

P74 : IMPLEMENTATION OF GOOD MANUFACTURING PRACTICES

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Purpose

In this study, Good Manufacturing Practices (GMP) in European Union and Turkey and the relation between GMP and Granting Biocidal Products Manufacturing License in own and loan Premises are assessed.

Method

In this study, national and international legislation and practices in the countries of the European Union are reviewed. Findings There are two Directives related to Good Manufacturing Practices (GMP) in the EU. These are 2003/94/EC Directive repealing Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products. In Directive 2003/94 /EC, Good manufacturing practice is defined as "the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use". In By-Law on Premises of Medicinal Products Official Gazette numbered 27th April 2013 and No 28630, Good manufacturing practice is defined as "the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use". It is also intended to help to ensure that active substances meet the requirements for quality and purity that they purport or are represented to possess. In these guidelines "manufacturing" includes all operations of receipt of materials, production, packaging, repackaging, labeling, relabeling, quality control, release, storage and distribution of active substances and the related controls. The GMP Guide as a whole does not cover safety aspects for the personnel engaged in manufacture nor aspects of protection of the environment. These controls are inherent responsibilities of the manufacturer and are governed by other parts of the legislation. These guidelines are not intended to define registration requirements or modify pharmacopoeia requirements and do not affect the ability of the responsible competent authority to establish specific registration requirements regarding active substances within the context of marketing/manufacturing authorizations. Good examples of GMP in Turkey are premises of medicinal products and the medical gas plants. In case of a product to be manufactured in Turkey and where the applicant is not the manufacturer, the notarized contract manufacturing agreement is executed with a manufacturer that satisfies the requirements specified in the By-law on Manufacturing Sites of Medicinal Products for Human Use, published in Official Journal 25268 of 23.10.2003. In case of a product that is imported or manufactured on license for which an application is pending, the other country /countries where an authorization application for the product is pending, In such applications it is required to submit a copy of the authorization certificate approved by health authorities from any of the listed countries before authorization is granted in Turkey. Requirements of Good Manufacturing Practices (GMP) for disinfectants are not mandatory in EU. Acc. to the studies done on the GMP in Nepal, since some microorganisms can grow readily in dilute disinfectants, dilutions of disinfectants should not be stored unless they are sterilized and It is advisable to use different disinfectants over a period of time to prevent the development of disinfectant-resistant strains of microorganisms.

Result Manufacturing Practices (GMP) are different from the license for the operation of the unhealthy establishments and the grant of biocidal products manufacturing license in own and loan premises. There is no information showing that Good Manufacturing Practice (GMP) for disinfectants is mandatory in EU- and developed countries.

Keywords: GMP, the grant of biocidal products manufacturing license in own and loan premises