Counterfeit Medicines

The view from the EMEA

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Introduction

- Counterfeit Medicines are not a “victimless crime” – They endanger lives
- Problem of public perception
- Corrective action required
- Discussion needs to be based on facts and figures

Whose Problem is it?

- EMEA has no formal responsibility to combat counterfeiting in the EU
- Formal pharmaceutical legislation is silent on counterfeits
- EU: investigation of allegations of counterfeit medicines and legal action -> MS as part of supervision of manufacture and distribution
- The MAH
- Health care professionals
- Patients

The Problem (1)

- Counterfeit Medicines are a danger to public health -> ADRs,
- They are a threat to IP and thus to the competitiveness of European pharmaceutical industry
- The problem is not local but global

The Problem (2)

- Majority of counterfeit products not associated with tightly controlled legitimate supply chain but involve direct sales routes (mail order, Internet) or illegitimate or criminal routes – but there are also cases affecting the legitimate supply chain

Legal Provisions in the NML (1)

- Directives 2004/27/EC and 2004/28 EC increase control over the activities of
  -Active pharmaceutical ingredient manufacturers
  -Pharmaceutical manufacturers
  -Brokers
  -Distributors
  -Re-packagers
- Starting materials must be manufactured in line with GMP guidance

Legal Provisions in the NML (2)

- Supervisory Agencies may now carry out inspections of manufacturers of starting materials and to take samples for independent testing
- Inspections may be unannounced, triggered by suspected non-compliance with GMP guidance, or request for conformity certificate,
- Inspections may be requested by the Agency, the European Commission or the MAH

Legal Provisions in the NML (3)

- Supervisory authorities have also been granted powers to inspect the premises, records and documents of marketing authorisation holders.
- Community database to record information on manufacturing authorisations, and the outcome of inspections

EMEA Thoughts on Elements of a Solution (1)

- Responsibility is national, Problem is global ->
  issues of liaison, coordination and information sharing are key to its control

EMEA Thoughts on Elements of a Solution (2)

- The current system for supply and distribution of legitimate medicinal products is undermined by ineffective controls of illegal products.
  -> **Better information sharing and coordination between member states is an important step to help combat this crime.**

EMEA Thoughts on Elements of a Solution (3)

- Large range of organisation working on combating counterfeits
  -> **EMEA would support rationalisation and streamlining of efforts.**

EMEA Contributions towards a Solution (1)

- EMEA supports work of EMEO (European Medicines Enforcement Officers), and has offered to host meetings of EMEO and sends an observer to all meetings

- EMEA collaborates with WHO.

EMEA Contributions towards a Solution (2)

- MRAs and FDA confidentiality arrangements means that information sharing can be extended beyond EU member states

EMEA Contributions towards a Solution (3)

- EMEA chairs quarterly meetings on Inspection related matters and provides opportunity for feedback from EMEO and European liaison on enforcement related issues and suspected counterfeits

EMEA Contributions towards a Solution (4)

- EMEA's Roadmap mentions the role of the Official medicines Control laboratories in analysing potential counterfeits, EMEA is collaborating with Official control laboratories on a possible pilot phase to sample market and test for medicinal products that are known to be counterfeit targets

EMEA Contributions towards a Solution (5)

- Reporting form for rapid alerts has recently been adapted to ensure that information on suspected counterfeits can be communicated rapidly between member states and coordinated action taken
- EMEA is looking at an adaptation of the EU GMP guide to reinforce the role of national GMP inspectors in dealing with counterfeits

EMEA Contributions towards a Solution (6)

- EMEA will support the Commission in information gathering and developing concrete proposals. In addition to information sharing between European and other authorities, EMEA consider that other legislative activities to strengthen distribution controls and to facilitate tracking of medicines (markers etc.) may need to be considered in the future.

EMEA Contributions towards a Solution (7)

- Make use of / modify new EU databases EudraGMP / EudraVigilance/ EudraVigilance Medicinal Product Dictionary / EuroPharm to include information on counterfeit products

Conclusions

- Counterfeit medicinal products are a risk to public health and to the IP of pharmaceutical industry
- Action is needed involving all stakeholders and across national boundaries
- Solutions need to be technically mature, proportionate to the threat and affordable