protection of the market against substandard and counterfeit medicaments, and also promotes successful implementation of the top-priority national project entitled "Health".

Overall, implementation of the new system has proved itself, in spite of the large number of questions arising among pharmaceutical community. In addition, experts of the Federal Agency for Technical Regulation and of the Federal Service for Supervision in the sphere of healthcare and social development are prepared to answer questions posed by interested persons, and the customs authorities, in turn, in order to avoid any delays in the import of medicaments into the Russian Federation, release medicaments conditionally, in accordance with Resolution No. 470-r of the Federal Customs Service of Russia, dated 26 December, 2006, "On Conditional Release of Goods Subject to Declaration of Compliance" without the declaration of compliance being submitted.