THE FALSIFIED MEDICINES DIRECTIVE (FMD)

(Origin, Mission and Provisions)

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This article is solely written by him to guide the Pharmaceutical Companies/Export Houses/Traders/Brokers especially those involved in export to European Union to streamline their facility, systems, and distribution practices as per the Falsified Medicine Directive implemented under Directive EC 2001/83/EC taking effect from 1.1.2013

INTRODUCTION

The commercial activities in pharmaceutical involves manufacturing (own, contract, P to P), importing, indenting and wholesale distribution of Excipients, API, Finished Dosage Forms, Colors and Flavorings. It has been observed that with the advances in time the falsification in the drug manufacturing and supply chain has increased all over the world at an alarming rate. The falsification is taking place through illegal as well as legal trading channels.

Falsification in drug products has been shown to result in treatment failure including death. Currently, falsification has become potential threat to health of patients specially those who are terminally ill.

Considering this many countries in the world are serious to bring the falsification of medicines under the legal frame. The first step for the same has been taken by EC. They had framed various provisions to prohibit falsification under directive 2001/83/EC on February 16, 2011 and now the directives are being enacted with effect 1.1.2013

The focus of the Directive is to protect the public against the major health threat that can arise from falsified medicines. The measures introduced by the Directive will apply generally to all prescription products unless they are specifically exempted, but not to non-prescription medicines unless they are considered to be at high risk of falsification.

The Directive does not deal with unintentional quality defects or the protection of intellectual and industrial property such as registered trade marks or patent rights. Falsified drugs are not counterfeit drugs, which often contain no active ingredients. Rather, falsified drugs may contain substandard ingredients, or active ingredients in the wrong dosage.

To motto of the directive is to enhance and safeguard the health of the public by ensuring that medicines and medical devices work and are acceptably safe.

This article is written to give highlight salient features of the act to all those who are involved in Pharmaceutical /API trade with UK and EU at large.

1.0 MODES OF FALSIFICATION AS IDENTIFIED ANND PROHIBITED BY THE DIRECTIVE

The act prohibits falsification in medicines manufactured, imported or indented in EU region. Followings are some of the most common modes of falsification prohibited under the act:

1. The branding of the product to appear like the competitive brand in the market
2. The designing of the product container to resembles standard approved products
3. The labeling of the product using fonts, texts and diagrams similar to the original product.
4. Assigning the ditto or closely similar name as that of approved product
5. Declaring composition which the drug product does not have actually.
6. Including active ingredients/excipients much less or much more amount than indicated on the label.
7. Assigning falsified specifications for the ingredients included in the product.
8. The manufacturing of the products under unhygienic and non GMP environment.
9. The distribution of the products under falsified (untruthful) records

2.0 GENERAL PROVISIONS OF FALSIFIED MEDICINES DIRECTIVE

The general provisions under Falsification Medicine Directive are as per follows:

1. Each person/organization in supply chain should disclose entire admin/establishment information to the competent authority. Further, they shall disclose the complete list of their products along with the details on valid marketing authorization issued for each product by the European Medicines Agency or by the Competent Authority in an EEA Member State

2. Each manufacturer shall adopt a system of serial numbers so as to enable verification of the drug authenticity at the pharmacy level. This could be implemented in a way that would allow pharmacists to determine whether a drug had been recalled or previously dispensed and thus intercept possible falsified medicines before they reach the public.

3. At present, internet sales of medicinal products are the most important channel by which falsified medicines enter the EU market .The internet pharmacies will be required to setup a trust mark authorized by Member States. Internet pharmacies would be subjected to increased regulation and registration requirements. In addition, the public would be warned of the potential dangers of purchasing drugs from internet sites.

4. MA holders of API/Excipients/Dosage forms should ensure that their products are authentic and comply with GMP

5. Falsification will be recognized as a crime and the defaulters will be served with "effective, proportionate and dissuasive" penalties

6. Qualified Person (QP) declaration will be required that the manufacture complies with GMP

7. Each supplier will be required to establish and document supply chain traceability

8. Each manufacturer of medicinal products will be required to adopt a system to identify false representations of his products (particularly each individual package of high-risk products)

9. There will be improvement on the control at the EU external borders to prevent entry of false medicinal products

10. The repackaging of medicines by parallel traders will be permitted but they will be required to built-up necessary safety features to prohibit falsification.

11. Manufacturers, distributors and brokers should report all suspicious falsified medicines to the regulators

12. Manufacturers, importers and brokers (Medicines broker - a medicines broker are those who do not handle medicinal products but negotiate for others) should register with the competent authorities of the relevant Member State

13. The control over the supply chain will be strengthened .The facilities of manufacturer, importer and brokers will be subjected to regular audits as per EU Directives. Good manufacturing procedures will be formalized

14. The manufacturerers will be required to provide unique identifier – (an obligatory authenticity feature) on the outer packaging of medicines.

15. Each Manufacturers, importers and distributors of active substances will be required to be registered with the Competent Authority of the Member State in which he is established. Registrations will be entered onto a database operated by the European Medicines

16. Each manufacture/ importer/distributor/indenter will be required to declare the followings:
    Name, address and qualifications for persons responsible for overseeing activities
    The intended end-use of the active substance(s)
    The quantities handled
    Description of arrangements for maintaining records, and any quality system in place
    Details of any other activities taking place at sites named in the registration (e.g. manufacture/distribution of bulk chemicals

17. All Registered businesses related to Pharmaceutical will be required to submit an annual statement of changes to the competent authority unless those changes could present a risk to active substance quality or safety in which case they should be notified immediately.

4.0 PROVISIONS FOR BROKERS OF MEDICINAL PRODUCTS

As pert he provisions of the act each broker of the medicinal products shall register himself with the competent authority in each EU State with the following details:
Registered address of the business
Contact name
Contact telephone number
Contact email address
Details on all subsidiaries and branches all over the world
No of persons directly employed at office
Name of the drug for which he is broker
The details on valid marketing authorization issued for each drug by the European Medicines Agency, or by the Competent Authority in an EEA Member State
Name of trade associations with which he is registered

Further, he shall maintain record of all his Business Dealings in following format:
The date of the brokering transaction
The name of the medicinal product
The quantity of product brokered
Name and address of the supplier or consignee, as appropriate
PN: These records should be kept for five years and may be subject to inspection

The broker of medicinal product shall cooperate to respond to Recall Notice as and when issued by competent regulatory authorities or by manufacturers or marketing authorization holders.

He shall also maintain a valid an emergency plan for effective recall of medicines covered under his transactions

5.0 PROVISIONS FOR WHOLESALERS OF MEDICINAL PRODUCTS

Each wholesaler should register his firm with the competent authority in each EU State with the following details:
Company Name of the firm
Registered address of the firm
Contact name
Contact telephone number
Contact email address
Details on all subsidiaries and branches all over the world
No of persons directly employed at office
Name of trade associations with which it is registered.
Details on valid Wholesale Drug License issued by national Authorities

Further, he is required to cooperate during inspection of premises by competent authority. Straightforward inspections can last one full working day.

He shall Follow EU Good Distribution Practice Directives in his day today business.

He shall have well defined responsibilities for each staff.

An appropriate risk management plan shall be duly maintained by him to handle emergency situations.

Under this directives he shall check that “safety features” used on the outer packaging of a product are intact and the product is not falsified by any means.

He shall record the batch number when supplying medicinal products to his customers
Whenever there is a doubt, he shall ensure the truthfulness through cross checking with competent regulatory authorities

6.0 PROVISIONS FOR THE MANUFACTURERS OF THE MEDICINAL PRODUCT S

Each Manufacturer should register his firm with the competent authority in each EU State with the following details. He must know that inappropriate or incomplelete information may require action in accordance to FMD
Name of the company
Registered company address
Contact name
Contact telephone number
Contact email address

Details on all subsidiaries and branches all over the world
No of persons directly employed at office
List of the drugs for which he has valid marketing authorizations
Name of trade associations with which his company is registered.
Name of the authorized Persons for manufacturing, Quality Control and Quality Assurance and other critical functions

He should get audited the suppliers of active substances for "GMP" compliance
The manufacturer should assess the risk to product quality originating from inappropriate quality of excipients used in manufacturing the same

He should ascertain that the appropriate good manufacturing practices necessary to assure the safety and quality of the excipients are followed.

He should inform both the Competent Authority and Marketing Authorization Holder in case he has valid information that API/Excipients used by him are falsified in the supply chain

He shall verify that the suppliers of active substances are registered with the Competent Authority of the Member State

He shall comply with the relevant GMP as described in Part II of the EU Guidelines on Good Manufacturing Practice

7.0 SOME QUERIES ON THE FMD DIRECTIVE

There are few major queries and trade concerns on the current FMD Directive.

- How the directive will be applicable to the medicinal products in transit?
- How the directive will be applicable for medicinal products imported in Europe for re-export to the countries outside EU?
- What are the high risk factors for manufacturerers and wholesalers under the act?
- If the Advertising Agencies will also be covered under the act?
- How the act will be applied to OTC products?
- How the individual defaulter especially outside EU will be penalized?
- If any action under the act will be on case to case basis?
- How large number of API Facilities in India and China who are the major exporters to EU will be inspected?
- If Indian exporters will require time to organize them in accordance with the act?
- If our export of API to Europe will come to halt?
- If the medicinal product manufacturers who are also importing, or distributing (including export outside of Europe) active substances will also be required to register those activities distinct from their manufacturing authorizations?

It's hoped these queries will be resolved as the act gets enforced.

SUMMARY

Falsification is increasing all over the world at alarmingly high rate. European Drug authorities have become highly vigilant about the whole supply chain involved in manufacturing and distribution of the medicinal products. The Falsified Medicines Directive 2011 will be a great legal instrument to control falsification of medicines at large in coming times.

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