EPF'S POSITION ON THE LEGISLATIVE PROPOSAL regarding the ENTRY INTO THE SUPPLY CHAIN of MEDICINAL PRODUCTS WHICH ARE FALSIFIED[1]

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EPF is working closely with our sister organisation the International Alliance of Patient Organizations (IAPO), on this proposal given their extensive international experience in this arena.

1.EPF welcomes the proposal and strongly supports the development of anti-counterfeiting measures

EPF welcomes the European Commission's proposal to tackle counterfeit medicinal products since they represent a serious threat to public health and there is an alarming increase of these products on the market: for example, according to DG Taxation and Customs Union[2], 2.7 million counterfeit medicines were seized at the EU's borders by custom authorities in 2006, which represents a 380% increase on the products seized in 2005 and an increase of 628% between 2005 and 2007. They relate not only to 'lifestyle' products, but also to treatments against life threatening diseases. These products contain sub-standard or falsified ingredients, or no ingredients or ingredients in the wrong dosage, including active ingredients, representing thus a substantial risk for patients.

Therefore, EPF strongly supports the development of appropriate anti-counterfeiting regulations and effective enforcement regarding the manufacture of medical products and the medical products supply chain, with consideration of their impact, especially on patients' access to quality and safe medicines.

2.Broader legal basis and a patient-centered approach

EPF argues that the proposal should have a broader legal basis and highlight explicitly Art 152 of the Treaty of the European Union, which clearly states that the activities of the Community shall include "a contribution to the attainment of a high level of health protection". All strategies and legislative measures to combat counterfeit medical products should be in line with the principles of patient-centred healthcare[3] (respect, choice and empowerment, patient involvement in health policy, access and support, information), considering the impact of those strategies on the patient in terms of access to safe, quality and appropriate treatments and information.

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[1] DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source

[2] Report on Community customs activities on counterfeit and piracy. Results at the European border 2007; http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics2007.pdf

[3] International Alliance of Patients Organisation's Declaration on patient-centered healthcare http://www.patientsorganizations.org/showarticle.pl?id=712&n=312

3.All medicinal products should be subject to measures combating counterfeit medicines

For patients to be effectively protected against counterfeiting, all medicines, not only prescription-only medicinal products, but also generic medicines and over-the-counter medicines should fall under the scope of the Directive. All of them should be subject of a risk-based assessment. This will ensure consistency with the objectives of the Directive which are to ensure the protection of public health.

4.Information and communications campaigns

Public awareness campaigns and communications strategies to tackle sales of counterfeit medicines, including Internet-based sales

In addition to the measures proposed to combat the entry of counterfeit medicines into the legal chain, it is essential that national competent authorities develop communications strategies and campaigns to inform patients and the general public about the risks of counterfeit medicines.

Communications should stress that it is important to engage with health services and purchase prescription medicines and over-the-counter medicines from licensed sources, rather than self-diagnosing and self-medicating outside of the healthcare system. This information should reflect the recent EU developments on quality principles on information to patients endorsed during the Pharmaceutical Forum process.

Patients and patients' organisations should be involved in such European and national initiatives to raise public and patients' awareness of counterfeit medicines. Patients' organisations have the experience to provide relevant, accurate and accessible information for the communities that they know well. For example, patients should be encouraged to know their medicines – to assess their quality and provenance, to be vigilant for signs that may indicate a counterfeit medicine, any differences in the medicine itself or its packaging, and to encourage them to go to a health professional if they have any concerns. Attention should be paid to how patients are provided with information. This must be done this with care and thought in order not to cause panic.

5.INTERNET - Quality label for health website and accessible databases which include authorized internet pharmacies across Member States

Information and communications strategies should also address **Internet,** as this is one of the most used channels of selling counterfeit medicines (according to WHO, more than 50% sales from illegal internet sites). Evidence shows that a number of illegal internet pharmacies operate internationally and sell counterfeit products of unknown origin, containing wrong substances, without any safety information. Although Internet is not in the scope of this Directive[4], information and communications measures can be taken within the existing legal framework and should reflect current moves towards a quality label for all health websites, to enable patients and citizens to discern between trustworthy websites and unlawful sites.

In those countries where on line sales of medicines are authorized patients should be provided with appropriate tools to identify legal and trustworthy websites: internet pharmacies

[4] With respect to the Internet, the Commission has stated that "addressing illegal supply chains requires a separate problem definition, with separate underlying causes, separate objectives and separate policy options".

that are legally approved should be part of a public database which is easily accessible (ex. In Germany there is a public register of legal internet pharmacies, with a specific logo).

In conclusion, the focus on the legal supply chain is not enough. EPF urges the Commission to act on the issue of Internet and strengthen the European cooperation.

6. The proposed safety measures should not lead to more expensive medicines
It is essential to ensure that the costs of the new safety measures proposed are not borne ultimately by patients and that they are spread alongside the supply chain, among industry, wholesalers' distributors and manufacturers of the active pharmaceutical ingredients.

7.Factors leading to purchase of counterfeited medicines
Although this is not in the scope of the current proposal, EPF calls for health strategies to consider what factors lead patients to buy medicines from unregulated sources, such as unlicensed online pharmacies, and address these. Factors may include cost, accessibility, convenience, stigma attached to certain conditions, such as mental and sexual health conditions, as well as lack of awareness of the dangers.

8. Public health impact at EU and global level
Finally, the effects of the proposed amendments to the Directive must be evaluated in terms of the public health impact that they have. This includes not only the number of incidence of counterfeit medical products available in Europe, but also in terms of how the measures affect the availability and access to medical products for patients not only in Europe, but around the world.

The **European Patients' Forum** (EPF) was founded in 2003 to become the collective patients' voice at EU level, manifesting the solidarity, power and unity of the EU patients' movement. EPF currently represents 40 member organisations - which are chronic disease specific patient organisations working at European level, and national coalitions of patients organizations. EPF therefore reflects the voice of an estimated 150 million patients affected by various diseases in the European Union.

EPF's vision for the future is high quality, patient-centred, equitable healthcare throughout the European Union.