WHPA Prague Call to Action
21st November 2011

1. Invited by the World Health Professions Alliance (WHPA), representing International Council of Nurses (ICN), the International Pharmaceutical Federation (FIP), the World Confederation for Physical Therapy (WCPT), the World Dental Federation (FDI) and the World Medical Association (WMA), **We**, leaders and student associations on behalf of nurses, pharmacists, physical therapists, dentists and physicians came together on the 21st November 2011 to express our determination to address the real and alarming public health threat of falsified medical products[1] within Central and South Eastern European countries [2].

2. **We** recognize that the infiltration and sale of falsified medicines in the legitimate supply chain has the potential to cause disease, disability and death to patients and healthy individuals around the world. Failure to adequately act to prevent this would be a fundamental breach of the trust patients place in public health structures both at European and international levels.

3. **We** note the adoption of Directive 2011/62/EU[3] of the European Parliament and of the Council on the 8th June 2011 to improve the protection of public health with new harmonized, pan-European measures to ensure that medicines are safe and that the trade in medicines is rigorously controlled by 2nd January 2013.

4. **We** are extremely concerned about the current absence of harmonized international legislation, non-deterrent sanctions on falsification of medical products that were not proportionate to the harm caused to patients. Such international law has to both prohibit intentionally falsified products and promote good quality products, without inadvertently criminalizing those good quality products or punishing manufacturers for accidental oversights of quality. In this regard, we applaud the intention of the Council of Europe for putting forth the MEDICRIME Convention as a first step in that direction.

5. **We** recognize that new technologies can offer significant protection against breaches in the legitimate supply chain. However, this also demands greater clarity on how best to use these features to provide robust protection. To that extent, we note the joint position paper of the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Pharmaceutical Group of the European Union (PGEU), the European Association of Full-line Wholesalers (GIRP) that highlighted ten core principles to protect patients from falsified medicines.

6. Therefore, **We** strongly affirm our obligations to governments and the international community to utilize healthcare professionals uniquely position to accelerate our fight to increase the awareness of this problem and implement definitive strategies towards curbing it through the following interventions:

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[1] Any medicinal product with a false representation of:
(a) Its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
(b) Its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
(c) Its history, including the records and documents relating to the distribution channels used.
This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.

[2] Croatia, Czech Republic, Hungary, Poland, Romania and Slovenia

[3] http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

7. **To increase capacity of our healthcare professionals to educate the public**

    a. Acknowledging that many patients and healthy individuals seek advice on use of medical products from nurses, pharmacists, physical therapists, dentists or physicians.

    b. We undertake to:
        i. Raise awareness of the threat of falsified medical products amongst health professionals and patients.

        ii. Recommend the inclusion of issues related to the public health impact of falsified medical products in undergraduate healthcare professional curriculum and pre-service training. This could be part of training on ethics, patient safety and relevant legislation, where appropriate.

        iii. Support provision of continuing education programmes to healthcare professionals and community based health workers on the detection and reporting of falsified medical products

8. **To foster regional cooperation initiatives**

    a. Acknowledging the need to be cognizant of the current situation in which falsified medical products continue to move in international commerce including through the Internet, representing a major threat to public health.

    b. We undertake to:

        i. Work towards establishing national and regional alliances of healthcare professional associations including patient/consumer groups and other relevant partners to promote interdisciplinary coordination for better information exchange and sharing of best practices, where appropriate

        ii. Work together with regional entities such as the WHO regional office for Europe, the Pharmaceutical Group of the European Union (PGEU), the Directorate General for Health and Consumers of the European Commission (EC), the European Directorate for the Quality of Medicines & Healthcare (EDQM) of the Council of Europe, the European Federation of Pharmaceutical Industries and Associations (EFPIA), the EUROPharm Forum and the European Federation of nursing and midwifery associations (EFNMA) and European Federation of Nurses (EFN)

9. **To strengthen collaborative practice when managing patients**

    a. Acknowledging the need to understand and acknowledge the fact that escalating complexity of care demands a interdisciplinary approach. Healthcare professionals must be vigilant and work together when managing unusual, unexpected or adverse responses to medical treatment.

    b. We undertake to:

i. Work together across various disciplines to raise awareness of and actions against falsified medical products amongst patients, the general public, their colleagues and government leaders including health authorities.

ii. Encourage our members to take an active role in identifying, reporting and eliminating falsified medical products from the legitimate supply/distribution chain.

10. To improve collaboration with health and enforcement authorities plus other key stakeholders

a. Acknowledging that any effective solution must drive immediate change, be effective in the long term and receive the support and active engagement and collaboration of all stakeholders managing the medicines supply chain, especially with patient and consumer organisations.

b. We undertake to:
   i. Fully support the implementation of the EU Directive on falsified medicines to introduce mandatory, harmonised pan-European safety features for medicines at risk of falsification.
   ii. Encourage communication with student organisations to be involved in raising awareness and informing society about the harmful effects of falsified medical products.

   iii. Support working together with relevant stakeholders in establishing an efficient, viable and effective medicines verification system at point of dispensing to protect patients against the threat of falsified medicines in the EU that builds on existing, if any, coding or unique serialization systems in the various countries and meeting the needs of patients and all stakeholders in the pharmaceutical supply chain.

   iv. Support our national drug regulatory authorities to reinforce national reporting systems to enable healthcare professionals and patients to easily report and obtain feedback about inter alia, adverse events due to potentially falsified medical products.

The Participants of this WHPA regional workshop agree unanimously on the WHPA PRAGUE "CALL TO ACTION" and plan in cooperation to support it.