Public consultation in preparation of a legal proposal to combat counterfeit medicines for human use

European Research into Consumer Affairs (ERICA), founded in 1978, undertakes research leading to action for all European consumers, but particularly those who are disadvantaged. It sets out to improve life for Europe's more vulnerable consumers by identifying key problems, researching them and proposing solutions. Its brief includes healthcare and it has previously contributed to consultations regarding the advertising of pharmaceutical products and the legal proposal on information to patients.

ERICA welcomes the Commission’s initiative in introducing this public consultation in preparation of a legal proposal to combat counterfeit medicines for human use which would provide additional consumer protection although does not go far enough in certain areas. ERICA makes the following general points:

- Any restriction of legal provision to certain drugs could move counterfeiters to those areas least regulated. (Paras. 4.1.3 and 4.1.5)

- It does not cover sales of medicines on the internet and yet internet security experts believe that nearly 25% of all emails - 15 billion messages a day - are spam advertising drugs. According to WHO, more than 50% of medicines offered by websites that conceal their physical addresses are fakes. In January 2008, the Royal Pharmaceutical Society released new research revealing that more than 2 million people in the UK buy prescription medicines over the Internet without knowing if the online pharmacy or the medicines are legitimate, and almost a third of these medicines are counterfeit.

- It does not make any provision for informing consumers how they can protect themselves. In one report on counterfeit drugs, it was mentioned that pharmaceutical companies did not want consumers to know the extent of the problem because it could affect their choice of drugs. An example of the kind of information which should be provided to consumers is provided by the National Consumer League’s Fraud Center (www.fraud.org/fakedrugs/).

ERICA is also concerned that the costs of regulation will be passed on to consumers either directly or by a health authority not being able to purchase more efficacious drugs because of price.

ERICA hopes that the Commission will take notice of the Council of Europe’s expert panel on pharmaceutical crime. It is aware that WHO and the EU are considering...
some aspects of the problem, the Council of Europe's convention will cover "topics where no international legally binding instrument exists".

Finally, ERICA believes that the Commission should also look at counterfeit medical devices. While there appears to be very little about the incidence of these, UsingRFID.com published an article in November 2004 stating that, “More counterfeit medical devices are appearing on the market. Both finished goods and parts have been faked. Typically, they are "look-alike" devices, with high-quality packaging and authentic-seeming appearances, but do not meet medical standards and are not capable of performing intended functions. Examples include everything from aortic pumps to mesh implants for hernia repairs. Counterfeiters have also moved into diagnostic equipment, like stethoscopes and testing systems.”