

# Pharmaceutical Industry Perspective

## Wellcome Trust & APG Counterfeit Medicines: Perspectives & Actions 26 October 2009

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*Johnson & Johnson*

# Manufacturer's Perspective on Counterfeiting Agenda

- Why is Brand Protection Important?
- The Counterfeiting Challenge
- Supply Chain Risks & Vulnerabilities
- Industry Response: Comprehensive Protection Model
- Anti-Counterfeiting Strategies & Actions
- Public/Private Alliance Recommendations
- Summary

# Why Focus on Counterfeits & the Discipline of Brand Protection?

It is important to our industry and to our company...

1. Responsibility to Patients
2. Business Impact
3. Consumer Confidence (trust mark)

# Overview of the Challenge

**The global pharma supply chain is being violated**

Counterfeiting and illegal diversion\* have become significant global problems for the industry fueled by....

- Free trade agreements & move towards a global economy
- Growth and capitalization of emerging (BRIC) markets
- China – “the world’s factory”
- Internet – “the world’s dispensary”
- Counterfeiters are well-funded and technologically advanced
- Under-resourced regulatory and enforcement agencies
- Profitability of illicit trade practices - high reward to risk ratio
- Lack of respect & protection for IP in some countries
- Liberal rules governing repackaging in cross border trade
- Lack of control and visibility of supply chain activities

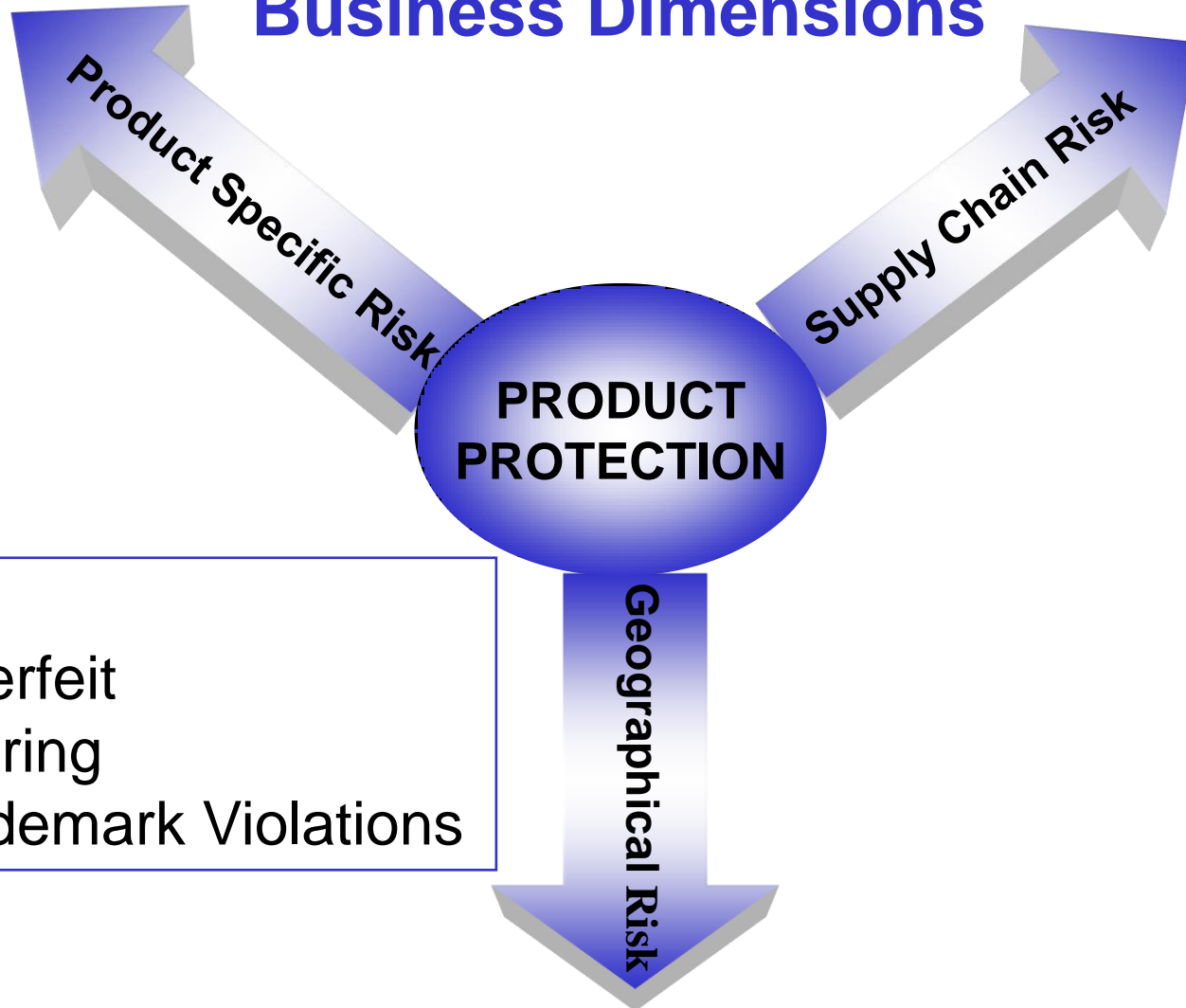
Note: Cross border trade among the 27 member states of the European Union is a legitimate and legal activity.

# Definition of Counterfeit

“A counterfeit medicine is one 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 correct ingredients or with wrong ingredients, without active ingredients, with insufficient ingredient or with fake packaging.”

*World Health Organization 1992*

# Risk Originates in three Business Dimensions

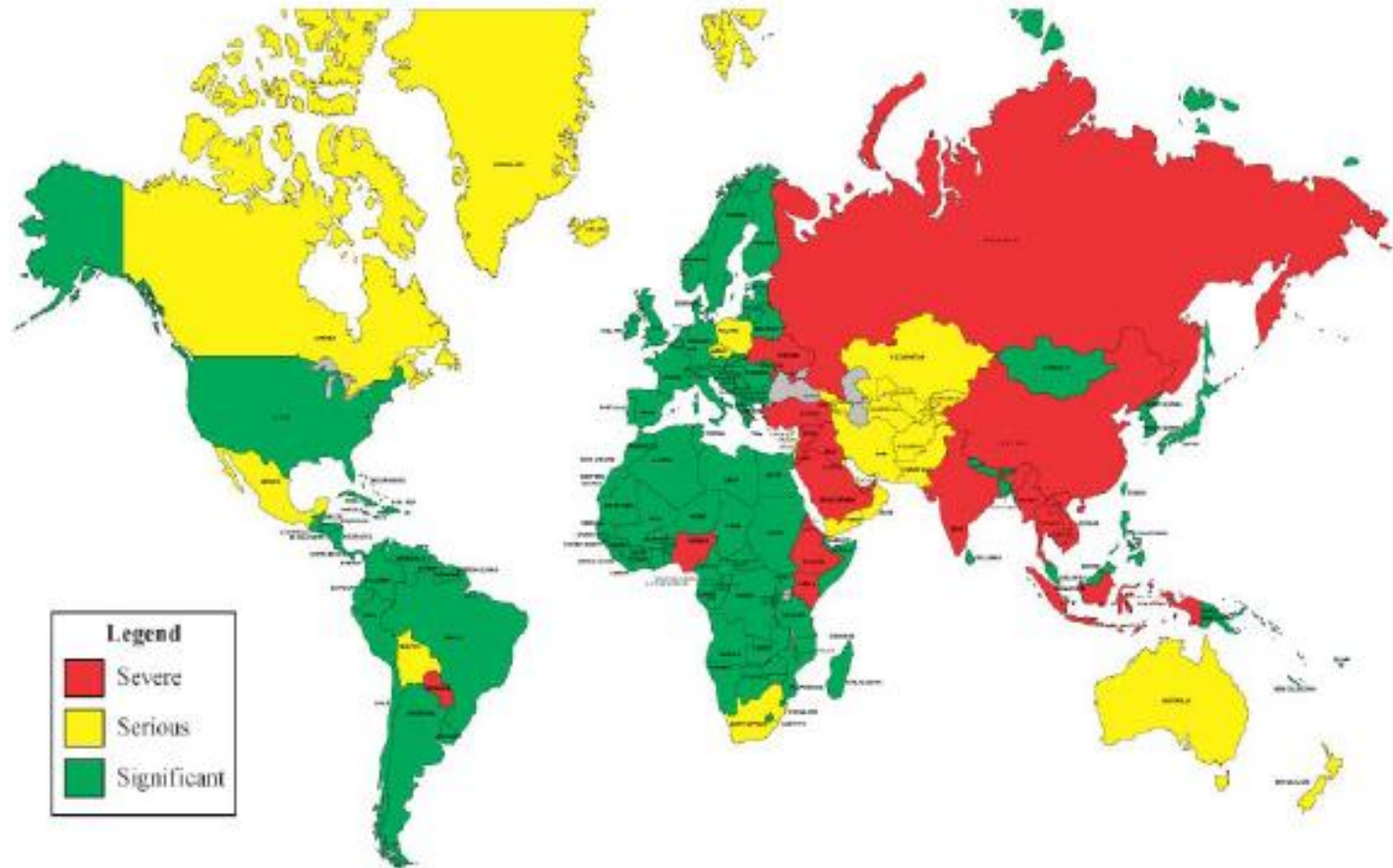


## Risks:

- Counterfeit
- Tampering
- IP/Trademark Violations

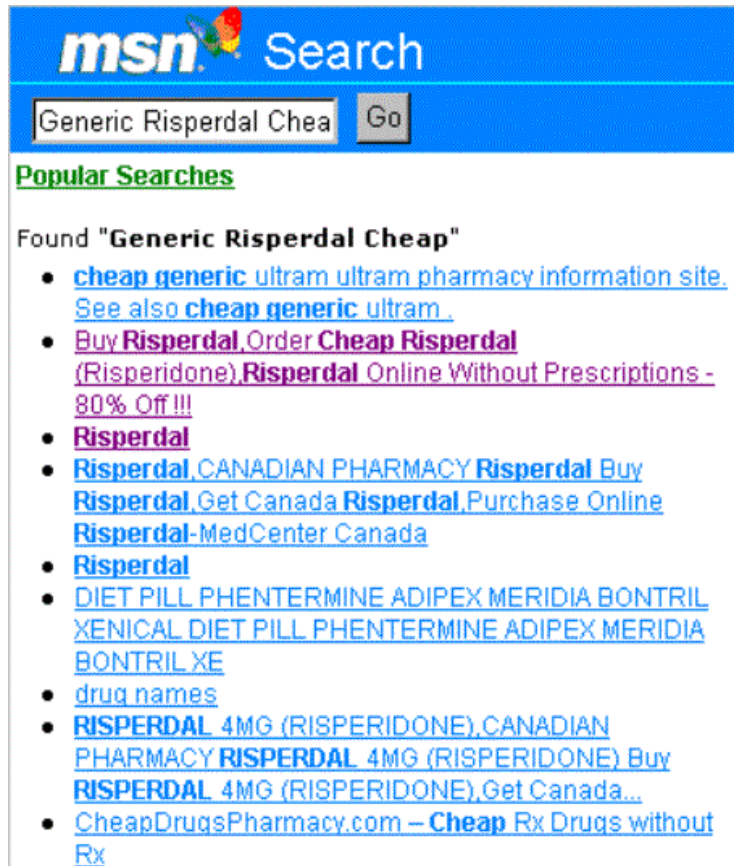
# Geographical Risk: Interpol Data

Global Counterfeiting Hotspots



# Product Risk: Example Risperdal®:

High price, high volume, history of tampering



The screenshot shows the msn.com search interface. The search bar contains the text 'Generic Risperdal Cheap' and a 'Go' button. Below the search bar, there is a section titled 'Popular Searches' and a heading 'Found "Generic Risperdal Cheap"'. A list of search results follows, including links to various online pharmacies and generic drug suppliers.

msn Search

Generic Risperdal Cheap Go

Popular Searches

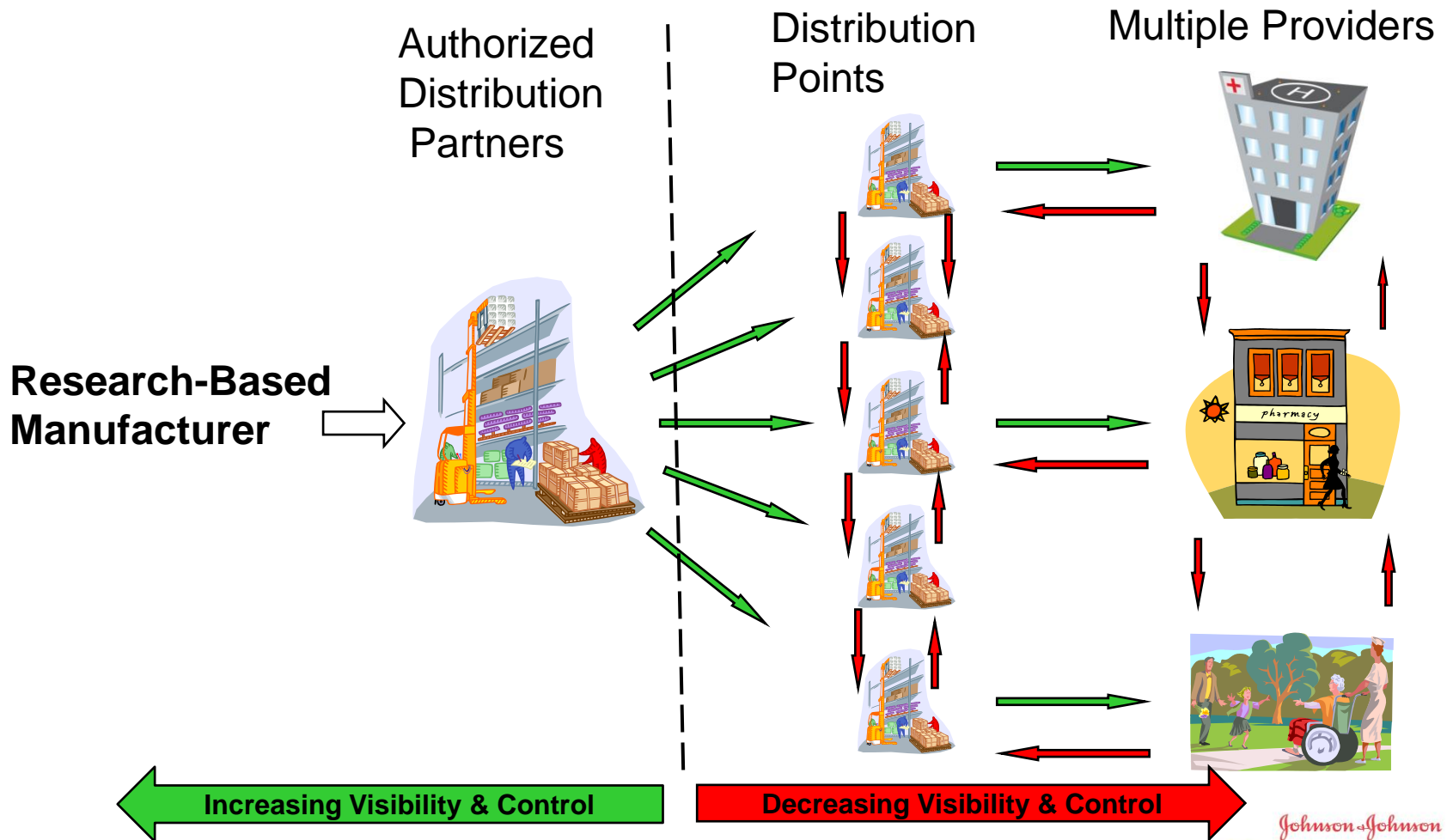
Found "Generic Risperdal Cheap"

- [cheap generic ultram ultram pharmacy information site. See also cheap generic ultram.](#)
- [Buy Risperdal, Order Cheap Risperdal \(Risperidone\), Risperdal Online Without Prescriptions - 80% Off!!!](#)
- [Risperdal](#)
- [Risperdal, CANADIAN PHARMACY Risperdal Buy Risperdal, Get Canada Risperdal, Purchase Online Risperdal-MedCenter Canada](#)
- [Risperdal](#)
- [DIET PILL PHENTERMINE ADIPEX MERIDIA BONTRIL XENICAL DIET PILL PHENTERMINE ADIPEX MERIDIA BONTRIL XE](#)
- [drug names](#)
- [RISPERDAL 4MG \(RISPERIDONE\), CANADIAN PHARMACY RISPERDAL 4MG \(RISPERIDONE\) Buy RISPERDAL 4MG \(RISPERIDONE\), Get Canada...](#)
- [CheapDrugsPharmacy.com - Cheap Rx Drugs without Rx](#)



# Supply : Chain vs Network:

The normal pharmaceutical supply chain (→) is complex yet controllable  
... the actual distribution network (↔) is risky and lacks sufficient safety controls and visibility



# Top 10 Supply Chain Vulnerabilities\*

1. Business & consumer trading borders weakening
2. Policy enforcement agencies & regulators under-resourced
3. Arbitrage opportunities leads to lateral trade of counterfeits
4. Suppliers do not dictate who their trading partners can sell to
5. Repackaging from original containers & labeling
6. Uncoordinated product protection measures across supply chain
7. Weak penalties for counterfeiters
8. In-transit cargo is at risk
9. Lack of end-to-end tracking or point of use product authentication
10. Internet

**Control & Visibility**

\* The Blue Fin Group



# Brand Protection Model

“Focused on Prevention”

Market Monitoring

Communication

Influencing Policy

Secure Supply Chain

Product Protection

Business Value Protection

Patient Safety

# Industry Anti-Counterfeiting Strategies & Actions

## Create a Culture Shift in Industry

- Adopt a mindset of “control & visibility”
- Treat ‘supply integrity’ with same reverence as product R&D work
- Hold intermediaries/repackagers accountable for supply chain integrity

## Adoption of New Practices & Technologies

- Report all incidents, investigate, prosecute and assess preventative measures
- Implement closed loop “track & trace” (pedigree) systems for high-risk categories as appropriate
- Utilize authentication and information technologies to increase visibility/control
- Test new business models among traders based upon safe passage of goods

## Increased Communication & Public Awareness

- Communicate to suppliers and handlers that healthcare is a regulated industry which requires ongoing surveillance, vigilance and accountability
- Increase private & public sectors’ knowledge of the business of trade (money flow, inventory management, reverse logistics, regulatory issues)

# Industry Alliance with Public Sector

## 1. Common Industry & Government Objectives

Alignment on anti-counterfeiting priorities and resources among industry associations and government agencies (EFPIA, PhRMA, IFPMA, EAASM, Border Patrol, Regulators, etc.)

## 2. Supply Chain Visibility

Develop track & trace (pedigree) systems and implement authentication methods to strengthen the normal distribution channels (e.g. EFPIA serialization pilot project in Sweden)

## 3. Internet Control

Collaborate on international regulatory & legislative sanctions and penalties governing internet pharmacies & auction sites

## 4. Monitor Cross-Border Trade

Apply technology and shared data systems to evolve from sampling & auditing to continuous monitoring (risk-based)

# Pharma Industry Anti-Counterfeiting Summary

## Conclusions

- Counterfeiting is growing problems in the global pharma industry impacting patient safety and business value
- The proliferation of illicit trade has awakened the pharmaceutical industry to collaborate with governments in securing the global supply chain
- Manufacturers and supply chain stakeholders are responding proactively to achieve increased visibility and control of pharmaceutical distribution networks

## Summary

Worldwide patient safety concerns and the capitalisation of emerging markets are driving the need for new regulations in health care sourcing, distribution and delivery which will require unprecedented resource investments and public/private cooperation