

# **IMPACT OF ELECTRONIC COMMERCE ON THE EUROPEAN PHARMACEUTICAL SECTOR**

**- An Overview -**

**By**

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## 1. INTRODUCTION AND SUMMARY

This study provides an overview of the background to, and focuses on, some of the major issues arising from the marketing and sale of pharmaceuticals<sup>1</sup> on-line. The study is not intended to provide a complete summary of the current pharmaceutical regulatory regime in the EU, nor to provide an exhaustive description of obstacles to the introduction of electronic commerce in the pharmaceutical sector.

It starts by providing a brief background to the current debate and by setting out the present position in the EU pharmaceutical sector. It then examines some of the barriers which currently inhibit the exploitation of electronic commerce in the sector - in particular, the restrictions on electronic commerce across national borders (including cross-border delivery) caused by barriers to parallel imports and other practical and regulatory issues relating to cross-border purchases (including pricing systems).

The study includes seven Annexes providing more detailed background to the pharmacists' monopoly, price controls and reimbursement, the EU regulatory framework for pharmaceuticals, the regulation of advertising and promotion of pharmaceutical products and jurisdiction over intellectual property ("IP") disputes. Another Annex summarises answers to a questionnaire sent out to around 180 market players in the EU and elsewhere seeking their views on current issues in the pharmaceutical market. Each Annex briefly considers the situation in the EU, while also covering distinctive local variations in the UK, France, Italy, Germany and Belgium and, to a limited extent, the situation in the US and other non-EU countries.

The volume of electronic commerce is increasing at an exponential rate, and there is no reason to believe that the pharmaceutical sector will remain unaffected. Patients will seek to obtain better health care delivered more efficiently; EU Member States want the same but it must be delivered at a reduced cost. Both will use electronic commerce if it provides these benefits. National boundaries and regulatory barriers will not necessarily be a deterrent. As a result, EU Member States have a choice: either they can react to electronic commerce developments in the pharmaceutical sector (and probably therefore not meet their citizens' expectations); or they can facilitate them, by allowing the development of new services which add value, while establishing new safeguards that will continue to protect the consumer and ensure national health care standards.

By way of conclusion, we propose the following tentative recommendations:

- (a) In considering the adoption of any policy on the impact of electronic commerce on the European pharmaceutical sector, the Commission should recognise:
  - (i) the global nature of the Internet;
  - (ii) the importance of public funding and the health insurance industry;

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<sup>1</sup> Medicinal products are referred to in this study as either 'pharmaceutical products' or as 'pharmaceuticals'.

- (iii) the drive by producers and wholesalers for continuing cost reduction in pharmaceutical distribution;
  - (iv) the opportunities to benefit the retail distribution chain as a whole from doctor through pharmacist to patient .
- (b) The Commission should review the regulatory barriers inhibiting cross-border on-line ordering of prescribed as well as OTC pharmaceuticals, including product categorisation, pricing and reimbursement policy, advertising and areas where the principle of mutual recognition of national authorisations should be applied.
- (c) The Commission should identify minimum standards of consumer protection and safeguards to maintain public confidence in pharmaceutical products and their distribution, in particular, in such fields as privacy, data protection, security/encryption and liability issues.
- (d) The Commission should consider launching an educational programme to alert citizens of the risks related to the procuring of pharmaceuticals from non-reputable, uncontrolled organisations, whether nationally or cross-border.
- (e) The Commission should increase co-operation in global fora, with other governments and professional organisations, to establish codes of conduct and co-ordinated legislative frameworks that will assist the global provision of quality healthcare and the establishment of instruments for the prevention of cross-border abuses of existing pharmaceutical regulations.

## 2. **BACKGROUND**

The increasing use by consumers of electronic means of communication such as the Internet has been recognised in the EU by, for example, the Information Society Action Plan and more recently in the public debate over electronic commerce. However, whilst the Information Society is global in nature, an important part of the regulatory responsibility for pharmaceutical products currently rests with individual EU Member States. The tension resulting from this is likely generally to hinder the realisation of a single market in pharmaceutical products and, specifically, inhibits the use of electronic commerce for the supply of such products.

Further (and partly as a result), whilst electronic commerce is widely used at the business-to-business level in the EU pharmaceutical sector, it is almost completely absent from the final link in the chain - that of business-to-end-user - namely, between the pharmacist/wholesaler/pharmaceutical company and the patient. Normal competitive market dynamics are encouraging the growth of E-commerce in all areas where the regulatory regime allows it. Although concerns over security of data and shortage of technical skills act to slow those dynamics, it is expected that E-commerce will continue to develop based on need and will follow trends experienced in other business sectors. The regulatory regime inhibits its use currently at the retail level and therefore this study will concentrate on this aspect.

### 3. THE CURRENT POSITION

#### 3.1 EC Pharmaceuticals Market realities (or how the market works)

##### (a) Role and use of E-commerce currently

E-commerce is used currently by manufacturers principally in a business-to-business context (largely through EDI).<sup>2</sup> In particular, contracts between manufacturers and wholesalers are often made electronically. At the retail level, manufacturers' web presences are largely passive - providing only marketing and clinical information. Outside the EU such information provision has become widespread - indeed access to health information is now the second most popular purpose for surfing the Internet in the US. The use by wholesalers and chains of pharmacists of E-commerce is, however, more restricted<sup>3</sup> and seems to be related to the size and sophistication of the business in question. Some wholesalers provide limited product information over the web and use EDI for transactions with pharmaceutical companies and pharmacists<sup>4</sup>, but our survey found that in some EU jurisdictions this use was still largely experimental. Use by individual small pharmacists and patients for anything other than information gathering is largely non-existent. The exception to this relates to some orders placed outside the EU - for which see the section on parallel imports in point (c) below. The emergence of this non-EU market is evidenced by unsolicited bulk e-mailing of EU citizens with material advertising pharmaceutical products. An example of a recent unsolicited e-mail is attached as Annex 7 to this study.

##### (b) Distribution characteristics

The distribution of pharmaceuticals in the EU is largely driven by the regulatory regime in which it operates. It currently takes place at three points - hospitals/surgeries, pharmacists and other retail outlets. The pharmaceuticals distributed may be divided into two categories: "prescription" - which must be prescribed by a medical practitioner; and "over the counter" ("OTC") - which need not be prescribed.

##### (c) Parallel imports

The purchase of pharmaceutical products from non-EU countries has always happened, even though the importation of some pharmaceuticals in some countries might be illegal, at least if not done directly by the patient<sup>5</sup>. E-commerce, and more specifically the Internet, radically increases the ability of patients to acquire pharmaceuticals from abroad, which causes concern to manufacturers, wholesalers, pharmacists, health authorities and the medical profession although for a variety of different reasons.

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<sup>2</sup> Electronic Data Interchange. See Annex 6 - Section A of the survey results.

<sup>3</sup> See Annex 6 - Section A of the survey results.

<sup>4</sup> See, in respect of the UK, the Monopolies and Mergers Commission Report on the proposed merger of Unichem and Lloyds Chemists - February 1992.

<sup>5</sup> The importation of medical preparations (which are authorised in the Member State of importation and are available in that State without a medical prescription) which was purchased in a pharmacy in another Member State by a private individual for his personal needs cannot be prohibited by national provisions - such provisions are incompatible with Articles 30 and 36 of the EC Treaty (*Schumacher* (C215/87) [1989] ECR 617).

The market in pharmaceutical products is heavily regulated, in particular as to price, by each Member State. These regulations are intended to ensure that citizens have access to pharmaceuticals of a minimum standard and that the cost of health care provision is controlled. Parallel imports in the pharmaceutical sector occur, for example, where pharmaceuticals are imported from low price countries (such as Spain) into high price countries (such as Germany or the UK) and thereby sold at a lower price than that of similar non-imported pharmaceuticals<sup>6</sup>.

With the exception of the recent Viagra example, patients appear to have largely avoided electronic commerce for the direct importation of pharmaceuticals; parallel trade has been essentially restricted to up-stream, non-retail distribution. However, the Viagra case has made individual end-users aware of pharmaceutical distribution possibilities either because products are not available in their own market or because the price in another market is substantially lower. The obligation on suppliers not to provide controlled pharmaceuticals without a prescription will remain a deterrent to such imports, but Viagra showed that this too could be overcome, though not necessarily in the best interests of the purchaser's health.

#### (d) **Avoidance/evasion of laws and regulations**

In the EU, large scale commercial avoidance or evasion of pharmaceutical laws and regulations is limited. The whole thrust of the EU legislative regime has been to protect consumers and patients from such exploitation. There is however, some tension between EU regulation and low grade private pharmaceutical importation (such as, for example, the private import of melatonin, a product widely available in the US but, not in the EU) - the scale of which is very difficult to assess. The burden of enforcing Member States' regulations in this area falls on national customs authorities and is likely to be rated as a low priority for them. Whilst there is no doubt that Internet access has the potential of increasing the level of private importation, attitudes in certain Member States (e.g. Denmark) have largely been to treat marketing on the world-wide web from sites based outside the EU as extra-jurisdictional and therefore not subject to the EU regulatory regime.<sup>7</sup> Consumers taking advantage of such extra-jurisdictional marketing have therefore fallen within the "private importation" exemption from restriction. A more detailed discussion of these issues is set out in Annexes 4 and 5 to this study.

### 3.2 **Market trends**

There is a growing trend, where authorised by law, for pharmacies to get together as a purchasing group and acquire their product needs directly from manufacturers. There is also a

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<sup>6</sup> The ECJ has ruled that if a parallel importer supplies pharmaceuticals from one Member State in which market authorisation has been lawfully obtained, the country of importation will infringe Article 30 EC if it subjects the parallel import to a second authorisation or licensing procedure. See *De Peijper*, [1976] ECR 613 and more recently, *R. v. Medicines Control Agency, ex parte Smith & Nephew Pharmaceuticals Limited*, [1997] 1 CMLR 812.

<sup>7</sup> Manufacturers and regulators have found some non authorised vendors of pharmaceuticals beyond their reach - for example, we understand that Pfizer, the manufacturer of Viagra, found that many unauthorised suppliers of the product were providing (controlled) links to Pfizer's own web-site to give their own marketing efforts an appearance of legitimacy. Although the use of such links would probably be considered an infringement of copyright or trade mark rights in a number of jurisdictions (including the US and the UK), they were not necessarily so recognised in the jurisdiction in which the web-site providers were based.

trend for wholesalers to acquire chains of pharmacies. Economies of scale and distribution efficiency are the primary drivers in a climate of diminishing returns for the wholesaler/independent pharmacist.

Whilst some countries (particularly where the pharmacist lobby remains strong) remain unaffected by this trend, most market observers believe the trend is unavoidable. Government and health insurance organisations' pressure to reduce healthcare costs will force legislative changes allowing more efficiency in the distribution of pharmaceuticals; this may result in a reduction, albeit progressive, of the number of independent pharmacies.

Potential new modes of distribution are being considered by major market players, of which electronic ordering is a strong contender. Already most wholesalers are equipped with electronic ordering systems and the fast delivery networks needed to support them.

As a result of the trend towards outsourcing, it appears unlikely that manufacturers will engage in significant wholesale or retail distribution of their products, thereby leaving the wholesaler as the principal link in the distribution process. On the other hand, wholesalers (who over the last few years have moved from a restricted, national presence to become large European-wide operators) are now substantial market players. While the physical delivery of pharmaceuticals could remain organised on essentially a national basis, it seems inevitable in the long run that the organisation of wholesale functions will eventually rest with a handful of European groups.

Competitive pressure will induce cost savings<sup>8</sup> and encourage improved distribution networks. However, since there is at present in many Member States no flexibility in the final market prices of prescription pharmaceutical products, competitive advantage at the wholesale/retail level will principally come from the quality of service offered<sup>9</sup> and improved economies of scale.

In owning or controlling the retail distribution level (i.e. the pharmacies), the wholesalers will give themselves a brand name and direct access to the patients as well as retailing skills. They are then well placed to offer the patients an array of new, additional services ranging from simple electronic mail ordering to full healthcare management services. There is no question here of bypassing the pharmacies but, rather, of integrating both aspects of the pharmaceutical distribution process and building on that synergy to create new added value. Recent diversification of wholesalers in the home care market supports this view.

A parallel development to wholesaler concentration is the desire of governments and health insurance organisations to encourage individuals to take responsibility for their own health and to provide focused individual healthcare management. The primary aim is the provision to every citizen of better medical support through the improved recording and availability of relevant information in individual patients' files. An equally important aim is the control of healthcare costs. Computer generated records of purchases of pharmaceuticals are one of

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<sup>8</sup> E.g. negotiation of prices with suppliers, economies of scale, efficiencies in warehousing and distribution, reduction in inventory levels, etc.

<sup>9</sup> Note however that the UK currently operates a pharmaceutical pricing system linked to reasonable profits of the pharmaceutical manufacturer- full details are set out in Annex 2.

the data streams that would assist in meeting both aims. Prescription Benefits Management ("PBM"), which produces such data streams, is one of the control tools that is therefore likely to be put in place. Wholesaler access to PBM systems would allow a new range of focused added value services to be marketed to healthcare providers.

Lastly, there is growing public acceptance of the Internet as an effective communications and transaction medium. It is beyond the scope of this study to forecast the potential future growth in Internet use, but it is worth mentioning in brief the success of the recent Parthenay experiment in France, where access to E-commerce (groceries and household goods) has transformed a local online information service with a relatively low initial take up rate, to one that exceeds the pre-launch estimates, thereby invalidating data about the country's most computer-averse population in the EU.

#### **4. POTENTIAL FOR E-COMMERCE DEVELOPMENT**

##### **4.1 Advantages and disadvantages of E-commerce in the pharmaceutical sector**

###### **(a) Patients**

Electronic prescription will require revised systems for pharmaceutical delivery - linking doctors, pharmacies, social security systems and possibly patients. This is already partially achieved in hospital environments and also by the delivery of prescriptions from doctors to pharmacists by facsimile. Such new market mechanisms will hinge on regulatory changes in the pharmacist-patient relationship.

For patients, the possible advantages of E-commerce can be grouped under the following broad headings:-

- convenience: e.g. home delivery (especially for repeat prescription or long term treatment of the acutely ill - see 4.2 below); wider choice of products<sup>10</sup>; more public information available about a pharmaceutical; direct debit payments; electronic handling of reimbursement and other paperwork;
- the availability of pharmaceuticals which are not marketed locally.
- speed of delivery;
- price differentials encouraging the acquisition of cross-border products at lower prices (see section 6 below on cross-border E-commerce);
- cost reduction through economies of scale, PBM or use of generic substitutes;

The disadvantages that E-commerce could bring to patients include:-

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<sup>10</sup> The success of Amazon, the online book store, is an example of how extended product choice by comparison with conventional competitors can be a key factor underpinning online sales success.

- the machine interface - new skills are required and "the human touch" is lost (but note the success of tele-shopping);
- the possible perception of a degradation in service levels (e.g. cycle time from order to delivery) or costs (e.g. non-reimbursable delivery charges);
- risks perceived because of lack of security of payments or confidential information, mishandling of personal data or unknown quality of products (where generic substitutes used).

The net balance of perceived advantages and disadvantages will depend on each patient's circumstances.

**(b) Pharmacists**

Pharmacists are the only group who can legally provide a pharmaceutical sales service in most EU countries. The introduction of E-commerce into this environment is not possible in many EU Member States due to regulatory restrictions<sup>11</sup>. With some adaptation of the regulatory framework several aspects of the transaction could be successfully computerised. However, pharmacists apparently see E-commerce as a force eroding their professional role and status in the eyes of patients<sup>12</sup>.

For those pharmacists who embrace E-commerce, it could result in a more effective service to their clients/patients, an extension of their market reach, and also some cost reductions in inventory management, cash flow improvements and personnel requirements.

On the other hand, pharmacists would have to cope with a different approach to patient contact (maybe by e-mail or telephone), invest in and then master E-commerce technology and set-up a rapid delivery system that may well have to reach beyond their current neighbourhood<sup>13</sup>. It is possible that such investment could only be economically justified if pharmacists group together to provide sufficient critical mass. It is also likely that, in several EU countries, this process will be vigorously resisted.

**(c) Wholesalers**

Wholesalers will, once authorised to sell direct to consumers, be best placed to offer the range of electronic mail-ordering services that patients could ask for. It is a logical extension of their present activities - for which they have the technical and organisational know-how - particularly those that already own chains of pharmacists with well-known brand names. Wholesalers who do not have such pharmacist skills will need to acquire and brand them. Such developments could further lead to cost advantages, part of which could be passed on to patients, EU Member States or health insurance organisations.

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<sup>11</sup> See Annex 1 to this study for a description of such restrictions.

<sup>12</sup> This is borne out by our survey results - for which see Annex 6 to this study.

<sup>13</sup> At least in the UK, pharmacists already accept orders and prescriptions by fax and deliver to patients.

(d) **Pharmaceutical companies**

The relationship between pharmaceutical companies and wholesalers is already highly mechanised, using EDI or other electronic data systems. The supply of information by pharmaceutical companies to doctors is one of the most critical business flows in the pharmaceutical sector - most pharmaceuticals would not be sold if not prescribed by a doctor. Whilst on-line electronic data-banks of clinical information and some forms of electronic mail may help the information process they will not, in the short to medium term, drastically reduce the need for doctor visits by pharmaceutical company representatives, printed information, symposia or other traditional means of conveying the medical relevance of pharmaceuticals. As doctors have little incentive in "pulling" the information, manufacturers will have to continue to "push" it.

(e) **Others**

The role of social security systems and health insurance organisations (authorisation of therapies, reimbursements of pharmaceuticals, etc.) varies vastly from country to country and will be important in an analysis of the opportunities presented by E-commerce as they are principal administrative agents of the health systems of most EU Member States.

High Street supermarkets and other retail stores currently offer some OTC pharmaceuticals on their shelves in some countries. E-commerce in this area would be a straightforward extension of E-commerce already available today, or soon to be implemented, for non-pharmaceutical product lines.

#### 4.2 **Specific examples of electronic commerce opportunities**

If regulations permit, there are sufficient potential benefits for consumers to encourage the development of E-commerce in the pharmaceutical retail sector. Set out below is a non-exhaustive list of examples of how patients might benefit from the development of E-commerce:

(a) **Long-term treatments**

Where a patient is given a series of pre-programmed prescriptions to cover changing requirements during a lengthy period of treatment, the prescriptions (if electronic) could be forwarded (automatically or by the patient) to the E-mail-ordering supplier at each step of the treatment (this already occurs by facsimile in the UK). Alternatively, the supplier could administer the series of shipments on behalf of the patient, possibly even with medical follow-up on behalf of the prescribing doctor (e.g. as part of a Home Healthcare Management System).

(b) **Chronic diseases or repeat treatments**

Refill prescriptions could be registered once with the E-mail-ordering provider, and triggered if and when needed by the patient. No further prescriptions would be required. With the advance of electronic certification based on cryptography, the prescription could be registered

with a mutually recognised certified 'clearing system' and the patient would be able to get the medicine simply by quoting a verifiable reference number.

(c) **Elderly, handicapped, disabled**

Rather than being dependant on others, these patients could take advantage of E-mail prescribing and ordering combined with home delivery

(d) **Remote rural areas**

As already practised in Nordic regions, patients with difficult access to pharmacies (because of distance, road conditions or lack of public transportation) would benefit from E-mail prescribing and ordering combined with either home or pick-up point delivery

(e) **Working households**

In line with developments in the grocery and household goods retail sector, members of a working household would welcome the possibility to order pharmaceuticals on-line and get delivery outside usual working hours at a convenient pick-up point

(f) **Computer-centred purchasers**

The development of electronic commerce will create a new class of purchasers that will almost exclusively purchase on-line. For many, pharmaceutical needs will be no different than other product lines and they will therefore seek to purchase pharmaceutical products on-line.

(g) **Low-income patients**

Where patients presently have to claim reimbursement after the purchase of pharmaceuticals, electronic commerce could provide links with health insurance organisations that would avoid them having to reclaim urgently needed cash.

#### 4.3 **Experiences in other countries**

The country which has most experience of E-commerce in the pharmaceutical industry is the US. A description of the US pricing controls, regulatory system and advertising regulations are set out respectively in Annexes 2, 3 and 4 to this study.

Having conducted extensive surveys of interested parties in relation to Internet trading, the FDA<sup>14</sup> has stated publicly (last month) that it considers the Internet just another promotional medium. Consequently, they argue that little new regulation is required in the US to regulate the on-line market. This has been borne out by their experience of on-line infringement, which has followed the same pattern as violations in traditional media. Typically these include misleading claims and lack of fair balance in describing risks and effectiveness.

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<sup>14</sup> Food and Drug Administration.

While the FDA has yet to publish full guidance on its attitude to marketing and sales on the world wide web, they have already issued warning letters to companies setting up web sites which they consider infringe US legislation. Given US practice to date it seems likely the FDA will also take an aggressive jurisdictional line on sites based outside the US but available to US consumers.

## 5. **BARRIERS TO ELECTRONIC COMMERCE**

E-commerce will require, for most EU Member States, a review of the regulatory environment under which pharmaceutical products are offered for sale to patients. Our survey of market participants raised issues relating to the provision of quality healthcare, the protection of the patient's health as well as his or her privacy, the abuse of pharmaceutical consumption and the potential negative impact of E-commerce on local communities (given the likely decline in the number of neighbourhood pharmacists and doctors). On the other hand, the development of E-commerce could be viewed as a natural evolution of current practices and, therefore, easily subject to the same high quality professional care and appropriate regulatory safeguards. Some of the problems which the current regulatory regime in EU Member States raises in relation to E-commerce are set out below.

### 5.1 **Regulatory constraints**

#### (a) **The definition of “OTC” and “prescription”**

Pharmaceuticals may be divided into four categories, determined by the regulatory requirements imposed upon them. These determine how and where such pharmaceuticals may be purchased and how they may be paid for. Although the specifics of each category vary from country to country<sup>15</sup>, the categories may broadly be described as follows:-

- prescription pharmaceuticals which are restricted to hospital use (most are fully or partially reimbursed);
- prescription pharmaceuticals which are distributed through pharmacies (most are subsidised);
- non-prescription or over-the-counter ("OTC") pharmaceuticals which are distributed through pharmacies only (generally not subject to reimbursements but could be subsidised or partially reimbursed when specifically prescribed by a doctor or if they are part of a reimbursable treatment); and
- OTC pharmaceuticals distributed through retail outlets (in principle not reimbursable).

These distinctions may be incompatible with the sale of such pharmaceuticals electronically.

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<sup>15</sup> New products approved through the European procedure (EMEA) will henceforward be considered either prescription or non-prescription for the whole of Europe.

(b) **Marketing authorisations**

A pharmaceutical product cannot be put on the market in a Member State without a marketing authorisation. As it is practically impossible to restrict access to Internet sites to the residents of a particular Member State, the following situations are possible :

- (i) inter-EU - a prescription pharmaceutical product which has a marketing authorisation in one Member State is marketed on the Internet and is accessed in another Member State where the product has not obtained a marketing authorisation;
- (ii) inter-EU - a pharmaceutical product which is considered as OTC in one Member State is marketed on the Internet and is accessed in another Member State where it requires a prescription;
- (iii) extra-EU - pharmaceutical products which are authorised in countries with a well respected medicines agency (e.g. the US) are marketed on the Internet and accessed in Member States where the pharmaceutical product is not authorised; and
- (iv) extra-EU - pharmaceutical products which are authorised in countries without a well respected medicines agency are marketed on the Internet and accessed in a Member State where the pharmaceutical product is not authorised.

One way of dealing with all the above cases would be to make it clear to Internet users whether or not the particular pharmaceutical product is approved by the medicines authorities in any particular country and whether the sale of a pharmaceutical product is equivalent to a private importation of pharmaceutical products. This could be done by a statement on the web-site which precedes any details relating to the pharmaceutical product or to the actual purchasing process and which must be 'accepted' by the Internet user before proceeding (like a "click wrap" procedure).

Another way would be to look more closely at the whole issue of the regulation of marketing authorisations themselves to determine issues such as:

- (i) whether or not a 'mutual recognition' of marketing authorisations could be established, for E-commerce purposes, between Europe and other countries with well established regulatory regimes, such as the US. Such a centralised "Mutual Recognition" procedure could go some way towards also achieving a parallel "mutual recognition" within Europe itself; and
- (ii) whether marketing authorisations could include provisions which permit marketing through the Internet. The Internet marketing authorisation provision could relate to specific web sites, which could easily be inspected by the competent authorities and reciprocity clauses could be provided to ensure uniformity in respect of non-EU countries

Whilst it is beyond the scope of this study to deal with all regulations which may be affected by E-commerce, consideration may need to be given to amending current regulations so as to deal with, for example, pharmaceutical companies granting exclusivity to import products in certain countries only through the Internet, thus creating a niche of Internet distribution parallel to traditional distribution channels. Furthermore, enforcement in a cross border environment will fall increasingly on state customs authorities raising government costs, in the face of a commensurate decline in domestic sales tax revenue.

Finally, it may be important to determine whether the liabilities which attach to the holder of a marketing authorisation for the marketing of pharmaceutical products can also apply to the party who actually resells the pharmaceutical product through the Internet. This raises issues of content responsibility and the liability of others (such as an Internet service provider) should the content be misleading.

(c) **The Pharmacists' monopoly**

The medical responsibility for the delivery of a prescribed pharmaceutical lies with the prescribing doctor. The pharmacist's input is generally limited to usage recommendations. In contrast, the legal responsibility of the pharmacist is to ascertain that there is a prescription when required, that the patient is eligible for reimbursement or subsidy for any given purchase<sup>16</sup> and to comply with the administrative requirements of the reimbursement systems<sup>17</sup>.

In addition, throughout the EU Member States, in particular in relation to OTC pharmaceuticals, pharmacists have a counselling role that is perceived as highly critical with regard to public health protection. This role has however largely disappeared in respect of household-type products such as aspirin, common cold medicine or first aid kits, that consumers consider little different from hygiene or skin-care products. Nevertheless, the pharmacists' monopoly is still prevalent in several countries (e.g. Italy) even for the distribution of this latter category of pharmaceutical products.

Whilst the counselling role may now seem inappropriate given the increased levels of education and self-responsibility attained by citizens of EU member states, both currently constitute barriers to the successful use of E-commerce in the pharmaceutical sector.

(d) **Advertising, promotion and labelling**

A summary of advertising restrictions on pharmaceutical products is set out in [Annex 4](#) but, in short, the current regulatory regime operates on the basis of both national and international regulation. Despite the substantial acceptance of international standards adopted by the WHO and IFPMA, nearly two thirds of the world's countries still do not have laws to regulate pharmaceutical promotion or do not enforce those that they have.

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<sup>16</sup> Some insurance plans do not cover all reimbursable pharmaceuticals and some reimbursements are conditional upon specific authorisations - with time and/or quantity restrictions - by the health insurance organisation.

<sup>17</sup> There are situations where patients have to claim reimbursement themselves, however this is generally on the basis of documentation provided by the pharmacist.

In the EU, regulation has followed a substantially more rigorous line than in the US where indications and counter-indications, medical effectiveness, dosage, side effects, and even sometimes price information can already be found on web sites for many popular products. It is becoming increasingly unacceptable for a patient to be denied access to information that could help him assess and discuss with his doctor possible alternatives to his prescribed treatment. However, the difference between valuable information and promotional material is sometimes difficult to define; in these circumstances the protection of the consumer from misleading information as to pharmaceutical products is clearly important. Regulatory authorities will need to provide recognised standards for vetting and approving the disseminating of such information.

European Community law prohibits the advertising of prescription-only pharmaceuticals to consumers (whether by web-site or otherwise) whereas US law does not. Clear forms of approved wording (such as those used in the advertising of financial services) could enable compliance with territorial or EU regulations without restricting business enterprise. In addition, regulators may consider that certain kinds of OTC pharmaceuticals could be commercially distributed and as a result revise rules in order to allow these products to be more freely advertised and promoted.

(e) **Delivery**

Technological developments raise questions about potential new forms of product distribution. As an example, is there any real distinction between a computer order placed by a patient at his neighbourhood pharmacy (whether for pick-up by himself or for home delivery) and the same order placed by phone or fax (as already occurs) or using a set-top box and television? Would this be considered distance selling and/or tele-shopping? Distance ordering and mail ordering where the patient "pulls" the commercial information, must be clearly distinguished from commercial offerings where the seller "pushes" the information to the consumer.

Given that one of the major advantages of the Internet is its global reach, Article 14 of the Distance Selling Directive, which entitles Member States to prohibit any distance selling of pharmaceutical products on their territory, or the overall ban on tele-shopping for pharmaceuticals will, arguably, give a competitive advantage to other countries such as Switzerland and the US. Patients will seek to access such markets, for example where there are clear price or quality differentials, or where highly publicised pharmaceuticals as yet unlicensed or otherwise unavailable in the EU are readily available by mail order.

(f) **Pricing and reimbursement systems**

(i) Pricing

Current price differentials discourage industry support for pharmaceutical trading on the Internet. On the commercial front, Internet trading makes cross-border price differentials much more transparent, increasing the opportunities for parallel trading - already a significant concern for the pharmaceutical industry. The introduction of the Euro will further increase the transparency of prices and the effects of sales tax.

In theory, suppliers could be forced to vary the price of the product on offer depending on the location of the customer who has accessed their web-site. Legally, if they fail to observe national pricing restrictions (applicable to prescribed pharmaceuticals), the supplier may be subjected to scrutiny and prosecution by the national bodies responsible for policing the pricing system. Their products may also be liable to be seized by customs officials on the way to market.

Alternatively, the relevant authorities may take the view that the supplier is free to price products on a web-site according to the pricing restrictions in the territory in which the server is located. This would enable suppliers with web-sites in, for instance, the US, where there are no (or very few) restrictions on pricing, to offer pharmaceuticals for sale at whatever prices they choose and can commercially maintain. This is subject to the problems caused by national reimbursement systems which are discussed in detail in Annex 2 to this study - specifically who would reimburse the patient (if anyone) and with how much?

(ii) Reimbursement

Patients under most healthcare/social security systems in the EU have the costs of their pharmaceuticals subsidised by a method of reimbursement by the State. Reimbursement works in at least three ways: either the consumer (as in France) or the pharmacist (as in Belgium) claims directly his reimbursement or the supplier claims his reimbursement on the back of a sale (the UK system). All systems are designed to operate only within that Member State's borders, though the cases discussed in more detail at Annex 2 show how that may no longer be appropriate.

Reimbursement, together with the issues of product categorisation and pricing, may affect the development of E-commerce, in particular with respect to prescribed pharmaceuticals, by influencing the cost considerations of the patient. Member States' price and reimbursement systems could hinder free competition in the EU market for pharmaceuticals by encouraging certain purchases from only certain jurisdictions.

## 5.2 **Legal restrictions**

In addition to the regulatory constraints identified above, the following legal restrictions, many of which are of horizontal nature, can be considered as barriers to E-commerce in the pharmaceutical sector:

(a) **Jurisdiction and Applicable law**

Jurisdiction is one of the more vexed legal issues relating to the Internet. Which country's law is to apply to an infringement of medicines regulations or intellectual property rights resulting from an offer for sale made on the Internet? It is far from clear to what extent the mere fact of having a web-site will subject the site owner to the laws of that given country. At present each case must be considered on its own facts and, in many instances, the answer will depend

upon the laws in the country in which the question is being raised. However, due to a lack of international conventions dealing specifically with cross-border Internet related transactions, national courts are having to adapt traditional concepts of jurisdiction, including the need to establish first where the infringement occurred and secondly which country has jurisdiction over that infringement. There is also scope for national courts to interpret the European conventions inconsistently, even those intended to harmonise national laws.

The international dimension of E-commerce raises issues as to which law will govern the relationship between the parties in question, whether all legal requirements for forming a valid contract have been met and the difficulty of identifying terms and conditions which underpin the transaction<sup>18</sup>.

National legal systems have differing requirements as to *when* and consequently *where* a contract is formed and the necessary factors for validity and enforceability. For example, some jurisdictions place severe procedural restrictions on the sale of goods unless documents are signed by hand (calling into question the effect of digital signatures), while others require contracts to be in the local language of the country where the customer is located. Local consumer protection laws will also affect the contractual relationship and its validity. These laws apply as much to contracts involving the sale or supply of pharmaceuticals as to any other product or service.

While many academic commentators seem to agree it is open to an on-line trader to state clearly those terms and conditions (including the applicable law) which will govern the parties' relationship and asking the customer to accept these prior to placing an order, it still remains to be seen how different national courts will deal with such situations; harmonising legislation may therefore be required.

The issue of liability is similarly problematic, whether it be contractual, civil, regulatory etc.<sup>19</sup>, particularly in the context of identifying the jurisdiction where loss, damage or penalties have been suffered. These issues remain unresolved, although the draft directive on electronic commerce<sup>20</sup>, published on the day of this report, addresses the question of liability, by removing liability from service providers where they are providing "conduit services" only. In relation to web-site providers, they will, it is proposed, be regulated on the basis of the laws applying in their place of economic activity. It remains unclear how this will afford consumer protection (even allowing for mutual recognition of consumer protection laws between EU Member States) where the origin of web-sites is unclear, or where the site provider is multi-national in nature (as is common in the pharmaceutical market).

(b) **Privacy**

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<sup>18</sup> The European Commission proposed, on 18 November 1998, a draft Directive on Legal Aspects of Electronic Commerce, which covers areas such as jurisdiction and liability ( See Commission press release IP/98/999).

<sup>19</sup> In the context of Ecommerce in the pharmaceutical sector, liability may arise in relation to the on-line prescription by the electronic doctor, in relation to the pharmacist's advice on OTC, in relation to the quality or effect of pharmaceuticals provided and in relation to non-delivery or late delivery of the pharmaceutical products.

<sup>20</sup> See press release reference IP/98/999

The European Data Protection Directive<sup>21</sup> attempts to harmonise data protection legislation throughout the EU. The Directive regulates the processing of personal data (including data relating to patients - such as health records - suppliers and doctors) and focuses on the security of personal data and the right of individuals to be informed of, and object to the use of, their data.

EU legislation is more restrictive than most other countries in respect of data protection legislation, and the Directive includes a provision prohibiting the transfer of personal data outside the EEA to countries which do not have adequate levels of data protection. Two of the most significant countries which might be considered not to have adequate levels of data protection are the United States<sup>22</sup> and Japan. Clearly this has consequences for electronic commerce in the pharmaceutical sector since personal data is likely to be transferred outside the EEA to vendors of products and data controllers have little control over the route data takes between the two parties.

The Directive also distinguishes a category of personal data as "sensitive" which includes information as to the physical or mental health of individuals. Where sensitive personal data is processed there are more stringent conditions to comply with. For instance, in order to process information such as patients' health information, the data controller will have to obtain the explicit consent of the patient for the processing.

These conditions will in particular apply to pharmacists and doctors attempting to consider medical records or patient medical information and then prescribing electronically on the basis of that information or supplying according to such prescriptions<sup>23</sup>. The clear consent of participants in such an electronic health care environment would be required in order for data relating to them to be manipulated.

### (c) **Intellectual Property Protection**

#### (i) Copyright

The transmission of material over the Internet could infringe the copyright of a third party. Problems arise in determining who to sue (e.g. the service provider, the host server or the third party accessing the material, each of whom could "copy" a copyright work) and where jurisdiction lies. Current case law is unclear and it is arguable whether the position as clarified in relation to copyright jurisdiction in respect of, for example, satellite broadcasting (i.e. the "country of origin" principle) can as easily be applied to E-commerce transmissions on the Internet, which can be copied and re-copied

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<sup>21</sup> Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ 1995 L 281/31.

<sup>22</sup> Negotiations on a 'Safe Harbour' are currently ongoing with the US, and although the implementation period set for the Data Protection Directive ended on 24 October 1998, there is an understanding that pending the conclusion of the negotiation, the Directive would not be used against US companies.

<sup>23</sup> The recent Viagra case is an example of a situation in which EU citizens have provided personal information to US on-line doctors in order to obtain a prescription for Viagra.

in transmission to millions of users in many different countries, thus making it in practical terms difficult to trace the country in which the message originated.

(ii) Patents

Patent law throughout the Community is relatively harmonised. In relation to E-commerce and the pharmaceutical industry, it is likely that most issues of patent infringement will arise as a result of parallel importation from a country with no patent protection to one which has (the law relating to which is well recognised) or in relation to the offering to dispose of products or offering a process for use over the Internet (or both). In relation to the second point, the jurisdictional problems are familiar, for example whether or not the receipt of an offer of sale of a product which is legal in the country of origin, but which happens to be accessed in a country where such offer infringes the patent rights of a third party, constitutes patent infringement. The position is complicated by the position that, despite harmonisation, the decisions of national courts within the EU can conflict. The position in relation to E-commerce patent infringement may benefit from guidelines as to what constitutes patent infringement on the Internet. It may also benefit from a Unitary Court structure and procedure at community level for resolving litigation, as is anticipated by the Community Patent Convention.

(iii) Trade Marks

Trade mark rights are of particular importance to the pharmaceutical industry. The main problems raised by the use of E-commerce in relation to trade marks are, first, those raised by the likely increase in parallel importation (the law relating to which is well known) and, second, that the inability to control access could result in trade marks being 'used' in countries where such use may amount to an infringement of a third party's rights, or may be illegal for some other reason. Potentially, an infringing act can be committed in any country from which a web site can be accessed and where there are either trade mark registration rights or rights due to use. The continuing success of the Community trade mark and Madrid routes, together with use of a single trade mark to market a given pharmaceutical product throughout the EU (as opposed to different trade marks in different countries) may help to lessen trade mark infringement problems on the Internet. However, the essentially national nature of trade marks means that infringement issues are inevitable unless world-wide trade mark protection is obtained by pharmaceutical companies. As this would be costly and impracticable, other methods of defences to trade mark infringement on the Internet, such as statutory recognised disclaimers in respect of countries where it is not intended to use a particular trade mark, may need to be considered.

(iv) Confidential Information

The main problem with regard to the transmission of confidential information over the Internet is lack of security, coupled with the difficulty of establishing

an express contractual obligation of secrecy with parties such as Internet service providers or third parties who are able to access such information in transmission, or by chance, and pass it on. Protection options for pharmaceutical companies at the moment include the use of encryption, clear notices informing recipients of the information that there is an obligation of security in respect of it, and the use of Intranets to exchange confidential information between authorised users only.

### 5.3 **Technical barriers**

#### (a) **Security of information and encryption**

Among the now traditional objections to Internet-based transactions (whatever their nature) is the potential accessibility by third parties of personal and financial information of those conducting the transaction and the subsequent use or abuse of that information. In the context of this study, the personal information involved is the private medical information of the patient - which may include past medical records - and financial information, i.e. bank account details, debit/credit card details, smart card details etc.

At present there seem to be few technical barriers to maintaining the security of the necessary data. While no encryption method is likely to be perfectly secure, the ever increasing complexity of encryption methods seems to provide adequate security for all practical and commercial purposes (and they are a good deal more secure than passing the same information by fax or telephone). The introduction of Secure Electronic Transactions (SET) - an accepted payment protocol - signifies a recent advance and a clear confirmation, currently evident in the realm of business-to-business transactions, that adequately secure methods of dealing with financial information can and do exist. The issue of personal information may be a more sensitive one, though the obvious advantages of accessing medical records instantly from anywhere in the world may help the public to accept any risks that may exist.

Other electronic security devices include digital signatures and digital watermarking. Thus, digital watermarks in electronic prescriptions should make it more difficult to re-use or reproduce prescriptions. As any original digitally watermarked electronic prescription is capable of uniquely identifying a doctor, prescribed pharmaceutical or patient, the traceability of any abuser should act as a deterrent. The proposed use of licensed trusted third parties for the actual transmission of the encrypted data, and the potential requirement for recognised digital signatures to access personal data should allay most rational fears.

#### (b) **Internet penetration**

Assessing levels of Internet penetration with precision faces two problems. Firstly, methods of measuring penetration depend on survey evidence. Secondly, such is the speed of growth of online use that such figures are frequently out of date almost the moment they are published.

A number of general statements can however be made about Internet access availability and E-commerce volume. Firstly, to date growth has been "exponential" since the first use of the

world-wide web. Secondly, penetration in the US has now exceeded 40% of the population and is showing initial signs of a reduction in the rate of growth. Third, whilst take-up in Europe and South-East Asia has lagged behind the US - it appears to follow the same pattern of growth. Penetration rates in the major economies of Europe average between 7 and 10%. Penetration in both the US and Europe show a marked age, sex and education variation. The typical purchaser of online services is 36, male, relatively wealthy and has been through higher education.

Irrespective of what level of penetration Internet access finally reaches it is likely therefore that some parts of society will not gain access to the Internet - whether by choice or through lack of resources. Typically, they will be the elderly the uneducated and the poor. Several respondents to our questionnaire raised concerns that E-commerce would create a "two class society" divided by whether or not they had access to online facilities. Whilst this certainly is likely to occur, it is no different from the historical development of other products which have become commonplace over time such as television or the telephone.

(c) **Bar coding**

Bar codes on pharmaceutical packets contain country specific segments of code. These vary from jurisdiction to jurisdiction and are used for a variety of reasons, including pharmaceutical details and social security information. Whilst this issue will not concern the consumer, small pharmacy chains or health organisations who source pharmaceuticals outside their own jurisdiction may find their stock bearing codes that are inappropriate for their own jurisdiction. However, some purchasers will be able to negotiate re-labelling of bar codes or alternatively be able to resource the production of alternative bar code labels internally once the goods have arrived in the purchaser's jurisdiction - although the latter could not be done in a manner which affected the ability of the manufacturer to identify the production batch of the products in question for product recall/liability purposes. It is worth mentioning that no respondent to our survey raised bar codes as a potential hindrance to E-commerce.

## 6. **ELECTRONIC COMMERCE ACROSS NATIONAL BORDERS**

### 6.1 **Who would order abroad?**

The situations where this may happen fall under the following four categories.

(a) **The cross-border traveller**

Cross-border travellers that have forgotten, run out of or lost their usual medication could ask, on-line, for a fast delivery to the cross-border country where they are staying. Such cross-border travellers may well prefer to obtain their usual medication in this way, rather than use local pharmaceuticals that they do not normally use and are not familiar with. This would also allow travellers to consult their local doctor (in their jurisdiction) and use their home pharmaceutical retail system, in both cases in their own language and with which they are consequently much more comfortable.

**(b) The temporary cross-border resident**

Typically, these patients will remain registered with their home doctor and remain affiliated to a home-based health insurance organisation. Outside of emergencies, they have no incentive to comply with local practices. Mail or online ordering of their pharmaceutical requirements would seem perfectly logical, if the capability exists to obtain pharmaceuticals from their home country and would seem to be attractive, unless there were significant cost penalties.

This approach could probably be extended to all pharmaceutical products, prescription or not, that the patient is used to being supplied with (i.e. "household" medicines, homeopathic preparations etc.). As with travellers, their ability to also use their own language would be a further incentive.

**(c) The long-term cross-border resident**

These patients would be much more likely to register with a local doctor and become affiliated with a local health insurance plan. The appeal of purchasing some of their pharmaceutical needs from their home country, besides the ability of using their own language, would be more likely to depend on the same considerations as apply to a national resident.

**(d) The national resident**

The most obvious circumstances in which national patients are likely to use electronic ordering to acquire pharmaceuticals from abroad are as follows:

- (i) e-commerce is not available for ordering pharmaceuticals from suppliers in their own country;
- (ii) the pharmaceutical is not available in their country and there are no adequate substitutes. The recent Viagra example falls into this category;
- (iii) the pharmaceutical is (much) cheaper abroad. The incentive will increase depending on the net price differential, after reimbursement and the length of treatment; or
- (iv) the patient's knowledge that it is not subject to a prescription or other restrictive regulation in another country.

Cases (a) to (c) above would not appear to be of major concern to health authorities or the medical profession, as in each case the cross-border patients are following practices that are locally acceptable in their home country. Case (d) may be more concerning to the country involved, since such private importation of unregulated pharmaceuticals is contrary to the regulatory and legislative system that have been established to control pharmaceutical use in that patient's jurisdiction.

**6.2 Could the risks related to cross-border purchases be reduced ?**

The inability of national regulators and enforcement agencies to control cross-border operators raises some interesting questions regarding what practical measures that could address the main issues.

- (a) The first question is whether it is possible to reduce the attractiveness of ordering pharmaceuticals from abroad. Three actions could help:-
  - (i) provide (competitive) electronic commerce domestically;
  - (ii) establish greater harmonisation in product categorisation (namely prescription, OTC and retail pharmaceuticals) and brand names on a European or global basis (and in particular with neighbouring countries); and
  - (iii) seek to avoid large price differences from country to country for reimbursable products and leave prices free to adjust to market forces for other products.
- (b) The second question is whether there is a public health concern if patients order pharmaceuticals from a reputable cross-border organisation which has received market approval from a recognised medicines agency. Though the rules and regulations under which they operate may be different from those of the country of the purchaser, this does not necessarily mean that purchasers are likely to put themselves at risk. If it can be established that the local organisations use the same code of conduct for domestic and cross-border deliveries, rules of reciprocity can be applied. It may be that the problem can be reduced by the proper identification of the reputable organisations in each country, which can be resolved by co-operation between the respective national authorities and by ensuring liability for defective products falls on the company at fault.
- (c) The third question is whether illicit suppliers can be discouraged. Taking the economic incentive away must be the preferred long-term solution. Again two courses of action could be considered:-
  - (i) improved global co-ordination of product categorisation, together with an attempt at the reduction of price differences, would reduce economic incentives. Improved tracking of product distribution, to trace how pharmaceuticals are distributed and through what channels, might also be a deterrent; and
  - (ii) a parallel approach would be to attempt to reduce demand through concerted educational programmes for patients, stressing the potential problems of not dealing with approved suppliers, whether nationally or internationally. Some form of CE marking of approved online suppliers might assist this - such CE marks could be hypertext linked to the list of approved online suppliers kept by the relevant national regulatory body (hence preventing illegitimate suppliers simply copying the CE symbol without approval).
- (d) The fourth question is whether pharmacists in one country should be able to accept, as discharge of their legal duty, a prescription issued in another country (or one given

online by an online doctor) and whether such a prescription would entitle reimbursement of the patient, pharmacist or supplier (depending on the type of national system).

- (e) The fifth question is how to counter the willingness of some doctors - or fraudulent operators - to deliver (electronic) prescriptions without regard to the genuine requirements of the patient. This is a problem that exists already and has proved difficult to counteract. Nevertheless with technology such as electronic watermarking and electronic signatures available, whilst the possibility of copying a true prescription to form a forged or fraudulent one remains, it could be easier to track such fraudulent prescriptions because of the complex "data-trail" left by electronic prescriptions (in PBM systems for example).

## 7. CONCLUSIONS AND RECOMMENDATIONS

E-commerce is already extensive in Europe in the business-to-business market place and, on a small scale, between vendors outside the EU and patients. Whilst it does not currently take place between European vendors of products and patients to any significant extent, the desire for such a market undoubtedly exists. If that market is to operate effectively the EU will need to address the issues of price inequalities between Member States, reimbursement, parallel imports, advertising and marketing regulation, the future role of pharmacists and, perhaps most importantly, how to ensure continued public health and public confidence in the pharmaceutical supply system.

In the light of the above, we propose the following tentative recommendations:

- (a) In considering the adoption of any policy on the impact of electronic commerce on the European pharmaceutical sector, the Commission should recognise:-
  - (i) the global nature of the Internet;
  - (ii) the importance of public funding and the health insurance industry;
  - (iii) the producers' and wholesalers' drive for continued cost reduction in pharmaceutical distribution; and
  - (iv) the opportunities to benefit the retail distribution chain as a whole from doctor through pharmacist to patient.
- (b) The Commission should review the regulatory barriers inhibiting cross-border on-line ordering of prescribed as well as OTC pharmaceuticals, including product categorisation, pricing and reimbursement policy, advertising and areas where the principle of mutual recognition should be applied.
- (c) The Commission should identify minimum standards of consumer protection and safeguards to maintain public confidence in pharmaceutical products and their distribution, in particular, in such fields as privacy, security/ encryption and liability issues.

- (d) The Commission should consider launching an educational programme to alert citizens of the risks related to the procuring of pharmaceuticals from non-reputable, uncontrolled organisations, whether nationally or cross-border.
- (e) The Commission should increase co-operation in global fora, with other governments and professional organisations, to establish codes of conduct and co-ordinated legislative frameworks that will assist the global provision of quality healthcare and the establishment of instruments for the prevention of cross-border abuses of existing pharmaceutical regulations.

**ANNEX 1**  
**Summary of regulation of registered pharmaceutical chemists**

1. **UK**

1.1 **General**

The registration and general control of registered pharmaceutical chemists ("**pharmacists**"), are the responsibility of the Pharmaceutical Society of Great Britain (the "**Society**"), of which all pharmacists have to be a member.

Under UK law the primary national legal regulation of pharmacists is included within the Medicines Act 1968 ("**M A 1968**"). There is also a specific Act providing additional regulation for pharmacists, namely the Pharmacy Act 1954, which addresses the membership, and disciplinary and other powers of the Society.

1.2 **Prohibitory framework**

The M A 1968 creates the foundation of a prohibitory framework:-

*"Except in accordance with a ...product licence (or marketing authorisation)...no person shall, in the course of a business carried on by him,....*

- (a) sell, supply or export any medicinal product, or*
- (b) procure the sale, supply or exportation of any medicinal product, or*
- (c) procure the manufacture or assembly of any medicinal product for sale, supply or exportation." (section 7(2) M A 1968)*

"Medicinal product" is defined broadly to mean any substance or article (not being an instrument, apparatus or appliance) which is for use by being administered to one or more human beings for a medicinal purpose or as an ingredient for such.

"Medicinal purpose " is defined broadly to include inter alia treating or preventing disease, diagnosing disease and inducing anaesthesia.

*"No person shall, in the course of a business carried on by him, manufacture or assemble any medicinal product except in accordance with a licence..." (section 8(2) M A 1968)*

1.3 **Pharmacists monopoly**

Section 10 M A 1968, however, exempts pharmacists from the prohibitory framework of section 7 and 8:-

*"..sections 7 and 8 of this Act do not apply to anything which is done in a registered pharmacy , a hospital or a health centre and is done there by or under the supervision of a pharmacist and consists of:-*

- (a) *preparing or dispensing a medicinal product in accordance with a prescription given by a practitioner, or*
  - (b) *assembling a medicinal product provided that where the assembling takes place in a registered pharmacy -
    - (i) *it shall be in a registered pharmacy at which the business in medicinal products carried on is restricted to retail sale or to supply in circumstances corresponding to retail sale and the assembling is done with a view to such sale or supply either at that registered pharmacy or at any other such registered pharmacy forming part of the same retail pharmacy business, and*
    - (ii) *the medicinal product has not been the subject of an advertisement;**
- ... or anything done by or under the supervision of a pharmacist which consists of procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a practitioner, or of procuring the assembly of a medicinal product."*

#### 1.4 **General sale list (or Over The Counter ("OTC")), and prescription only products**

Sections 50 to 60 M A 1968 create a system of categories of medicinal products. There are three primary categories:-

##### (a) **General sale lists (or OTC products)**

These are the lower order medicinal products, which are specified as being products which can with reasonable safety be sold or supplied without the need for a pharmacist (Section 51).

The pharmacists role here is limited, as the products (e.g. headache pills, first aid kits are by their nature regarded as sufficiently safe and straight forward as not to require detailed personalised guidance. The pharmacists do not have a monopoly over this category of products.

##### (b) **Non-general sale lists products (which are also not prescription only)**

These are the middle category medicinal products, which require the supervision of a pharmacist at a registered pharmacy, but are still regarded as OTC products.

Here the pharmacist has the most important role, as the products have not been prescribed, and the pharmacist must give advice on the appropriate product to use and the correct dosage.

(c) **Prescription only products**

These are the most potentially dangerous products, which can only be distributed by pharmacists in accordance with a prescription given by an appropriate practitioner, for example by a doctor or dentist. (Within this category is a further category of those prescription products which can only be distributed through hospitals.)

The pharmacist's role here is normally limited to ascertaining that a prescription is required, advising on usage recommendations and reimbursement. The primary responsibility, however, rests with the prescribing practitioner.

1.5 **Other regulations over pharmacists**

Section 63 M A 1968 provides that it is an offence to add to or subtract anything from a medicinal product.

Section 64 M A 1968 provides that it is an offence to sell any medicinal product which is not of the nature or quality demanded.

Section 75 M A 1968 provides that pharmacists must submit details of the premises from which a retail pharmacy business is being run.

Section 85 M A 1968 provides that it is an offence to describe any medicinal product wrongly on a label or mark.

2. **GERMANY**

The pharmacist's monopoly is laid down in Section 43 of the "Law relating to the Manufacture and Distribution of Pharmaceuticals" ("Arzneimittelgesetz-AMG"). According to this provision, only qualified pharmacists are entitled to sell medical products falling within the scope of the definition given by the AMG. In principle, the monopoly of pharmacists affects both medical products which are subject to prescription and OTCs. However, some OTC-products and some which are subject to prescription are excluded from the pharmacist's monopoly.

Regulations related to Pharmacists are laid down in the "Law on Pharmacies" ("Apothekengesetz"). According to Section 1 pharmacists are obliged to provide for an orderly supply of medical products in the interest of the general good. Any qualified pharmacist must be ad personam authorised to run a pharmacy. The "Law on Pharmacies" is based on the idea of the self-employed pharmacist running his own and only one pharmacy. This provision is intended to guarantee that the pharmacist devotes all his efforts

to one pharmacy and feels personally responsible for his pharmacy in the public interest. As a consequence, chains of pharmacies do not exist in Germany.

In 1994, the ban on the ownership of more than one pharmacy was modified to adjust German legislation in line with the European law. Following the amendment of the “Law on Pharmacies” individuals who are authorised by German law to run a pharmacy are now entitled to run one or several pharmacies in other Member States according to the Member States’ relevant legislation. Conversely, pharmacists running one or several pharmacies in one or more other Member States are entitled to run no more than one pharmacy in Germany, in addition to the pharmacies run in other Member States on condition that the respective Member States do not impose an obligation on the pharmacist to be present in his pharmacy at all times. Apart from this amendment, the German legislator did not feel an obligation to repeal the ban on the ownership of more than one pharmacy.

According to a decree dealing with the pharmacy business (“Apothekenbetriebsordnung”) the pharmacist is, in principle, not entitled to sell anything other than medical products. As a general rule, he may only sell anything other than medical products as far as it does not affect the orderly operations of the pharmacy. Section 25 Apothekenbetriebsordnung contains a list of products the pharmacist is entitled to offer for sale besides medical products.

Pharmacists obtain their pharmaceutical supply either directly through the manufacturer or, this is more common, through the wholesaler. However, to achieve a stronger bargaining position in relation to manufacturers and wholesalers pharmacists have formed co-operatives for the common purchase of medical products.

Pharmacists are not allowed to advertise or promote for their pharmacy.

### 3. **ITALY**<sup>24</sup>

Under Italian Law, medicinal products -as defined in EU Directives- can only be purchased by final consumers through pharmacies. This applies as well to the category of “*presidi medico-chirurgici*”<sup>25</sup>, as well as to a number of OTC products and cosmetics.

Italian law provides for a number of provisions that are applicable to pharmacies and pharmacists. Some of them are strictly inherent to the profession of pharmacies and to the exercise of their activities. Other provisions apply directly to the marketing of pharmaceuticals.

As far as the first group of provisions is concerned, the profession of pharmacist can be carried out only if the person satisfies a number of requirements and is duly registered with

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<sup>24</sup> This section is up to date to 31 December 1997

<sup>25</sup> This category of pharmaceutical products includes both products for human beings (e.g. female hygiene products could fall within) as well as for animals or even those for agricultural purposes. Some devices, such as surgeon gloves, could also be “*presidi*”.

the Pharmacists Society<sup>26</sup>. Pharmacists are subject to a number of duties. Examples of infringing behaviour are the grant of discounts to consumers or advertising of the pharmacist's activity.

## 4. BELGIUM

### 4.1 Regulatory framework

The regulation of the profession of pharmacists in Belgium is similar to that in the UK. The profession of pharmacists is mainly governed by Royal Decree No. 78 of 10 November 1967 on the profession of doctors, nurses, paramedics and the medicinal commissions (the "**Decree**"). Pharmacists need to be member of a legally constituted professional organisation for pharmacists (*Orde van apothekers/Ordre des pharmaciens*). This organisation, *inter alia*, supervises the good conduct of the profession and can impose disciplinary and other measures set out in separate regulations.

### 4.2 Legal monopoly

Article 4 of the Decree grants pharmacists a monopoly for the provision of pharmacy services and the sale of pharmaceutical products, as defined in the Decree. A university degree in pharmacy, a certificate by the municipal commission and a registration on the list of the professional organisation for pharmacists is required. In addition, the opening of a pharmacy is subject to a special permit issued by the Belgian Ministry of Public Health. The issuing of such a permit depends on the density of the population and the distance from other pharmacists in a given area.

However, doctors can provide pharmaceutical products directly to their patients but only in urgent circumstances.

Note that the Decree prohibits doctors to be pharmacists at the same time (Article 4bis). Hence a person who holds a degree in medicine and a degree in pharmacy cannot perform both professions simultaneously.

### 4.3 Duty to deliver and the right to substitute for pharmacists

In principle a pharmacist is under a duty to deliver the product prescribed by a doctor and is not entitled to substitute it with another product. However the Decree provides for the possibility to allow the pharmacists to substitute certain prescribed products with others provided that the active ingredients are identical, the doctor has not explicitly prohibited the possibility of substitution and the price of the substitute product is lower than the prescribed one.

## 5. FRANCE

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<sup>26</sup> The Pharmacist society is a body with administrative law relevance.

The Public Health Code provides for a list of products which fall under the scope of the pharmacy monopoly and which can, therefore only be distributed through pharmacies:

- the wholesale and retail of medicines;
- the preparation of medicines;
- the preparation and sale of medical dressings;
- the retail of essential oils;
- the retail of lacteal products for infants;
- the sale of medicinal herbs/plants

The retail of these products must be a direct sale, i.e. there must be no intermediary between the pharmacy and the customer.

In case of breach of the pharmacy monopoly, the following sanctions apply :

- fine from FRF 3,600 up to FRF 18,000; and/or
- from 6 days to 6 months prison sentence.

#### 6. **Impact of E-commerce on single pharmacies and groups of pharmacies and supply chain**

The pharmacists as a result of the above legislation have been granted a significant monopoly in dispensing medicinal products. This is a reflection of the importance attributed to their role in ensuring the safety of consumers.

There has been a move in recent years in this field for pharmacies to be acquired by those above them in the distribution chain from wholesalers to manufacturers. Chains of pharmacies are particularly tempting for these acquisitions and therefore may be viewed as more vulnerable. One of the primary benefits for the purchasing entity is that it gives direct access to the consumers or patients, so that they can attempt to bring added value to the consumer. In practise it seems likely that only the pharmacy chains would have sufficient resources in the short term to invest in technology to facilitate e-commerce transactions on a large scale.

Within the existing legislative regime there will still be a need for pharmacists to supervise distribution of non-general list products, although their role may change to an indirect supervision via e-mail rather than through a traditional shop premises.

#### 7. **Regulation of the advertising and promotion of medicinal products**

See Annex 4.

#### 8. **Regulation of reimbursement for medicinal products**

See Annex 2.

## ANNEX 2

### Price controls and reimbursement of medicinal products

#### 1. General

The market in medicinal products is strongly partitioned on the basis of price throughout Europe and the world. In addition to the normal competitive forces which cause price variation within any product market, the price of pharmaceuticals is influenced by a number of direct and indirect controls.

In most countries, there is some form of governmental intervention in the pricing of pharmaceutical products. In some cases, the control arises by virtue of the government (through its control of the national health care system) or other healthcare provider in the jurisdiction which is the principal purchaser of medicinal products. Consequently it can maintain a strong negotiating position and exert strong downwards pressure on prices.

Alternatively, the control of prices may be achieved through laws or regulations, including direct control of prices for new and/or existing medicines on a product by product basis, indirect price control by limiting reimbursement levels and generating a reference pricing system, profit controls, and mandatory cuts or freezes in medicine prices generally. It is the differences in these systems which contribute to the maintenance of large price differentials between countries.

Below is a table which summarises the techniques for regulating pharmaceutical prices employed by a sample of different countries both within and outside the EU<sup>27</sup>.

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<sup>27</sup> "International Transfer Pricing in the Ethical Pharmaceutical Industry", Maurice H Collins, IBFD Publications BV.

Country	price fixing	restrictions on prescription	reimbursement rules	profit controls
UK	No direct fixing.	Negative list excludes certain pharmaceuticals (in particular branded pharmaceuticals) from reimbursement.	Patient pays a comparatively small flat fee for each item on prescription (unless they qualify for exemption). Pharmacists are reimbursed the excess cost of the pharmaceutical (on condition that it is not on the excluded list).	Under the Pharmaceutical Price Regulation Scheme limits are placed upon the overall profitability of a given pharmaceutical company (across their product range), measured by the rate of return on capital employed, on sales of products supplied under the National Health Service. The permitted rate of return for a given company is determined through negotiations with the UK Department of Health. If a company's profits exceed its agreed rate of return it must negotiate either a repayment of past profits or agree future price reductions <sup>28</sup> .
France	Prices have to be approved by the Government Medicines Directorate (which can take several years after a market authorisation has been granted). Pricing approval depends	A prescription is required. Reimbursement restricted to pharmaceuticals which are positively listed, i.e. the medicine must feature on a list of	The patient pays the full price for his medication and then receives reimbursement at one or other of a small variety of rates related to the severity of the disease. Thus the 100 percent rate	None

<sup>28</sup> The scheme is due to expire at the end of 1998 and negotiations are under way in relation to the form of the scheme which will replace it.

Country	price fixing	restrictions on prescription	reimbursement rules	profit controls
	on factors such as the therapeutic advantage and improved efficacy of the pharmaceutical and the research effort underlying it. Comparison is made with the prices of a basket of comparable products in the therapeutic class.	refundable medicines established by order of the Ministry of Health and the Ministry of Social Security.	applies to certain life-saving therapies, the 60 percent rate to the majority of pharmaceuticals and the 30 percent rate to pharmaceuticals treating minor disorders.	
Germany	Decree which lists authorised medicines with a corresponding price to which pharmacists are bound.	<p>Negative list excludes certain pharmaceuticals from reimbursement, including those:-</p> <ul style="list-style-type: none"> <li>(a) whose effects are not certain because of the various active agents the pharmaceutical contains,</li> <li>(b) which do not contain components essential for achieving the therapy's objectives,</li> <li>(c) whose therapeutic effectiveness could not be proved.</li> </ul>	<p>A reference price system operates. Reimbursement is capped at a reference level which is determined by the average price of pharmaceuticals which:-</p> <ul style="list-style-type: none"> <li>(a) are constituted of identical active ingredients;</li> <li>(b) are constituted of pharmacologically and therapeutically comparable active ingredients; and</li> <li>(c) which operate in a pharmacologically comparable manner.</li> </ul> <p>The patient has to pay the difference between the cost of the pharmaceutical prescribed and the reimbursement level of</p>	None

Country	price fixing	restrictions on prescription	reimbursement rules	profit controls
			prescribed and the reimbursement level of the reference pharmaceutical <sup>29</sup> .	
Italy	To be eligible for reimbursement the price of the pharmaceutical must be approved by the Government Pricing Committee. Therapeutic advantages and production costs are all taken into account.	A negative list excludes a considerable number of pharmaceuticals from reimbursement.	The cost of most pharmaceuticals is only partly reimbursed. The patient pays a small fixed prescription charge plus a co-payment or 'ticket'. The ticket is a percentage of the price of the pharmaceutical. It varies according to the product Class. The pharmacist claims reimbursement of the remainder.	None
Australia	Price negotiations take place with the Independent Pharmaceutical Benefit Pricing Authority (PBPA). In determining the price the PBPA takes into account, inter alia:-  (a) the level of activity of the company in Australia;  (b) prices of comparative therapeutic products; and  (c) manufacturers costs.  For products already on the list due	Positive list exists. Costs of pharmaceuticals are only reimbursed if they are included on a positive list under the Pharmaceutical Benefits Scheme (PBS). The Commonwealth Department of Community Services and Health (DCSH) decides on applications to have a product included in the list on the basis of recommendations made by the Pharmaceutical Benefits Advisory Committee.	A co-payment from the patient is generally required which varies according to the category of the patient. A reference pricing system also operates. It sets a minimum price for a pharmaceutical product where competing brands are available. The level of reimbursement is based on the price negotiated for the cheapest brand (the "bench-mark"). Patients have to pay the difference between the price of a pharmaceutical and the bench-mark.	None

<sup>29</sup> Patented pharmaceuticals which are truly innovative are excluded from the reference price system and patients pay a small flat prescription fee for them.

Country	price fixing	restrictions on prescription	reimbursement rules	profit controls
	PBPA performs a biennial price review taking the same factors into account.			
Japan	Prices are set by the Special Committee on Drug Prices. Prices for all pharmaceuticals are included in the official pharmacopoeia or registry of pharmaceuticals approved for use in Japan. The price is set by comparison with the approved price for a pharmaceutical with similar properties (efficacy, structural formula, pharmacological action etc) already listed by the Ministry or, where there is no such pharmaceutical, by reference to the cost of manufacture. After two years on the market the price of the pharmaceutical can be revised downwards.	None	Patients pay a proportion of the full cost of a prescription pharmaceutical, the rest is reimbursed.	None
United States	No controls.	None	There are limits to the prices which authorities will pay for pharmaceuticals prescribed for Medicaid patients (covers only 10 to 15 percent by value of the US domestic pharmaceutical market). Under US legislation those pharmaceuticals must	None

Country	price fixing	restrictions on prescription	reimbursement rules	profit controls
			<p>be sold to Medicaid administrations at a discount from the wholesale price. The maximum discount represents the difference between the average selling price paid to the manufacturers and the lowest price paid by any US company. Other (non Medicaid) patients pay the full cost of their medicines, subject to private insurance cover in some cases.</p>	
Belgium	<p>The Belgian Minister of Economic Affairs is the competent body for the approval of prices for pharmaceutical products. Prices for products on prescription have to be approved within 90 days and for OTC products within 60 days after the application. Pricing approval depends <i>inter alia</i> on a consultation with the Commission for the Pricing of Pharmaceutical Products (<i>Prijzencommissie voor de Farmaceutische Specialiteiten-la Commission des Prix des Spécialités Pharmaceutiques</i>) market conditions and pricing in other EU Member States.</p>	<p>Reimbursement restricted to pharmaceuticals which are positively listed</p>	<p>The patient pays the full price for his medication and then receives full or partial reimbursement depending on the type of pharmaceutical</p>	<p>None</p>

## 2. **The problems with Internet trading**

Price differentials present a number of problems for pharmaceutical trading on the Internet. On the commercial front, Internet trading makes price differentials much more transparent, potentially increasing the opportunities and incentives for parallel trading - already a significant concern for the pharmaceutical industry.

In theory, suppliers could be forced to vary the price of the product on offer depending on the location of the customer who has accessed their web-site. If they fail to observe national pricing restrictions the supplier may be subjected to scrutiny and prosecution by the national bodies responsible for policing the pricing system.

Alternatively, the relevant authorities may take the view that the supplier is free to price products on their web-site according to the pricing restrictions in the territory in which the server is located. This would enable suppliers with web-sites in, for instance, the US where there are no (or very few) restrictions on pricing to offer pharmaceuticals for sale at whatever prices they choose and can commercially maintain. This is subject to the problems caused by national reimbursement systems.

## 3. **Reimbursement**

Taking the example above, the freedom of the supplier to set its prices may operate smoothly if the consumer is personally funding the purchase. However, the supplier's freedom may be academic if the consumer is seeking to take advantage of the reimbursement system operated by the national health care provider in the territory in which the consumer is located.

There are two scenarios: the first in which the consumer is responsible for obtaining reimbursement, (for example the French system); and the second in which the supplier is responsible for obtaining reimbursement from the health care provider (as in the UK for example). In the first situation, the consumer will not purchase the product on the Internet from a territory outside that in which they are located unless they are confident that they will ultimately be able to obtain reimbursement. In the latter situation, the supplier will not dispense products to the consumer unless it can be confident it will be able to recover the full price of the product and that the administrative burden of doing so will not be so great as to negate its profit.

In the EU, where approximately 65% of the pharmaceutical market (by value) is accounted for by products that are reimbursed, this hurdle could prove to be insurmountable resulting in Internet trade being restricted in the EU to a grey market in which the patient pays the full price of product. Two recent ECJ decisions, however, have a bearing on how pharmaceutical Internet trade develops in the EU.

The two decisions<sup>30</sup> concern the reimbursement of Luxembourg citizens for medical costs which they incurred abroad. In the first case, the patient had purchased a pair of spectacles from an optician established in Belgium on a prescription from an ophthalmologist established in Luxembourg and sought to recover the cost from the Luxembourg Sick Fund. In the second case, the patient sought authorisation from the Sick Fund to receive treatment from an orthodontist established in Germany. In both cases the Luxembourg health care provider refused to reimburse the cost of the treatment on the basis that it had been or was to be purchased abroad and, in the first case, on the basis that prior authorisation for the purchase had not been maintained.

The ECJ decision centred on whether the national legislation permitting the health care providers to refuse reimbursement was consistent with Article 30 and 36 of the EC Treaty, or whether such provisions fall outside the scope of these articles in that they concern social security issues. In finding that the provisions do not escape the effect of Article 30 merely because they fall within the sphere of social security, the ECJ acknowledged that Member States are entitled to establish their own reimbursement systems, but held that they must nevertheless comply with Community law when exercising their powers under these systems.

On the facts, the ECJ held that the provisions are capable of hindering intra-community trade and the Court therefore upheld the right of every citizen to obtain goods and services relating to medical care and treatment from whichever Member State they choose.

The above decision is unlikely to be extended to purchases outside the EU, particularly if the principles established in the *Silhouette* case<sup>31</sup> are applied by analogy. Consequently the above decisions are only likely to be helpful in relation to intra European Internet trade and not trade with, for example, the US.

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<sup>30</sup> *Nicolas Decker -v- Caisse de Maladie des Employés Privés* (28 April 1998, Case C-120/95) and *Raymond Kohll -v- Union des Caisses de Maladie*, (28 April 1998, Case C-158/96).

<sup>31</sup> *Silhouette International Schmied GmbH & Co. KG -v- Hartlauer Handesgesellschaft mbH* (16 July 1998, case C-355/96)

## ANNEX 3

### Regulatory Issues

#### 1. Background

World-wide regulation by Government Authorities has a significant effect on the development, production, marketing, labelling and reimbursement of medicinal products and devices, regulating, inter alia, the placing on the market of medicinal products and medical devices (marketing authorisations), product testing (pre-clinical and clinical trials), and classification, labelling and advertising of medicines.

Any analysis of E-commerce and the pharmaceutical industry must take account of the current regulatory framework within which the pharmaceutical industry is required to operate. Whilst this paper concentrates on European issues, the world wide nature of the Internet necessitates an awareness of how Europe sits within the world-wide pharmaceutical regulatory regime and the regulatory issues which arise from the world-wide nature of E-commerce.

#### 2. European Union

The regulation of medicinal products and devices in Europe is determined at Community level by Directives which are implemented in each Member State by national laws and enforced at a national level by national agencies (for example the Medicines Control Agency in the UK and the Geneesmiddelencommissie, Commission des Médicaments in Belgium). Brief details of the Directives which are of primary relevance from an E-commerce perspective are set out below:

##### 2.1 *Marketing Authorisations for medicinal products- Council Directive 65/65 EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products*

This Directive sets out the general principle that any medicinal product must have a marketing authorisation before it can be placed on the market in the European Union (Article 3). Medicinal products are defined in Article 2 as being:-

*"Any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans beings or in animals is likewise considered a medicinal product", where 'substance' means:*

*"any matter irrespective of origin which may be:- human e.g. human blood and human blood products; animal e.g. micro-organisms, whole animals,*

*parts of organs, animal secretions, toxins, extracts, blood products etc.; vegetable e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts etc.; chemical e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.*

Prior to 1 January 1998, national marketing authorisation applications could be made concurrently to each member state. This system has now been totally replaced by the "Mutual Recognition System" and the "Centralised System" for obtaining European marketing authorisations. With effect from 1 January 1995, the European Agency for the Evaluation of Medicinal Products ("EMA") has taken responsibility for the co-ordination of scientific resources within the EU, with a view to evaluating and supervising medicinal products for human and veterinary use across the EU. On the basis of the EMA's opinion, the European Commission authorises the marketing of a product approved by the Centralised System and arbitrates between member states on other applications submitted via the Mutual Recognition System.

(a) ***The Centralised System***

The Centralised System is compulsory for certain biotechnology products, and optional for certain other medicinal products, including new active substances not previously authorised in the European Union, products administered by innovative and novel delivery systems and significant new indications for existing products. The EMA co-ordinates the registration process. However, the CPMP, a body of scientific experts drawn from each Member State, undertakes the scientific assessment of each product dossier and gives an opinion as to whether the product meets the criteria for authorisation. Time periods are laid down for various stages in the approval process, including allowances for questions and appeals. The decision to grant or refuse a marketing authorisation is taken by the Commission and, when granted, the single marketing authorisation obtained is valid throughout all Member States and the European Free Trade Association.

(b) ***The Mutual Recognition System***

The Mutual Recognition System is based upon a marketing authorisation granted by one national regulatory authority, the "Reference Member State" or "RMS". Having obtained a marketing authorisation from the RMS, the authorisation holder may apply to the regulatory authorities of other Member States to "recognise" that prior authorisation and to issue national marketing authorisations on the same terms. Such applications can be made sequentially. There are procedures and time limits according to which objections by member states can be raised and appeals may be heard, which can significantly lengthen the time from initial application to approval. Arbitrations are handled by the CPMP whose decision, when adopted by the Commission, is binding on all Member States.

Marketing authorisations are generally granted for a five year period and are renewable for five-year periods thereafter. Regulatory authorities will continue to supervise a

pharmaceutical once it has been placed on the market and they generally have the power to vary, suspend or revoke a marketing authorisation at any time if they are no longer satisfied as to the product's safety, quality or efficacy. There is a continuing obligation on the holder of the authorisation to study adverse events to the relevant authorities and to keep the safety of products under review.

## 2.2 ***Medical Devices - 93/42/EEC***

This Directive provides that any medical device must be "CE" marked, following which it may be sold freely anywhere in the European economic area without further control.

In order to affix the CE mark to a device, a manufacturer must declare conformity of the product with the provisions of the Directive, including the "essential requirements". The essential requirements with which the product must comply depend upon the classification of the device in question. Devices are classified into one of four categories: I (low risk), IIa and IIb (both intermediate) and III (high risk). The system is intended to be self-regulating, with manufacturers themselves deciding into which class their products fall. For certain Class I devices, the manufacturers themselves may declare conformity with the provisions of the directive. Other classes require the involvement of a Notified Body, a certification organisation appointed to ensure that the appropriate assessment procedures have been followed by manufacturers of medical devices. In each member state, Notified Bodies are designated by the competent authority in that territory which is the body which acts on behalf of the Government of the relevant member state, to enforce the requirements of the directive. In the UK, the Secretary of State for Health has delegated the running of this process to the Medical Devices Agency.

The following two Directives, containing broadly equivalent requirements, govern the marketing of active implantable devices (such as heart pacemakers) and invitro diagnostic products.

## 2.3 ***Classification of Human and Prescription Only Medicines - Council Directive 92/96 EEC of 31 March 1992 concerning the classification for the supply of medicinal products for human use***

This Directive contains provisions which classify the supply of medicinal products for human use in the Community into those which are subject to medicinal prescription and those which are not. The relevant guidelines are set out in Article 3 as follows:-

- (i) *Medicinal products shall be subject to medical prescription where they:*
- *are likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision, or*
  - *are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or*

- *contain substances or preparations thereof the activity and/or side effects of which require further investigation, or*
  - *are normally prescribed by a doctor to be administered parentally.*
- (ii) *Where Member States provide for the sub-category of medicinal products subject to special medical prescription, they shall take account of the following factors:*
- *the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions in force (United Nations Conventions of 1961 and 1971), or*
  - *the medicinal product is likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes, or*
  - *the medicinal product contains a substance which, by reason of its novelty or properties, could be considered as belonging to that group as a precautionary measure.*
- (iii) *Where Member States provide for the sub-category of medicinal products subject to restricted prescription, they shall take account of the following factors:*
- *the medicinal product, because of its pharmaceutical characteristics or novelty or in the interests of public health, is reserved for treatments which can only be followed in a hospital environment;*
  - *the medicinal product is used in the treatment of conditions which must be diagnosed in a hospital environment or institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere, or*
  - *the medicinal product is intended for outpatients but its use may produce very serious side-effects requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.*
- (iv) *A competent authority may waive application of paragraphs (i), (ii) and (iii) having regard to:*
- *the maximum single dose, the maximum daily dose, the strength, the pharmaceutical form, certain types of packaging; and/or*
  - *other circumstances of use which it has specified.*
- (v) *If a competent authority does not designate medicinal products into sub-categories referred to in Article 2(2), it shall nevertheless take into account the criteria referred to in paragraphs 2 and 3 of this Article in*

*determining whether any medicinal product shall be classified as a prescription-only medicine.*

**2.4 *Leafleting and Labelling -Council Directive 92/97/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets***

This Directive sets out the requirements for the labelling of medicinal products for human use and the content of leaflets inserted in the packages of such products. The Directive, at Article 2, sets out detailed requirements for the labelling of the outer or immediate packaging of medicinal products. These requirements are:-

- (i) *the name of the medicinal product followed by the common name where the product contains only one active ingredient and if its name is an invented name; where a medicinal product is available in several pharmaceutical forms and/or several strengths, the pharmaceutical form and/or the strength (baby, child or adult as appropriate) must be included in the name of the medicinal product;*
- (ii) *a statement of the active ingredients expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names;*
- (iii) *the pharmaceutical form and the contents by weight, by volume or by number of doses of the product;*
- (iv) *a list of those excipients known to have a recognised action or effect and included in the guidelines published pursuant to Article 12. However, if the product is injectable, or a topical or eye preparation, all excipients must be stated;*
- (v) *the method and, if necessary, the route of administration;*
- (vi) *a special warning that the medicinal product must be stored out of reach of children;*
- (vii) *a special warning, if this is necessary for the medicinal product concerned;*
- (viii) *the expiry date in clear terms (month/year);*
- (ix) *special storage precautions, if any;*
- (x) *special precautions for disposal of unused medicinal products or waste materials derived from such products, if appropriate;*

- (xi) *the name and address of the holder of the authorisation for placing the medicinal product on the market;*
- (xii) *the number of the authorisation for placing the medicinal product on the market;*
- (xiii) *the manufacturer's batch number;*
- (xiv) *in the case of self-medication, instructions on the use of the medicinal products.*

Article 7 of the Directive provides that the packaging leaflets must include the following information in the following order:-

- (xv) *for the identification of the medicinal product:*
  - *the name of the medicinal product, followed by the common name if the product contains only one active ingredient and if its name is an invented name; where a medicinal product is available in several pharmaceutical forms and/or several strengths, the pharmaceutical form and/or the strength (for example, baby, child, adult) must be included in the name of the medicinal product;*
  - *a full statement of the active ingredients and excipients expressed qualitatively and a statement of the active ingredients expressed quantitatively, using their common names, in the case of each presentation of the product;*
  - *the pharmaceutical form and the contents by weight, by volume or by number of doses of the product, in the case of each presentation of the product;*
  - *the pharmaco-therapeutic group, or type of activity in terms easily comprehensible for the patient;*
  - *the name and address of the holder of the authorisation for placing the medicinal product on the market and of the manufacturer;*
- (xvi) *the therapeutic indications;*
- (xvii) *a list of information which is necessary before taking the medicinal product:*
  - *contra-indications;*
  - *appropriate precautions for use;*
  - *forms of interaction with other medicinal products and other forms of interaction (for example, alcohol, tobacco, foodstuffs) which may affect the action of the medicinal product;*
  - *special warnings;*

*this list must:*

- *take into account the particular condition of certain categories of users (e.g. children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions);*
- *mention, if appropriate, potential effects on the ability to drive vehicles or to operate machinery;*
- *detail those excipients, knowledge of which is important for the safe and effective use of the medicinal product and included in the guidelines published pursuant to Article 12;*

(xviii) *the necessary and usual instructions for proper use, in particular:*

- *the dosage;*
- *the method and, if necessary, route of administration;*
- *the frequency of administration, specifying if necessary the appropriate time at which the medicinal product may or must be administered;*

*and, as appropriate, depending on the nature of the product:*

- *the duration of treatment, where it should be limited;*
- *the action to be taken in the case of an overdose (for example, symptoms, emergency procedures);*
- *the course of action to take when one or more does have not been taken;*
- *indication, if necessary, of the risk of withdrawal effects;*

(xix) *a description of the undesirable effects which can occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case; the patient should be expressly invited to communicate any undesirable effect which is not mentioned in the leaflet to his doctor or to his pharmacist;*

(xx) *a reference to the expiry date indicated on the label, with:*

- *a warning against using the product after this date;*
- *where appropriate, special storage precautions;*
- *if necessary, a warning against certain visible signs of deterioration;*

(xxi) *the date on which the package leaflet was last revised.*

Packaging and leaflet information must be in the official language or languages of the Member State where the product is placed on the market (Article 4, Clause 2 and Article 8).

2.5 ***Advertising - Council Directive 92/98/EEC of 31 March 1992 on the advertising of medicinal products for human use***

This Directive sets out several important provisions which regulate the advertising of medicinal products. These are:-

- (i) Article 2, Clause 1 provides that *"Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorisation has not been granted"*;
- (ii) Article 2, Clause 3 provides that *'the advertising of a medicinal product - shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties - shall not be misleading'*;
- (iii) Article 3 provides:-

*"(1) Member States shall prohibit the advertising to the general public of medicinal products which:-*

- *are available on medical prescription only, in accordance with Directive 92/26/EEC (8);*
- *contain psychotropic or narcotic substance, within the meaning of the international conventions;*
- *may not be advertised to the general public in accordance with paragraph 2.*

*(2) Medicinal products may be advertised to the general public, which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical doctor for diagnostic purposes of for the prescription or monitoring of treatment, with the advice of the pharmacists, if necessary."*

Please refer to [Annex 4](#) for further information on the regulation of the Advertising and promotion of medicinal products.

2.6 ***The Distance Selling Directive - Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts***

The object of this Directive is, according to Article 1 *"to approximate the laws, regulations and administrative provisions of the Member States concerning distance contracts between consumers and suppliers"*, where 'distance contract', means:-

*"any contract concerning goods or services concluded between a supplier and a consumer under an organised distance sales or service-provision*

*scheme run by the supplier, who, for the purpose of the contract, makes exclusive use of one or more reasons of distance communication up to and including the moment at which the contract is concluded".*

The Directive includes a specific reference to medicinal products at Article 14, which states:-

*"Member States may introduce or maintain, in the area covered by this Directive, more stringent provisions compatible with the Treaty, to ensure a higher level of consumer protection. Such provisions shall, where appropriate, include a ban, in the general interest, on the marketing of certain goods or services, particularly medicinal products, within their territory by means of distance contracts with due regard for the Treaty".*

## **2.7 Self Regulation/Other Legislation**

The above Directives are supported by national provisions, self regulation through codes of ethics and practice and the general restriction to pharmacies of the supply of medicines to the public. Please refer to Annex 1 (regulation of registered pharmaceutical chemists) and 4 (Regulation of the Advertising and promotion of medicinal products) for further details.

## **3. THE UNITED STATES**

### **3.1 General**

The problems which are posed by the application of the EU regulatory regime to E-commerce are probably best illustrated by highlighting the current differences between the EU regulatory regime and the regulatory regimes of other countries. The US is usually the country of comparison in this area. Brief details of the US regulatory regime are set out below to provide an initial point of reference.

### **3.2 US Marketing Authorisations**

In the US, the principal regulatory agency is the FDA. The criteria for authorisation applied by the FDA are essentially the same as the European criteria but the trials which the applicant carries out to generate data for the application must comply with FDA regulations which, in certain circumstances, may vary from the equivalent European standards. The FDA will accept reports of foreign clinical trials but it is uncommon for the agency to approve a product without some evidence from clinical trials conducted in the US. Once granted, as for Europe, marketing authorisations are generally granted for a five year period and renewable for five year periods thereafter, subject to powers to vary, suspend or revoke any marketing authorisation

### **3.3 Medical Devices**

US regulators require that the manufacturers of most medical devices submit information to the FDA, via the Centre for Devices and Radiological Health, and receive clearance before a product is introduced onto the market. Devices are classified into one of three classes, depending on the degree of risk imparted to patients by the device. The regulatory requirements are more onerous in respect of high risk devices i.e. Class III devices, than lower risk devices i.e. Classes I and II.

A new device may be introduced to the US either via a pre-market notification (a so-called 510(K)), or via a Pre-Market Approval Application ("**PMA**"). Under the 510(K) procedure, the applicant must submit certain information to the FDA (including the trade and common name, labelling and advertising details, intended use and directions for use and the classification of the device) to establish that the device is "substantially equivalent" to other devices currently being offered for sale in the US. If the FDA is satisfied with the information submitted, then the manufacturer is authorised to market the device in the US, so long as the production process complies with the requirements for Good Manufacturing Practice. It generally takes from three to twelve months from the date of a submission to obtain clearance of a 510(K) application.

Devices with new technological characteristics, or with a different safety or efficacy profile, will not be substantially equivalent and will require approval via the PMA procedure. This may involve, for example, a review of toxicological, immunological and other data, in addition to the examination of clinical results, where available. FDA review of a PMA application generally takes one or two years from the date the application is accepted for filing, but can take significantly longer.

## ANNEX 4

### **Regulation of the Advertising and Promotion of Medicinal Products**

#### 1. **General**

At present regulation of the advertising and promotion of medicinal products operates at a national level. Many countries have a combination of self regulatory codes (generally created and enforced by their national pharmaceutical association) and national legislation (generally enforced by government bodies).

There have been attempts to create international standards (for instance by WHO and the IFPMA - see section 2 below), but despite these attempts, recent studies suggest that two thirds of the world's countries still do not have laws to regulate pharmaceutical promotion or do not enforce the ones they have<sup>32</sup>.

The aim of regulation in this area is to create an acceptable balance between the supplier's right to produce commercial product information, intended to increase the sales of a pharmaceutical, and the rights of consumers and health care professionals to independent objective product information. Until recently regulation on a national basis has been reasonably successful. The system is now, however, being challenged and undermined due to the nature of the Internet and the ability of users to access sites located in any territory which may carry material which does not comply with the regulations of the country in which the user is located. This can be problematic for the consumer, used to being able to rely on regulated information, being exposed to unregulated material. It can also be problematic for suppliers, exposing themselves to the scrutiny of a whole network of regulatory bodies in territories in which they are not consciously operating.

Section 2 provides an account of the various international codes of practice on this subject - Section 3 provides an account of regulation at the European level and within EU member states, using the UK as a particular example. Section 4 contrasts the system in the US. Section 5 describes attempts to harmonise national systems and to create a consistent approach which is capable of dealing with medium of the Internet.

#### 2. **International Regulation**

Over 10 years ago WHO published ethical criteria on all aspects of pharmaceutical advertising and promotion. The ethical criteria establish a set of broad and general standards for the promotion of medicinal products.

WHO also recognises the International Federation of Pharmaceutical Manufacturers Association (IFMPA) which is a non governmental organisation having as its members, either directly or through regional organisations, the pharmaceutical industry associations of 50

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<sup>32</sup> "Blurring the Boundaries: New Trends in Drug Promotion", Barbara Mintzes, Health Action International, 1998.

countries in all parts of the world<sup>33</sup>. IFMPA represents the research-based pharmaceutical industry and other manufacturers of medicines which are intended for sale as prescription items or under the supervision of health care professionals.

The IFPMA Code of Pharmaceutical Marketing Practices is consistent with WHO's ethical criteria. It is a condition of the IFPMA Code that national associations should accept the conditions of the Code on behalf of their member companies. The Code sets minimum standards but some countries choose to adopt a more demanding national code.

IFPMA enforces the code, dealing with all bona fide alleged breaches reported to it. Where a breach has been found to occur the objective is to effect a rapid correction of matters. Publicity is given to breaches of the Code and periodic reports are issued on the operation of the Code.

The Code sets out a series of general principles which cover standards of promotion, supporting scientific evidence, provision of essential safety data, restrictions on the disguising of promotions, pre-registration communications, communications to the public and internal clearance of promotions. The most general principle of the Code states that all promotional material for pharmaceutical products should be:-

- (a) accurate;
- (b) fair;
- (c) objective; and
- (d) presented in such a way so as to:-
  - (i) conform with legal requirements and high ethical standards; and
  - (ii) be in good taste.

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The countries where FAMA has Member Associations are:-

Argentina*	Chile*	Italy	Poland
Australia	Colombia*	Japan	Portugal
Austria	Denmark	Kenya	Singapore
Belgium	Ecuador*	Korea	South Africa
Bolivia*	Finland	Malaysia	Spain
Brazil	France	Mexico*	Sri Lanka
Canada	Germany	Morocco	Sweden
Central America*:	Greece	Netherlands	Switzerland
<i>Costa Rica</i>	Hong Kong	New Zealand	Thailand
<i>Guatemala</i>	India	Norway	Turkey
<i>Honduras</i>	Indonesia	Pakistan	UK
<i>Nicaragua</i>	Ireland	Peru*	Uruguay*
<i>El Salvador</i>	Israel	Philippines	USA
			Venezuela*

\* Latin American associations are affiliated to IFPMA through their membership of the regional Federation FIFARMA.

The International Code also has sections dealing with the training and conduct of Medical Representatives, conduct of symposia, congresses and other means of verbal communication, hospitality, printed promotional material, audio-visual and computer based promotional material and samples.

Under the Code, communication directly to the consumer is only permitted if it is allowed under local laws and then it must be accurate, fair and not misleading. This clearly allows for significant variations between countries on their approach to direct to consumer advertising.

### **3. Regulation within the EU**

At the community level, regulation in the EU is again both legislation based and self imposed.

#### **3.1 Self Regulation**

The European Federation of Pharmaceutical Industries Association (EFPIA) is the representative body of the pharmaceutical industry in Europe. Its members are the national industry associations of the sixteen pharmaceutical - producing countries in Western Europe.

The EFPIA has adopted the European Code of Practice for the Promotion of Medicines which is consistent with European legislation and which sets out the minimum standards which the EFPIA considers must be adopted and enforced by its member associations. Individual members must adopt the European Code or ensure that their own national codes fully reflect the standards of the European Code in a manner compatible with national laws. Enforcement of the European Code (or relevant national code) is the responsibility of each member association in their respective territory.

The European Code is compatible with the International Code but includes greater detail and more rigorous and specific requirements in certain cases. For example, it states that promotional material must include "essential information compatible with the summary of product characteristics and the classification for the supply of the product". This is not addressed specifically by the International Code, although it may be covered by some of the general principles.

The EFPIA Code does not apply to direct-to-consumer advertising which is covered by the European Code of Standards for the Advertising of Medicines. This Code was adopted in 1977 by the Proprietary Association of Europe. It only relates to certain over the counter (OTC) medicines as promotion of prescription medicines and some OTC medicines is not permitted under EC Law (see section 3.7 below).

#### **3.2 Legislation**

Relevant EU legislation can be divided into that which is specifically directed to the promotion of medicinal products and that which is directed to advertising in general.

**Council Directive 92/28/EEC** on the advertising of medicinal products for human use contains a series of restrictions and guidelines directed specifically to pharmaceuticals. The material provisions are as follows:-

- (a) the advertising of medicinal products which are not authorised in the community is strictly prohibited (Article 2);
- (b) direct-to-consumer advertising of medicinal products which are only available on prescription (and certain other products for which self-medication is not suitable) is prohibited (Article 3); and
- (c) where it is permitted, the advertising to the general public of medicinal products must be in conformity with the very strict provisions laid down in the Directive (Article 4 and 5).

Certain aspects of the Directive are optional, and it is left to member states to decide, for example:-

- (a) specific rules in relation to products the cost of which may be reimbursed (Article 3(3));
- (b) whether to impose more onerous obligations in respect of information to be included in promotions (Article 4(1)(b)); and
- (c) the number of samples which can be provided to a health professional (Article 11(2)).

This has resulted in a degree of non-harmonisation in the EU. In relation to point (c) above, for example, the number of samples that can be provided to a health professional is limited to one per product per year in Finland and Norway, ten in the UK and in Belgium a total of no more than 600 samples per year for all products<sup>34</sup>.

**Council Directive 97/34/EEC amending Directive 89/552/EEC** on the co-ordination of certain provisions laid down by law, regulation or administrative action in member states concerning the pursuit of television broadcasting activities, applies to advertising in general but it contains a total ban on advertisements and teleshopping in relation to all medicinal products, including OTCs (Article 14).

**Council Directive 84/450/EEC** relating to the approximation of laws, regulations and administrative provisions of member states concerning misleading advertising contains regulations on advertising of general applicability. The Directive requires member states to implement adequate and effective means for controlling misleading advertising in the interests of consumers, competitors and the general public.

### 3.3 Regulation within member states - the UK example

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"The Internet and the Code of Practice for the Pharmaceutical Industry", Heather Simmonds of the ABPI.

As stated above, the EU Legislation has not totally harmonised advertising practices within the EU. Taking the UK as an example, there is still a complex network of regulations relating to the advertisement of medicinal products.

On the legislative side, the Medicines Act 1965 contains specific provisions relating to promotions and advertising. Under Part VI of the Act (sections 92 - 97) licensed products must not be recommended for any uses other than those listed in the licence and no false or misleading advertisements or representations can be made in relation to licensed medicines. The act is enforced by the Department of Health.

The 1992 EU Advertising Directive is implemented by the Medicines (Advertising to the Public) Regulations 1978<sup>35</sup>. The regulations are enforced by the MCA.

The 1984 EU Misleading Advertising Directive is implemented by the Control of Misleading Advertisements Regulations 1988<sup>36</sup>. These regulations are enforced by the Office of Fair Trading. The Director General of Fair Trading can apply to the High Court for an injunction preventing the further publication of a misleading advertisement. Most complaints are handled by the Advertising Standards Authority (ASA) or local trading standards department.

Recently in the UK, local trading standards departments have joined forces with their international counterparts (led by the Australian trading standards authorities) to carry out a global sweep of the Internet for health scams. Operators of sites such as one US site which promotes "herbal remedies which can make you cancer free" were warned that it is not necessarily the law of the site in which they reside that applies to their activities<sup>37</sup>. The results of the sweep, which was aimed at maintaining an enforcement presence on the net, are being collated by the Australian Competition and Consumer Commission and will be available in due course.

On the self regulatory side, the UK has general regulations in the form of the British Codes of Advertising and Sales Promotion which cover all forms of advertising. The Code is co-ordinated by the Committee of Advertising Practice and enforced by the Advertising Standards Authority which promotes the highest standards in non-broadcast advertisement in the UK.

Industry specific self regulation comprises a series of codes including:-

- (a) the Association of British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry which controls the promotion of prescription pharmaceuticals; and

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<sup>35</sup> SI 1978/41.

<sup>36</sup> SI 1988/915.

<sup>37</sup> Office of Fair Trading press release No. 38/98.

- (b) the Proprietary Association of Great Britain (PAGB) Codes of Practice which control non-prescription pharmaceuticals (including the PAGB Professional and Consumer Codes).

The ABPI Code of Practice is consistent with the 1994 Regulations but imposes stricter requirements than the 1992 Directive. The Code covers all sales promotion, in whatever form and whatever the mechanism of communication (including promotions on the Internet). Compliance with the Code is obligatory for ABPI member companies.

Complaints submitted under the Code, the majority of which are from healthcare professionals, are considered by the Code of Practice Panel, the decision of which can be appealed to the Code of Practice Appeal Board. Where breach of the Code is ruled the company concerned must give an undertaking that use of the material has ceased forthwith and that all possible steps have been taken to avoid a similar breach of the Code in the future.

The ABPI has been pro-active in formulating a policy in respect of Internet complaints and publishing guidelines on their approach to advertising on the Internet. The ABPI's view is that whilst the Code applies to Internet promotions, it is only enforceable in respect of information put on the Internet by companies operating in the UK. The ABPI will only take action in relation to advertisements placed on the Internet outside the UK if use of the UK product is specifically referred to or the site is otherwise promoted in the UK e.g. by medicinal representatives of the company promoting the site.

The ABPI received a complaint in May 1997 about an Internet site run by Janssen-Cilaq and Organon, which was on a Belgian server and which referred to the site owners product, Risperdal. On appeal, no breach of the Code was ruled<sup>38</sup>. The fact that the server was not in the UK, that no information specific to the UK product had been added and that the information had to be "pulled" by a searcher (i.e. by surfing the net) and was not "pushed" by the company was instrumental in the decision reached. The approach of the ABPI which is illustrated by this case is that if the information provider is not really intending to advertise in the UK then it will not fall foul of the UK regulations.

### 3.4 Regulation within Member States - the German example

Regulation of advertising and promotion of medical products is provided for by a specific law ("Gesetz ueber die Werbung auf dem Gebiet des Heilwesens-HWG") and additionally by a general law covering any unfair practices in competition independent of the nature of the practice and of the product ("Gesetz gegen den unlauteren Wettbewerb-UWG"). The HWG constitutes public law whereas the UWG constitutes private law. There is also a degree of self regulation. Dealing with each in turn:-

- (a) In the past, the HWG had been amended several times for the purposes of implementing (the above mentioned) Council Directives dealing with advertising and promotion of medical products. Save for some exceptions, the law does not only apply

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Case Auth/543/5/97 and Auth 544/5/97.

to direct-to-consumer advertising but covers any advertising of medical products independent of the addressee.

According to the HWG, any false or misleading advertisement of medical products falling within the scope of application of the “Law relating to the Manufacture and Distribution of Pharmaceuticals” (“Arzneimittelgesetz-AMG”) is prohibited. Advertising of medical products which are subject to prescription or which are neither authorised in Germany nor in another Member State of the European Union is entirely prohibited. Advertisements must provide for specific information as to the pharmaceutical’s effects, side-effects, contraindications etc (paragraph 1 of Section 4 HWG). The information must be visibly separated from other advertising information. According to Section 4a HWG, leaflets inserted in the packages of medical products shall not include advertisements for other medical products.

The HWG is enforced by the health care authority of that federal state (“Bundesland”) in which the individual or establishment violating the provisions of the HWG is domiciled.

- (b) The UWG constitutes the general law protecting competitors against any unfair or misleading advertisements. Any infringement of the provisions of the HWG simultaneously constitute a violation of Section 1 of the UWG and may therefore be challenged by competitors of the person or establishment responsible for the advertisement. However, the UWG may also cover advertising and promotion practices which do not fall within the scope of application of the HWG. In a case of 1987 the German Supreme Court ruled that the consumer is misled by an advertisement in which the manufacturer of a medicine is named with the German academic title “professor” without any clarifying addition as to the fact that the title was not conferred on him by a German university but in South America. The HWG was not applicable to this advertising measure. However, the court held that the use of the foreign academic title constituted a misleading advertisement prohibited by Section 1 of the UWG.

Furthermore, it is worth mentioning that on the grounds of the UWG, the German courts strictly prohibit comparative advertising.

The UWG is not enforced by any specific body but by private action. The law only applies if a competitor sues another competitor for unfair advertising practices in competition.

- (c) Industry-specific self-regulation is imposed on members of the Association of the German Pharmaceutical Industry by a special code (“Kodex der Mitglieder des Bundesverbandes der pharmazeutischen Industrie”). Apart from prohibiting false and misleading advertisements, the code contains specific rules according to which a manufacturer of medical products is obliged to study any extraordinary incidents with regard to a specific medical product he produces to the Regulatory Authority.

Furthermore, the code contains rules for the scientific co-operation of doctors and the pharmaceutical industry.

As the code constitutes self-imposed regulations it is enforced by the association.

Section 10 AMG sets out the requirements for labelling of medical products. The Section complies with the Leafleting and Labelling Council Directive 92/97/EEC of 31 March 1992. The label of a medical product offered for sale in Germany has must be written in the German language.

### 3.5 Regulation within Member States - the Italian example

In relation to Italy, particular provisions apply to a category of professionals ("information scientific") the role of which is to promote the marketing of medicinal products as well as equipment essentially with hospitals and medical practices. These professionals must satisfy specific requirements and are registered on an *ad hoc* register. They cannot be equalised to distributors, because they do not have the power to sell products on behalf of their principal. Also, they are not agents, because they do not (directly) promote sales but are specifically entrusted with the activity of illustrating the features of a given product or device.

It is worth noting that their activities although subject to administrative scrutiny are carried out on behalf of companies and not for the direct benefit of consumers. It is difficult to transport their current role to that of an E-commerce environment. Their position, however, is one on which views will need to be sought in relation to E-commerce advertising in Italy.

### 3.6 Regulation within Member States - the Belgian example

#### (a) Regulatory framework

The regulation of advertising and promotion of medicines is primarily set out in the Medicines Law of 25 March 1964 (*Wet op de Geneesmiddelen / Loi sur les Médicaments*; the "Law") as recently amended by the Law of 20 October 1998 published in the Belgian Official Gazette on 11 November 1998<sup>39</sup> and the Royal Decree of 7 April 1995 on the information and advertising of medicines intended for human consumption (*Koninklijk Besluit betreffende de voorlichting en reclame inzake geneesmiddelen voor menselijk gebruik / Arrêté Royal relative à l'information et à la publicité concernant les médicaments à usage humain*; the "Decree"). The Decree brings into effect the 1992 EU Advertising Directive.

Furthermore, unlawful or misleading advertising practices for medicines can also be sanctioned under the general Fair Trade Practices Act of 14 July 1991 (*Wet betreffende de Handelspraktijken en de Voorlichting en Bescherming van de Consument / Loi sur les*

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<sup>39</sup> The amendments set out in the Law of 20 October 1998 do not affect the discussed rules on the advertisement and promotion of medicines.

*Pratiques du Commerce et sur l'Information et la Protection du Consommateur*). For present purposes we will only focus on the rules specifically relating to medicines.

**(b) Restrictive use of advertising and dissemination of information on medicines**

The Decree contains the rules on advertising of and the dissemination of information about medicines. It provides, *inter alia*, rules about the information which should be stated on instructions, advertising to the public and to medicinal professionals and general information on the medicine.

With regard to advertising, the general rule of the Law is that advertising of medicines is prohibited for unlicensed medicines and advertising intended for the public is in any case prohibited for prescription medicines and medicines remedying certain diseases as identified by the High Health Council (*Hoge Gezondheidsraad / Conseil supérieur d'hygiène public*). Further details relating to advertising are set out in the Decree.

The Decree states, *inter alia*, that advertising of licensed medicines should emphasise the rational use of the medicine and may not be misleading. Furthermore the advertisement of licensed medicines is prohibited through certain defined means including software programmes and billboards.

**(c) Advertising on radio and television**

With regard to advertisements of licensed medicines intended for the public, the licence holder has to obtain an authorisation for the advertisement on radio and television. Note that the Internet is not been covered by this rule. The Belgian regulators are of the view that it is impossible to supervise information flow relating to medicines on the Internet.

The competent authority is the Minister of Public health (*Minister van Sociale Zaken, Volksgezondheid en Leefmilieu / Ministre des Affaires sociales, de la Santé publique et de l'Environnement*). The Minister acts upon the advice of the Supervising Commission for the Advertisement of Medicines (*de Commissie van Toezicht op de reclame voor geneesmiddelen / La Commission de Contrôle de la publicité des médicaments*). The request for authorisation has to be lodged by the licence holder of the medicine with the General Pharmaceutical Inspector (*Algemene Farmaceutische Inspectie / Inspection Générale de la Pharmacie*) who is in charge of administering the application.

Once the authorisation is granted, the advertisement can be repeatedly used by the advertiser during an initial term of two years and an extension of this time limit can be granted upon request.

### 3.7 Regulation within Member States - the French example

Only medicines which have an authorisation for market release (AMM, the French equivalent of a marketing authorisation)) may be advertised. An AMM is granted by the Director General of the Medicines Agency (Agence des Médicaments).

There is a distinction between advertising to the general public and advertising to the medical profession as follows:-

(i) Advertising intended for the public

For medicines, the conditions are:

- medicines must not be subject to medical prescription
- medicines must be non-refundable
- the AMM of the medicine in question must not carry any restriction in respect of advertising

In addition, advertising permit is required, the conditions for which are :-

- Prior authorisation granted by the Director General of the Medicines Agency for most products.
- Products labelled "beneficial for health" are dealt with by the Ministry of Health.
- The advertising permit is granted following a consultative procedure carried out by the Advertising Control Commission (*commission de contrôle de la publicité*).

(ii) Advertising intended for the medical profession:

Special rules apply to advertising in this area, with a degree of professional self-regulation. Memorandum and recommendations from an ethics committee are the means of establishing the principles of self-regulation in areas where regulation is unclear or silent.

#### 4. Regulation in the US

The Federal Food, Drug and Cosmetic Act contains the main US provisions relating to advertising and promotion of pharmaceuticals in the US. The regulations are implemented and enforced by the FDA.

The most significant difference between the US and EU position is that direct-to-consumer advertising of prescription products is not prohibited in the US, although the content of such advertisements is the subject of tight control. The Division of Drug Marketing, Advertising and Communications is the organisation in the FDA responsible for regulating prescription pharmaceutical promotion.

The FDA has not yet issued any guidance on its approach to advertising on the Internet, expressing the view that the Internet as just another promotional medium and the existing regulations and guidelines cover the practice. This view was reached following extensive public consultation on the issues arising from Internet trading. Debate in the US over use of the Internet has focused on, amongst other things, whether promotions on the Internet qualify as labelling or advertising and consequently which specific regulations should apply. The main

difference between the regulations is the requirement for full disclosure in relation to labels compared to a brief product summary for advertisements. Most companies which post product information have opted to comply with the stricter labelling regulations and have included the package insert for products featured on their web-site.

As a result of the differences between the EU and US regimes, consumers can now view advertisements in relation to prescription pharmaceuticals (and in certain cases purchase such pharmaceuticals) on US web sites. So long as the sites do not specifically refer to UK products the approach of the UK authorities at least is that such sites do not fall within their jurisdiction.

## 5. **Steps to harmonisation**

One approach to harmonisation is that adopted by the UK authorities - only police those sites which are directed at, and intended to, reach the UK public (even if the UK public has easy access to them). Such an approach may be sufficient in relation to sites regulated by the FDA but the same may not apply to sites in territories with no regulation or control of the quality and content of pharmaceutical advertising.

The World Health Organisation (“**WHO**”) is adopting a different approach. Following a number of Working Group Meetings in 1997 and 1998, the World Health Assembly adopted a resolution in May 1998 on cross border advertising, promotion and sale of medicinal products through the Internet.

The WHO resolution calls for member states to review existing regulations and guidelines and to collaborate to ensure that adequate cover is implemented, monitored and enforced. The resolution also encourages the industry to formulate an acceptable international self-regulatory systems and to maintain legal and ethical standards in cross-border advertising.

## 6. **Other issues**

Many commentators have focused on the unique nature of Internet communications as a means of overcoming the cross-border regulatory issues. They note that on the Internet, it is the customer/patients who initiates contact with a web-site and not the owner of the site. People are seeking out information "with every click of their mouse". Queries have accordingly been raised as to whether advertising on the Internet is in fact direct-to-customer advertising or indirect communication. Indirect communication about prescription medicines is permitted under most regulatory regimes so long as it is of a "non-promotional" nature. Although this can lead to disputes as to what constitutes information and what strays into promotion - the interpretation of Internet communication as "indirect" could be adopted as an approach in certain circumstances to overcome the cross-border issues.

Following on from the above point, it is possible that the best approach to dealing with the flood of apparently unregulated information on the Internet is through positive steps, such as consumer education. In line with this, the WHO is co-ordinating the generation of a “Guide for Internet Users” specifically aimed at pharmaceutical products. Such measures could be

combined, for instance, with approval by national regulatory authorities (via their own web sites perhaps) of specifically authorised web sites. Accredited web sites could then carry a “smart” accreditation symbol (like the CE mark) which linked directly to that list (so that mere copying of the symbol by pirate sites would be insufficient for them to claim to consumers that they were accredited).

As mentioned above, in the US labelling regulations, which are more onerous than advertising regulations, are thought by some to apply to all Internet promotions. On this interpretation the Labelling Directive (92/27/EEC) would apply to EU Internet advertisements. This Directive requires that medicinal products must be labelled in the language of the country where the product is placed on the market, and must contain a patient package leaflet in that language. Whilst the nature of the Internet is such that it is not necessarily problematic or financially prohibitive to add more information to a site this is a further requirement with which companies using the Internet must contend.

There are peripheral laws and regulations relating to advertising which may also cause cross border problems. For example, the rules relating to comparative advertising are very different in the US and Europe. In the US, comparisons which would be considered acceptable may amount to trade mark infringement in the EU. Site owners would need to take into account the differences in such rules.

The above account only sets out the regulations affecting suppliers seeking to advertise medicinal products on the Internet. If they seek to go one step further and sell via the Internet, other regulations will affect their activities. For example, under Article 14 of the Distance Selling Directive (97/7/EEC), member states are entitled to prohibit any distance selling of medicinal products in their territory, which would theoretically cover Internet transactions.

## ANNEX 5

### Jurisdiction over IP disputes

#### 1. Introduction

Jurisdiction is by far the most problematic and vexed legal issue relating to the Internet generally, and E-commerce in particular. It is far from clear to what extent the mere fact of having a web-site will subject the site owner to the laws of the given country. There are currently no specific laws which deal with E-commerce which means that the starting point is from the normal rule that the owner of an intellectual property right can take action to enforce that right in the courts of the country where an infringement takes place. At present each case must be considered on its own facts and, in many instances, the answer will depend upon the laws enforced in the country in which the question is being raised. However, due to a lack of legislation dealing specifically with cross-border Internet related transactions, national courts are having to adapt traditional concepts of jurisdiction. Jurisdictional issues in relation to E-commerce are not industry specific; the pharmaceutical sector will face the same problems as other industry sectors in this regard. However, the pharmaceutical industry is strongly reliant on intellectual property rights, in particular, patents, trade marks, copyright, and confidential information/know-how ("**IPR**") and their protection. The purpose of this Annex is to provide a general introduction to jurisdictional issues in this area, concentrating on where infringement of IPRs occur and which country has jurisdiction over that infringement. UK law is used as the basis for discussion in each case. However, given the relative harmonisation of IPR laws throughout the Community, the issues raised are likely to apply through-out Europe.

#### 2. Where does infringement occur?

2.1 There do not appear to be any clear rules giving a clear indication of where infringement of IPR occurs over the Internet. The most common discussion concerns whether infringement occurs in the country of location of the server or whether it occurs in the country in which the material is downloaded. A discussion of the position in relation to IPR of most relevance to the pharmaceutical industry is set out below.

##### (a) *Copyright infringement*

Copyright is the exclusive right to reproduce certain types of creative works. It arises automatically upon the creation of such works without the need for registration. In the UK, the law is governed by the Copyright, Designs and Patents Act 1988 (the "1988 Act"). Section 1 of the 1988 Act states that copyright subsists in the following categories of work:

*"(a) original literary, dramatic, musical or artistic works;*

*(b) sound recordings, films, broadcasts or cable programmes, and*

(c) *the typographical arrangement of published editions*".

It is worth noting that a 'literary work' is defined to mean any work which is written, spoken or sung and includes tables or compilations and, importantly, computer programs. The application of copyright law to computers was clarified by the amendment of the 1988 Act by the Copyrights (Computer Programs) Regulations 1992. These regulations were brought in to harmonise UK law and that of other EC Member States in accordance with the Directive for the legal protection of Computer Programs<sup>40</sup>. Copyright will also protect the preparatory design material for a computer program. "Literary work" has also been defined to include databases by The Copyright and Rights in Databases Regulations 1997<sup>41</sup> which implement a Directive harmonising the copyright laws of EC Member States on the legal protection of databases.

The following provisions of the 1988 Act are also relevant:-

- (i) the general rule is that the owner of a copyright work is the person who creates it (section 9) (there are exceptions in relation to employees and certain categories of copyright such as crown copyright);
- (ii) copyright does not subsist in a literary, dramatic or musical work unless and until it is recorded "in writing or otherwise" (section 3(2));
- (iii) the literary, dramatic, musical or artistic work must be 'original' (section 1). In the UK, there is a low threshold of originality and the basic requirements are that the work originated from the author and is the result of minimum skill, effort or judgement;
- (iv) the owner of the copyright in a work has the exclusive right to copy the work, issue copies of the work to the public, perform, show or play the work in public, broadcast the work or include it in a cable programme service or make an adaptation of the work, in the UK (section 16). Copyright is thus infringed by the carrying out of any of these acts;
- (v) the 1988 Act also sets out, at chapter IV, certain moral rights of authors, which are the rights to be identified as author of the work, the right to object to derogatory treatment of the work and the right to object to false attribution of the work;
- (vi) an infringement of copyright is actionable by the copyright owner. The remedies available for infringement of copyright include damages or an

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<sup>40</sup> Directive 91/250, OJ 1991, L122.

<sup>41</sup> SI No. 1997/3032.

account of profits, injunctions, order for delivery up or destruction of infringing copies, and costs (Chapter VI).

In addition to the above provisions of the 1988 Act, as a result of the provisions of the Directive harmonising the term of protection of copyright and certain related rights<sup>42</sup> the term of copyright protection for artistic, literary, dramatic and musical works throughout the EC now generally expires 70 years after the death of the author (Section 12, 1988 Act as amended by The Duration of Copyright and Rights in Performances Regulations 1995<sup>43</sup>. For computer-generated works, sound recordings, broadcasts, computer programs, the period of copyright protection is generally 70 years from the end of the calendar year in which such works were made available to the public (Sections 12-14 1988 Act as amended).

The transmission of material over the Internet could infringe the copyright of a third party. Problems arise in determining who to sue (e.g. the access provider, the host or the third party, each of whom could "copy" a copyright work) and where jurisdiction lies. There are no clear answers to these questions. However, the two cases discussed below give an idea of how courts are approaching the issue in Europe and the US.

EC Council Directive 93/83/EEC relates to copyright applicable to satellite broadcasting and cable retransmission but may be applicable to IPR by analogy. This Directive states that the act of communication to the public by satellite occurs solely in the Member State where the programme-carrying signals are introduced into an uninterrupted chain of communication leading to the satellite and down towards the earth. Further, where the act of communication to the public by satellite occurs in a non-Member State, if the programme-carrying signals are transmitted to the satellite from an uplink station in a Member State, then that communication is deemed to have occurred in that Member State. If there is no use of such an uplink station but a broadcasting organisation established in a Member State has commissioned a communication to the public, then the communication is deemed to have occurred in the Member State in which the broadcasting organisation has its principal establishment in the Community.

The recent case of **British Sky Broadcasting Ltd v The Performing Right Society Ltd**<sup>44</sup> considered this Directive and made the point that questions have arisen as to the place where the broadcast takes place and what constitutes the act of broadcasting. Section 6(4) of the 1988 Act states that in the case of a satellite transmission the broadcast occurs from where the signals were transmitted to the satellite. The observation was made that the restricted act in which the copyright owner had the exclusive right was the placing of broadcasting signals into this uninterrupted chain of communication. It could no longer be argued that the broadcasting took place where the signals were received. Therefore, a licence under

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<sup>42</sup> Directive 93/98, OJ 1993 L290/9.

<sup>43</sup> SI No. 1995/3297.

the broadcasting right carried with it the right to send signals via satellite to all EC member states.

The current uncertainty relating to copyright on the Internet can be illustrated by the US case of **Playboy v. Chuckleberry**<sup>45</sup>. In this case, the defendants operated a Web-site in Italy which contained a computerised version of Playboy Magazine in infringement of the plaintiff's copyright. The plaintiff claimed that this violated an injunction granted in 1981 by a US court against the publication of infringing copies of their publication. The defendants argued that this was the same as selling the magazine in Italy, where it was legal. The court held that, although the prohibited activity originated in Italy, it was received in the US without difficulty and so infringed that injunction.

Copyright is one of the most challenging areas in European intellectual property law. It is used to protect many different kinds of work in fields where the speed of technological progress is rapid and it is an area where there has been some disharmony between the laws of Member States. The European Commission has already implemented several initiatives to amend copyright law to keep up with technological progress, including Directives on the Protection of Computer Software, Databases, Term of Copyright, Satellite Broadcasting and Cable Retransmission and Rental and Lending Rights. A similar initiative may be useful in respect of copyright and E-commerce issues such as jurisdiction.

(b) ***Patent Infringement***

Patent law throughout the Community is relatively harmonised because of the European Patent Convention (signed in 1973) pursuant to which 17 European countries including all the Member States of the European Community, have agreed to a single examination and grant system through the European Patent Office. Upon grant, the patent becomes a separate right within each of the signatory countries. In addition, there is the Community Patent Convention 1975 ("CPC"), which is a treaty between EC Member States providing for a Community wide patent. The CPC is not, however, yet in force. The UK Patents Act 1977 (the "**1977 Act**") was intended to amend UK national patent law to make provision for both the EPC and the CPC. The 1977 Act provides the owner of an invention which is new, involves an inventive step, is capable of industrial application and which does not fall within a specified list of exceptions, a monopoly in respect of that invention for a period of 20 years from the date of filing the application for the patent (sections 1 and 25).

Under section 60 of the 1977 Act, a person infringes a patent for an invention if, while the patent is in force, any of the following things are done in the UK in relation to the invention without the consent of the proprietor, namely:-

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<sup>44</sup> [1998] RPC 467.

<sup>45</sup> 939 F.Supp.1032 (S.D.N.Y. 1996.)

- (a) *where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;*
- (b) *where the invention is a process, he uses the process or he offers it for use in the UK when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;*
- (c) *where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.*

In relation to the E-commerce and the pharmaceutical industry, it is likely that most issues of patent infringement, and whether or not there is jurisdiction to sue, are likely to arise in relation to offering to dispose of products, offering a process for use and offering to dispose of a product obtained directly by means of a process, over the Internet. The problems are the familiar ones, namely whether or not, as in the **Playboy -v- Chuckleberry** case (discussed in relation to copyright above), receiving, for example, an offer of sale of a product which is legal in the country of origin, but which happens to be accessed in a country where such offer infringes a patent right, constitutes patent infringement. Uniformity of decisions on these issues throughout Europe may be difficult because, despite harmonisation, there have been examples of conflicting decisions as to what constitutes infringement in national courts. The distortions created by the conflicting decisions of national courts within the EC will, in theory, be resolved when the Community Patent Convention eventually comes in to force. However, the position in relation to E-commerce infringement would benefit from guidelines as to what will constitute patent infringement on the Internet. There are no clear solutions. One suggestion to deal with E-commerce issues relating to patents may be to attempt to revise the Community Patent Convention to deal with E-commerce issues before it is implemented. Certainly, the existence of a unitary court structure and procedure at Community level for resolving litigation, (as suggested by UNICE (the Union of Industrial and Employer' Confederations of Europe) in October of this year would provide a good basis for dealing with patent litigation resulting from E-commerce.

(c) ***Trade Mark Infringement***

A trade mark is a sign (such as a name or logo) used by a business to distinguish its goods or services from the same or similar goods or services coming from another source. Trade marks can be registered or unregistered and both types of trade mark can be licensed. Domain names are also of relevance, particularly in relation to E-commerce and the pharmaceutical industry.

Dealing with each in turn:-

(i) **Registered Trade Marks**

Trade mark rights are effectively national. An application can be made to register a trade mark in respect of specific goods or services at the relevant country's trade mark registry or through the Community trade mark, Madrid Protocol and Madrid arrangement systems. When the registration process is complete the registered proprietor has a monopoly to use the mark in respect of the specified or confusingly similar goods or services. Registered trade marks can last forever provided renewal fees are paid and the marks are not removed from the register. In the UK, the Trade Marks Act 1994 (the "**1994 Act**") implements Council Directive No 89/104/EEC of 21 December 1988 to approximate the laws of Member States relating to trade marks. Section 10 of the 1994 Act sets out the acts which infringe a UK registered trade mark as follows:-

*"A person infringes a registered trade mark if he uses in the course of trade a sign which is identical with the trade mark in relation to goods or services which are identical with those for which it is registered.*

*A person infringes a registered trade mark if he uses in the course of trade a sign where because:-*

- the sign is identical with the trade mark and is used in relation to goods or services similar to those for which the trade mark is registered, or
- the sign is similar to the trade mark and is used in relation to goods or services identical with or similar to those for which the trade mark is registered,

*there exists a likelihood of confusion on the part of the public, which includes the likelihood of association with the trade mark.*

*A person infringes a registered trade mark if he uses in the course of trade a sign which:-*

- is identical with or similar to the trade mark, and
- is used in relation to goods or services which are not similar to those for which the trade mark is registered,

*where the trade mark has a reputation in the UK and the use of the sign, being without due cause, takes unfair advantage of, or is*

*detrimental to, the distinctive character or the repute of the trade mark.*

*For the purposes of this section a person uses a sign, in particular, he:-*

- affixes it to goods or the packaging thereof;
- offers or exposes goods for sale, puts them on the market or stocks them for those purposes under the sign, or offers or supplies services under the sign;
- imports or exports goods under the sign; or
- uses the sign on business papers or in advertising.

*A person who applies a registered trade mark to material intended to be used for labelling or packaging goods, as a business paper, or for advertising goods or services, shall be treated as a party to any use of the material which infringes the registered trade mark if when he applied the mark he knew or had reason to believe that the application of the mark was not duly authorised by the proprietor or a licensee.*

*Nothing in the preceding provisions of this section shall be construed as preventing the use of a registered trade mark by any person for the purpose of identifying goods or services as those of the proprietor or a licensee.*

*But any such use otherwise than in accordance with honest practices in industrial or commercial matters shall be treated as infringing the registered trade mark if the use without due cause takes unfair advantage or, or is detrimental to, the distinctive character or repute of the trade mark."*

Registered trade marks are enforced by taking infringement proceedings in the High Court against an infringer in relation to the above;

(ii) **Unregistered Trade Marks**

Unregistered trade marks are simply marks used by a party to identify goods or services, or any trading or business names used by a party, which have not been registered. In appropriate circumstances, the owner of an unregistered trade mark or trading/business name may be able to prevent third parties from using the same or a similar mark or name. In the UK, an action of this sort would be based on the common law of 'passing-off' (in which a trader who

has established a significant reputation and goodwill in his marks can restrain a third party from using similar marks if he can prove that use of those similar marks by the third party has caused the public to confuse the third party's goods with his own). In most other European countries there will be a similar right to restrain others from using the mark through an action for unfair competition;

(iii) **Domain Names**

A domain name is an alphanumeric representation of an electronic machine readable address (called an Internet Protocol Address) which is used by networking computers (including those which operate the Internet) to route messages from the sender to the recipient. Registration for domain names is carried out by non-profit making companies appointed for this purpose by the Internet Society, an international body created for the purpose of co-ordinating the Internet, on a first-come first-served basis.

A domain name forms an important part of an e-mail address (e.g. Adam.Smith@Company.com) or of a business (or other person's) home page website address. It consists of two elements, a word/number designated by the proposed registrant and a generic designation known as a top level domain such as ".com" or ".co.uk" for commercial entities. Although the suffix ".com" is specific to the regulatory company for the US ("Network Solutions Inc") it has become established as a suffix for commercial entities operating on an international basis. The UK equivalent (".co.uk") is regulated by Nominet UK Limited. It is typical for a company to want to use its name or the words which feature in its most important trade marks as part of such a website or e-mail address. In order to obtain a domain name the applicant must apply to one of the not-for-profit companies which were set up to register domain names which are allocated on a first-come, first-served basis.

The process of allocating names has created some difficulties for trade mark owners. A number of companies with well-known brand names were rather slow in identifying the increased usage of domain names or decided not to register all possible domain names simply by dint of the sheer number and possible variety. As a result, a number of applications were made for domain names featuring well known trade marks by individuals who were not the proprietors of such trade marks. In some cases, offers were made to sell the domain names to the proprietors of the trade marks sometimes for not inconsiderable sums. This has led to a number of disputes both in the UK and elsewhere, which the regulatory companies and their dispute resolution procedures have (in broad terms) been unable to resolve. A number of these matters have therefore been the subject of court proceedings. In **British Telecommunications plc and others v One in a Million**<sup>46</sup> the High Court

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<sup>46</sup>

The Times, 2 December, 1997.

held that a trade mark owner could obtain a final injunction to restrain the threatened use of its trade mark as part of a domain name and to require to take steps to "transfer" the domain name registration to it.

The registrants of domain names have also attempted in some cases to register the domain names as trade marks. The UK Trade Marks Registry has issued a statement indicating that domain names can be trade marks and may be registered according to the normal rules but that the usual domain name endings such as ".com" are to be regarded as not having any distinctive character. In these circumstances there would appear little to be gained in attempting to register a domain name consisting purely of an already registered trade mark and a domain name ending.

(d) ***Confidential Information***

Confidential information encompasses technical information and know-how and other expertise which is not generally known or available. In the pharmaceutical business, it is not uncommon for a company to disclose confidential information to third parties or for third parties to disclose confidential information to it (e.g. for the purposes of evaluating joint product development opportunities). This area of IPR is not subject to legislation in the UK. Certain pre-conditions to establish breach of confidentiality have been set out by case law, namely that the information must not be generally available, it must be imparted in circumstances importing an obligation of confidence and there must have been an unauthorised use of that information to the detriment of the party communicating it. The main problem as regards the transmission of confidential information over the Internet is lack of security, coupled with a difficulty in establishing an express contractual obligation of secrecy with parties such as an Internet service provider or any third party who accesses the information by chance and passes it on. Protection options for pharmaceutical companies at the moment include the use of encryption, clear notices informing recipients of the information that there is an obligation of security in respect of it and the use of intranets to exchange confidential information between authorised users only. In addition, it may be appropriate to create specific legislation to deal with breach of confidential information in relation to E-commerce.

3. **Enforcement**

3.1 ***General***

Currently, the enforcement of IPRs is carried out by national courts on a case by case basis, which enforce the right to take action in the courts of a country where infringement of an IPR right takes place. This right is also set out in the Brussels Convention 1968. The Convention rights and Court rights are discussed below. In relation to E-commerce, the question for discussion is whether these conventions need to be amended to cover E-commerce jurisdiction in general, which would have general applicability to all industries, including the pharmaceutical industry.

### 3.2 *Convention Jurisdiction*

(a) The Brussels and Lugano Conventions

Where the parties involved in the international contract are European, the relevant principles will normally be found either in The Brussels Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters 1968 (the "Brussels Convention") (entered into by the Member States of the European Union) or The Lugano Convention. The principles which apply according to the choice or otherwise by the contracting parties of a governing jurisdiction are set out below.

(i) *The parties choose a jurisdiction*

The rules vary depending on where the contracting parties are domiciled. Whether parties are domiciled in a relevant Member State depends upon the internal law of the country in question (Article 52). A company, for example, will be treated as being domiciled in the UK if it has its seat there.

Where at least one of the contracting parties is domiciled in the EU (or a relevant EFTA country for the purposes of the Lugano Convention), the parties are generally completely free to choose which court should have jurisdiction to hear any dispute, and should do so to avoid uncertainty. If they agree that an EU or relevant EFTA court is to have jurisdiction, an English court will usually regard that court as having exclusive jurisdiction (Article 17).

However, in proceedings concerned with the registration or validity of patents, trade marks, or other similar registered rights, the courts of the Member State in which the registration took place will have exclusive jurisdiction, regardless of domicile and the parties' choice of jurisdiction will be overruled. (Article 16).

If none of the parties is actually domiciled in a Member State but they nevertheless agree that a Member State court should have jurisdiction, the relevant court may decide whether it accepts jurisdiction. The court of another Member State may only accept jurisdiction if the first court declines.

(ii) *The parties do not choose a jurisdiction*

Article 2 makes the general rule that persons domiciled in a Member State shall, whatever their nationality, be sued in the courts of that state. This means that a person can be sued in the country in which he is domiciled even if the infringement did not occur there. This remedy is of limited use where the claimant wants to obtain injunctive relief in the country where the infringement is occurring but is useful where the claimant is more concerned with obtaining damages.

(iii) Interim orders

Even where the court of one Member State has jurisdiction over the substance of a matter, Article 24 allows parties to apply to the court of a different Member State for interim relief such as an injunction.

(iv) Recognition and enforcement of foreign judgments

The general rule is that a judgment obtained in one Member State must be recognised and enforced in any other (Articles 26 and 31). This is subject to some exceptions, for example, where recognition or enforcement would be contrary to public policy under the law in question (Articles 27 and 34).

(b) Where neither Brussels nor Lugano Conventions apply

The general rule is that, in deciding whether to accept jurisdiction, the court of a Member State must apply its own rules (Article 4). The English courts will traditionally accept jurisdiction where the defendant has actually submitted to that jurisdiction or where he is present in England at the time he is served with the writ. Unless the defendant submits to the jurisdiction, the English court will only give leave for service of the writ outside the jurisdiction where it believes it will be proper to do so.

The European Court of Justice in the defamation case of **Shevill v. Press Alliance SA**<sup>47</sup> gave the plaintiff the choice of bringing their action in either the place where the damage emanated, being the place of publication, or the place where the resulting damage occurred, being one of the countries of distribution, thus opening up the possibility of forum shopping.

### 3.3 *Court Jurisdiction*

Courts have full authority with respect to residents of their country, so that proceedings can be served on a resident of the court's country even if they are outside the jurisdiction. In addition, in certain circumstances, courts have jurisdiction over non-residents who are not physically present in the jurisdiction. To date, the application of jurisdiction of national courts in relation to its residents and non-residents have not been consistent. There has not yet been

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<sup>47</sup>

Case 68/93 [1995] E.C.R. 415.

a lot of European guidance on this issue. However, there have been cases in the US where Courts have accepted and declined jurisdiction over non-residents. For example, in **Bensusan Restaurant Corp. v King**<sup>48</sup>, a federal district court in New York held that a Web-site alone is not sufficient to establish personal jurisdiction. The defendant in that case operated a Web-site advertising its Missouri night-club, which shared its name with the plaintiff's New York night-club. The plaintiff sued for trade mark infringement based on the Web-site advertising. The court refused to extend jurisdiction, reasoning that, "The mere fact that a person can gain information on the allegedly infringing product is not the equivalent of a person advertising, promoting, selling or otherwise making an effort to target its product in New York." This case can be contrasted with **CompuServe v Patterson**<sup>49</sup> a US Court of Appeal case, where Patterson, a resident of Texas entered into an on-line agreement with the Ohio-based CompuServe for the distribution and sale of his computer programs. Three years later, he complained to CompuServe, via e-mail and regular mail, of alleged trade mark violations and unfair trade practices based on CompuServe's marketing of a similar program. CompuServe filed an action to preclude these claims. The US Court of Appeal held that Patterson's transmission of the computer files, combined with his CompuServe subscription, the on-line contract agreement and the e-mail complaints, demonstrated that Patterson had 'knowingly reached out' to Ohio and so he should be sued there. The court cautioned, however, that it did not consider the issue of whether a CompuServe subscription alone would be sufficient for a finding of personal jurisdiction.

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<sup>48</sup> 937 F.Supp. 295 S.D.N.Y.

<sup>49</sup> 39 USPQ 2d/502.

## ANNEX 6

### Questionnaire

Ashurst Morris Crisp - solicitors

in association with

Executive Perspective S.A.

## Electronic Commerce in the Pharmaceutical Sector

### Summary of the responses to the E-commerce questionnaire

Survey questionnaires were sent to approximately 180 organisations across Europe with an interest in the pharmaceutical sector. Organisations who were mailed the questionnaire broadly broke down into four categories - pharmacists' associations, wholesalers and wholesalers' associations, manufacturers and regulators. Many organisations however had yet to consider the implications of E-commerce internally (indeed our requests prompted such an internal examination in a number of cases) and as a result there are a large number of European organisations (including some of the most significant players in the market place) who have yet to determine their attitude towards E-commerce.

In summary, the survey results reveal that manufacturers, wholesalers and pharmacists have very different approaches towards E-commerce. The pharmacists' associations are strongly opposed to E-commerce in the pharmaceutical market. They deny that E-commerce could have any advantage to the consumer and, instead, refer to possible threats to the patient's health this new trade channel could involve.

On the other hand, manufacturers are largely in favour of E-commerce and expect that the on-line sale of pharmaceutical products to consumers will be used significantly in the future. However, the survey showed a clear uncertainty about what issues constitute constraints to E-commerce, and how E-commerce should be regulated.

Wholesalers showed less interest in the subject. As the phone calls to companies who did not respond to the questionnaire revealed, some wholesalers still seem to be unaware of the importance E-commerce could have to their business. Others recognise the importance of E-commerce in the future though not necessarily welcoming it wholeheartedly. They, too, are unsure about existing constraints and the issues a regulatory framework should address.

Amongst the Regulators few common themes emerged. Unsurprisingly, Regulators views were largely determined by their attitudes to regulation and the free-market in general, so that once that dogmatic issue had been resolved, regulators followed a largely consistent pro-free-market or pro-regulation line.

There follows a list of the questions asked (set out in bold type) together with a short summary of the answers given to each question. The answers to each question are broken down by distribution levels:-

1. **Market Information**

1.1 **What do you see as the principal roles to be played by E-commerce in the EU pharmaceutical sector?**

- (a) **in the next 5 years;**
- (b) **thereafter?**

Manufacturers

Manufacturers saw the principal role of E-commerce during the next five years as being in the business to business sector. They expected E-commerce increasingly to be used for trading with wholesalers, hospitals and retail pharmacy outlets. One step further would be the sale of non-regulated products to consumers via the Internet, and information exchange with physicians via web based media. In the long term, manufacturers expected regulatory revisions, allowing on-line prescribing and direct trading to consumers.

Wholesalers

Whilst some wholesalers saw little future for E-commerce, the majority expected the gradual development of E-commerce - particularly in relation to "generic" products and marketing. Some thought that, in the long term, E-commerce would substitute traditional commerce.

Pharmacists' associations

Pharmacists' associations expressed the opinion that E-commerce in the pharmaceutical sector would not play any role in the future, or at least should not in order to protect consumers' health.

Regulators

Regulators only went so far as to say that they thought E-commerce would play a role in future.

1.2 **To what extent do you use E-commerce already? By which means (e.g. Internet, EDI)? Do you have plans to use it?**

Manufacturers

Most of the E-commerce currently used by manufacturers is restricted to business to business trade via EDI. The Internet is used by some manufacturers to provide physician and patient information resources.

### Wholesalers

Only one of the wholesalers questioned used the Internet for Ecommerce, though some provide information over the web. EDI is used, though on an experimental basis, by the majority.

### Pharmacists' associations

None of the pharmacists' associations which responded referred to any current E-commerce use by pharmacists. One association explained that there is a "data interchange and account" between pharmacists and the Pharmacist' Salary Disbursement Fund for Austria, which settles the health insurance institutions' account with the pharmacies. This can be carried out by electronic means.

### Regulators

Whilst regulators do not trade, some of them use EDI for emergency pharmaceutical authorisation and the reporting of adverse pharmaceutical reactions.

1.3 **Please identify and explain any existing and/or future constraints on the development of E-commerce in the EU pharmaceutical sector (other than legal regulation - for which see below). Do they include: -**

- (a) **unreliability of electronic media (e.g. connection problems on the Internet);**
- (b) **the insecurity of electronic media;**
- (c) **costs;**
- (d) **problems with electronic payment systems;**
- (e) **lack of structure on the Internet (e.g. no index for sites or companies); or**
- (f) **the "anonymity" of Internet participants.**

### Manufacturers

In general, the manufacturers did not seem to be concerned about any of these issues though some mentioned that line speed and security could constitute constraints.

### Wholesalers

Costs and technical problems were not regarded as barriers to Ecommerce by most wholesalers (though there were concerns raised at the current lack of speed of the web). All wholesalers stated that a comprehensive and standardised security system for payments was necessary and that any new law must cover all people who are involved in E-commerce. Finally, some mentioned that lack of quality assurance of products might become a major problem.

### Pharmacists' associations

Rather than referring to actual constraints to E-commerce in the pharmaceutical market, the pharmacists' associations expressed their concern about patients' health being threatened by counterfeit pharmaceuticals, lack of personal advice, and abuse of the prescription system through pharmaceutical ordering without medical advice. They also thought that lay people could find it difficult to find relevant information on the Internet. Furthermore, they saw security problems and some created a scenario of a two class society consisting of people who are able to pay electronically and receive their pharmaceuticals quickly and others who are not.

### Regulators

Regulators varied widely in their estimation as to which of the named issues constituted constraints on the development of E-commerce. In addition to the examples given in the questions, the lack of EDI standards was mentioned.

## 1.4 **What are the key drivers promoting E-commerce in the EU pharmaceutical sector. Is competition one of them? Is reducing costs another?**

### Manufacturers

Both competition and cost reduction were seen as key drivers by most of the manufacturers. Other key drivers which were mentioned were direct contact with consumers, personal contact with health care providers and the creation of a network of potentially interested customers.

### Wholesalers

Both competition and cost reduction were seen as key drivers. Complexity of the information to be conveyed to customers was mentioned by one wholesaler.

### Pharmacists' associations

The pharmacists' associations did not see any key drivers promoting E-commerce in the pharmaceutical sector. One association argued that E-commerce in this sector would constitute unfair competition. On-line traders would be able to undercut pharmacies prices since they do not have to provide costly professional advice. This would constitute an unfair advantage, to the detriment of consumer's health.

### Regulators

Both competition and cost reduction were seen as key drivers, as well as increased speed through avoiding use of conventional paperwork.

1.5 **What do you see as the principal advantages of using Ecommerce in the EU pharmaceutical sector generally?**

Manufacturers

The new “communication opportunity” provided by the Internet was regarded as one major advantage. It was argued that more complex information could be made accessible and at a pace suited to the audience. Other advantages mentioned were lower trading costs, better customer support and improved competitiveness.

Wholesalers

There was little consensus amongst wholesalers, but some mentioned costs, speed, availability of information or security in the logistical chain. Others did not see any advantages in E-commerce.

Pharmacists’ associations

Pharmacists’ associations saw the only potential advantage of E-commerce in the pharmaceutical sector as being in improvements to the distribution chain between producers/wholesalers and wholesalers/pharmacists.

Regulators

Cost, competition (particularly in combating the threat posed by direct marketing from the US) and flexibility were named as advantages. One regulator expressed its opinion that EDI has the potential for enhancing both quality and productivity.

1.6 **What do you see as the principal disadvantages of using E-commerce in the EU pharmaceutical sector generally?**

Manufacturers

Some manufacturers expressed their concern that E-commerce cannot be used in a very targeted way, and that face-to-face dialogue was missing. Others mentioned that the development of necessary skills to implement E-commerce effectively will be time-consuming, costly and risky.

Wholesalers

The majority of wholesalers were concerned about the dangers of an uncontrolled media and of excessive liberalisation. Some stated that there are easier ways for commerce to take place, without explaining this comment.

Pharmacists’ associations

Pharmacists' associations referred to possible health risks due to free availability of pharmaceuticals and lack of appropriate advice. They feared an increase in medicine consumption and consequently an augmentation of public expenses due to the hospitalisation caused by incorrect use of medicines. They were also concerned that the network of pharmacies could be undermined by Internet traders who concentrate on the sale of profitable pharmaceuticals. They could push pharmacies from the market, with the consequence that less profitable medicines would not be readily available.

#### Regulators

The main concern of the regulators was consumer health. They were concerned that patients may not obtain necessary information (or that the poorer parts of society would be deprived access to information on the Internet), confuse products or buy low quality counterfeits when using E-commerce. A minority were also concerned about the implementation costs and security (particularly over prescribing over the net).

### 1.7 **Which media do you prefer for E-commerce (e.g. Internet, EDI) and for what reasons?**

#### Manufacturers

Both Internet and EDI were regarded as suitable for E-commerce. However, EDI was still preferred for business-to business commerce since manufacturers do not see any existing Internet capable of replacing EDI.

#### Wholesalers

EDI was the preferred media.

#### Pharmacists' associations

As a result of the concerns expressed above, Pharmacists' associations did not prefer any media for E-commerce.

#### Regulators

All regulators preferred the Internet because it is easily accessible, cheap and used widely already.

## 2. **Regulation**

### 2.1 **Does the legislation of your country allow E-commerce in pharmaceuticals, including both OTC products and prescription products?**

See Appendices 1 and 3 to the main study for discussion of the relevant regulations.

2.2 **If there is no outright prohibition of E-commerce in pharmaceuticals, do you think that there are any barriers to the use of E-commerce in the pharmaceuticals sector in your country or in the EU raised by the current regulations which are applicable in this sector? For example:**

- (1) **the advertising or packaging regulations;**
- (2) **the pharmacists monopoly;**
- (3) **general legislation, such as tax rules;**
- (4) **prescription requirements.**

#### Manufacturers

The prescription requirements were regarded as the main barrier to E-commerce in pharmaceuticals. In addition, tax rules and the pharmacists monopoly were cited.

#### Wholesalers

All of the points above (save general legislation) were seen as major barriers to E-commerce by certain wholesalers though each of them placed a different emphasis on which was key. Prescription requirements were cited in particular.

#### Pharmacists' associations

No answers given.

#### Regulators

Regulators named advertising/packaging regulations, the pharmacists monopoly and prescription requirements as barriers to E-commerce.

2.3 **Do you think the current regulatory framework for pharmaceuticals is capable of dealing adequately with issues relating to the use of E-commerce in the EU pharmaceutical sector? Please give reasons.**

#### Manufacturers

Manufacturers regarded the current regulatory framework as not sufficient. According to them, prescription and reimbursement will remain problems for some years. They hoped that gradual harmonisation on an international level will occur.

#### Wholesalers

Most wholesalers thought that the current regulatory framework was not capable of dealing with E-commerce (and this was expressed in the strongest terms). Some felt that there was a greater chance of success in respect of business to business sales under the current regulatory regimes and a small minority felt no new regulation was required in this regard.

### Pharmacists' associations

Pharmacists' Associations did not want any change in the current regulatory framework as they were opposed to E-commerce.

### Regulators

All regulators that replied were of the view that the current regime is not capable of dealing with E-commerce.

## 2.4 **How do you think a regulatory framework should address the following particular issues: -**

### **(a) electronic contracting (negotiating, concluding and executing contracts made electronically) between: -**

- (A) **manufacturers and wholesalers;**
- (B) **wholesalers and retailers;**
- (C) **retailers and consumers; and**
- (D) **direct sales to consumers (from wholesalers or manufacturers);**

### Manufacturers

Some manufacturers stated that electronic contracting should be made possible. Others proposed that the normal codes of practice for non-electronic trading should apply in the electronic world.

### Wholesalers

Only (A) and (B) need to be addressed. Any regulatory framework should also address data protection issues.

### Pharmacists' associations

It was proposed that a regulatory framework should solve all problems related to liability of producers and traders in case of incorrect use of medicines and despatching of counterfeit pharmaceuticals. This should be dealt with by an international agreement that must increase the co-operation among states to enforce the rules about liability and to combat any criminal activity.

### Regulators

Contracting between manufacturers and wholesalers as well as between wholesalers and retailers should be addressed. One respondent raised particular issues regarding the

replacement of the pharmacists role when dealing with consumers - they suggested providing sufficient information regarding indications, incompatibilities and adverse pharmaceutical reactions would provide sufficient alternative consumer protection to the current pharmacy system.

- (b) electronic payment systems (including the setting of international standards and security issues such as the authentication of digital signatures and authorisation of payments by financial institutions);**

Manufacturers

Should be addressed. Some stated that electronic payment systems must be based on general commercial systems.

Wholesalers

Should be addressed. Any payment system should be direct from the customer's bank.

Pharmacists' associations

No answers given.

Regulators

Only two regulators answered this question - one stating that electronic payment systems do not need to be addressed by a regulatory framework, and the other saying that EU wide regulation was required.

- (c) electronic sale of prescription-only or restricted pharmaceutical products (including the giving of product advice on-line and verification of buyers' identity);**

Manufacturers

Should be addressed or be subject to existing codes of conduct.

Wholesalers

Should not be addressed.

Pharmacists' associations

No answers given.

### Regulators

Only two regulators answered this question - one stating that this area should not be addressed, whilst the other felt that EU wide regulation was required and an IT network of pharmacists and physicians should be set up.

- (d) **electronic advertising and commercial communications (including issues regarding content and trade practices and the provision of on-line diagnoses and advice);**

### Manufacturers

Should be subject to existing codes of conduct or be covered by country of origin.

### Wholesalers

The majority of wholesalers felt that this should not be addressed but rather be subject to self regulation within the industry only. A minority felt that it should be subject to some form of prior screening process by a regulatory body.

### Pharmacists' associations

No answers given.

### Regulators

Regulators expressed different views as to whether the provision of medicinal information and advertising should be regulated. Some denied any regulation was required (and this was the majority view in relation to non-prescription pharmaceuticals), others found it worth considering. One regulator in particular argued effectively for more information being made available to the public about prescription pharmaceuticals - so long as the information was "objective".

- (e) **privacy (including the processing and use of personal data);**

### Manufacturers

Should be guaranteed as much as possible.

### Wholesalers

Should be addressed.

### Pharmacists' associations

No answers given.

### Regulators

Only two regulators answered this question - both followed a well developed theme in their survey replies with one arguing for no more regulation, the other for an EU wide approach.

- (f) **liability (the on-line provision of services involves a chain of communication. Content can also be accessed anywhere and may therefore breach various national laws). This raises issues as to who should be liable, to whom and on what basis for: -**

- (A) **products;**
- (B) **trade mark infringement;**
- (C) **breach of supply contracts;**
- (D) **breach of statutory duties;**
- (E) **criminal activities; or**
- (F) **negligent acts.**

### Manufacturers

It was proposed that the liability should be governed by the law of the relevant plaintiff's country.

### Wholesalers

Regarding product liability, it was proposed that there is no difference between E-commerce and other forms of commerce. Liability for breach of supply contracts should be covered by the contractual provisions; breach of regulations or criminal law by the relevant statutory provisions.

### Pharmacists' associations

No answers given.

### Regulators

An EU wide approach is required particularly in relation to liability for criminal activity and negligent acts.

- (g) **applicable law (e.g. which country's law should govern the contract, determine product liability and regulate the content of web sites).**

### Manufacturers

The answers varied widely on this question. One opinion was that the law of the country of origin should apply. Another opinion was that the jurisdiction should be agreed by the contracting parties. According to a third opinion the law of the plaintiff's country should apply.

#### Wholesalers

It was proposed that the law of the country in which the web site is established should apply, alongside community wide legislation.

#### Pharmacists

No answers given.

#### Regulators

The law of the country where the seller is situated should apply (if possible EU law).

### 2.5 **How will electronic trading in the pharmaceutical sector affect: -**

- (a) product licensing;**
- (b) national price reimbursement;**
- (c) competition by generic copy products; and**
- (d) parallel importation.**

#### Manufacturers

Some manufacturers did not see a major effect on the first three areas. Others expected a grey market to develop until a price reimbursement system for E-commerce in pharmaceuticals is created. They also expected that there will be generic copy products offered on the Internet which should be subject to medical approval. One manufacturer mentioned that licence agreements will have to include a reference to this new distribution channel in the territories section.

In respect to parallel importation, some manufacturers argued that it could be significantly enhanced by E-commerce which simplifies the comparison of national prices. Others argued that price differences will be reduced, if not become largely uniform, due to the introduction of the Euro and that parallel imports will become a less important issue.

#### Wholesalers

Wholesalers did not seem to see any significant impact on product licensing though there was a perceived need by a minority for an on-line database of information. They saw price reimbursement as a technical problem to be solved and it was felt that generic products and parallel importation would be significantly enhanced if E-commerce was allowed.

### Pharmacists' associations

Pharmacists did not make a statement in respect to the first three parts of the question, but stated that they did foresee a possible increase in parallel imports.

### Regulators

Most regulators thought that national price reimbursement and parallel importation will be affected. One regulator restated its opinion that national price reimbursement could be affected through an IT network that connects physicians and pharmacists. The opinions differ regarding product licensing and competition by generic products.

## 2.6 **What possible effects could E-commerce have on competition (e.g. do you think that any levels could be eliminated from the pharmaceutical supply chain)?**

### Manufacturers

Manufacturers expected competition to become more vigorous and the market players to alter as a result. Wholesalers could be forced by competition to deliver products direct to customers and as a consequence pharmacists could be threatened.

### Wholesalers

Most wholesalers thought that competition will be increased for them and that the role of pharmacies will be seriously threatened. A minority denied any possible effects.

### Pharmacists' associations

Most pharmacists' associations did not see any chance of success for E-commerce in the pharmaceutical sector. One association expressed its concern that E-commerce could have a negative effect on pharmacists' profit margins.

### Regulators

Regulators thought that E-commerce will have an important economic effect on the pharmaceutical industry though it could be restricted to OTC products. This could reduce the pharmacist's role in distribution to consumers.

## 3. **General**

### Manufacturers

One manufacturer commented that the restrictions on E-commerce in Europe will slow down the adoption of this new facility, but the cost advantages for the patient and the payer will

ensure its eventual dominance as the primary means of pharmaceutical delivery at all levels of the market.

#### Wholesalers

Some of the wholesalers stated that they were not in favour of E-commerce for pharmaceuticals at a consumer level because they thought that pharmacies were an indispensable filter in the pharmaceutical market. One wholesaler's association went so far to say that they were not willing to accept E-commerce in the pharmaceutical sector at all. Equally though, some associations appreciated that E-commerce was of great interest to the public.

#### Pharmacists' associations

Pharmacists' associations emphasised the important role pharmacists play in the pharmaceutical market. They regarded sales over the Internet as a threat to consumer health.

#### Regulators

No further comments given.

**ANNEX 7**

**Sample unsolicited email relating to pharmaceutical product marketing**

Free Sample of our Weight Loss Pill!

We believe so strongly in our revolutionary weight loss product "Thermolift" that we are willing to give you a sample FREE to try it!

**INCREASE YOUR ENERGY LEVEL & FIRM UP WITHOUT GIVING UP THE FOOD YOU LOVE!**

- \* All Natural Energizer \* Reduce Sugar Cravings
- \* Burn the Fat While You Keep the Muscle \*Eat the Foods You Love
- \* Preferred by Fitness Experts \* 100% Safe and Natural

Anyone who has struggled to lose weight can tell you diets alone don't work! That's because your size, or your weight, has more to do with your metabolism than what you eat.

Changes International has designed a product that works several ways to help you achieve maximum results from your weight-loss program. This unique blend of herbs, botanicals and Chromium Picolinate improves your metabolism so your body relies more on stored body fat and less on stored proteins.

To get your FREE Sample reply to this e mail with the following information to me and I will immediately ship your FREE sample of Thermolift to you.

Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
city/State/Zip: \_\_\_\_\_  
e mail address: \_\_\_\_\_

The information contained in this e-mail was derived from many medical, nutritional, and media publications. It is not intended for medical or nutritional claims but for informational and educational purposes. Please consult a health professional should the need for one be indicated.

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