

Chapter 15

THE IMPACT OF PRODUCT LIABILITY LEGISLATION ON THE PROCUREMENT OF PHARMACEUTICALS WITHIN HPSS TRUSTS IN NORTHERN IRELAND

Ruth Fee and Jill Mairs

INTRODUCTION

In National Health Service (NHS) Trusts within N. Ireland, pharmacists are responsible for procuring medicinal products and other pharmaceutical products for administration to patients. Pharmaceutical care has previously been defined as the responsible provision of drug therapy for the purpose of achieving outcomes that improve a patient's quality of life (Hepler & Strand, 1990). Pharmacy is involved in ensuring the quality of the medicines management systems from the initial purchasing and supply of a medicine through supporting good quality prescribing and dealing with errors to ensure continuity of care on discharge. Recent developments in clinical governance and risk management within the NHS have highlighted the significance of product liability legislation to pharmacists, as the legislation applies to pharmaceutical products.

The introduction of clinical governance as a key component of the UK Government's modernisation strategy provided, for the first time, a coherent framework for quality improvement in the NHS. Clinical governance was introduced in the NHS Executive (1998) *White Paper "A First Class Service."* It was defined as "a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which excellence in clinical care will flourish" (see <http://www.doh.gov.uk/newnhs/quality.htm>). The Chief Executive of any NHS Trust is now directly responsible for the quality of clinical care and the role of medicines is a key area for the attention of Chief Executives, as the use of drugs and the quality of prescribing will be a significant element of clinical governance arrangements.

The importance of risk management within the procurement process has also been highlighted within the NHS Executive (1999), *Governance in the*

New NHS: 1999/2000 Risk Management and Organisational Controls and in the NHS Executive (2001) *Governance in the new NHS: Controls Assurance Statements 2000/2001*. Controls assurance is a holistic concept based on best governance practice. It is a process designed to provide evidence that NHS organisations are doing their “reasonable best” to manage themselves so as to meet their objectives and protect patients, staff, the public and other stakeholders against risks of all kinds. The Controls Assurance Standard on Purchasing and Supply requires that:

There is an environment which ensures, as far as reasonably practicable, that all purchasing and supply activity is managed to meet the needs of the organisation through the consistent delivery of best value and appropriate management of risk and complies with the relevant statutory requirement” (NHS Executive’s controls assurance website www.doh.gov.uk/riskman.htm).

NHS Controls Assurance Standards have already been implemented in England and will soon be implemented in N. Ireland and it is therefore critical that the pharmaceutical procurement process should consider how to manage issues of product liability and how they impact on patient safety.

Product liability refers to the legal liability that arises out of the design, manufacture, distribution, sale and disposal of a product. If a product is defective or causes harm or injury to a person or his/her property while it is being used for its intended purpose – or in a reasonably foreseeable manner – the manufacturer, seller or both may be liable. This paper therefore aims to review the current UK and European product liability legislation and case law and assess the implications for the purchasing and supply of pharmaceutical products within NHS Trusts. Following evaluation of the legal issues, it aims to review the need for subsequent changes in these pharmaceutical procurement processes to address issues of product liability. The authors map the actors and agents in the present pharmaceutical procurement process, and highlight the complex nature of the process and the significant number of actors and agents which pharmacists need to be aware of, and comply with, when procuring pharmaceuticals

RELEVANT LEGISLATION

Sale of Goods Act 1979

Currently all consumer sales transactions in the UK are governed by the provisions of the Sale of Goods Act 1979. The main provisions are those contained in S.13, s 14(2) and s.14(3). These three sections imply terms into a contract of sale between a consumer and retailer requiring goods to meet

the contract description, be of satisfactory quality and be fit for a particular purpose made known to the retailer before the sale was completed.

The statutory implied terms in contracts for the supply of goods offer extensive protection to a person who purchases goods, which could prove to be defective. Breach of the implied term may entitle the buyer to reject the goods and claim damages for any losses caused by the breach, including for personal injuries and damages to other property as well as for the reduced value of the defective goods themselves. Being based on the statutory implied terms, the claim lies in the contract and, as a result, is a claim against the immediate supplier of the goods. The protection of implied terms is limited by the doctrine of privity of contract, and the terms therefore give the buyer no rights against the manufacturer of the goods, or anyone else involved in the distribution of the goods.

However, it was established in *Donoghue v Stevenson* [1932] AC 562 that in certain circumstances a manufacturer owes a duty of care to the ultimate user of his products, and may therefore be held liable in negligence if, as a result of negligence in manufacture, the product is defective and causes loss or injury to the consumer. In addition a manufacturer may now incur strict liability in tort under the Consumer Protection Act 1987.

Consumer Protection Act 1987 (Part 1)

Part 1 of the Consumer Protection Act 1987 ('CPA') which implements into UK law the Product Liability Directive 985/374/EEC, came into force on 1st May 1988. Although Part 1 applies in Great Britain only, equivalent provision for Northern Ireland was made by Order in Council. Part 1 of the Act, and the Northern Ireland Order, excepted primary agricultural products and game (i.e. food sold in its raw state) from the scope of the legislation. However Directive 1999/34/EC amended the 1985 Product Liability Directive by requiring the removal of this exception with effect from 4th December 2000. From this date food sold in its raw state is included in the legislation. This was implemented in the Product Liability (Amendment) Act (Northern Ireland) 2001.

Part 11 of the CPA, containing consumer safety provisions, came into force on 1st October 1987. These provisions apply throughout the UK. Further information on the CPA is available in a guide published by the Department of Trade and Industry (DTI) (website: <http://www.dti.gov.uk/ccp/topics1/safety.htm>). The legislation imposes strict liability on producers for harm caused by defective products. This means that people who are injured by defective products can sue for compensation without having to prove the producer negligent, provided they

can prove that the product was defective and the defect in the product caused the injury. The CPA removes the need to prove negligence. A customer can already sue a supplier, without proof of negligence, under the sale of goods law. The Act provides the same rights to anyone injured by a defective product, whether or not the product was sold to them. The Act does not affect any existing civil laws governing product liability. No liability is imposed under the Act in respect of products first supplied before 1st March 1988.

An injured person can take action against producers, importers and own-branders (suppliers who put their own name on the product and give the impression that they are the producers). Other suppliers such as wholesalers and retailers are not liable unless they fail to identify the producer importer or “own-brander” if asked to do so by a person suffering damage. Liability under the Act is joint and several, so the plaintiff may sue both (or all, if more than two) defendants. It is not possible to exclude liability under the Act by means of any contract term or other provision. The legislation applies to all consumer products and products used at a place of work. The Act is not intended to extend to pure information. Printed matter is not therefore covered, except in the case of instructions or warnings for a product (in which case the producer of the product – not the printer- will be liable for errors or omissions in the instructions or warnings that make the product unsafe). This is of particular relevance to the pharmaceutical industry.

A defective product is defined as one where the safety of the product is not such as persons generally are entitled to expect. This definition provides an objective test of defectiveness and refers neither to the particular injured person nor to the particular producer. A product will not be considered defective solely because it is of poor quality. A product will not be considered defective simply because a safer version is subsequently put on the market.

When deciding whether a product is defective a court will take into account all the relevant circumstances including:

- The manner in which the product is marketed,
- Any instructions or warnings that are given with it,
- What might reasonably be expected to be done with it, and
- The time the producer supplied the product

A person can sue under the Act for compensation for death, personal injury and damage to private property (provided the amount of loss or damage to

property is £275 or more). The Act imposes no financial limit on a producer's total liability. A plaintiff must begin a court action within three years of the date he or she was injured or if later, the date when they knew that they had a claim against the defendant. However, an injured person cannot sue under this part of the Act if ten years have elapsed since the defective product was supplied by the producer.

The European Commission has recently reviewed the Product Liability directive (85/374/EEC and 1999/34/EC), as required every five years. The Commission launched the review by publishing a Green Paper on Liability for Defective Products in July 1999. A summary of the Green Paper can be accessed via the DTI's website (<http://www.dti.gov.uk/ccp/topics1/safety.htm#prod%20liability>).

General Product Safety Regulations 1994

The general safety requirement under section 10 of the CPA has been largely superseded by the General Product Safety Regulations 1994 (the GPS Regulations) which came into force on 3 October 1994. The GPS Regulations – made under the European Communities Act 1972- implement the General Product Safety Directive, which introduced a Community- wide general safety duty. Although Section 10 of the Act remains in force, it will now apply only in very limited circumstances. A revised General Product Safety Directive (Directive 2001/95/EC) was adopted in October 2001. The revised text was published in the Official Journal on 15th January 2002. Member States have until 15th January 2004 to transpose the revised Directive into their national legislation.

Products covered by the GPS Regulations include (but are not restricted to) clothing, medicines, primary agricultural and horticultural products, DIY tools and equipment, food and drink, household goods and motor vehicles. The regulations place a general duty on all suppliers of consumer goods to supply products that are safe in normal or reasonably foreseeable use.

The General Product Safety Directive is intended to fill the gaps in European consumer safety legislation. It achieves this by specifying that products supplied to consumers, whether for a consideration or provided free of charge, must be safe; defining a safe product; and laying down a framework for assessing safety.

The Consumer Safety Unit of the Department of Trade and Industry has overall policy responsibility for the Regulations, but the departmental sectoral responsibilities for safety matters remains unchanged. The

Medicines Control Agency has responsibility for licensed medicines for human use.

The Regulations apply to all persons in the business supply chain who are established in the UK and supply consumer goods in the UK. Suppliers include manufacturers, importers, wholesalers, retailers, hirers and in certain circumstances, letting agents and auctioneers. Suppliers are categorised as producers and distributors. Producer in relation to a particular product means:

- a. The manufacturer (where he is established in the European Community);
- b. Any person who presents himself as the manufacturer by putting his name or trade mark on the product;
- c. Any person who repairs or reconditions the product; or
- d. Other professionals in the supply chain if their activities may affect the safety properties of a product after it has been supplied to them.

A distributor is required (regulation 9) to act with due care to help ensure that the products he supplies are safe. In particular he must not supply products, which, as a professional, he knows or should have presumed, on the basis of the information in his profession, to be dangerous. A professional is considered to refer to the knowledge and expertise which the distributor could reasonably be expected to have available to him, either alone or with others, having regard to the nature of business activity and to other relevant factors (e.g. whether he is required to have a specialist education, knowledge or training in order to enter that business).

The Medicines Act 1968

The manufacture and sale or supply of medicinal products was first brought under legal control by the Medicines Act 1968. This was subsequently incorporated into European Law by EEC Directive 65/65. The Medicines Act (which was a response to the 1960's thalidomide tragedy in the UK) involves licensing, regulation and surveillance of medicine manufacture, supply, promotion and provision. The Medicines Control Agency (MCA) is an Executive Agency of the Department of Health and is responsible for protecting public health by ensuring the safety quality and efficacy of medicinal products. A recent National Audit Office Report (2003) on the regulation of medicines in the UK reported that the MCA has a good track record in ensuring licensed medicinal products have a favourable balance of risks and benefits when used as directed.

Article 3 of Directive 65/65/EEC states that no medicinal product may be placed on the market unless a Marketing Authorisation (more commonly known as a Product Licence in the UK) has been issued.

The Medical Devices Regulations 1994

The EC Medical Devices Directive 93/42/EEC was implemented in the UK by the Medical Devices Regulations (SI 1994 No 3017). Products that are defined as medical devices, are regulated by the Medical Devices Agency and cannot be placed on the market without a declaration of conformity which is subject to approval by an independent certification house (known as a notified body). As from 1st April 2003, the Medicines Control Agency and the Medical Devices Agency have merged to form the Medicines and Healthcare Products Regulatory Agency (MHRA).

The Consumer Guarantees Directive (Directive 99/44EC)

In May 1999, the European Union adopted its Directive on Certain Aspects of the Sale of Consumer Goods and Associated Guarantees (The Consumer Guarantees Directive). Whilst this had to be implemented by the Member States by 1st January 2002, the UK government has yet to implement the Directive. The Department of Trade and Industry (DTI) recently published its second consultation, together with draft Regulations, on the implementation of the Directive. The proposals for implementation put forward by DTI are discussed in a recent article by Twigg-Flesner (2002). The Directive essentially contains three sets of rules: first it creates a quality standard (the conformity with the contract requirement). Second it introduces a two-stage remedial regime which applies when a consumer has bought a product which is not in conformity with the contract. Finally, there are some rules on free guarantees that are sometimes given out by retailers and manufacturers: these guarantees have been a grey area as there is no existing domestic legislation specifically addressing them.

PRODUCT LIABILITY CASES FOR PHARMACEUTICAL PRODUCTS

In the UK, although there has not been a tide of US-scale litigation in relation to product liability for pharmaceutical products, there have been a few recent cases, which could have a bearing on the future direction of product liability cases. It is arguable that all medicinal products carry a risk of adverse reactions, even in a minority of consumers, and that these consumers are not necessarily entitled to expect that the products will be risk-free. Despite the emphasis on consumer expectation Goldberg (2002) stated that there is an inherent logic in addressing the problems of defective

medicinal products, by weighing the risks against anticipated benefits and against 'costs' of not using the product, such as the risk of disease. In the United States a risk-utility analysis has often been made in such cases.

In a succession of major English cases from the mid 1970's, a total of around 23,600 claimants brought claims in a succession of multiparty claims against manufacturers involving DTP vaccine, Opren, Myodil contrast media, benzodiazepine tranquillizers and the Norplant subcutaneous contraceptive (Hodges, 1999). However, no case proceeded as far as a final trial on liability. The failure of the DTP vaccine, tranquillizer and Norplant litigation in the UK can be contrasted with the fact that the manufacturers settled similar claims in the USA at enormous cost in order to avoid even greater costs of years of litigation. In 2000, a case was heard relating to the failure of a condom resulting in pregnancy, but the judge held that the defendant's in the case had never claimed that a condom was 100% effective, and therefore the claim failed¹ In March 2001, the first ever successful UK product-related class action (*A v National Blood Authority* [2001] 3 All E.R. 289) under the Consumer Protection Act strict liability was decided, when six test cases (representing a total of 114 claimants) obtained awards of up to £210,000 from Hepatitis C infection from NHS blood transfusions. Goldberg (2002) notes the implications of this case, as it was the first opportunity of its kind in the UK to assess the problem of strict medicinal product liability in the context of a multi-party action.²

A further indication of the consumer expectation approach in the European Union was evidenced by the case of *Scholten v Foundation Sanquin of Blood Supply* [1999] H/98.0896, County Court of Amsterdam. The claimant received an HIV infected blood transfusion from a donor. The Court held that the blood product was defective because the general public expected that blood products in the Netherlands had been one hundred per cent HIV free for some time. In contrast, the UK High Court has recently thrown out the case against Schering, Organon and Wyeth based on research finding in 1995 that the so-called third generation oral contraceptives (OC) posed a greater risk from venous thrombosis than the second generation (*XYZ v Schering Health Care Ltd* [2002] EWHC 1420 (QB)). The court found, having carried out a "most exhaustive examination" that there was no such increased risk (PharmaLaw Newsletter, 2002). However, the OC case has not deterred new claims; for example, a firm of UK solicitors has set up the "Seroxat Users Group" for patients who receive the antidepressant alleging links between the product and suicide, addiction and aggression.

IMPLICATIONS FOR PHARMACEUTICAL MANUFACTURERS

All companies are likely to supply defective products at some stage. In many circumstances, the product will not cause any harm; however this is not usually the case for defective medicines. Further, Europeans are following North Americans in becoming more aware of their rights in product liability cases and less willing to tolerate corporate mistakes (Bell, 2000). Compensation for serious personal injury claims can amount to several millions of pounds particularly where permanent healthcare is required and there is a significant loss of future earnings. Claims against pharmaceutical companies in the UK are rare, but if they do occur, the number and cost can be substantial.

Liability may arise in tort, by contract or, under the EU Directive on Product Liability 1985 (Directive 85/374/EEC). Liability in tort arises from negligence and is based on the idea that a supplier of goods owes a duty to the consumer to take reasonable care. In the UK this principle was established in 1932 (in *Donoghue v Stevenson, op. cit.*) when a woman became ill after drinking some of the contents of an opaque bottle that was found to include a decomposed snail. Liability in contract arises from agreements between the parties to contract but also includes the implied terms that apply to all agreements to sell goods – namely, that they are fit for their intended purpose and of sufficient quality to be sold. So how therefore can managers defend their pharmaceutical companies against the risk of these claims? There are several defences, the most notable being the development risks defence.

Development Risks Defence

This defence prevents producers from being liable for defects or dangers of which they could not possibly have known as they were beyond scientific and technological knowledge at the time a product was supplied. This very controversial defence was included in Article 7 (e) of Directive 85/374/EEC at the insistence of the UK government. The defence could be particularly important in relation to innovative, high technology products and new drugs.

The inclusion of the developmental risks defence is controversial for two reasons. First as a matter of general policy, it undermines the principle of strict liability and lowers the level of consumer protection provided. The Pearson Royal Commission on Civil Liability and Compensation for Personal Injury, which recommended the introduction of a system of strict product liability in the UK in 1977, opposed the inclusion of such a defence, on the grounds that to exclude developmental risks from a regime of strict product liability would be to leave a gap through which, for example, the

victims of another Thalidomide disaster might easily slip. Secondly, it has been argued that the wording of the UK legislation is more favourable to the producer than that of the directive. The directive permits the producer to be exempted if “the state of scientific and technical knowledge at the time he put the product into circulation was not such as to enable the existence of the defect to be discovered”. The directive therefore seems to be concerned with the state of scientific and technical knowledge generally, whereas the CPA refers to what a producer of similar products might be expected to discover. The European Commission therefore brought proceedings against the UK government for failing to properly implement the directive (*EC Commission v United Kingdom* (C 300/95) [1997] All ER (EC) 481). The European Court of Justice however, held that the Commission had not established that the UK legislation would not achieve the same effect as the directive. The Commission has expressly sought feedback on the operation of the development risks defence in its 1999 Green Paper on the Directive. The European Federation of Pharmaceutical Industries and Associations (EFPIA) (1999) produced a position paper in response to the Product Liability Green Paper and EFPIA stated that the development risks defence is critical to the protection of European innovation for medicinal products.

Cases of Failure to Warn

In the USA, historically, medicinal products and medical device manufacturers has successfully asserted a “learned intermediary defence” against failure to warn liability suits (Quinley, 2003). This legal doctrine holds that companies only have a duty to warn the doctor – not the patient/consumer- of contraindications and potential complications of using a product. It was recently reported that 20 patients in the UK have been granted legal aid to sue a number of doctors and authorities claiming that the anti-epileptic, sodium valproate caused fetal defects. Despite strong warnings on the labelling about use of the products in women of childbearing age, it is alleged that the risks were not sufficiently brought to the attention of relevant patients (*PharmaLaw Newsletter*, 2002).

IMPLICATIONS FOR THE PROCUREMENT OF PHARMACEUTICALS WITHIN NHS TRUSTS

As previously discussed the Consumer Protection Act (1987) introduced the concept of “strict product liability” to medicines. If a patient can demonstrate he/she has suffered injury whilst undergoing a course of treatment and the medicinal product was defective, then he can bring an action for damages against the manufacturer of the medicine, without

proving negligence. This applies to all medicines, whether licensed or unlicensed. In manufacturing and selling pharmaceuticals, companies owe to consumers, a duty of care to assure that their drugs, medications and medical devices are reasonably safe when used as intended.

In Northern Ireland the Pharmaceutical Contracting Executive Group (PCEG) is responsible for the strategic management of the procurement and supply of pharmaceuticals by HPSS Trusts. Its fundamental role is to ensure that regional contracting for pharmaceuticals is fully effective in securing the optimum value for money and appropriate management of risk. The Management Executive of the DHSS published Mini Code Guidelines on Contract procedures (DHSS Circular HSS (WS2) 1/74) in April 1974 which applied financial limits for quotations, tenders and open competitive tendering for all goods and services purchased within the NHS. A subsequent amendment HSS (PPD) 2/93 amended the financial limits and recently they were again revised by DHSS&PS (HSS (PPD) 12/2003) on the 21st January 2003. All orders above £30,000 in value must be subject to open competitive tendering. Moreover, the UK Public Supply Contracts Regulations 1995 implements the EC Supplies Directive into UK legislation ensuring that all contracts for the supply of goods (including pharmaceuticals) exceeding £154,477 limit are subject to the Regulations.

The PCEG in NI is responsible for the following major contracts: Regional Medicinal Products Contract; Regional Surgical Dressings Contract; Regional Medical Gas Contract; National Contract for Childhood Vaccines. As purchasers, pharmacists must ensure that all procurement and tendering processes must comply with the statutory regulations, departmental guidance and also consider issues of product liability and patient safety (Cotter, 2001) describes four generic types of product defect, lack of safety in design, manufacturing defects, defects due to inadequate warning or instructions and a failure to conform to express warranty. The objective test for a defect requires safety to be such as persons *generally* are entitled to expect. Therefore, to ensure the procurement process minimises the risk of any defect occurring in pharmaceuticals, a number of following issues need to be considered: These issues are explored beneath before attempting to map the actors and processes in the procurement process.

Design Defects	Licensing, Standards and Specifications
Manufacturing Defects	Quality and Technical Issues, Supplier Vetting, Product Recall
Inadequate warning	Labelling, Packaging and Patient Information Leaflets (PIL's)

Licensing

The Medicines Control Agency (MCA) is an Executive Agency of the Department of Health and is responsible for protecting public health by ensuring the safety quality and efficacy of medicinal products. The licensing procedures for relevant medicinal products for human use have recently changed to guarantee uniform standards of safety, efficacy and quality across the European Union. The European Medicines Evaluation Agency (EMA) was established in January 1995 and marketing arrangements for medicines that will be binding across the European Union were introduced. No relevant medicinal product for human use can be placed on the market without a Product Licence, or Marketing Authorisation. All distributors of medicinal products must have a Wholesale Dealers Licence.

Unlicensed Medicines

The term 'unlicensed medicines' is normally applied to those medicines which do not have a Marketing Authorisation (MA) formerly Product Licence (PL) issued by the Medicines Control Agency (MCA) or the EMA. It is applicable also to licensed medicines when they are used for unlicensed indications. For good clinical reasons, the use of such medicines is widespread in hospitals. The use of unlicensed medicines is the responsibility of the prescriber and, when procuring unlicensed medicines, the ordering pharmacist is considered to be the manufacturer. If a patient is harmed by a defective medicine, whether unlicensed or licensed, then the supplier of that medicine is liable for the harm. If the supplier can identify the manufacturer of the medicine, then liability passes to the manufacturer. If the medicine has been prepared by or under the supervision of a pharmacist, then the pharmacist is liable for the harm, as the manufacturer of the medicine. If the medicine is unlicensed or is used for an unlicensed indication (i.e. in breach of the terms of its Marketing Authorisation) then the pharmacist who placed the order is considered in law to be the manufacturer and is liable as such.

It is therefore in the interest of the ordering pharmacist to establish an adequate system to ensure the quality of unlicensed medicines. Pharmacists have a duty to ensure that, if informed by the prescriber that a product is to be used for an unlicensed indication, the prescriber is made fully aware of his professional responsibilities and liabilities in respect of the use of that product. He/she must also give written advice to the prescriber that a medicine is unlicensed as the prescriber can avoid liability if he/she can demonstrate that he was unaware of a medicines unlicensed status.

Parallel Imports

Parallel trade for medicinal products, as with other classes of goods is based upon two fundamental European Union principles:

- Free movement of merchandise; and
- Exhaustion of patent and trade mark rights.

All parallel imports must be imported from a Member of the European Community and have a valid Marketing Authorisation (MA) under Directive 65/65EEC. The products must be manufactured by (or under licence to) the same group of companies as the UK product. They must also have no differences, having a therapeutic effect, from the UK product. Parallel importers are required to hold a Wholesale Dealers Licence and a Manufacturing licence (assembly only). Parallel importers are required to ensure that all imported medicinal products are labelled in English according to the Medicines Act 1968. The shape and colour of the parallel-traded brand as well as the outer packaging may vary in some instances from the UK version and in a very few cases the additives may be different. Therefore it is important that pharmacists assess parallel imported products and their suitability for patients. Although the parallel importer will be liable for the quality of the product, the pharmacist may have a duty of care responsibility to ensure the product meets a patient's need.

A Health Authority, Board or Hospital Trust is required to indemnify its employees against the financial consequences of personal liability claims in accordance with the Clinical Negligence Funding Scheme or equivalent, except where such negligence arises from actions of bad faith, misconduct or gross lack of care. However, an employer cannot indemnify his employees against the personal consequences of criminal liability.

Specifications /Standards

Relevant British or European Standards can be taken into account in assessing the safety of a product and can be included in tender specifications. The British Standards Institution (BSI) can provide information about published safety standards for general products. Their website can be visited on <http://www.bsi-global.com>. However, as previously discussed, presently the Medicines Control Agency (MCA) is responsible for safety issues for medicinal products and the Medical Devices Agency is responsible for medical devices. The MCA merged in April 2003 with the Medical Devices Agency to form the Medicines and Healthcare Products Regulatory Agency.

There are two pharmacopoeias that have legal status within the UK – the British Pharmacopoeia (BP) and the European Pharmacopoeia (Ph Eur). The BP and Ph Eur compose monographs, which set out the mandatory standards for active substances, excipients and formulated preparations. The BP 2000 was published in May 2000 and came into effect on 1 December 2000. It is produced by the MCA as a package of printed volumes, CD-ROM or on the web-site <http://www.pharmacopoeia.org.uk>. The Ph Eur is produced by the European Pharmacopoeia Commission (EPC), which is part of the Council of Europe's European Directorate for the Quality of medicines (EDQM). The current edition was published in August 2000 and came into effect on 1 January 2001. It is available in book form and on CD-ROM or on the web-site <http://www.pheur.org>

Pharmacopoeial standards are objective, public standards for medicines and their components. They are compliance requirements, that is, they provide the means for an independent judgement as to the overall quality of a product. The standards apply throughout the shelf-life of a product and are used by a wide variety of organisations including suppliers, purchasers, inspectors, medicine regulators etc. Contracting authorities are required to state in the tender notice and tender documents and in the contract, the technical specifications to be met by the products concerned. In order to avoid discriminatory use of standards, the EC Supplies Directive requires the use of European Standards where they exist. Therefore, for medicinal products (where they exist) the relevant European Pharmacopoeial Standard should be used first followed by the British Pharmacopoeial Standard. Specifications must not be used which refer to goods of a specific make or source or to a particular process and which have the effect of favouring or eliminating particular goods or suppliers. Therefore generic (non-proprietary) descriptions must be used instead of proprietary names for medicinal products. On January 1 1994, Directive 92/27/EEC came into force, giving the requirements for the labelling of medicines and outlining the format and content of patient information leaflets to be supplied with every medicine. The directive also requires the use of Recommended International Non-proprietary names for drugs.

Quality and Technical Issues

In Northern Ireland, the Regional Pharmaceutical Laboratory Service (RPLS) co-ordinates a reporting mechanism for sub-standard pharmaceutical preparations. This system primarily concerns less serious faults but is of considerable importance in gauging the extent of individual problems, informing the contracting process, providing feedback to the industry in the interest of improving product quality. The Pharmaceutical

Contracting Executive Group (PCEG) strongly supports this scheme which is detailed in Substandard Pharmaceutical Preparation (RPLS, 1996).

Supplier Vetting

To prevent contracting authorities eliminating suppliers on the grounds that are discriminatory, the EC Supplies Directive lists a number of possible selection criteria. These relate to the good repute, professional qualifications, economic and financial standing and technical knowledge of the supplier. Distributors should also be vetted to ensure they maintain the appropriate standards and hold the relevant licences (e.g. for medicinal products a Wholesale Dealer's Licence).

Defective Product Recall and Reporting

If it becomes necessary to withdraw a product because it is discovered to be potentially dangerous, recall procedures can ensure that the defective products are traceable. This can be critical in relation to pharmaceutical products. The Medicines Control agency is responsible for monitoring the safety and efficacy of medicinal products and implementing recalls of defective products. In June 2001, the pharmaceutical branch of DHSS&PS issued revised Guidance to Boards and Trusts on reporting defective medicinal products (CPh5/01). This guidance did not represent the introduction of a new scheme but aimed to clarify the established scheme and provide the basis for a consistent approach to the reporting of suspected defective medicinal products throughout the HPSS. Boards and Trusts are required to report defects in medicinal products to the DHSS&PS and the Medicines Control Agency. The guidance also requires Boards and Trusts to take action following issue of Drug Alerts by the DHSS&PS. Adverse reactions to medicinal products are dealt with separately under the Adverse Reactions Reporting scheme ("Yellow Cards") operating under the Medicines Act 1968.

Following withdrawal of a medicinal product the company may face product liability litigation. For example, Bayer withdrew (cervistatin) Baycol, which was sold under the name Lipobay in countries outside the United States, in August 2001 after it was linked with more than 50 deaths worldwide. Side effects complained of include depression, stomach and kidney problems and heart failure. Wenning (2002) stated that the company now faces 3,500 lawsuits in the United States. In Germany, US lawyers were understood to have joined forces with a German law firm so as to add German and other non-US plaintiffs to a US class action (under which the

damages would potentially be greater than any likely award in Europe). Claimant lawyers suggest that damages could amount to \$800 million.

A similar monitoring system for medical devices is regulated by the Medical Devices Agency (MDA). The UK Medical Device Regulations implement the EC Medical Devices Directives. These require medical device manufacturers to report to the Medical Devices Agency (MDA) certain incidents regarding their products.

The Northern Ireland Adverse Incident Centre (NIAIC) is responsible for investigating reports of events relating to medical equipment, non-medical equipment, buildings and plant. DHSS&PS issued guidance on the Reporting of Adverse Incidents and Disseminating Warning Notices relating to medical equipment, non-medical equipment, building and plant in November 2000 (PEL(00)15). It is clearly critical that pharmacists have adequate recall procedures in place and do not supply a defective product to a patient. If they did supply (after a product was recalled by MCA or MDA) could they (as well as the manufacturer) face product liability litigation?

Labelling, Packaging and Patient Information Leaflets (PIL's)

The safe use of all medicines depends on users reading the labelling and packaging carefully and accurately and being able to assimilate and act on the information presented. Medication errors occur due to many factors such as training, communication, storage and supervision. Recently the Committee on Safety of Medicines has reviewed factors that are involved in labelling and packaging and as a result of their work have agreed the principles that should be used when labelling for medicines is drawn up. Subsequently, Best Practice Guidance on the Labelling and Packaging of Medicines were published by MCA in December 2002.

When the guidance is applied it will help to ensure that the critical information necessary for the safe use of the medicine is legible, easily accessible and that users of medicines are assisted in assimilating this information so that confusion and error are minimised. This best practice guidance is to be read alongside the legislative requirements, which are set out in Title V of Council Directive 2001/83/EEC. It has no legal standing but will be taken into account when the MCA assess the labelling provided with mutual recognition and national licence applications.

The law requires that all medicines with marketing authorisations in the UK have an approved leaflet, which will be included in the packaging before the medicines are sold or supplied. Recently DHSS&PS (2002) have issued guidance on the provision of Patient Information Leaflets (PIL's) for

medicinal products. When patients have medicines administered to them in hospital, the requirement to include a PIL in the packaging does not arise. However, the leaflet should be available in the pharmacy or on the ward so that it can be supplied to the patient on their request. Systems should be in place to ensure that patients are aware of the availability of PIL's. The relevant patient information leaflets should be supplied to patients who are self administering medicines whilst in hospital. Medicines supplied to patients that are intended for use outside hospital must be accompanied by a PIL. Patient information leaflets are available for download from the Electronic Medicines Compendium at www.emc.vhn.net. It is important that patients are fully informed regarding their medication as one of the liability concerns would be failure to warn.

The quality and availability of technical information on how to administer and reconstitute the product is important for healthcare staff. This may represent a risk to the patient and increase medication errors, if information is unclear, incomplete, unavailable or is different to the details of a previously routinely used product. A recent example of this is reconstitution of a new BCG vaccine that was issued in Northern Ireland with the wrong diluent. This was a change from the previous diluent used for the old routinely used vaccine and also because the required diluent was supplied in a separate box. This risk is more critical for specialised injectable products where the outcome may be fatal. Therefore staff training on the use of new products is required to minimise this type of risk.

PRODUCT LIABILITY RISK ISSUES FOR NHS TRUSTS

In the past most health services around the world have underestimated the scale of unintended harm or injury experienced by patients as a result of medical error and adverse events in hospitals and other health care settings. This situation is changing. The whole issue of patient safety, medical error and adverse event reporting is becoming a high priority in health care systems in this country and across the world. Building A Safer NHS For Patients (2001) sets out the Government's plans for promoting patient safety following publication of the report An Organisation with a Memory (2000) and the commitment to implement it in the NHS Plan. It places patient safety in the context of the Governments NHS quality programme and highlights key linkages to other Government initiatives. Central to the plan is the new mandatory national reporting scheme for adverse healthcare events and near misses within the NHS.

A new independent body, the National Patient Safety Agency (NPSA) has been established within the NHS. It will implement and operate the

system with one core purpose – to improve patient safety by reducing the risk of harm through error. One of the National targets identified for action is to reduce by 40% the number of serious errors in the use of prescribed drugs by 2005. In addition to this, one of the other areas identified in the report where action could provide some early gains in risk reduction include building safety into purchasing policy within the NHS.

FINDINGS

Legislative

Following the review of the current relevant legislation, it is evident that the major change in product liability legislation within the United Kingdom began when the Council of the European Communities adopted the European Product Liability Directive in 1985. This Directive required all Member States to adopt similar measures for the protection of customers. The UK implemented the directive through Part 1 of the Consumer Protection Act (CPA) of 1987. The CPA has major implications for pharmacists as suppliers of pharmaceutical products as the consumer/patient does not have to prove negligence, only that the product was defective. The review of the case law on pharmaceutical products has highlighted that although there have been few product liability cases against pharmaceutical companies in the UK, when they do occur the damages are substantial. The Blood Transfusion case (*A v National Blood Authority* [2001] 3 All E.R. 289) is likely to be of general application to most product liability cases in the UK under the Consumer Protection Act.

Pharmacists must ensure that strict product liability can be passed back to the pharmaceutical company by adequate record keeping. However, if the medicine is unlicensed or is used for an unlicensed indication (i.e. in breach of the terms of its Marketing Authorisation) then the pharmacist who placed the order is considered in law to be the manufacturer and is liable as such. Pharmacists who purchase parallel imports (which have a Marketing Authorisation) will have a duty of care (under GPSR) to patients to ensure the products are safe and also (under CPA) that any instructions and warnings are available.

The General Product Safety Regulations (GPSR) requires that (as distributors) pharmacists must address product liability issues at all stages. A distributor is required (regulation 9) to act with due care to help ensure that the products he supplies are safe. In particular he must not supply products, which, as a professional, he knows or should have presumed, on the basis of the information in his profession, to be dangerous. A

professional is considered to refer to the knowledge and expertise which the distributor could reasonably be expected to have available to him, either alone or with others, having regard to the nature of business activity and to other relevant factors (e.g. whether he is required to have a specialist education, knowledge or training in order to enter that business). Therefore, under the GPSR, pharmacists will be expected to have a knowledge and expertise as a distributor of pharmaceutical products, which ensures the products are safe. Also the GPSR state the definition of a producer to include other professionals in the supply chain if their activities may affect the safety properties of a product after it has been supplied to them. Pharmaceutical procurement, distribution and stock control are complex processes that require professional expertise. Pharmacists will now have to refer to the 1994 Regulations for their duties and obligations and the criminal sanctions that will be faced if there is a failure to comply with them. Health Trusts cannot indemnify their employees against the personal consequences of criminal liability.

In 2000/2001 the total annual hospital expenditure in N. Ireland on medicinal products was approx £38 million. Therefore the procurement process must also comply with the Public Supply Contracts Regulations 1995 which implemented the EC Supplies Directives.

Internal Controls

As well as complying with the legal requirements, pharmacists also must comply with internal NHS governance controls (both financial and clinical). As previously highlighted, there are product liability issues within the new NHS Executive (2001), *Controls Assurance Standards in Purchasing and Supply, Professional and Product Liability and in Medicines Management*. The procurement process within Trusts must also comply with their current NHS Standing Financial Instructions (SFI's) and the DHSS&PS (1993) Contract Procedure – Supplies, Circular HSS (PPD) 2/93, 6 August 1993.

Professional

Pharmacists also have professional responsibility under their Pharmaceutical Society of Northern Ireland, Code of Ethics and Practice (1997) to familiarise him/herself with and keep abreast of, changes in the legislation relating to his particular field of practice and act within his professional competence. They also have professional responsibility to comply with relevant DHSS&PS professional guidance.

The mire of legislation, policy and professional standards applying to pharmacists in Northern Ireland has never been fully mapped, highlighting all the actors and agents. Therefore, this review of the current position has clarified the major legal, professional and internal NHS product liability responsibilities of pharmacists as purchasers and distributors of pharmaceutical products.

RECOMMENDATIONS

At present, the pharmaceutical procurement process does have a number of controls built within both the procurement and tendering process. However, it is now critical that issues of product liability and risk factors are addressed to ensure patient safety and protect NHS Trusts from any future litigation. Under the GPSR (regulation 9) the distributor has a duty of care responsibility to ensure the integrity of the products. Therefore product liability must be addressed in the day-to-day processes of order, receipt, storage, distribution and recall of products within the Trust pharmaceutical departments.

Standard operating procedures should be in place for:

- Order procedure;
- Purchase and release of non-licensed materials including named patient products;
- Receipt procedure including product acceptance, requiring special handling, recording of batch numbers and expiry dates etc.;
- Stock location and rotation;
- Stock issues and returns;
- Handling breakages and expired stock;
- Product recalls;
- Reporting faults and defects; and
- Reporting supplier problems

The Medicines Control Agency Guidance (1997) MAL 99 requires that all medicinal products be stored and transported under conditions which ensure the quality of the product is maintained according to the manufacturer's recommendations and comply with the terms of the product licence. Therefore, it is critical that the integrity of the product is maintained by an appropriate storage and distribution environment. This is more

important for certain products, which require cold temperature storage (2-8C) to ensure potency and efficacy. Appropriate environmental monitoring should be in place.

There should also be a policy for the retention, archiving and eventual disposal of records in line with current legislation. This is important, as under the Consumer Protection Act, suppliers may be held liable for a defective product if they fail to reveal the name of the producer or importer within a reasonable time. Therefore accurate records on the manufacturers need to be retained for at least 10 years. Staff should be appropriately assessed and trained on the Standard Operating Procedures and they should be audited on a regular basis.

Therefore, it is recommended that an approved audit manual for hospital pharmacy procurement, storage and distribution should be implemented by HPSS Trusts in N. Ireland. The Procurement and Distribution Subgroup of the Guild of Healthcare Pharmacists have produced an Audit document, available on their web-site <http://www.pdig.org>. This audit document is endorsed by the NHS Executive and the National Pharmaceutical Supplies Group.

The aim of the regional contracting process for pharmaceuticals is not only to achieve value for money for the HPSS but also to manage risk. The regional tendering and contracting process has already certain controls in place, but these should be reviewed to minimise product liability risks, particularly for pharmaceutical products, which represent a high risk to patients. Controls can be implemented at different stages of the contracting process (tender, evaluation, and monitoring) to minimise the risk of defective products being procured. However, these controls must not restrict competition and must comply with the Public Supply Contracts Regulations 1995.³ It is strongly recommended that a product liability risk assessment tool for pharmaceutical products should be developed and implemented in the future regional tendering/ contracting process. This may be developed within a Purchasing for Safety Strategy for HPSS Trusts

CONCLUSION

The NHS in England current spends about £11 billion a year on goods and services (Audit Commission, 2002). In 2000/01, NHS acute hospitals spent £1.2 billion on medicines, which accounted for 4.6 per cent of total costs. Many NHS Trusts in N. Ireland are under extreme financial pressure and reducing the costs of purchases represents a relatively painless means of achieving economy. Pharmacists influencing clinicians at the point when

prescribing decisions are made in part to achieve effective financial control. However, although procurement must be linked to clinical decisions, any cost savings must not compromise patient safety. Trusts cannot waive the requirements of the Consumer Protection Act and General Product Safety Regulations under any circumstances. These are statutory regulations and Trusts must ensure full compliance to avoid legal challenges by patients in the courts.

This review has highlighted that pharmacists have a major role in ensuring that product liability issues are addressed when procuring pharmaceutical products for NHS Trusts. A recent Audit Commission Report on Medicines Management (2002) highlighted that many pharmacy departments offer examples of good practice and demonstrate the importance of ensuring professional involvement and expertise in purchasing decisions. The hospital pharmacy service underpins effective medicine management. This is central to risk management and delivery of clinical governance requirements within hospitals. As previously discussed, the National Patient Safety Agency (NPSA) has recently been established within the NHS. One of the National targets identified for action is “building safety into purchasing policy within the NHS”. This will represent a significant challenge in relation to pharmaceutical procurement.

Pharmacists need to continue to play a prominent role to ensure that goods and services are of adequate quality, do not increase clinical risks and are purchased economically. This role will become more important in the changing NHS environment. An understanding of the importance of recent developments in product liability legislation is critical to this role. Therefore, there is a need for a review of the pharmaceutical procurement process to take account of the proposed recommendations within this report. The implications of product liability legislation should also be included in any future procurement training for pharmacists.

Further research is required on the product liability legislation in relation to purchase of unlicensed medicinal products, the purchase of parallel imports (particularly in an expanding European Union) and case law in relation to “failure to warn” claims.

NOTES

1. In *Richardson v L.R.C. Products Ltd* [2000] Lloyd’s Rep. Med.280, a female claimant brought an action for damages under the Consumer Protection Act 1987 for personal injuries suffered when a condom manufactured by the defendants failed and she became pregnant.

However it was held that the condom was not defective. The judge explained that although the user' expectation was that the condom would not fail, taking into account the safety that persons generally were entitled to expect in all circumstances, in terms of section 3, the defendants had never claimed that a condom would never fail. Also no one had ever supposed in the circumstances that any method of contraception would be one hundred percent effective.

2. The claimants alleged that the blood was defective under Article 6 (the equivalent being section 3 of the CPA) and that the defendants could not escape liability under the development risk defence of Article 7(e) (the equivalent being section 4(1)(e) CPA). Anthony Mallen of Deas Mellen the solicitors which led the action, noted that it was a landmark decision for consumer rights and shows that the EU Directive has been significantly to strengthen product liability law
3. Public procurement is regulated at the European level by a series of Directives, implemented into UK law by a set of national Regulations. The EU regime is based on a number of directives covering the award of public works, supplies and service contracts by public authorities and by entities operating in the water, energy, transport and telecommunications sectors. The basis of the procurement rules lies in provisions guaranteeing the free movement of goods, services and capital, non-discrimination on grounds of nationality and fundamental principles such as equality of treatment, transparency, and mutual recognition. The public procurement directives have an economic rationale which aims to create the competitive conditions in which public contracts can be awarded without discrimination between EU nationals and also to ensure value for taxpayer's money, ensure suppliers have access to a single market with major sales opportunities, and to strengthen the competitiveness of the European supplier base.

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