



## **Position Paper**

### **Counterfeit drugs put patients' health at risk**

#### **Summary**

- Counterfeit drugs have become a serious global problem in recent years.
- Counterfeit drugs can endanger the health – or even the lives – of unsuspecting patients.
- Only informed patients can avoid the risks associated with counterfeit drugs and obtain the best possible treatment for their illnesses.
- Apart from consistently providing patients with information, only stricter laws, systematic prosecution and punishment of the counterfeiters and close co-operation between all affected groups and across geographic boundaries will help against counterfeit medicines.

#### **Issue**

The World Health Organization (WHO) defines counterfeit drugs as “a medicine, which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging”. The World Health Organization estimates that approximately 10% of drugs sold in developing countries are counterfeits. In some countries in Africa this number is clearly exceeded. Even in industrialized countries with a strong regulatory structure, like the USA and Europe, up to 1% of all medicinal products sold are counterfeits.

What makes the business with counterfeits so attractive to internationally operating criminals are the profits that are higher than those in drug trafficking – but with a much lower risk of detection and punishment. The US-based “Center for Medicines in the Public Interest” estimates that the trade in counterfeit drugs will have a turnover of up to 75 billion dollars this year.

In order to seriously engage in the fight against counterfeit drugs, two components are crucial: it is important that patients are informed and made aware of the considerable dangers of buying medicines through non-accredited procurement channels, such as the Internet. On the other hand, the criminal counterfeiting networks need to be internationally exposed and those who profit from the illegal trade severely and effectively punished.

#### **Background**

While people take drugs to treat their diseases and to regain their health, it is obvious that a drug counterfeiter is not concerned with providing patients with suitable, high-quality medicine to achieve the patients aim. The dangers with counterfeit drugs are obvious since, by their very nature, they harm patients as a result of the impurities or insufficient therapeutic ingredients that they can contain. Counterfeit medicines are regularly of a lower quality, for example as a result of incorrect manufacturing processes or storage. Not without reason does the legislation provide for a complex process for the clinical testing, authorization and post-marketing surveillance of medicinal products.



Counterfeiters target those products with which they are likely to reap the greatest rewards. This applies equally to patent-protected medicines and to generics. Especially lucrative for shady dealers are expensive prescription-only medicines for the treatment of AIDS and cancer, for example. Antibiotics are the most affected globally, whilst so-called “lifestyle medicines” such as drugs for the treatment of erectile dysfunction increasingly appear high on the list.

## **Our position**

Bayer HealthCare does not promote or endorse the use of counterfeit products and will not accept responsibility for counterfeit drugs that are illegally produced / purchased. Bayer HealthCare as such cautions the public against purchasing prescription-only medicines from dubious and illegal sources where safety, efficacy and quality of the product cannot be assured. Prescription drugs should only be obtained through secure and accredited channels, following a full medical examination.

We believe that only informed patients can avoid the risks of counterfeit drugs and obtain the best possible treatment for their illnesses. Bayer HealthCare, therefore, places high priority on the health and welfare of patients and seeks to protect its patients against misuse and counterfeit drug products. To raise public awareness of the subject, BHC is putting greater effort into education and has started the “Beware of Counterfeits” campaign. The company is already making a contribution to combating the problem through technical product security measures, the use of internal and external investigators and legal prosecution.

Beyond raising awareness, Bayer has integrated a number of safety measures into its production processes and in the product design / packaging of its products.

Bayer is legally committed to observing proper distribution channels and complies with the stipulations governed by the relevant legislation in regard to the distribution of drug products.

We believe that stricter laws, systematic prosecution and punishment of counterfeiters in close co-operation between all affected groups - starting with pharmaceutical manufacturers, including doctors and pharmacists and the authorities, as well as patients and consumers at national, European and international level – are needed to address the issue of counterfeits. This is why Bayer HealthCare is working globally with the authorities and is also actively supporting the anti-counterfeiting activities of the World Health Organization in the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) and of the European Federation of Pharmaceutical Industries and Associations (EFPIA). Bayer HealthCare is also a member of the Pharmaceutical Security Institute, the German product and trade mark piracy action group, and many other national action groups devoted to combating counterfeit medicines.