

OPINION OF THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD
PRODUCTS INTENDED FOR CONSUMERS

OPINION

CONCERNING

KETOCONAZOLE

adopted by the SCCNFP during the 21st Plenary Meeting
of 17 September 2002

1. Terms of Reference

1.1. Context of the question

During its 8th plenary meeting of 23 June 1999, the SCCNFP adopted an opinion on the use of Ketoconazole stating that the substance can be used safely in both rinse-off and leave on cosmetic products, excluding oral care products, at a maximum authorised concentration of 2.0% in the finished cosmetic product. However, and in order to avoid any risk by accidental intake, the SCCNFP recommended that cosmetic products containing Ketoconazole should not be used by nursing mothers.

In the frame of the adaptation to technical progress of the Annexes to Directive 76/768/EEC on cosmetic products, a majority of Member States questioned the safe use of Ketoconazole in cosmetic products due to possible development of (cross-)resistance to Ketoconazole by fungi.

1.2. Request to the SCCNFP

The SCCNFP was asked to perform an expert review on the basis of the data provided and to answer the following questions :

1. Does the SCCNFP see any possibility for the development of resistance or cross-resistance by fungi to Ketoconazole, if Ketoconazole is used in cosmetic dandruff shampoo at concentrations of either 1 % or 2 % ?
2. Does the SCCNFP propose any recommendation of concentration at which Ketoconazole can be used in cosmetic dandruff shampoo ?

2. Opinion

2.1 Introduction

The present opinion has been drafted predominantly on the basis of the opinion onazole antimycotic resistance, adopted by the Scientific Steering Committee at its meeting of 27-28 June 2002.

In the framework of reported increasing resistance of human pathogenic fungi against antimycotic substances, the Commission requested the Scientific Steering Committee (SSC) to examine the issue and to determine which options they could identify to manage them.

Although a possible resistance of fungi from cosmetic use of antimycotic substances, and to Ketoconazole in particular, are not expressively discussed by the SSC, its opinion and recommendations do apply.

2.2 Conclusions and Recommendations

In the light of conclusions and recommendations expressed in the opinion of the Scientific Steering Committee on azole antimycotic resistance, adopted by the SSC at its meeting of 27-28 June 2002, and on the basis of the information provided, the SCCNFP is of the opinion that :

There is at present no scientific evidence of development of resistance or cross-resistance of fungi to Ketoconazole, if Ketoconazole is used in cosmetic dandruff shampoo at concentrations up to 2 %.

Consequently, there is no scientific reason to modify the opinion on Ketoconazole adopted at the 8th plenary meeting of the SCCNFP of 23 June 1999 (doc. n° SCCNFP/0164/99).

However, the SCCNFP endorses the options to manage the resistance proposed by the SSC in its above mentioned opinion, and in particular the option that there might be a need for “an assessment of the extent to which cosmetic (e.g. shampoos) and medical uses (dermatological applications) are contributing to the development of azole resistance to fungi”.

3. References

1. SSC opinion on Azole antimycotic resistance, adopted at the SSC meeting of 27-28 June 2002
2. SSC opinion on microbial resistance, adopted at the SSC meeting of 28 May 1999
3. Janssen Pharmaceutica. Evaluation of the resistance potential of Ketoconazole on *Malassezia furfur* in the treatment of dandruff. 21 May 2001 (confidential)