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Guideline on Counterfeit, Illicit or Out-of-the Legal Supply Chain Medicines has been Published

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On 5 January 2022, the Turkish Medicines and Medical Devices Agency ("**Agency**") has published the Guideline on Counterfeit, ?llicit or Out-of-the Legal Supply Chain Medicines ("**Guideline**").

The Guideline aims to provide the guidance on the actions that can be carried out by the relevant third parties, primarily the Authority and the license holder company, in the fight against counterfeit, illicit or illegal medicines.

Most notably, the Guideline states that:

- In Turkey, in order to prevent counterfeit and illicit medicines, there is a QR code requirement on medicine packages. The Medicine Tracking System (ITS) was developed to ensure effectiveness in the fight against counterfeit and illicit medicines by monitoring and tracking medicines with the use of QR code.
- Regarding products suspected of being counterfeit/smuggled; patients, citizens, health personnel, international organizations such as WHO, PIC/S, EMA, PANGEA, and other institutions and organizations can make complaints to the Ministry of Health, Agency, local health authorities or the license holder company.
- In the event that the licensed medicines with QR code reported to the Agency from various sources, which are detected in non-pharmacy sources, first of all, the source of exit of the products out of the legal supply chain is investigated by using the ITS system, and judicial and administrative action is taken against those concerned within the scope of the provisions of the relevant Law.
- Similarly, if the products reported to the Agency are determined not to have marketing authorization license and contain active pharmaceutical ingredients, legal proceedings will be initiated and the relevant authorities will be informed that the products are not suitable for use and that they must be destroyed.
- The procedures to be carried out by the Authority, license holder company, pharmacy warehouse responsible manager, pharmacy responsible manager, hospital authorities, the manufacturing place of medicine, physicians and other health personnel, local health authorities, the Ministry of Health, and patients are given in detail.
- Actions taken by the license holder company are the followings:
    - In the product notifications made to the license holder company, which is suspected to be counterfeit/smuggled, evaluating the complaint and applying to the Authority together with the Counterfeit/Ilicit Medicine Company Notification Form in the annex of the Guideline, submitting a detailed report to the Authority after all necessary examinations and analyzes regarding the suspected counterfeit/smuggled product are made.
    - If the product suspected to be counterfeit/smuggled or the product found to be counterfeit is physically available, delivering it to the Authority for examination and evaluation.
    - Making a risk analysis in terms of patient safety regarding the product in question and reporting it to the Agency in detail.
    - Immediate submission of all information and documents requested by the Agency.

- The sale or promotion of medicines over the Internet is against the law, and it is the Agency's responsibility to determine these activities and to take the decision to block access.
- In the event that the sale or promotion of medicine is detected on the website/page under review, pursuant to the relevant legislation, the Agency makes a decision to block access to the website/page, and the websites that are decided to block access are reported to the Access Providers Association. In addition, the

Authority notifies the necessary authorities for commencing judicial and administrative proceedings.

Please see this link for the full text of the Guideline. (Only available in Turkish).

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