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

If there is a doubt on whether the products are within 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 not be 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
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