IAPO's response to the EC Consultation on Counterfeit Medicines

International Alliance of Patients' Organizations
A global voice for patients

The International Alliance of Patients' Organizations' (IAPO) Response to the Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use

Key Ideas for Better Protection against the Risk of Counterfeit Medicines

About IAPO: IAPO is the only global alliance representing patients of all nationalities across all disease areas and promoting patient-centred healthcare worldwide. Our members are patients' organizations working at the local, national, regional and international levels to represent and support patients, their families and carers. IAPO has 200 members which span over 40 countries and 50 disease areas and through membership represents an estimated 365 million patients worldwide.

Introduction and Summary

The International Alliance of Patients' Organizations (IAPO) welcomes this opportunity to comment on the European Commission's document outlining key ideas for better protection of patients against the risk of counterfeit medicines. There is no doubt that counterfeit medicines pose an unacceptable threat to the health of citizens all over the world.

IAPO strongly supports many of the ideas outlined in this paper, a number of which will be mentioned specifically in this response. Our comments, which are elaborated in this response, fall into the following four main categories:

1. **Patient-Centred Healthcare** - All strategies developed to combat counterfeit medicines should be in line with the principles of patient-centred healthcare, considering the impact of those strategies on the patient in terms of access to safe, quality and appropriate treatments and information. Only with the involvement of patients and patients' organizations in these strategies, can they be truly patient-centred.
2. **Regulatory Framework** - IAPO strongly supports the development of appropriate regulations and effective enforcement regarding medicines manufacture and the medicines supply chain with appropriate consideration of their impact especially on access to quality and safe medicines.
3. **Broader anti-counterfeiting strategies -** In addition to strategies to prevent counterfeit medicines reaching patients through legal measures, it is essential that a communications strategy is developed to inform patients organizations, patients and the general public about the risks of counterfeit medicines, and what patients should be vigilant of when buying and taking

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their medicines, since presently it is not possible to guarantee that counterfeit medicines will not reach patients. Patients and patients' organizations should be involved in global, European and national initiatives to raise public and patient awareness of counterfeit medicines.

4. **Counterfeit medicines is a global issue and each country and region has a responsibility** - The issue of counterfeit medicines is a cross border problem, and while it is increasingly affecting the EU, it is also a huge problem in other regions such as Africa. We cannot be complacent and have a duty to support other regions.

Methodology used to develop this IAPO response

This response has been developed using IAPO's Policy Framework (www.patientsorganizations.org/policyframework) as a basis. Given the short timescale available, a draft response was prepared by IAPO, based on the principles outlined in IAPO's Declaration on Patient-Centred Healthcare and policy statements relevant to these issues, along with previous consultations and workshops with IAPO members as outlined below. The content of this paper has been shared with IAPO's members and the European Patients Forum and reflects their comments and has been approved by IAPO's Governing Board, made up of nominated member representatives.

- IAPO Declaration on Patient-Centred Healthcare – available online at www.patientsorganizations.org/declaration
- IAPO Policy Statement and Guidelines on Patient Involvement in Health Policy – available online at www.patientsorganizations.org/involvement
- IAPO Policy Statement and Guidelines on Health Literacy – available online at www.patientsorganizations.org/healthliteracy
- IAPO's Workshops on Counterfeit Medicines at the Global Patients Congress 2006 and 2008.

Expansion of main points:

1. **Patient-Centred Healthcare**

   A fundamental premise of patient-centred healthcare, a goal shared by our members and many of our partners worldwide, is that patients and patient groups are involved in all stages of healthcare decision-making, including setting of international policy. Patients and patients' organizations deserve to share the responsibility of healthcare policy-making and performance monitoring through meaningful and supported engagement in all levels and at all points of decision-making, to ensure that they are designed with the patient at the centre. There is a moral imperative for their involvement in initiatives to combat counterfeit medicines which have the awful potential to

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affect all and any of our lives. A key requirement for patient-centred healthcare, as outlined in IAPO's Declaration on Patient-Centred Healthcare, is that patients have access to safe, quality and appropriate healthcare services. This reflects the new EU Health Strategy 'Together for Health'.

2. Legislative Strategy and Impact Assessment

IAPO supports proposals to amend legislation and technical guidelines, and develop policy options. Whilst it is difficult to comment specifically on the areas the Commission is considering as outlined in section 4 without having further details, IAPO would like to make the following points:

- Patients have a right to access safe, quality and appropriate services, treatments, preventive care and health promotion services. To this end, the legal proposal must ensure that all medicines, wherever they are developed or produced, must pass through a stringent regulatory framework that guarantees:
  - The quality of the manufacturing process
  - The security of the supply chain, and
  - High quality information is provided to patients, e.g. information to help patients take their medicines correctly and hence safely and to help patients identify counterfeit medicines (this issue is further examined in point 3 below).

Note however, that measures to assure the quality of the manufacturing process and security of the supply chain should also be considered in light of how they affect the cost of medicines and level of access of the medicines to patients. All measures should be 'fit for purpose', and not result in access barriers or additional costs to the end users.

- In particular relating to item 4, IAPO would support developments to improve integrity and traceability, increase transparency and increase the effectiveness of enforcement mechanisms.
- The regulatory requirements and their mechanisms for enactment must be those that are necessary and sufficient to ensure that only high quality medicines reach patients. Inspections and demonstration of adherence must be conducted to assure that the regulations are being met but these should be responsible and reasonable; they must not impose unnecessarily burdensome requirements on lawful manufacturers and distributers of medicine so as to unnecessarily impede patient access. To these ends, impact assessments must be undertaken on a regular basis to ensure sufficient supply and reasonable costs to meet patient needs.
- In relation to item 4.3, IAPO supports the objective to develop regulatory frameworks for manufacture, active substances and inspections. It is important that these developments

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should recognise emerging trends in medicine, for example, the increasing prevalence of biological medicines, and be tailored to meet the specific characteristics and sensitivities of each type of medicines' manufacture and distribution process.

- There should be coherence between legislative proposals on counterfeiting, and the Commission's current proposals regarding pharmacovigilance and a broader patient safety framework, with the common overriding aim of enhancing the safety of all patients.

3. **Broader anti-counterfeiting strategies**

   a. **Raising patient and public awareness**

   The consultation document is focussed on preventing the counterfeiting of medicinal products in the EU which is entirely appropriate. However, since the elimination of counterfeit medicines in the EU cannot be achieved overnight we need to take a broader multi-faceted approach with multiple courses of action to protect patients from harm. Therefore, in addition to developing and strengthening the regulatory environment, IAPO would stress that it is essential to develop a communications strategy to inform patients and the general public to raise awareness about counterfeit medicines. This information should reflect recent developments at EU level with regard to quality criteria on information to patients.

Those at the point of medicines delivery, patients themselves and health professionals, can play a valuable role in detecting and reporting counterfeit medicines, and protecting the public. Patients' organizations have the experience to provide relevant, accurate and accessible information for the communities that they know well. In collaboration with other stakeholders in health, information must be provided to encourage patients to know their medicines – to assess their quality and provenance - and 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 their pharmacist, nurse or doctor if they have any concerns. We need to do this with care and thought in order not to cause panic which could result in patients stopping taking their medicines and thereby causing more harm, which we have seen can be a negative result of health scares. For example, the increased risk of measles prevalence as a result of the reduction in uptake of the MMR vaccine in the UK due to adverse publicity.[1]

As many patients take more personal responsibility for their health which is in itself positive, communications must be clear that informed decision-making on health issues is the safest and most effective in partnership with health professionals. Communications should stress that it is important to engage with the health service and purchase prescription and over-the-counter

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medicines from licensed sources, rather than self-diagnosing and self-medicating outside of the healthcare system. In particular, proposed anti-counterfeiting legislation and policy should reflect current moves towards a quality label for all health websites to enable patients and citizens to discern between bona fide reputable sites providing health information that meet certain quality criteria, and unlawful, bogus sites that may also be vehicles for the marketing and distribution of counterfeit medicines.

Health strategies must 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.

4. **Global issue and responsibility -** IAPO considers that a global multi-stakeholder approach is essential if there is to be any significant progress in reducing the proliferation of counterfeit medicines around the world. A global approach is vital because counterfeit medicines have a global reach and no one country or region can be complacent that its population is protected from them. Also, we have a global responsibility to prevent counterfeit medicines harming patients in the poorest and least protected regions, where patients may have a lower awareness of the risks or may have less opportunity to purchase medicines from a licensed source, for example because they can only afford to buy medicines from unlicensed market traders. A particular commitment is needed to empower all patients with information, choice and solutions.

   IAPO would like to share with the European Commission two initiatives to educate and empower patients and health professionals globally on counterfeit medicines. The first is a Toolkit on Patient Safety that IAPO is finalizing and which provides information and tools to patients' organizations on patient safety issues including counterfeit medicines, which will be published in mid 2008. The second is the World Health Professions Alliance Toolkit on Counterfeit Medicines which includes an information leaflet for patients, which has been reviewed and endorsed by the International Alliance of Patients' Organizations.
   (http://www.whpa.org/Toolkit_BeAware_Patients.pdf)

   IAPO considers that the European Commission's role supporting and collaborating with World Health Organization's International Medical Products Anti-Counterfeiting Task Force (IMPACT) and in funding the development of the World Health Organization's IMPACT 'Principles and Elements for National Legislation against Counterfeit Medical Products', is to be commended and we would

[1] http://adc.bmj.com/cgi/content/full/91/6/465#R3

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urge the European Commission and the World Health Organization to maintain close collaboration and exchange.

Conclusions

As the European Commission has highlighted, counterfeit medicines have become an increasing threat to public health over the past few years and it is therefore vital that strategies to combat counterfeit medicines are given appropriate attention, political commitment and resources to ensure they are developed and implemented as soon as this can be done effectively. While even one patient being harmed by a counterfeit medicine is unacceptable, unless we take effective action now, the scale of the problem and harm caused is continuing to increase and will only get worse.

IAPO considers that a European approach to combat counterfeit medicines should aim to ensure a strong regulatory environment that is well enforced and that each decision should be judged against its likely impact on patients' timely access to safe, quality treatments and be patient-centred. Communicating with patients and patients' organizations to raise awareness of the dangers of counterfeit medicines and how patients can be vigilant regarding their medicines is an essential complementary strategy to regulation. Lack of awareness of the dangers of buying medicines from unregulated sources and other factors which put patients at risk of counterfeit medicines must also be considered.

Support

The European Patients' Forum (EPF) has provided input and supports this response.

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