



*Strategy & Policy*

# The Pharmaceutical Safety Chain: a concept paper<sup>1</sup>

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<sup>1</sup> Disclaimer: While this work was undertaken for the UK pharmaceutical industry, it does not represent the position of the Association of the British Pharmaceutical Industry. Additional material on the safety chain is available from the author. This document © Tremblay Consulting 2005.

It is now generally agreed that the main approach to improving patient safety will be through the development of systems to support safety. For some time now, the pharmaceutical industry has been concerned about the proliferation of counterfeit drugs. Recognising that this required a systematic solution, the ABPI established the Coding and Patient Safety Group to assess how industry could harness information, authentication and identification technology, to develop a unique coding system to benefit patient safety.

Integral to safety improvement is the use of a *Safety Chain*, to link together the various organizations involved with medicines: pharmaceutical manufacturers, intermediaries, purchasers, and health care professionals and patients. The "Pharmaceutical Safety Chain" provides an integrated and *interlocking* approach to safety by creating expectations, responsibilities and accountabilities which define safety priorities and responses of these organizations. Drawing on lessons from maritime, food, banking and agricultural industries, the "pharmaceutical safety chain" represents a state of the art approach to safety improvement.

There are lessons for patient safety more widely, where the safety chain approach may be helpful in defining patient safety within complex, interlinked but separate systems. This is an area for future development.

This document describes a concept of a pharmaceutical safety chain.

## 1 Enhancing Safety Through a Pharmaceutical Safety Chain

There are vulnerabilities in the trade in medicines, with evidence of systematic efforts to compromise the supply chain with counterfeit medicines. The Pharmaceutical Industry believes that there is sufficient cause for concern that concerted effort is needed to enhance safety to maintain public confidence in the safe supply of medicines.

The situation is complicated by the variety of national regulators, and the absence of any international approach to safe supply of medicines. Trade in medicines crosses national borders and jurisdictions where opportunities exist to compromise security and safety. Pharmaceutical crime rarely exists in national legal systems, and the extraterritorial nature of the problem makes enforcement and surveillance more difficult.

At present, the trade in pharmaceuticals lacks a shared approach to safety at national and international levels. Other industries have moved to avoid this, and have developed safety chain models integral to concerted safety improvement and action.<sup>2</sup> A similar approach is recommended to deal with medicines safety and specifically address the existence of counterfeit medicines.

It may be easier for the international pharmaceutical industry to propose 'soft law' approaches to dealing with counterfeit medicines, as governments will encounter more difficulties seeking to extend jurisdiction into intergovernmental areas of responsibility; industry leadership with

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<sup>2</sup> See Appendix 3.

government support offers one approach that is compatible with approaches to international safety from other sectors.

Safety is a shared responsibility, and a collaborative approach is necessary to identify and solve safety problems. The proposed approach, using standards, track and trace technologies, and uniform event reporting, provides higher standards of safety and security through a system of interlocking obligations between actors across the supply chain. This requires supply chain actors to verify that both the origin of the medicine they are purchasing or handling, and its next destination involve organisations which adhere to standards of a “*Pharmaceutical Trade Safety Chain*” defined as:

a voluntary assurance system of everyone involved in the trade of medicines to enable consistent safety practice through high standards, the transparent exchange of information from surveillance and monitoring of trading practices, to support and enhance public confidence.

Information on the movement of medicines will be collected using appropriate technologies and disseminated to support compliance and trading transparency. Standards will be developed and adhered to by the groups participating in the safety chain<sup>3</sup>:

- the manufacturers of the medicine,
- licensed traders, who move medicinal products through the supply chain,
- governments and regulators, who have responsibility for the legislative and regulatory environment governing trade in medicines and public safety,
- dispensers of medicines,
- the patients.

## 1.1 Benefits of a Safety Chain

A safety chain yields direct benefits for safety:

1. Capturing information on the movement of medicines makes it easier to track and trace products;
2. The safety chain makes it easier to identify and remedy risky or non-compliant trading activities;

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<sup>3</sup> See Appendix 1 for these groups and their safety interests.

3. It will be easier to identify non-conforming or non-participating organisations to determine whether non-compliance is a form of evasion or failure to meet desired standards;
4. Purchasers of products at any stage of the supply chain can expect suppliers to meet the obligations of safety chain practices and standards, and vice versa;
5. An electronic database, forming the spine of the safety chain, will provide seamless information to support safety chain activities, support transparency and enable greater accountability.

## 1.2 Responsibilities

The diagram summarises responsibility within the Safety Chain, highlighting responsibilities and where collective and coordinated action would be appropriate.<sup>4</sup>

**Diagram: Responsibilities of Safety Chain Actors**

		safety actions				
		pro-action	prevention	preparation	mitigation	recovery
safety tools	Planning	Develop safety model	Understand stakeholder needs	Develop responses	Develop responses to deal with all eventualities e.g. bioterrorism, counterfeits, fraud.	Return to normal and learn the lessons
	Standards	Define standards e.g. Unique Product Identification; batch number, expiry date.	Generally applicable, transparent, flexible e.g. adoption of an EU wide coding standards		Review and improve standards	Produce revised standards
	Database	Define information reporting, alerts, etc.	Data quality, access, reporting through a centrally held, but shared database.			
	Coding	Agree coding technologies e.g. Reduced Space Symbology, EAN 128	Information collection through the electronic reading of standard bar codes			
	Implementation	Agree practice – collaboration between healthcare providers and pharmacists	Assurance system for standards enforcement; collaboration with the EMEA	Build industry response capabilities, to ensure the integrity of the supply chain	Standards of practice	Solve the safety problem

Responsibility of Organizational Actors

Responsibility of all Actors

<sup>4</sup> See Appendix 2 for definitions.

### 1.3 Implementation

Many of the implementation needs can be addressed by existing regulatory bodies. The other implementation requirements can be met by through a neutral body acting on behalf of collective interests and which manages and administers the information database.

#### 1.3.1 Can be done by existing regulatory bodies

- develop and maintain standards,
- issue alerts,
- monitor safety compliance,
- monitor the wider safety environment to improve best regulatory practice.

#### 1.3.2 Can be done by a new neutral body

- receive and organise coding information,
- host the information database,
- provide appropriate reports to all safety chain participants.

#### 1.3.3 Can be done by all safety chain participants together

- monitor their role in the safety chain and propose changes to improve regulation or safety practice.

## Appendix 1: The Pharmaceutical Safety Chain Actors

Table: The Groups Comprising the Links in the Safety Chain						
The Pharmaceutical Trade Safety Chain						
Group	Originators of medicines	Licensed trading companies including final purchasers of medicines	Governments and regulators	Dispensers of medicines	End-users	
<b>Definition</b>	Manufacturers of medicines	Firms that operate between manufacturers and end-users, to move products through the supply chain, comprising wholesalers, shippers, redistributors and parallel traders; included here are state or public purchasers and their national distribution systems	Bodies that are concerned with the legal or regulatory aspects of trade in medicines	Those who also dispense, and are the last step before the patient, comprising pharmacists in hospital or community, dispensing doctors, hospital specialists	These are patients, parents, informal carers and consumers, as well as non-dispensing prescribers	
<b>Safety Interests &amp; Priorities</b>	Integrity of the manufactured medicinal product Safety of the medicine	Control of the logistics process and movement of the actual product Quality and value for money	Public safety and public health EU legal and regulatory compliance	Mitigation of product-related risk Customer service and quality	Product quality Trust in the safe supply of medicines	

## Appendix 2: Definitions

Key steps in the safety chain are adapted from those used in civil protection<sup>5</sup> comprising a comprehensive framework covering planning about safety and the prevention of accidents, preparations to respond to incidents, the mitigation of the consequences of safety-related incidents, as well ways to learn from the experience, implement changes, to maintain a high standard of safety. The key activities are:

### **Pro-action**

Safety standards need to be established along with agreement on information requirements by everyone including agreement on an appropriate technology platform to support coding. Consensus is needed on day-to-day operations and links with existing practice.

### **Prevention**

The safety needs of everyone in the supply chain must involve shared understanding. Central to prevention is an over-arching single responsible body, similar to organisations in other industries (e.g. International Maritime Organisation).

### **Preparation**

Everyone needs to build response capabilities to assure the public that everyone is taking appropriate steps.

### **Mitigation**

The development of interventions to manage problems is a shared responsibility, with agreed methods.

### **Recovery**

Everyone must learn from mistakes, and accidents, and take appropriate steps to reform practice, and revise standards.

To implement these various activities, we need specific tools and techniques. All the most effective safety chains studied utilized in some form or other these key tools. Overall, these will require a 'technology platform' to enable the Database and Coding.

### **Planning**

Agreement by everyone on the values, purpose and design of the safety system. This will require discussion and development, plus continuing commitment to safety, through a shared planning framework

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<sup>5</sup> Adapted from: *Integrated Public Safety Policy*, Ministry of the Interior, Government of the Netherlands, 1993

## **Standards**

The Safety Chain depends on agreement and application of standards covering trading methods, types of information that is required, reporting requirements, trading practices, and regulatory practice. These would apply nationally and crucially across borders.

## **Database**

All the safety-related information needs to be organized, including alerting of problems, reviewing problems, supporting training and regulatory and trading standards compliance.

## **Coding**

A consistent approach to data elements is needed to support the ability of the Database to inform the Standards, and to support Implementation and compliance.

## **Implementation**

A single organization is needed to take overarching and international responsibility for ensuring the quality of the Standards, to receive the information from the Coding, to house the Database, and to report on compliance. This body should also see itself providing reporting to respond to public enquiries.

### Appendix 3: Background to the Development of the Safety Chain Concept

The development of a safety chain for pharmaceutical trade in medicines draws on thinking in other sectors.<sup>6</sup> A safety chain oversees maritime shipping, bringing together governments, insurers, ship owners and port authorities.<sup>7</sup> Food safety is governed by a chain linking retail outlets, farmers, and food processors and packers, and with track and traceability requirements to ensure food provenance with a duty of “due diligence” amongst supply chain actors.<sup>8</sup> Highlights of the safety lessons are summarised in the Table.

<b>Table: Lessons on Safety for the Pharmaceutical Industry from Other Industries</b>		
<b>Area</b>	<b>Feature</b>	<b>Design lesson for Industry</b>
<b>Banking</b>	Cheque clearing system and security Fraud and counterfeiting	Ensure security of processes, including knowing identity of sources and destinations of money
<b>Auto racing</b>	Inherently dangerous Manage and control risk	Some things are in fact dangerous, and in some cases risk needs to be managed, and danger unavoidable
<b>Airlines</b>	Design to eliminate risk as much as possible	Identify areas of risk and danger and design and train the risk out as much as possible
<b>Food</b>	Provenance “food safety chain” links public health, animal health, plant health and environment Due diligence between buyers and sellers	Formal links between different actors, with mutual expectations and checking of compliance Track and traceability technology and flow of information
<b>Environmental protection</b>	Precautionary Principle	It may be necessary to act on problems before there is sufficient evidence
<b>Shipping</b>	Maritime safety chain	Each party has defined and shared areas of responsibility Clear focus on addressing problems of non-compliance by the “weak links”
<b>Civil protection</b>	Population-based risk	Proactive approach which integrates both actors and processes

<sup>6</sup> The Safety Chain model was developed by Dr Mike Tremblay, Tremblay Consulting for the industry.

<sup>7</sup> International Maritime Organisation, **ISM Code (International Safety Management Code) and revised guidelines on implementation of the ISM Code. 2002 edition** (IMO-IA117E)

<sup>8</sup> §21, **Food Safety Act 1990**, UK.

In addition, thinking about safety itself was guided by the Institute of Medicine's **To Err is Human**<sup>9</sup>, and its key principles for safety:

1. the need for leadership, in this case to come from the pharmaceutical industry;
2. the development of simple transparent, understandable whole-system processes;
3. team-working, rather than silos of accountability, appropriate to the cross-jurisdictional nature of safety with the need for shared learning and without imposed solutions;
4. be proactive, rather than waiting for a crisis to justify action;
5. fostering a learning environment, based on training, research, standards, recognising that safety is a complex, multi-dimensional, cross-jurisdictional issue requiring iterative learning.

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<sup>9</sup> Institute of Medicine, **To Err is Human**, National Academy Press, Washington DC, 2000.