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HMPC statement on Environmental Risk Assessment of herbal medicinal products

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1. Introduction

The CHMP 'Guideline on the environmental risk assessment of medicinal products for human use' (CHMP/SWP/4447/00) indicates that "herbal medicinal products are also exempted due to the nature of their constituents" and that "In all cases, except for Type I variations and renewal applications, an environmental risk assessment or a justification for its absence should be provided in Module 1.6 of the Marketing Authorisation Application (MAA, see section 8)."

The present statement intends to establish a general justification for the above-mentioned exemption for herbal medicinal products.

2. Statement

According to Directive 2001/83/EC as amended, environmental risk assessment is required for all new marketing authorisation applications for a medicinal product. The directive defines environmental risks as those risks to the environment arising from the use, storage and disposal of medicinal products and not to risks arising from the synthesis or manufacture of medicinal products.

Herbal medicinal products are medicinal products that exclusively contain as active substances (one or more) herbal substances and/or (one or more) herbal preparations. Herbal substances and herbal preparations contain (complex) mixtures of primary (e.g. sugar, cellulose) and secondary (e.g. terpenes, glycosides) constituents. Because these mixtures of herbal constituents originate from the environment, they are considered as natural products. The use of herbal substances and preparations in small amounts in medicinal products is therefore not considered to be a risk to the environment.

The HMPC acknowledges there may be exceptional cases where further justification to the absence of an environmental risk assessment might be necessary.

3. References

CHMP 'Guideline on the environmental risk assessment of medicinal products for human use' (CHMP/SWP/4447/00) dated June 2006

Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products (EMA/HMPC/71049/07) dated January 2008