

# Counterfeit Medicines: An Ethical Approach

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## INTRODUCTION

**Bioethics:** biology combined with diverse humanistic knowledge forging a science that sets a system of medical and environmental priorities for acceptable survival (Potter, 1970)

**Counterfeit Medicines:** deliberately and fraudulently mislabelled drugs with respect to identity and/or source. May include products with the correct or wrong ingredients, without active ingredients, with insufficient or inadequate quantities of active ingredient or with fake packaging (WHO)

The WHO states that medicines obtained from illegal Internet sites that obscure their physical address are counterfeit in more than 50% of cases. The Falsified Medicines Directive (FMD) addresses this issue and has designed a logo that all certified online pharmacies must display in order to sell medicines at distance as a legal and reliable source for the consumer.

**Anti-Counterfeit INTERPOL'S Action:** Operation Pangea VIII (June 2015)

- Fake and illicit medicines seized: 20.7 million worth USD 81 million

- Most popular: Cancer Medication, Erectile Dysfunction, Nutritional Supplements, Blood Pressure

## OBJECTIVES

1. Highlight the necessity of bioethics in the pharmaceutical industry in addition to the regulations and codes of conduct
2. Study the current bioethical situation of the online drug market
3. Summarise the efforts made by the regulatory authorities to ensure the safety of medicines
4. State goals and challenges for the pharmaceutical industry to ensure an ethical behaviour and avoid the appearance of counterfeit drugs.

## METHODS

Bibliographic search on Google and PubMed of information relating bioethics and counterfeiting in the pharmaceutical industry related to the online market. Key words used: bioethics, counterfeit medicines, regulations, code of conduct, Internet

Bioethics Principles	Autonomy	Beneficence	Non Maleficence	Justice
Regulatory Authorities	Declaration of Helsinki Belmont Report FMD	ICH GxP FMD	ICH GxP FMD	ICH GxP FMD
Pharmaceutical Industry	Anti-counterfeit goals: Promotion of access to safe and efficacious medicines, advocating robust patient education and awareness about counterfeiting, and combating unsafe medicines  Challenges: Globalisation, Internet, bribery, drug costs, supply in poor countries			
Internet	Health Internet e-patient HONcode medCERTAIN medCIRCLE	?	?	?

FMD: Falsified Medicine Directive (Directive 2011/62/EU); ICH: International Conference on Harmonisation (ICH); GxP: Good Practices Guidelines; HONCode: Health On the Net Code; ?: no activity found in this research directed towards protecting this ethical principle

## CONCLUSIONS

1. Counterfeit medicines are a worldwide problem can only be solved by the collaboration of different parties: police, customs, government, pharmaceutical industry, regulatory authorities and healthcare professionals and patients.
2. Regulations enforced help to protect all bioethics basic principles; but they do not fully avoid the appearance of counterfeits
3. The Internet lacks an ethical code that protects the four basic bioethical principles.
4. Most of the measures taken to tackle this issue are focused on actions that protect the principle of autonomy, so the consumer can be aware of the situation and make informed decisions.
5. It is necessary that international regulatory authorities promote an ethical behaviour online to protect the principles of beneficence, non maleficence and justice so counterfeit medicines do not reach the online market, instead of solely warning the consumers to prevent the sale.

### References:

1. Beauchamp, TL., Childress, JF. 2001. Principles of Biomedical Ethics. 5th ed. New York: Oxford University Press.
2. Boyer, C., Selby, M., Scherrer, MS., Appel, RD. 1998. Computers in Biology and Medicine 28; 603-10.
3. Boyer, C., Baujard, V., Geissbuhler, A. 2011. Evolution of health web certification through the HONcode experience. Stud Health Technol Inform;169:53-7.
4. Mackey et al. 2014. A call for a moratorium on the .health generic top-level domain: preventing the commercialization and exclusive control of online health information. Globalization and Health, 10:62.
5. Norman C Morrow. Pharmaceutical policy Part 1 The challenge to pharmacists to engage in policy development. Journal of Pharmaceutical Policy and Practice. 6. Potter, VR. 1971. Bioethics: Bridge to the Future. Englewood Cliffs, N.J.: Prentice-Hall.
7. Rippen, H., Risk, A. 2000. e-Health Ethics Initiative, authors. e-Health Ethics Draft Code. J Med Internet Res;2(1):e2