MOROĞLU ARSEVEN

Withdrawal and Recall Guideline of Medical Devices and In Vitro Diagnostic Devices has been Published

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The purpose of the Guideline is to determine the procedures and principles regarding the withdrawal and recall of medical devices and in vitro diagnostic devices from the market, and the duties, authorities and responsibilities of Turkish Medicines and Medical Devices Agency ("**TITCK**"), economic operators and other public institutions and organizations in this context.

The prominent regulations in the Guideline are as follows:

The duties, powers and responsibilities of TITCK are regulated by The Article 5, and according to this provision, TITCK holds the following authorities:

1. To make a risk assessment about the devices that it considers to be risky,
2. To ensure that measures are taken for the withdrawal or recall of inappropriate devices from the market, depending on the degree of risks they carry,
3. To notify the economic enterprise of the measures taken and administrative sanction decisions, their reasons, solution proposals, if any, legal objections and time limits,
4. To inform on the precautions regarding device movements within the scope of the guideline through the Product Tracking System or similar software,
5. To monitor the effective and timely execution of withdrawals or recalls from the market and requests information and documents regarding these transactions from the interlocutors,
6. To announce the measures taken in line with the guide on its own website or by other methods it deems appropriate,
7. To notify the Commission and other authorized institutions of the decision to withdraw or recall the certificate, if the device carries a serious risk.

The duties and responsibilities of economic enterprises and other institutions and organizations are regulated within Article 6, and according to this provision, different duties and obligations have been determined for the responsible economic enterprises and other economic enterprises within the scope of the activities of withdrawing and recalling devices from the market.

- The important duties and obligations of the responsible economic enterprise within the scope of the activities of withdrawing and recalling devices from the market are as follows:

1. To establish and operates the procedure for effectively withdrawing and recalling devices from the market when needed,
2. To perform risk-based studies on devices that are reported to be unsuitable or that carry a risk in this direction,
3. To not supply the non-conforming devices to the market until they are made compliant and to withdraw or recall them when necessary.

4. To take the relevant measures within the scope of withdrawal and recall by TITCK, to determine the plans for this and notify TITCK.
5. If the devices that have been recalled or withdrawn from the market have been placed on the EU market, it shall inform the competent authorities of the relevant countries and the relevant incumbent economic enterprises.
6. In the event that a decision is taken to withdraw or recall a device imported from the foreign market, of which are being offered for sale in the country, to inform TITCK about the reason for the decision and the activities carried out by it.

- The important duties and obligations of the economic enterprise, which is not responsible for the withdrawal and recall of devices from the market, are as follows:

1. Stops the making, use and putting into service of the devices withdrawn or recalled from the market, and immediately initiates the necessary actions according to the direction of the responsible economic enterprise.
2. It carries out withdrawal and recall transactions from the market in cooperation with the responsible economic enterprise and informs TITCK regarding these transactions upon request.

- The classification criteria for nonconformity are set out in Article 7 and are mainly divided into three categories in terms of harming the health of the patient, user or other person or posing a serious public health threat:

1. First Class: Non-compliances that pose a serious risk that causes/may threaten serious deterioration in the health of persons, death or serious public health threat
2. Second Class: Non-compliances that cause/may cause temporary and treatable non-impairment in the health status of persons.
3. Third Class: Non-compliances other than the above specified ones.

- Withdrawals and recalls are applied for First Class non-compliances, and withdrawals are applied for second and third class non-compliances. However, if the TITCK deems necessary, it may apply one or all of the withdrawal and recall measures at the same time in terms of these non-compliances.
- The principles regarding withdrawal and recall from the market and the processes to be followed by the decision of the Institution are regulated in Article 8.
- Principles regarding voluntary withdrawal from the market and recall are regulated by Article 9. In this framework, the responsible administrative enterprise takes a voluntary withdrawal/recall action if necessary on the devices that are found to be non-compliant within the scope of surveillance activities, and this is determined in accordance with the provisions of Article 8. In cases where a decision is made to withdraw or recall the devices imported from the market abroad, the responsible enterprise informs the TITCK about the decision within five business days, except for force majeure, from the notification of the decision to their side. In line with the decision, the enterprise informs the TITCK about these activities within five business days, except for force majeure, following the completion of the activities carried out by them.

Please see this link for the full text of the Guideline published by the TITCK (only available in Turkish).

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