

Letter dated 8 May 2008 from Polish Patients Federation to DG ENTR

Response to the public consultation in preparation of a legal proposal to combat counterfeit medicines for human use

We are unhappy with the proposal to ban the repackaging of medicines contained in 4.1.3 of the document presented by the European Commission on 11 March 2008 for public consultation in connection with the preparation of new rules aimed at helping combat counterfeit medicines.

In our view, this proposal will not help combat the growing counterfeiting of medicines but may deprive Polish patients of secure and legal access to cheaper medicines by blocking parallel imports.

Parallel imports of medicines are repackaged in accordance with GMP requirements. These requirements are the same as for manufacturers. Introducing a ban on repackaging to combat counterfeit medicines would be disproportionate and backed up by no evidence, especially since Poland has yet to see a single case of counterfeit medicines entering legal distribution channels.

We are also afraid that such a proposal will draw the attention of the authorities and the public away from the real threat posed by market trading and illegal Internet sales.