E U R O P E A N E C O N O M I C A R E A

S T A N D I N G C O M M I T T E E
O F T H E E F T A S T A T E S

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EFTA WORKING GROUP ON TECHNICAL BARRIERS TO TRADE

EXPERT GROUP ON MEDICINAL PRODUCTS

COMMENTS BY THE EEA EFTA STATES ON THE EUROPEAN PARLIAMENT PROPOSAL FOR LABELLING OF NEWLY AUTHORISED MEDICINAL PRODUCTS – USE OF RED TRIANGLE

The EEA EFTA States are following closely the discussions in the European Parliament and the Council concerning the review of the Community Pharmaceutical legislation. In the draft European Parliament Report, it has been proposed to introduce a red triangle on the package leaflet on newly authorised medicinal products. The EEA EFTA States would like to point out that labelling products with a red triangle is being used in the Nordic countries as a warning on drugs that should not be used in connection with driving cars, or using other machinery because of its sedative effects. The EEA EFTA States are concerned with regard to the new proposal because it might cause confusion and misunderstandings in the Nordic countries.

1. Reference is made to the Commission Proposals on the review of the Community Pharmaceutical legislation (COM(2001) 404 final) and the draft European Parliament Report on the proposal for a Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (COM(2001) 404 – C5-0591/2001 – 2001/0252(COD)), as presented on 3 May 2002 by the rapporteur in the European Parliament Committee on the Environment, Public Health and Consumer Policy.

2. Amendment 15 of the draft Report proposes to include a new paragraph 3a into Article 13, introducing a special symbol in the package leaflet for newly authorized medicinal products:

> Article 13, new paragraph 3a:
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> "*In the first five years after being placed on the market, the package leaflet of every medicinal product must bear a red triangle and the phrase: 'Newly authorised medicinal product. Please notify any adverse reactions'*."

3. The EEA EFTA States would like to point out that labelling products with a red triangle has been in use in three EU Member States, Denmark, Finland and Sweden, as well as the two EEA EFTA States, Iceland and Norway, for nearly twenty years as a warning on drugs that should not be used in connection with driving cars, or using other machinery because of its sedative effects.

4. A red triangle refers more to traffic and roads than any other known sign and is commonly recognised among the population in the Nordic countries as a warning against driving in connection with certain drugs. It could cause confusion and result in misunderstandings if this proposal for the use of the red triangle in the package leaflet is adopted. The EEA EFTA States are concerned about the proposed new use of the red triangle and do therefore propose that the red triangle in Article 13, paragraph 3.a) to be changed into another symbol, e.g. red or orange hexagon and/or the warning text to be printed in red. The EEA EFTA States do support the European Parliament proposal in principle, but not the use of a red triangle as a warning sign.

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