

What risks can affect the supply of pharmaceuticals to the NHS?

Pharmaceuticals are a key input into healthcare treatment, so it is imperative that risks attached to the sourcing and passage of these products through to patients are identified and managed, says Liz Breen

Why do we need to examine risk and its management in the supply chain? The simple answer is that it has not been done before, judging by the lack of literature on the subject. Although risk management is a topical issue in both practice and academic circles, no research to date has investigated risks within the total pharmaceutical supply chain (PSC) as pertinent to NHS pharmacy. Such research is vital because pharmaceuticals are central to healthcare and are critical products.

Research suggests that practitioners believe that “pharmaceuticals are different; they cannot be treated like other commodities”.¹ This is because of the high cost and long duration of research and development and the repercussions of the product not being available, hence the criticality. Other unsupported perception-based factors that appear to make the pharmaceutical supply chain distinctive include the level of regulation in production, storage, distribution and consumption, and the complexity of the fabric of this supply chain.²

It would seem, from the research findings, that there is concern about the growing number of risks within the PSC, and the lack of any co-ordinated effort to assess and manage them. This is worrying, because the purpose of the PSC is to source pharmaceuticals and materials to provide treatment for the end-user. The research identified risks that would affect the performance of the total supply chain negatively (from raw material sourcing through to medicines dispensing). Yet, the contributors believe that there is a lack of cohesion, expertise and urgency within the supply chain to tackle such risks head on or work together to minimise them.

This article aims to highlight this issue, identifying the nature and prevalence of risk, as determined by supply chain users. It concludes that there needs to be a more structured and co-ordinated approach to risk management in the total supply chain within NHS hospital pharmacy, as opposed to the current pockets of expertise evident (as demonstrated by previous research, eg, clinical risk assessment and management).

Risk management in practice

Supply risk is defined as the potential occurrence of an incident or failure to seize opportunities with inbound supply, the outcome of which results in a financial loss for the affected company.³ Risk comes in many forms and can undermine confidence in the supply chain^{4,5} and lead to supply chain failure. However, managing risk is difficult within supply chains due to the number of players involved, their interdependence and the fact that factors that mitigate one risk can exacerbate another.⁶⁻⁸ This is relevant to the supply chain under discussion because of the convoluted nature of the PSC.

The response to managing risk will depend on the type of operation involved, resources, strategy and a multitude of other factors. When considering the PSC, “other factors” might include government directives and legislation, eg, from the Department of Health, and policies stipulated by the National Institute for Health and Clinical Excellence, the Medicines and Healthcare Products Regulatory Agency, or the NHS Purchasing and Supply Agency, to name a few.

The structure of the PSC is such that an examination focusing on risk needs to encompass the complete supply chain and composite network of buyers and suppliers. The whole supply chain needs to be the subject of assessment as opposed to individual entities or parties, eg, risks attached to a supplier or purely to patients. At a most basic level, risks in the PSC are associated with product discontinuity, product shortages,² poor performance, patient safety/dispensing errors, technological errors (causing stock shortages in pharmacies), internet pharmacies and counterfeit drugs, all of which cause delays in the system and anguish to the final users: patients. Medication errors alone equate to £200–£400m per year in the UK, and to this must be added the unknown cost of errors in primary care and costs of litigation.⁹

There is evidence to suggest that the convoluted nature of the PSC in the NHS (UK) is similar to that in other countries, and that similar issues exist, such as counterfeit medications, product shortages etc.¹⁰ Research has indicated that in Europe medicines can travel through as many as 20 to 30 pairs of hands before they finally reach patients.¹¹ The supply chain has become more fragmented with effectively 25 pharmaceutical markets in Europe. This, coupled with overwhelming growth in the number of wholesaler interme-

Panel 1: Attendance profile at risk-management workshop

- Mawdsley Brooks
- European Association of Euro-Pharmaceutical Companies
- UniChem Ltd
- Pfizer
- Association of the British Pharmaceutical Industry
- AAH Pharmaceuticals Ltd
- British Association of European Pharmaceutical Distributors
- Healthcare at Home Ltd
- Baxter Healthcare Ltd
- Durbin Plc
- NHS Procurement Specialist London & Eastern
- Royal Bolton Hospital
- NHS Procurement Specialist SW
- EXEL/DHL
- NHS — Purchasing and Supply Agency
- MICE Associates (Managing Innovational Change Exponents)
- Bradford Royal Infirmary
- IDIS
- National Patient Safety Agency*
- Medicines and Healthcare products Regulatory Agency*
- Department of Health*

* Interested, but unable to attend workshop event

diaries and traders involved in the European flow of medicines, as well as repackaging of original manufacturers' medicines and a lack of exchange of information, has led to a decrease in transparency in the supply chain.¹²

Workshop

In order to gain a more realistic understanding of the nature and prevalence of risk in the PSC, a workshop was held in November 2005 focusing on risk identification within the PSC. It was attended by 18 key PSC stakeholders (Panel 1).

The attendees were split into two groups, each containing a mix of pharmaceutical manufacturers and wholesalers and NHS personnel. The two groups were facilitated by NHS pharmacy procurement specialists and were asked to deliver key objectives:

- To identify risks in the PSC
- To rate their criticality
- To produce an agreed map of the structure of the PSC

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The two groups worked separately, but were brought together for interim group sessions to deliver their outputs. A consensual set of data was compiled by the researcher in the presence of the whole group. At each group session discussion was generated to validate or explain outputs.

After a comprehensive list of risks had been identified the individual groups reconvened to apply a criticality rating. The criteria used to develop such ratings were standard of those currently used within the PSC, namely, impact, control and occurrence. During the group sessions there was discussion and movement on the ratings, and a comprehensive list was compiled. As this was a preliminary investigation, further extrapolation and development of the risk ratings was not conducted.

However, further examination using tools such as "analytic hierarchy process" (AHP) could be applied using the ratings identified to assist in more structured decision making. The aim was to identify a clear goal — such as choice of optimum supply chain designs — election of alternatives or options for reaching the goal (selected number of supply chain designs to be considered) and the criteria (eg, cost, safety, structure and capacity) and sub-criteria (eg, litigation, government influence, counterfeiting, transport costs, supplier bankruptcy) that link the alternatives to the goal. A weighting would be applied to the criteria, reflecting importance and this could be extrapolated using the existing rankings to determine which supply chain design would be most effective at reducing risk levels.

Further discussion took place on the structure of the PSC. Owing to time constraints the final map was completed after the workshop by an NHS pharmacy procurement specialist, but was then circulated to the members of workshop group for further comments and amendments. However, no amendments were requested.

A workshop was the most appropriate approach to adopt in collating the data because there is a lack of published data on this subject, and the data produced would be accurate and timely. As a cross-section of companies was involved (18 companies/organisations represented) a tentative assumption could be made that the findings would be more representative of opinion on this subject within this field than not.

Findings

The outputs of the workshop indicated that there were 35 prevalent risks (Panel 2) with varying levels of criticality and that the structure of the PSC map was product-dependent. Therefore, were a specific product to be taken into consideration the map profile could be substantially different. The risks were rated using risk assessment categories such as impact, occurrence and controllability. It was agreed that the top 10 risks identified were representative of the state of play in the PSC. The top-rated risks included:

- Fragmentation of the supply chain (multiple channels leading to poor communication)
- Lack of visibility concerning placement and availability of stock
- Inappropriate forecasting conducted by the customer
- A general inability of capacity to meet demand

An outlying risk that was debated was that of counterfeit medicines. One member of the group was adamant that the risk attached to counterfeiting was greater than the rest of the group perceived it to be. This risk was placed as 23 out of 35.

The findings indicated that the risks identified are similar to those prevalent in industrial supply chains, regardless of the idiosyncrasies of pharmaceuticals. However, the group consensus was that caution must be applied in how such risks are addressed, since there are aspects of the product that highlight its uniqueness, eg, criticality (See Panel 2).

What do the findings mean?

The ratings produced were based on the criteria of control, occurrence and impact. A high rating indicates a greater potential for a more detrimental impact (financial or other) on the PSC, thus needing more structured recovery mechanisms. For example, the highest ranked rating was due to the fragmentation of the supply chain (10/10).

The group believed that there was a lack of uniformity in decision-making within the PSC, which led to problems and affected the efficacy of the complete supply chain. This was, therefore, a risk that needed to be addressed urgently, because it affected all parties and could result in financial loss. This view further supports the concerns within the industry of the increasing involvement of suppliers, manufacturers, parallel importers, generic manufacturers and wholesalers, to name a few. According to European sources, the PSC is becoming more complex, attracting new players and decreasing transparency.

Panel 2 shows that a large proportion of risks fall within the 5 and 6 rated categories. This indicates an average level of importance, which means that they need to be addressed, but are not as critical as those ranked 7–10. In addressing risks, the questions that have to be asked are:

- What is the impact of the risk
- Can it be controlled and hence reduce the risk
- If not, can a mitigation strategy be produced to reduce, eradicate or share the risk?

Moreover, whom does it affect? Although this is still part and parcel of the impact, the priority of an issue may change if it affects patients or the public as opposed to an individual entity, such as a supplier.

The control factor It is clear that a number of risks proposed are operational and functional and are therefore within the control of the industry. These include visibility of stock, communication channels, capacity management issues and information flow. That being the case, there is a need for more effective management of these risks.

The industry is less capable of controlling other risks, such as counterfeiting. This was rated as a 6/10, which is high risk, but was not considered high priority because of the low frequency of its occurrence. Governmental influences are also less controllable. These include the conflict between patients and profits, NICE approval and the introduction of procurement hubs, while others — such as unavailability of fuel, natural disasters and illness — are uncontrollable. In reviewing the risks produced, it can be assumed that some can be addressed effectively through better co-ordination and management of the PSC and some through effective mitigation strategies, as and when they arise.

Improvements The findings of this research indicate that there are clearly identifiable risks in the PSC as determined by industry practitioners. The practitioners were in agreement that although there is an emphasis on risk from the various agencies, companies and the NHS itself, there is no co-ordinated approach that governs risk across all the supply chain parties. Anecdotal evidence would suggest that, even though practitioners know that there is risk attached to core activities of the PSC such as procurement contracting, no risk assessment is conducted on suppliers to ascertain the level of risk in a proposed contractual relationship (a key risk being the potential to disrupt supply). Decision-making appears to reside with members of staff with pharmaceutical experience, rather than experience in risk management.

PSC overview The map of the PSC, (see Figure 1), as identified by the workshop group, presented an overview of the movement of the finished pharmaceutical product through the supply chain to the patient. This map was produced by a procurement specialist in the NHS, based on the group's contributions from the one-day session. Although it appears complicated, it could be said that it is simpler than other manufacturing supply chains, such as that in the automobile industry. The map indicates the number of players involved in the PSC as agreed by the attendees, but is not comprehensive and merits development.

As there are numerous players and lines of communication within the PSC, a suggestion could be that the supply chain would benefit from having a co-ordinating body that is responsible for setting targets and meeting deadlines, and implementing strategy. This body needs to recognise the interconnectivity between members of this network and to aim to support and nurture this, while ensuring

Panel 2: Risks identified and associated ratings (Risk Management Workshop, 2005)

Risk	Explanation	Rating
Fragmentation of SC — no single source, multiple channels, no communication, unilateral decisions	The supply chain is complex, involves many channels, buying and selling of commodities and there is no transparency in the different channels. Stock is difficult to track and easy to lose.	10
Lack of visibility of stock	It is not possible to ascertain at any time how much stock exists within the supply chain (and hence to move it to where it is most needed).	9
Unexpected increase in demand	Demand is independent and difficult to predict.	8.5
Demand versus capacity	There is not necessarily a relationship between demand and the capacity to produce product.	8.5
Information flow or lack of information	There is little and incomplete flow of information from user to producer on patterns of use or demand.	8.5
Lack of forecasting — customer side	Customers do not have capacity to amalgamate individual demand patterns into an overall picture.	8.5
Availability of raw material, true and commercially induced. Regulatory issues — manufacturing licensing/change of standards/drug recalls	There are often problems in obtaining raw materials for production, especially for more niche products. Any change in the manufacturing process necessitates a licence variation which often entails a delay.	8
Demand/economics — unable to respond to demand	It is not always possible or economic to ramp up supply to meet an increased demand.	8
Inadequate buffer stock — JIT/lean	Economies have been made in the stock held within the supply chain leading to increased fragility.	8
Contracting treated as a commodity — big contracts = big risk. Drive competitors out	There is an obvious increased supply risk attached to large contracts for secondary care, especially for products used in secondary care only (eg, IV antibiotics).	8
Transportation — unavailability of fuel, congestion, weather, illness.	Transportation links become more prone to disruption over time, especially for time dependent demand.	7.5
Manufacturer defence tactics	Some tactics have reduced competition (eg, there is now much less availability of parallel imports to secondary care in the UK).	7.5
Diversion of manufacturing capacity	Niche products can be squeezed in manufacturing schedules by higher profile products.	7.5
External influences — disaster recovery	Disaster recovery may be affected by external parties leading to inappropriate decision making.	7.5
Stock holding — more concentrated	Have been cut in some parts of the supply chain and stock may be concentrated in small parts of the chain.	7
Exploitation	Stock shortages can represent a chance for speculation by those holding some stock.	6.5
Dispensing/picking error — medication/packaging, prescription management	The NPSA have highlighted the risks involved in mispicking items as a result of bad labelling or packaging	6.5
Decrease in capacity linked to profit	The capacity of the manufacturing base is susceptible to retrenchment if profits are not available.	6.5
Too much information	We live in a data rich society where useful information can be lost in the background.	6.5
Short term SC planning	The temptation is to go with short term profit rather than making long term but necessary investments.	6.5
Operational in/efficiencies, eg, systems operating properly	Any system will inevitably go wrong on occasions, especially complex systems.	6
Non standard practice — customised policies per hospital; lack of common codes etc.	There are few supply chain wide standards employed by all. This leads to inefficiencies and errors.	6
Counterfeiting	There is an obvious risk if counterfeit material enters the bona fide supply chain.	6
Increase in demand due to NICE approval, patient involvement, press coverage	These types of external influences can have a big effect on the demand for a medicine and lead to shortages.	6
Rationalisation of range	Manufacturers remove unprofitable products from time to time. NB, the DoH initiative in this area has considerably reduced the risk.	5.5
Cash flow/cash management — threat associated with small companies and hospitals	If a small company fails, the market for any product they manufacture is destabilised.	5.5
Storage/cold chain	If this fails there is a risk to stock.	5.5
Reimbursement policies not consistent	Reimbursement policies are not always consistent.	5.5
Response of industry to shortages — communication?	Industry does not always respond to shortages in a coordinated way. NB, this has improved as a result of the DoH initiative in this area.	5.5
Loss of expertise — unsophisticated supply chain purchasing/practice?	There is increased risk if systems are run by less expert staff.	5
Risk of litigation — influence on market?	There is a perceived increased risk of litigation which may influence behaviour and lead to defensive rather than necessary behaviour.	5
Hubs — introduce more complexity	The introduction of collaborative procurement hubs may have introduced more complexity (who is the customer) but there is now agreement about who will contract for what.	4.5
Lack of knowledge regarding manufacturing process or source of supply	Customers may not fully understand the complexities or time lines of manufacture (eg, vaccine production) and consequently make inappropriate demands.	4.5
Theft	Can lead to unexpected shortages and if the stock is sold on to potentially unsuitable product being presented to the supply chain.	4.5
Prioritisation — conflict between patients/profits	Manufacturing priorities do not always reflect patient need, but rather economic return.	4

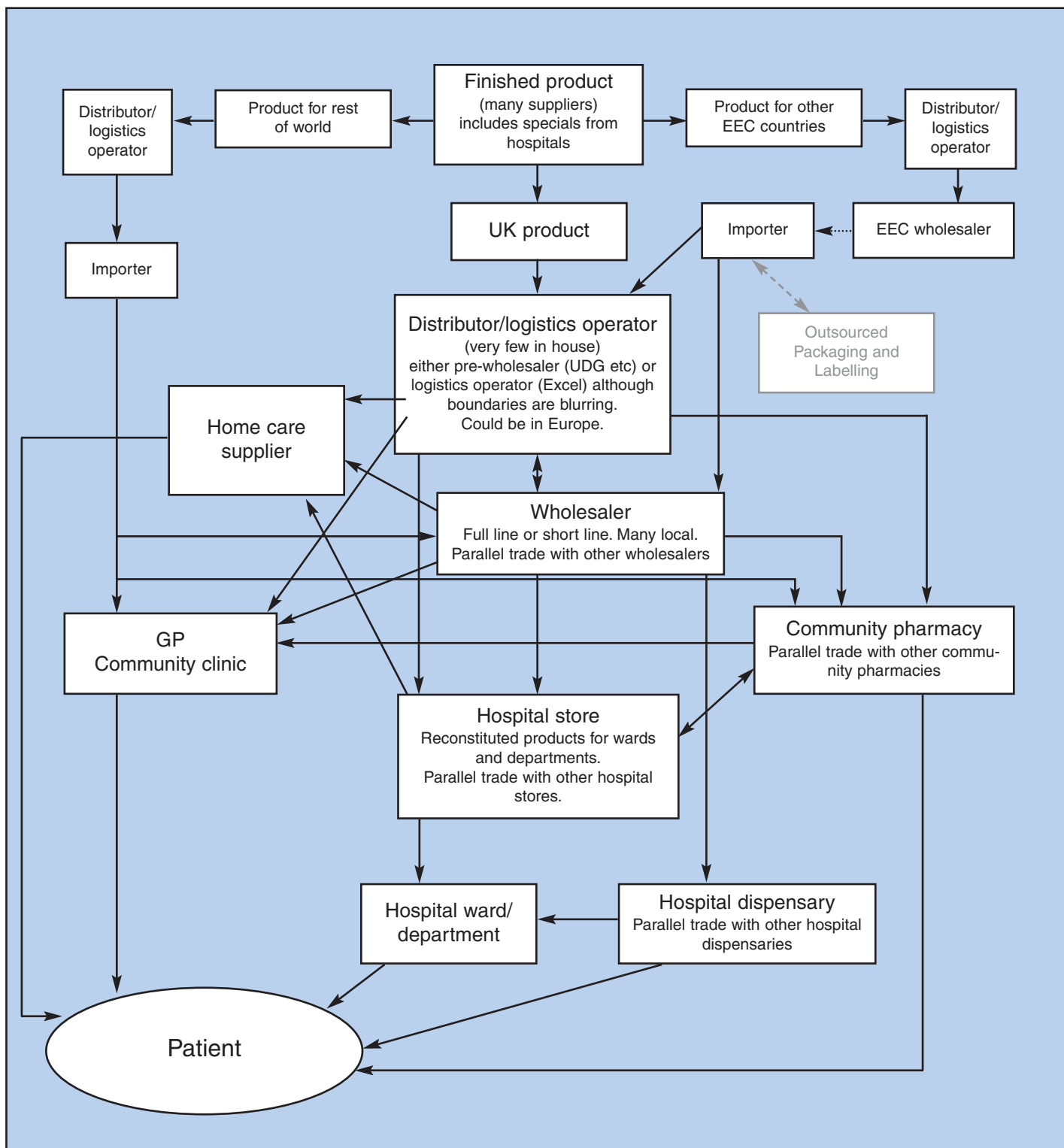


Figure 1: Map of the pharmaceutical supply chain as identified by the risk management workshop

that risk is not passed from one party to another. Attention must also be paid to instigating mitigation strategies that impact on the total supply chain (all entities) positively and do not exacerbate risk as a repercussion of the initial activity. In the case of the PSC, mitigating a risk attached to a product line should not increase the risk associated with another product line, or the relationship between the buyer and supplier.

Disruptions in the supply chain are a major source of risk. The findings from the risk management workshop indicated that

supply disruptions could be seen in the form of availability of raw materials, transportation, disaster recovery, lack of knowledge about the source of supply, rationalisation of product range and theft. Any of these could restrict or stop the flow of products through the supply chain, increasing the risk to the patient.

Conclusion

The aim of this project was to gain a more realistic understanding of the nature and prevalence of risk in the PSC as a preliminary

research exercise. The approach adopted was qualitative and exploratory, because there appeared to be a lack of research on the questions being asked. The aim was realised through the collation of data from a risk management workshop. The workshop proved to be extremely successful, the outputs indicating that further research is warranted.

Risk analysis in the PSC in the NHS is of key importance and has a valuable input into both practice and policy, and therefore research into improving understanding and

management of risk is justified. It affects not only the practitioners and policy-makers, but also the public, as current and future users of this service. Further studies could yield the following benefits:

- Greater visibility of pharmaceutical supply chain activities and players
- Identification and rating of risks
- More structured planning ability to strengthen practice and systems
- Informed contingency/recovery planning
- More effective management of the impact of high severity events on recipients, eg, unknown disasters
- Reduction in the impact of low severity events such as a breakdown in buyer-supplier relationships

However, while some of the industry seems to be active in pursuing this subject, others do not seem to be less enthusiastic. The 20 contributors to the risk management workshop were representative of a cross-section of this supply chain, thus their views are representative of general feeling and concern about the level of risk attached to key issues. The views produced were consensual, the key issues and ratings discussed and agreed by the whole group. This is evidence that despite the complexity of the PSC there is a willingness to come together as a joint body to discuss topical matters. Participants were brought together by a neutral party (University of Bradford School of Management), which also facilitated the sessions.

The workshop facilitated the coming together of members of the PSC to put forward their individual views on risk and its management. Of course, I am not blind to the fact that all organisations have their own interests and agenda when approaching this issue. Risk mitigation for one party can increase the risk for another, eg, the reduction in stock-holding levels by a supplier can negatively influence its customers' procurement practice. However, that is the business that the supply chain operates for and within, and this will not change. What can change is the way that risk strategies are approached if they do affect multiple parties. Again, success resides in members adopting a network approach to risk management, that considers all the af-

Panel 3: Recommendations

- There is a need for a structured approach to understanding the nature of risk in the pharmaceutical supply chain to manage it effectively. This would involve detailed analysis of the various party and agency activities concerning risk management, mitigation activity and successes.
- A responsible body or team needs to be identified to co-ordinate this activity.
- An assessment should be conducted to determine which areas of the PSC need to be risk assessed to minimise supply disruption, eg, do new suppliers need to be risk assessed to ascertain their ability to ensure supply continuity? Or does an appropriate body have an alternative activity in place which negates this?
- Consultations should be performed on a continuous basis with PSC participants, representative of the total supply chain.
- The question of whether there is a demand or need for a dedicated or customised risk assessment tool or framework needs to be explored. If there is a demand, its benefits over traditional models need to be defined. Decision-making should be assisted by risk management specialists.
- Adequate training packages need to be developed and disseminated to decision-makers within the PSC about the presence of risk and its mitigation strategies. This would involve strategists, policy makers, procurement bodies, staff and key pharmaceutical personnel, eg, pharmacy specialists. Such risk education is provided by the Health and Safety Executive to schools and higher level educational institutions to students as young as 14, so why not staff in the NHS (UK) where such training would be essential?

ected parties, as opposed to just considering themselves. This may make risk analysis more difficult and challenging, but could yield more effective results.

From the research findings a set of recommendations have been made to develop pol-

icy and practice within this area (Panel 3). At the end of this analysis, a question seems to be pertinent: is risk management something that is and has to be done but that no one gets that excited about? There is evidence in NHS literature and practice that risk assessments and risk management practice are conducted as a matter of expected and good practice.

This analysis did not attempt to examine risk assessment and management in health-care from a clinical perspective, but cannot ignore the fact that risk management practice appears to be well developed in this area, possibly because risk is perceived to be greater the closer to the patient, or because there is high-level visibility and public accountability at the "coal face".

There is no evidence, however, that there is a strategy that focuses on risk across the total pharmaceutical supply chain in the NHS. That is astonishing, considering the impact of supply disruptions. If pharmaceutical products or associated equipment are delayed in reaching hospitals or pharmacies, patients could die. This is not being melodramatic. It is a statement of fact.

Future research

A future research agenda has been identified to build on these findings. The aim will be to develop a typology of risk in the PSC as applied to NHS hospital pharmacy and provide appropriate and realistic mitigation strategies to manage risk more effectively. The research will encompass data collection from within the UK, the US and Europe. The outputs of this will indicate areas of success or centres of excellence in practice and outcome, eg, in product sourcing, supplier management etc, which should be developed further and shared nationally and internationally. A funding bid for this research is currently with the Engineering and Physical Sciences Research Council.

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Notes and references

1. Savage CJ, Roberts KJ, Wang XZ. A holistic analysis of pharmaceutical manufacturing and distribution: are conventional supply chain techniques appropriate? *Pharmaceutical Engineering* 2006; (July/August):10–18.
2. Knight LK. Roles, relationships and dynamics of the pharma network. A discussion document on opportunities for supply research. Draft internal report to the NHS Purchasing and Supply Agency 2005.
3. Zsidisin G, Melnyk SA, Ragatz GL, Burns LA. Preliminary findings from a supply risk audit instrument. *Proceedings to IPSERA Conference 2006*; Paper 43.
4. Christopher M, Lee H. Mitigating supply chain risk through improved confidence. *International Journal of Physical Distribution and Logistics Management* 2004;34: 388–96.
5. Zsidisin G, Ellram LM, Carter JR, Cavinato JL. An analysis of supply risk assessment techniques. *International Journal of Physical Distribution and Logistics Management* 2004;34: 397–413.
6. Peck H. Drivers of supply chain vulnerability: an integrated framework. *International Journal of Physical Distribution and Logistics Management* 2005;35:210–32.
7. Chopra S, Sodhi MS. Managing risk to avoid supply-chain breakdown. *MIT Sloan Management Review* 2004;46:53–61.
8. Hallikas J, Karvonen I, Pulkkinen U, Virolainen VM, Tuominen M. Risk management processes in supplier networks. *International Journal of Production Economics* 2004;90:47–58.
9. Matthew L, Bain T. Bridging the gap. Patient safety: the role of the National Patient Safety Agency in helping pharmacists to improve patient safety. *Pharmacy Management* 2006;22:2–8.
10. World Health Organisation. Counterfeit medicines. 2006. Available at: www.who.int/mediacentre/factsheets/fs275/es (accessed 12 January 2007).
11. Haigh J. IMS Global Consulting, quoted in 'Parallel trade in medicines'. Social Market Foundation: 2004.
12. European Federation of Pharmaceutical Industries and Associations. *Pharmaceutical Supply Chain Evolution*, EFPIA Position Paper.