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Fighting Counterfeits and Diversion : Approaches to Fighting Counterfeits in EU Pharma Package, US and WHO Proposals

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Facts and Trends

- Product Types
  - Most likely to be counterfeited are generally high value, high turnover, high demand
  - Though there has been some evolution, e.g., for medicines, the trend is moving from lifestyle to high value lifesaving drugs
- Origins
  - China, India and the UAE are major sources of counterfeit medicinal products
- Methods
  - Counterfeiters often employ complex supply chains and transhipments to “legitimise” and facilitate imports into the EU and UK
  - EU countries are usually end user markets or transit points
- Identity
  - Counterfeiters are becoming organised criminal enterprises connected with sophisticated distribution, supply and money laundering operations

Risks from Sales of Counterfeits

- All types of products:
  - Review or withdrawal could lead to severe financial losses and damage to the brand
  - Product liability claims that cannot be attributed to the counterfeits
- Medicinal products (as well as the above):
  - Adverse events that cannot be attributed to the counterfeits
  - If there are sufficient adverse events, regulatory authorities will review the safety profile or order withdrawal
  - Risk profile may depend on the nature of the product

Methods to Attack Counterfeits

- Lobbying governments to address counterfeiting in trade negotiations and World Trade Organisation challenges
- Co-operating with governments, regulatory and customs authorities, law enforcement and industry bodies
- Criminal prosecution
- Civil litigation
- Tagging and tracking solutions for legitimate goods
- Monitoring trade shows, distribution channels and the internet
- Training and incentives for employees, distributors and agents to recognise and report counterfeits (including contractual incentives and obligations)
- Public education
- Enforcing product standards

Difficulties of Civil Actions

- Identifying counterfeit products, tracking and arranging for seizure
- Determining where to tackle the problem - i.e. at source, during shipment, at destination
- Problems of proving infringement - e.g. where do the rights exist
- Determining which potential defendants to sue (or aid authorities bringing criminal prosecution) - e.g. against the manufacturers, importers, distributors, retailers
- Sales over the Internet
- Costs of bringing civil proceedings, including posting bonds
- Delay in concluding court proceedings
- Identifying assets and recovering damages

EU: Aids to Investigation and Enforcement

- Germany: Right of inspection Civil Code (patents and copyright); independent proceedings for taking evidence under the Civil Procedure Code; may use information obtained in proceedings in other countries
- France: Saisie-contrefaçon can be conducted at any time in French patent infringement claims
- Belgium: Saisie in relation to infringement claims of any European patent
- Italy: Descrizione is similar to the saisie, but patentee must show infringement
- UK: Obtaining evidence, assets
  - Pre-action disclosure (including obtaining evidence of infringement)
  - Search and seizure orders
  - Freezing orders
  - Disclosure orders – i.e. the identity of infringers (Norwich Pharmacal)

Solutions

- Civil Actions
  - Identifying and tracing assets on which to enforce
  - Proceedings for infringement of IPRs and/or joint tortfeasorship (common design, procuring)
- Customs Seizure
- Criminal Prosecution
  - Including for infringement, conspiracy and aiding and abetting
- Assets Recovery
- Regulatory
  - MHRA (Enforcement and Intelligence Group & Medical Devices Compliance Unit)

Overall Strategy

- To effectively fight against counterfeiters it is advisable to have a strategy that uses or takes advantage of:
  - Government resources and administrative actions
  - Criminal prosecutions
  - Civil actions and remedies
  - Private investigatory agencies
  - All other resources available including distributors, employees and members of the public
- The strategy needs to be flexible: The right procedure to catch the particular type of infringer

Relevant EU Laws

- EU Legislation
  - Medicinal products directive:
    - 2001/83/EC on the Community code relating to medicinal products for human use
  - Customs Regulation (EC) 1383/2003
    - EU Customs Authorities may seize goods that they suspect infringe patents, trade marks, copyrights and designs
    - IPR's holders can ask Customs to seize infringing goods
  - Customs Code Regulation (EC) 648/2005
  - Directive (EC) 48/2004 on the enforcement of IPR's
  - Unfair Commercial Practices Directive 2005/29/EC

IP Enforcement Directive – (EC) 48/2004

- Designed to harmonise the standards of enforcement of IPR's across the EU
- Contains provisions on evidence, rights of information, precautionary measures, corrective measures, damages and legal costs
- Implementation across the EU was due by 29 April 2006, but progress was slow: e.g. Germany did not implement the Directive until June 2008.

Recent Developments
The EU Pharma Package
A. Objective of Proposal

- Adopted by the European Commission on 10 December 2008 contains new provisions to combat the counterfeiting of medicinal products
- Primary objective: elimination of the risk of counterfeit medicines entering the legal supply chain
- Definition of counterfeit (or "falsified") medicinal products:

  "*medicinal products that contain sub-standard or counterfeit ingredients, or no ingredients or ingredients in the wrong dosage, including active ingredients*"
- Focus is on the legal supply chain: other measures are needed and are being undertaken to deal with illegal supply chains

B. Obligatory Product Safety Features

- Proposal would provide legal basis for the Commission to render obligatory specific safety features (e.g. serialisation number, seal)
  - These are features designed to ensure the identification, authentication and traceability of prescription medicinal products
  - Prohibition in principle of manipulation of safety features in between the original manufacturer and the last actor or end user
  - Commission may authorize the removal of obligatory safety features only under very strict conditions

C. Coverage of Entire Supply Chain

- Proposal would impose obligations on all operators in the legal distribution chain, including:
  - Traders that are not wholesale distributors and are typically involved in transactions without actually handling the products (e.g. by auctioning or brokering products)
  - Wholesale distributors that export medicinal products without placing them on the EU market
  - Any operator (esp. parallel traders) that repackages products

D. Obligatory Audits and Strengthened Rules for Inspections

- Wholesale distributors
  - Obliged to verify that their suppliers comply with good distribution practices
  - Must verify that the supplier holds a manufacturing authorization if supplier is the manufacturer or importer
- Inspections
  - Commission empowered to adopt detailed guidelines to harmonise inspections for holders of manufacturing and wholesale authorizations
  - Increased transparency of inspection results:

    Publication of list of wholesale distributors whose compliance established by Member State inspection

E. Impact

- Increased costs
  - Expected to fall mainly on manufacturers and importers
  - Lesser burdens for wholesale distributors and manufacturers of APIs
    - Here, the bulk of the costs are expected to fall on third country manufacturers
    - Impact on the sourcing of APIs from countries such as China and India
- Obligatory safety features/tampering ban will have a significant impact on parallel trade despite some possibility for repackaging
- Further measures are needed for counterfeits entering the market through illegal channels. Commission intends to:
  - Propose intensified exchange of information at both EU and international levels by the year 2012
  - Assist third countries in developing and enforcing legislation against counterfeits

Recent US Developments – PRO-IP Act

- Passage of Prioritizing Resources and Organisation for Intellectual Property Act of 2008 ("PRO-IP")
  - Strengthens civil IP laws
  - Increases damages for remedies
  - Increases criminal penalties for repeat offenders
  - Creates a new executive office branch – United States Intellectual Property Enforcement Representative ("USIPER")
- FDA Counterfeit Drug Task Force now works with other US agencies such as the Departmental Homeland Security (Customs and Border Protection), Department of Justice, and also the WHO's IMPACT

Recent WHO Developments

- WHO has addressed the issue of anti-counterfeiting with the creation of the International Medicinal Anti-Counterfeiting Taskforce ("IMPACT"). In 2007 IMPACT adopted a list of essential measures that national legislation against anti-counterfeiting should contain
- The list contains:
  - Responsibilities and obligations on the manufacturers, distributors, retailers, and other operators
  - Suggested definitions for illegal acts
  - Sanctions
- The list also focuses on intellectual property law, regulation of drug and medical devices, and criminal law

Anti-Counterfeiting Trade Agreement (ACTA)

- Proposed trade agreement aimed at providing an international framework that "improves the enforcement of intellectual property rights laws" beyond TRIPS
- Negotiations began in October 2007 among the following countries and community
  - Japan, US, EU and Switzerland
- As at November 2008, the following countries have joined the negotiations: Australia, Canada, Korea, Mexico, Morocco, New Zealand, and Singapore
- Three main components of ACTA
  - International Cooperation
  - Enforcement practices
  - Legal framework
- As at May 2009, negotiations are continuing

CONCLUDING REMARKS

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