

Wirtschaftsinformatik



Universität Münster
 Institut für Wirtschaftsinformatik
 Lehrstuhl für Wirtschaftsinformatik
 und Interorganisationsysteme
 Prof. Dr. Stefan Klein
 www.wi-ios.de
 mail@wi-ios.de

Pharmaceutical Supply Chain - Tracking & Tracing-

Research, applications, systems



Agenda


A. Empirical evidence of counterfeiting
B. Solutions for Tracking&Tracing
C. Current Research and ioBPR
D. Discussion



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Agenda

A. Empirical evidence of counterfeiting
1. What is drug counterfeiting?
2. Impact of counterfeited pharmaceuticals
3. Initiatives targeting counterfeiting
B. Solutions for Tracking&Tracing
C. Current Research and ioBPR
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What is drug counterfeiting?

1. Empirical evidence
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- During a meningitis epidemic in Niger in 1995, more than 50 000 people were inoculated with fake vaccines resulting in 2 500 deaths. The vaccines were received as a gift from a country which thought they were safe.
- 89 children died in Haiti in 1995 and 30 infants died in India in 1998 due to the consumption of paracetamol cough syrup prepared with diethylene glycol (a toxic chemical used in antifreeze).
- In 2001, in South-East Asia, a Wellcome Trust study revealed that 38% of 104 anti-malarial drugs on sale in pharmacies did not contain any active ingredients.
- In Cambodia, in 1999, at least 30 people died after taking counterfeit anti-malarials prepared with sulphadoxine-pyrimethamine (an older, less effective anti-malarial) which were sold as artesunate.

Source: <http://www.who.int/mediacentre/factsheets/fs275/en/>



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What is drug counterfeiting?

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Global Trade in Counterfeit Drugs
Fake and Substandard drugs cause treatment failure and waste money

Percentage breakdown of data on 325 of 771 cases of substandard drugs - including antibiotics, antimicrobials and anti-tuberculosis drugs - reported from around the world to WHO database

Source: http://www.gphf.org/web_en/projekte/minilab/hintergrund_arzneimittelfaelschungen_chart.htm

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What is drug counterfeiting?

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- Prominent example: Pfizer
 - Counterfeited medicines of Pfizer (amongst others):
 - Lipitor (Most sold drug in US; accounting for \$7,7bn in 2004)
 - Zolofit (6th often sold drug in US; accounting for \$3,1bn in 2004)
 - Viagra
 - And many more

Can You Tell The Difference?

Visually, the only distinction between these Lipitor tablets is that the counterfeit (far left) are slightly thicker than the authentic medicine.

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What is drug counterfeiting?

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- Pfizer: Global manufacturer with global counterfeiting threats

A Global Problem

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What is drug counterfeiting?

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- Estimation 15% of all sold drugs are fake
 - 1% in developed countries (mainly life-style drugs in Europe like Viagra)
 - Up to 50%+ in Africa and Asia (e.g. in Africa often vital medicine like AIDS related drugs)
- In 2001 80% of all medicines sold to Lagos pharmacies were faked
- FDA estimates that fake drugs comprise appr. 10% of global medicine market
- Prediction of US Centre for Medicines that counterfeit drug sales will reach US\$ 75 billion globally in 2010

Source: <http://medicine.plosjournals.org/p/eriserv/?request=slideshow&type=figure&doi=10.1371/journal.pme.d.0020100&id=25724>

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Folie 6

a3 Nochmal genau klären, was gemeint
alki; 23.05.2007

Folie 7

a4 Nochmal genau klären, was gemeint
alki; 23.05.2007

Folie 8


a2 Nochmal genau klären, was gemeint
alki; 23.05.2007

Impact of counterfeited pharmaceuticals

1. Empirical evidence
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- Customer/Patients:
 - Risk to health
 - Wasted money
- Administration:
 - Threat to population
 - Loss of tax revenue (VAT, customs duties)
- Manufacturer:
 - Brand/reputation damage
 - Loss of sales
- Information problem:
 - No clear figures available.
 - Manufacturers do not publish clear figures as this might have a negative effect on them.

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Initiatives targeting counterfeiting

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- Significance of the counterfeiting problem for companies in the supply chain

	Pharmacies	Wholesaler	Manufacturers
Critical – requires immediate top-level decisions	16,7%	21,7%	19,2%
Important – requires significant top-level attention	5,6%	13%	23,3%
Manageable – requires executing existing policies	18,5%	15,9%	28,8%
Trivial – does not require attention at the moment	59,3%	49,3%	28,8%

Source: Jarvis, Lisa (2005)



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Initiatives targeting counterfeiting

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- Political and governmental initiatives
 - IMPACT (WHO)
 - G8 Summit
 - FDA (e.g. white paper on RFID)
 - EMA (European Medicines Agency)
 - Italian health authority
 - ITAIDE
 - ...
- Pharmaceutical manufacturers
 - EFPIA (European Federation of Pharmaceutical Industries and Associations)
 - All large manufacturers face these problems



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Initiatives targeting counterfeiting

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- "As the originator of the product, the manufacturer has an obvious role to play in product authentication and supply chain control efforts with new technologies, track and trace initiatives, procedures for counterfeit prevention,"* Thomas Zimmer, chair of EFPIA's anti-counterfeiting working group.
- Pharmaceutical manufacturer tighten the supply chain:
 - Contractual tightening
 - Electronic pedigree
 - Certification



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Was genau meinst Du damit?

alki; 23.05.2007

Agenda Part B

A. Empirical evidence of counterfeiting
B. Solutions for Tracking&Tracing
1. Idea of Tracking&Tracing systems
2. Technologies supporting T&T
C. Current Research and ioBPR
D. Discussion



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1. Empirical evidence
2. Solutions for T&T
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Idea of Tracking&Tracing systems

- “track down”: where does the product go to? Who is involved?
- “trace up”: who has sold this product? Who delivered it? Who manufactured it?

- Idea: A system that is able to answer the questions above can discover weaknesses in a supply chain and detect where corrupted products enter the chain.
 - Possible systems have to address several issues:
 - What information is delivered?
 - Who gets access to information?
 - Where is information stored?
 - Can this information be corrupted/faked?
 - What indicates that a product is uncorrupted?(package, ingredients, information)



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1. Empirical evidence
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Technologies supporting T&T

- Some examples
 - Unfakeable packages (printing technique, holograms, Protexxion)
 - Genetic codes
 - Barcodes
 - RFID
 - Tests

- each technology fulfils different needs and incorporates different cost/benefit structures
- each stakeholder has different requirements and intentions
- therefore research project to identify requirements, technical possibilities and to determine critical success factors




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Agenda Part C

A. Empirical evidence of counterfeiting
B. Solutions for Tracking&Tracing
C. Current Research and ioBPR
1. Research Question
2. Levels of change (BPR, ioBPR, BNR)
3. Research approach
D. Discussion




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1. Empirical evidence
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Research Question

- Why do we bother about counterfeiting?
→ Motivation
- What do we want to achieve/understand?
→ Which factors/parameters have an impact on the solutions for securing the Pharma Supply Chain?
- What are our hypotheses?
- How do we want to do our research?
- What is the analytic unit?




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Levels of change

BPR Business Process Redesign	Improving internal processes, e.g. approval cycle, requisitioners rights, budget and knowledge management, desktop purchasing solutions
ioBPR interorganizational Business Process Redesign	Improving interorganizational processes, e.g. coordination among business partners, exchange of planning information, division of labor, e.g. continuous replenishment, materials management
BNR Business Network Redesign	Changing the structure of the supply chain, bypassing or adding (new) players (e.g. cybermediaries), building business networks, establishing market platforms.




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1. Empirical evidence
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Research approach

1. Contingency analysis
2. Requirements engineering
3. Identification and evaluation of alternative scenarios (Discussion)
4. Process management and implementation (Discussion)



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Process steps	Organisational scope	Technical scope
1 Contingency analysis		
1.1 industry structure	fragmentation, competition	usage of IOS in the industry
1.2 inter-organizational relationship	interdependence, power, trust	governance of IOS
1.3 process and technology	efficiency, intensity of interaction	EDI applications in related areas, existing standards that can be (re-)used, IS with external interfaces or process linkages, level of IS support for operations
1.4 competencies	strategic evaluation of business segments and functions	technical competence
2 Requirements engineering		
2.1 Individual analysis	identification of processes and their relevant contexts, process modelling and analysis	external interfaces, links to internal systems such as order management or inventory control
2.2 Participatory requirements analysis	inter-organizational process modelling and analysis, key benefit areas	specification of technical requirements
3 Identification and evaluation of alternative scenarios		
3.1 First order changes: ioBPR	interchange agreements, evaluation of the systemic and the individual process improvements, impact on internal processes (BPR)	improved informational representation of supply chain: bar coding, EDIFACT, preconditions of EDI benefits, standardisation on industry level required
3.2 Second order changes: BNR	scenarios related to coordination strategy: structural changes along the supply chain (outsourcing and intermediation), models of horizontal cooperation	standardisation issues
4 Process management and implementation		
4.1 Scope of participation	supply chain management, horizontal cooperation	standardisation and implementation issues
4.2 Negotiations	interchange agreements, division of costs and benefits	design of solutions

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1. Empirical evidence
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Contingency analysis

- Multiple perspectives possible:
 - Flow of goods/information/payments
 - Logistics
 - Relations between the actors
 - Regulations
 - Political layer
 - IT/technology
- Product characteristics:
 - Pharmaceuticals are vulnerable to temperature changes
 - Strict "best-before" dates
- Further possible factors:
 - Ownership structure of stakeholder
 - Profit structures

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1. Empirical evidence
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Flow of goods

- Supplier of manufacturer
 - active ingredients
 - Non-active ingredients
 - Packager
- Manufacturer
 - Research-based
 - Generics
- (Pre-)Wholesaling
 - Product range (full-line, short-line)
 - Distribution area
- Pharmacies
 - Channel (online vs. offline)
 - Location

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1. Empirical evidence
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Flow of goods

- What other actors come to mind?
- Tax authority
- Customs authority
- Approval authority
- ...

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Logistics



- The logistics incorporate new stakeholders
 - Logistic providers
 - National and international level
- Different levels of packaging units among the Supply-Chain (and their authentication)
 - Raw-material
 - Container
 - Palette
 - Box
 - Packet
 - Blister
- Storage of products
 - Which conditions have to be fulfilled?
 - How can the correct storage be ensured?

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Relations between the actors

- **Celesio – the healthcare group**
 - Turnover in 2006 €21,6 billion
 - Profit before tax €590 million
 - 36.105 employees
 - 16 countries (europeanwide)
- **Celesio-Wholesale**
 - 135 settlements
 - 14.135 employees
 - 100.000 deliveries per day
- **Celesio-Pharmacy**
 - 2.100 pharmacies
 - 20.223 employees
 - 500.000 customers served per day
- **Celesio-Services**
 - Supports pharmaceutical suppliers in terms of logistics and distribution solutions
 - 1.507 employees





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Regulations

- **Nationally quite different**
 - Price regulation (level specific)
 - Operating licence
- **National administrations**
 - Health authorities
 - Tax authorities
- **Especially on the pharmacy level**
 - Ownership
 - Location
 - New opening
 - Reimbursement
 - Profession
 - ...




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1. Empirical evidence
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Political Layer

- Associations
- National level
- EU level
- Global level
- Profession
- Alliances

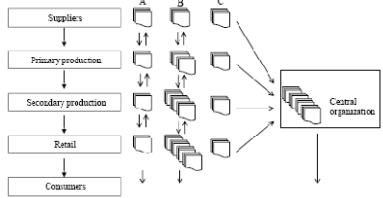


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IT/technology

- **Different scenarios:**
 - Central DB
 - DB at manufacturer
 - Information comes along with product
 - Just authentication check (genetics, barcode)
 - Sophisticated devices needed?
 - Fits for developed countries?



Source: Technical and economic considerations about traceability and certification in livestock production chains
Miranda P.M. Meuwissen*, Arnet G.J. Velthuis, Henk Hogeveen and Ruud B.M. Huime




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Agenda Part D

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Discussion

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- How can the core supply-chain be modelled?
- How can the other perspectives be illustrated?
- What has been neglected or overestimated?

→ Slides: 20-22

- What could be requirements of the different stakeholders?
- How do different technological systems confer different benefit/cost-relations to the stakeholders?
- What design decisions are important to the stakeholders?

→ Slides: 14, 27

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Lessons learned

1. Empirical evidence
2. Solutions for T&T
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- IOS consists of organizational and technical elements
- IOS is influenced by several parties with sometimes diverging interests
- Market structure and regulative environment are important constraints
- Initiation, development and roll-out are often depending more on political than economical (or rational) decisions

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Contact

Current research and projects:

- **ITAIDE**
 - EU funded project
 - www.itaide.org
 - Especially Drug Living Lab with focus on counterfeiting in the pharma industry

Universität Münster
Institut für Wirtschaftsinformatik

Lehrstuhl für Wirtschaftsinformatik und Interorganisationssysteme (IOS)
Prof. Dr. Stefan Klein
Leonardo-Campus 3
D-48149 Münster

Tel.: +49 (251) 8338-110
Fax: +49 (251) 8338-119

<http://www.wi-ios.de>



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