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P71 : COMPARISON OF AUTHORIZATION/REGISTRATION/NOTIFICATION PROCESSES AMONG BIOCIDAL PRODUCTS, COSMETICS, PLANT PROTECTION PRODUCTS AND HUMAN MEDICINAL PRODUCTS

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Purpose
In this study, comparison of the authorization/registration/notification processes of biocidal products, cosmetics, plant protection products and medicinal products are made and in this respect, the situation in EU is assessed.

Method
In this study, national and international legislation and practices in the countries of the European Union are reviewed.

Findings
The By-Law on the Biocidal Products was published in the Official Gazette and entered into force on 31st Dec, 2009 in parallel with Directive 98/8/EC concerning the Placing of Biocidal Products on the Market. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products will repeal and replace Directive 98/8/EC and will be valid in EU Member States as of 1 September 2013.The Regulation contains a number of new procedures and structural changes. According to current biocidal legislation in our country, after registration of low-risk biocidal products, these products will be the placing on the market in Turkey. Cosmetic products will be placing on the market in Turkey on a notification based in line with the Law on Cosmetics - Official Gazette numbered 23rd May, 2005 and No 25823. Regulation (EC) No 1223/2009 on cosmetic products repeals Directive 76/768/EEC on cosmetic products with effect from 11 July 2013. Plant Protection Products are authorized in line with the By-Law
on Authorization of Plant Protection Products, Official Gazette numbered 25th March 2008 and No 27885. EU legislation on Plant Protection Products is now the Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market repealing Council Directives 79/117/EEC and 91/414/EEC (Article 2 of 91/414/EEC) . Medicinal products for human use are authorized in line with the By Law on Authorization of Medicinal Products Official Gazette numbered, 19th Jan. 2005 and No 25705 in parallel with Directive 2001/83/EC on the Community code relating to medicinal products for human use.
If there ıs a doubt on whether the products are with in the scope of medicinal products for human use, biocidal products, plant protection products or cosmetic products, there is a hierarchy of legislation, with medicines above biocides. . Therefore if the regulatory authorities responsible for medicines determine that the product should be regulated as either a medicine. then it will be not a biocidal product within scope of Reg. (EU) No 528/2012. If any substance or combination of substances presented as having properties for treating or preventing a disease in human beings, these are medicinal products.
If any substance or mixture are intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with the intention exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors, these are cosmetic products. If any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action, as well as a treated article that has a primary biocidal function, these are biocidal products. Article 19.9 of Regulation (EU) NO 528/2012 concerning the Making Available on the Market and Use of Biocidal Products states that where a biocidal product is intended for direct application to the external parts of the human body (epidermis, hair system, nails, lips and external genital organs), or to the teeth and the mucous membranes of the oral cavity, it shall not contain any non-active substance that may not be included in a cosmetic product pursuant to Regulation (EC) No 1223/2009. Product-type 1: Human hygiene in Annex V to the Regulation is defined as "Products in this group are biocidal products used for human hygiene purposes, applied

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on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp. There is a doubt about
whether article 19.9 of the Regulation contradicts product-type 1: human hygiene human hygiene definition or not.

Result
Great importance should be given to the recent legislative developments in the European Union and that all the developments are closely followed and used to revise the national legislation in line with EU legislation

Keywords: authorization of biocidal products, cosmetics, plant protection products and human medicinal products