NEW TECHNOLOGIES FOR THE MARKETING AND SALE OF MEDICINES ON THE INTERNET AND TELEVISION NETWORKS

Final Study

Working document for the STOA Panel

Luxembourg, January 2000 PE 168.393/Fin.St.

Cataloguing data:

Title: **NEW TECHNOLOGIES FOR THE MARKETING AND SALE OF MEDICINES ON THE INTERNET AND TELEVISION NETWORKS**

Workplan Ref.: EP/IV/B/STOA/99/07/01

Publisher: European Parliament
Directorate General for Research
Directorate A
The STOA Programme

Author: Ferran Sanz PhD, Katrin Gaedt PhD, Albert Alonso MD PhD, Carlos Díaz

Research Group on Medical Informatics

Institut Municipal d'Investigació Mèdica (IMIM)

Departament de Ciències Experimentals i de la Salut

Universitat Pompeu Fabra

E-08003 Barcelona

Editor: Mr Dick HOLDSWORTH,
Head of STOA Team

Date: January 2000

PE number: **PE 168.393/Fin.St.**

NEW TECHNOLOGIES FOR THE MARKETING AND SALE OF MEDICINES ON THE INTERNET AND TELEVISION NETWORKS

Options for EU policy for consideration by the European Parliament

- ABSTRACT -

Ferran Sanz PhD, Katrin Gaedt PhD, Albert Alonso MD PhD, Carlos Díaz
Research Group on Medical Informatics
Institut Municipal d'Investigació Mèdica (IMIM)
Departament de Ciències Experimentals i de la Salut
Universitat Pompeu Fabra
Carrer Dr Aiguader, 80
E-08003 Barcelona

Phone: +34 93 225 75 87
Fax: +34 93 221 32 37
e-mail (F Sanz): ferran@imim.es
e-mail (K Gaedt): kgaedt@imim.es
e-mail (A Alonso): aalonso@imim.es
e-mail (C Díaz): cmdiaz@imim.es

This study, promoted by the Committee of Legal Affairs and Citizens Rights of the European Parliament, aims to provide the European Parliament with sound information useful for the adoption of policies with respect to the marketing and sale of medicines on the Internet and other new information technologies.

Medicinal products have important singularities affecting their launching, ways of distribution, information policies and their price. These singularities have been addressed in different European directives and member states' laws but none of them explicitly considers the case of new information technologies.

The possible extension of the Internet into the domain of the marketing and sale of medicinal products has arisen the concern of European health related organisations that call for the adoption of proper policies to protect consumers against its incorrect use. The adoption of such policies first has to recognise the cross-boundary nature of the Internet that requires, as far as possible, world-wide level approaches. Secondly, it must consider consumers' interests in terms of self-determination, economics, security and convenience. Finally, it has to take into account the economic interests of involved enterprises and authorities for what respects to public health expenditure. According to these considerations, the following feasible policy options are proposed:

1. Modification of current EU legislation on advertisement and commerce of medicines by explicitly considering the particularities of the electronic media and services. In case of adoption of EU regulation on the e-commerce of medicines more restrictive than those existing in third countries, the possibility of confiscate medicinal products arriving to the EU borders/customs as a consequence of the mentioned e-commerce should be considered. This could have discouraging effect on the potential clients.
2. To support the establishment, by credible EU bodies, of quality standards and labels for health services on the Internet to help consumers to identify and filter the useful, safe and secure services.
3. To favour the creation (maybe in relation with the European Medicine Evaluation Agency) of an observatory devoted to the follow-up of the activities related with the marketing and commerce of medicines on the Internet.
4. To push the pharmaceutical industry to establish agreements on "Good-Internet-marketing-

practice", that should serve as self-control instruments.

5. To promote educational activities in order to provide the EU Internet users with the relevant knowledge and skills in order to obtain the maximum benefits from new information technologies incurring in the minimum risks.

6.

NEW TECHNOLOGIES FOR THE MARKETING AND SALE OF MEDICINES ON THE INTERNET AND TELEVISION NETWORKS

Options for EU policy for consideration by the European Parliament

- OPTIONS BRIEF -

Ferran Sanz PhD, Katrin Gaedt PhD, Albert Alonso MD PhD, Carlos Díaz
Research Group on Medical Informatics
Institut Municipal d'Investigació Mèdica (IMIM)
Departament de Ciències Experimentals i de la Salut
Universitat Pompeu Fabra
Carrer Dr Aiguader, 80
E-08003 Barcelona

Phone: +34 93 225 75 87
Fax: +34 93 221 32 37
e-mail (F Sanz): ferran@imim.es
e-mail (K Gaedt): kgaedt@imim.es
e-mail (A Alonso): aalonso@imim.es
e-mail (C Díaz): cmdiaz@imim.es

When adopting any policy concerning medicines and the Internet, the singularities of the medicinal products and the world-wide nature of the Internet, should be taken into account. Hard law instruments on the Internet could have a very limited effectiveness if they are only applied to a confined territory (e.g. the European Union). Too restrictive European regulations could even provoke the emigration to third countries of Internet services addressed to the European market (e.g. websites containing advertisement of European medicines' brand names). This emigration, without eliminating the health problems that the regulations tried to solve, would generate difficulties to the European companies in order to participate in the potential economic benefits of the mentioned electronic services. Therefore, regulations at the world-wide level should be favoured whenever possible. However, it will surely not be feasible to adopt a world-wide ban on the sale of medicines over the Internet due to the positions of third countries (e.g. USA), where electronic distance commerce in the pharmaceutical sector is already well established.

Although the major part of the European organisations related with the pharmaceutical sector are not in favour of the development of the retail e-commerce of medicines, they consider the introduction and growth of such activities as an unavoidable phenomenon. For these reasons, they expect an active role of the European authorities in order to minimise the potential risks of these activities.

The evolution towards the European Single Market on Pharmaceuticals will be affected (accelerated) by the introduction of the electronic marketing and commerce of medicines.

According to the above mentioned points, the establishment of EU policies should consider:

- consumers' interests in terms of self-determination, economics, security and convenience,
- licit economic interests of involved enterprises, as well as
- authorities' interests in terms of public health and healthcare expenditure.

Specific policy options that we consider particularly relevant and feasible are listed below:

To modify the current EU legislation on advertisement and commerce of medicines by explicitly considering the electronic media and services (taking into account their particular characteristics).

- If the EU regulation on the e-commerce of medicines was more restrictive than those existing in third countries, the possibility of confiscate medicinal products arriving to the EU borders/customs as a consequence of the mentioned e-commerce should be regulated. This possibility, even being difficult to be executed in a significant rate of the deliveries, could have discouraging effect on the potential clients.

- To support the establishment, by credible UE bodies, of quality standards and labels for health services on the Internet. These services would help the consumers to identify and filter the useful, safe and secure services.

- To support the creation (maybe in relation with the European Medicine Evaluation Agency) of an observatory devoted to the follow-up of the activities related with the marketing and commerce of medicines on the Internet. This service could contribute to the aforementioned definition of quality standards and the administration of quality labels. It would also play an important role in denouncing and even pursuing bad practices of information, marketing and sale of medicines on the Internet. In order to fight against the pernicious Internet activities on medicines, the same electronic media should be intensively used to denounce them. The mentioned observatory could play an important role also for this purpose.

- To push the pharmaceutical industry to establish agreements on "Good-Internet-marketing-practice", that should serve as a self-control instrument for the pharmaceutical industry in order to safeguard consumers' interests.

- To promote educational activities in order to provide the EU Internet users with the relevant knowledge and skills in order to obtain the maximum benefits from new information technologies incurring in the minimum risks. In the case of medicines, special emphasis should be given to the activities carried out by educational and health institutions and professionals.

NEW TECHNOLOGIES FOR THE MARKETING AND SALE OF MEDICINES ON THE INTERNET AND TELEVISION NETWORKS

Options for EU policy for consideration by the European Parliament

- EXECUTIVE SUMMARY -

Ferran Sanz PhD, Katrin Gaedt PhD, Albert Alonso MD PhD, Carlos Díaz
Research Group on Medical Informatics
Institut Municipal d'Investigació Mèdica (IMIM)
Departament de Ciències Experimentals i de la Salut
Universitat Pompeu Fabra
Carrer Dr Aiguader, 80
E-08003 Barcelona

Phone: +34 93 225 75 87
Fax: +34 93 221 32 37
e-mail (F Sanz): ferran@imim.es
e-mail (K Gaedt): kgaedt@imim.es
e-mail (A Alonso): aalonso@imim.es
e-mail (C Díaz): cmdiaz@imim.es

This study, entitled "New technologies for the marketing and sale of medicines on the Internet and television networks" commissioned by the STOA unit, was promoted by the Committee of Legal Affairs and Citizens Rights of the European Parliament. Its aim is to provide the European Parliament with sound information to be used as a basis for the adoption of policies with respect to the marketing and sale of medicines on the Internet and other new information technologies. This study, and its resulting proposal of policy options, is based on: (1) background information regarding health issues, legal topics, and economics of the pharmaceutical sector and (2) the results of an *ad hoc* designed survey carried out to collect the opinions of key actors/organisations about the discussed topic.

In comparison with other goods, medicinal products, because of their importance with regard to citizens' health, have singularities affecting their launching procedures, distribution ways, as well as information and price policies.

In this way, launching of a new medicinal product requires scientific demonstration of its quality, safety and efficacy. Even once in the marketplace, the possibility of adverse reactions must be constantly monitored. Distribution is also strictly regulated and mostly restricted to licensed wholesalers and pharmacists. Finally, most member states governments follow a strict price control for prescription drugs while prices for non-prescription medicines are basically unregulated.

These singularities of medicinal products are addressed in different European directives and member states' laws. These laws establish the classification of medicinal products, their labelling and advertising as well as the price policies and the possibilities of reimbursement that may apply. With regard to the classification, the European directives recognise two basic categories: prescription and non-prescription medicines. Depending on the category and on the particular member state, different regulations of advertising and sale apply. Moreover, the legal status of some medicines differs from one member state to another creating a complex scenario and generating some conflicts.

For what respects to information about medicines, several directives regulate the labelling of medicines and their advertising. In the latter case, it is important to note that advertising for prescription medicines directly to the public is not allowed in the EU Member States. Apart from this, information is mostly unregulated. This point has been underlined by health-related organisations concerned about the quality and reliability of this information and their influence

on both prescribers and consumers.

In relation with the aforementioned regulations and established categories of prescription and non-prescription medicines, it is also important to consider consumers attitudes in terms of responsible self-medication and self-prescription.

Responsible self-medication, world-wide supported by different health authorities, implies the use of medicines approved and available without prescription and the supply of the relevant information to the citizen. From the consumer's side, self-medication is the option of choice for the treatment of some minor ailments.

On the contrary, self-prescription may not be regarded as a positive option since citizens' health is at risk by the purchase and use of prescription medicines without the required medical prescription and follow-up. In this context, it is important to note that the Internet might be (mis)used for this purpose and that the existing heterogeneity among different member states on the prescription-only status of some medicines could potentially influence this situation. Consumers may purchase a medicine as non-prescription in a member state whereas they need a medical prescription for it in another member state.

The situation of the marketing and sale of medicines described so far might change as a result of the introduction of new information technologies, especially in the case of the Internet and television networks. Though some of the European directives and national laws are applicable, none of them explicitly mentions the Internet or television networks. In addition, the trans-boundary and world-wide nature of the Internet, together with the heterogeneity of the different laws, introduces further problems.

A good example is that of any European customer accessing American websites dedicated to medicines. He or she will easily realise that marketing of medicinal products is common practice in the USA, since advertising of medicines is only regulated in some special cases. In addition, mail ordering and teleshopping of these medicines (both prescription and non-prescription) is also allowed. Finally, the customer will notice that prices are unregulated leading to a competition in the pharmaceutical market.

Though the same type of evolution in Europe in short or medium term is not foreseen, the introduction of these new information technologies in the medicinal domain is obvious and calls for the adoption of policies concerning medicines and the Internet.

To this end, it is necessary, first, to recognise the global and cross-border nature of the Internet

and so, regulations at world-wide level should be favoured whenever possible. On the contrary, too restrictive European regulations might be avoided since they could have a very limited effectiveness and could even provoke the emigration to third countries of Internet services addressed to the European market thus generating difficulties to the European companies willing to operate in this market place.

Secondly, it is important to consider consumers' interests in terms of self-determination, economics, security and convenience.

Finally, the licit economic interests of involved enterprises, as well as authorities' interests in terms of public health and healthcare expenditure must also be taken into account. The pharmaceutical sector in the EU can be regarded as significant in terms of contribution to the gross national product and number of employees. Besides, it is well known the concern of all European governments about the constant relative growth of healthcare costs.

According to the above mentioned considerations, the following feasible policy options are proposed:

- Modification of current EU legislation on advertisement and commerce of medicines by explicitly considering the particularities of the electronic media and services.
- In case of adoption of EU regulation on the e-commerce of medicines more restrictive than those existing in third countries, the possibility of confiscate medicinal products arriving to the EU borders/customs as a consequence of the mentioned e-commerce should be considered. This possibility, even being difficult to be executed in a significant rate of the deliveries, could have discouraging effect on the potential clients.
- To support the establishment, by credible EU bodies, of quality standards and labels for health services on the Internet. These services would help the consumers to identify and filter the useful, safe and secure services.
- To favour the creation (maybe in relation with the European Medicine Evaluation Agency) of an observatory devoted to the follow-up of the activities related with the marketing and commerce of medicines on the Internet. This service could contribute to the aforementioned definition of quality standards and the administration of quality labels. It would also play an important role in denouncing and even pursuing bad practices of information, marketing and sale of medicines on the Internet. In order to fight against the pernicious Internet activities on medicines, the same electronic media should be

intensively used to denounce them. The mentioned observatory could play an important role also for this purpose.

- To push the pharmaceutical industry to establish agreements on "Good-Internet-marketing-practice", that should serve as a self-control instrument for the pharmaceutical industry in order to safeguard consumers' interests.
- To promote educational activities in order to provide the EU Internet users with the relevant knowledge and skills in order to obtain the maximum benefits from new information technologies incurring in the minimum risks. In the case of medicines, special emphasis should be given to the activities carried out by educational and health institutions and professionals.

NEW TECHNOLOGIES FOR THE MARKETING AND SALE OF MEDICINES ON THE INTERNET AND TELEVISION NETWORKS

Options for EU policy for consideration by the European Parliament

- FINAL STUDY -

Ferran Sanz PhD, Katrin Gaedt PhD, Albert Alonso MD PhD, Carlos Díaz

Research Group on Medical Informatics

Institut Municipal d'Investigació Mèdica (IMIM)

Departament de Ciències Experimentals i de la Salut

Universitat Pompeu Fabra

Carrer Dr Aiguader, 80

E-08003 Barcelona

Phone: +34 93 225 75 87

Fax: +34 93 221 32 37

e-mail (F Sanz): ferran@imim.es

e-mail (K Gaedt): kgaedt@imim.es

e-mail (A Alonso): aalonso@imim.es

e-mail (C Díaz): cmdiaz@imim.es

Index

Foreword

This study, entitled “New technologies for the marketing and sale of medicines on the Internet and television networks" commissioned by the STOA unit, was promoted by the Committee of Legal Affairs and Citizens Rights of the European Parliament. Its aim is to provide the European Parliament with sound information to be used as a basis for the adoption of policies with respect to the marketing and sale of medicines on the Internet and other new information technologies.

1 Introduction, definitions and concepts

This section provides the non-specialist reader with a background to better understand the concepts that will be used in the remaining parts of the document. For the sake of clarity, it is structured under three different headings: health issues, legal topics, and economics of the pharmaceutical sector.
This study is focussed on the topic of sale and marketing on medicines on the Internet. The most relevant aspects for a full understanding of the subject have been considered. Special attention, when necessary, is paid to closely related topics as electronic health information and electronic commerce. In the latter case, however, only essential points are considered since more general in-depth information can be found elsewhere.[1]
Television networks are also included in the scope of the present document but this is limited to the case of new services to be provided by interactive television. As a consequence, the study does not deal with traditional television. It is also important to note that interactive television operates in a very similar way to the Internet, perhaps with some limitations in comparison to the world-wide coverage of the Internet. Furthermore, it is expected that Internet access will be possible through the television in the near future. This implies almost identical requirements and demands regarding marketing and sales of medicines. Therefore, for the sake of simplification, the study always refers to the Internet.

1.1 Health issues

1.1.1 Medicinal products and pharmaceutical market. Their singularities.

Recognising the singularities of medicinal products is a core issue previous to the adoption of any policy in the matter. In this study, a medicinal product is defined by its function, according to the definition provided by the Council Directive 65/65/EEC:

> "Any product or combination of substances1 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 human beings or in animals2 is likewise considered a medicinal product."

Though this directive is implemented into national law in all member states, it is interesting to note that in Belgium a medicinal product is defined by its destination, i.e. if there is the intention to use it as a medicine.

The special characteristics of medicinal products are widely accepted and, in fact, have important implications affecting the launching of products, ways of distribution or price policies.

Introducing a new medicinal product into the market is a long and costly process. It requires sound demonstration of interest for the public health by scientifically proving its quality, safety and efficacy. Additionally, once in the market, it has to be constantly monitored with respect to adverse reactions, a process that can even move health authorities to withdraw the product in specially serious situations.

The singularities of medicinal products are also reflected in their way of distribution, which is strictly regulated and mostly restricted to licensed wholesalers and pharmacists. This is an important feature because, as it will be later discussed, the distribution process is particularly suitable for the application of new technologies, as the experience observed with other types of goods and services largely proves.

Finally, prices for prescription drugs are strictly controlled by the government in most member states, while prices for non-prescription medicines are basically unregulated. This means that the pharmaceutical market does not always behave or react to the standard market forces (see section 1.3).

The above-mentioned singularities are also reflected in the regulations and restrictions affecting the information regarding medicinal products to be provided to the public and, particularly, in the case of advertising, as will be discussed later under section 1.1.3.

1.1.2 Prescription and non-prescription medicines. Switching from prescription to non-prescription status. Self-prescription and responsible self-medication.

This section presents concepts that are related to medicinal products' legal status (prescription and non-prescription) together with others reflecting consumers' attitudes towards the use of medicines (self-prescription, responsible self-medication). While the

1 These substances can be pure chemical compounds or mixtures of them. Each molecule with biological activity, which administered to a living organism alters its vital characteristics, is called "active principle".

2 In this study we will only refer to human beings for simplification.

meaning of each of them is important, their interplay also has important implications.

1.1.2.1 Prescription medicines

Following the Council Directive 92/26/EEC, medicinal products for human use are classified in two different groups: prescription-only and non-prescription medicines. Medicinal products are considered as 'prescription-only' when 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 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."

Though this directive is implemented into the national laws of all member states, some of them introduced further classifications in the category of prescription-only medicines, which include the following categories:

- "Medicinal products on renewable or non-renewable medical prescription". Ireland differentiates between products on prescriptions dispensed on just one occasion unless otherwise indicated (category S1A) and those dispensed for up to six months at appropriate intervals having regard to the dosage rate and quantity specified (S1B).
- "Medicinal products subject to special medical prescription". This group includes narcotics with different levels of classification in Germany and Greece or those medicines included in List I or List II of poisonous substances or in the list of narcotic drugs in France.
- "Medicinal products on restricted medical prescription, reserved for use in certain specialised areas". This group includes, in France, medicines restricted to hospital use, those cases when drug administration has to be initiated in the hospital and medicines requiring regular check-ups during treatment. In Greece, this group is limited to hospital drugs while in Ireland it corresponds to products dispensed only in a hospital (S1C).

In this context, it is worth noticing that advertising for prescription-only medicines is forbidden throughout Europe.

1.1.2.2 Non-prescription medicines

Non-prescription medicines are defined by exclusion, that is, those medicines that do not hold the prescription status as defined by the Council Directive. This implies that a citizen needs no prescription to obtain them.
The list of medicines that have the non-prescription status varies from one member state to another. Table 1 shows some examples of the differences existing among the EU states.
On the other hand, most member states further classify non-prescription medicines according to the place of sale. Generally the following categories are identified:

- medicines that are only sold in pharmacies, and
- products, which can also be sold in other retail outlets (in Denmark, Germany, Ireland, and the Netherlands).

However, this classification differs from member state to member state. Whereas in Germany only certain medicines, such as vitamins, minerals, or herbs can be sold in drugstores under certain circumstances, in Ireland paracetamol (upon certain dosage) and aspirin can also be sold in non-pharmacy outlets. Finally, in the Netherlands, all non-prescription medicines can be sold in drugstores, department stores and health shops.
A complementary classification of non-prescription medicines based on possible reimbursement also applies in some member states (France, Italy, Portugal and Spain). In these states, a non-prescription medicine can be either fully or partially reimbursed or excluded from reimbursement depending on whether this medicine has been prescribed by a medical doctor.
It is also interesting to note that the possibility of reimbursement may also affect the advertising of the medicinal product, i.e. in some countries only medicinal products, which are cannot be reimbursed, are allowed to be advertised (see section 1.1.3).

Table 1: Legal status of some of the most widely used self-medication active principles[2]

Ingredient	Austria	France	Germany	Italy	Nether-lands	Sweden	United Kingdom
Analgesics, anti-inflammatory agents and antipyretics							
Acetylsalicylic acid	NP	NP	NP	NP	NP	NP	NP
Diclofenac	NP	NP	Rx	NP	NP	Rx	NP
Etofenamate (t)	NP	--	NP	NP	--	--	NP
Ibuprofen (o)	NP	NP	NP	NP	NP	NP	NP
Ibuprofen (t)	NP	NP	NP	NP	NP	--	NP
Ketoprofen	NP	NP	NP	NP	NP	Rx	NP
Naproxen (t)	Rx	--	Rx	NP	NP	NP	--
Paracetamol	NP	NP	NP	NP	NP	NP	NP
Piroxicam (t)	NP	Rx	NP	NP	Rx	Rx	NP
Antifungal agents							
Clotrimazole (t)	NP	NP	NP	NP	NP	NP	NP
Clotrimazole (v)	Rx	NP	NP	Rx	Rx	NP	NP
Econazole	NP	NP	NP	NP	NP	NP	NP
Isoconazole (t)	NP	NP	NP	Rx	--	--	NP
Ketoconazole (t)	NP	NP	NP	NP	Rx	NP	NP
Nystatin	Rx	Rx	NP	Rx	Rx	Rx	Rx
Antihistamines							
Astemizole	NP	Rx	Rx	Rx	NP	--	--
Diphenhydramine	NP	NP	NP	NP	Rx	Rx	NP
Diphenylpyraline	NP	NP	NP	--	--	--	NP
Doxylaminesuccinate	Rx	NP	NP	NP	--	--	NP
Loratadine	NP	Rx	NP	Rx	NP	NP	NP
Antiviral agent							
Aciclovir (t)	NP	NP	NP	Rx	NP	Rx	NP
Corticosteroid							
Hydrocortisone (t)	Rx	NP	NP	NP	Rx	NP	NP
Various agents used in cough, cold and hayfever							
Acetylcysteine	NP	NP	NP	NP	NP	Rx	Rx
Ambroxol	NP	NP	NP	NP	--	--	--
Bromhexine	NP	Rx	NP	NP	NP	NP	--
Cromoglycate (sodium)	--	NP	NP	--	NP	NP	NP
Cromoglycic acid	NP	--	--	NP	NP	NP	NP
Xylometazoline (n)	NP	--	NP	NP	NP	NP	NP
Various gastro-intestinal agents							
Bisacodyl	NP	NP	NP	NP	NP	NP	NP
Lactulose	NP	NP	NP	NP	NP	NP	NP
Loperamide	Rx	NP	NP	NP	NP	NP	NP
Picosulfate (sodium)	NP	NP	NP	NP	NP	NP	NP
Anti-H2							
Cimetidine	Rx	NP	Rx	NP	NP	Rx	NP
Famotidine	Rx	NP	NP	Rx	NP	NP	NP
Ranitidine	NP	NP	NP	Rx	NP	NP	NP
Agent used in smoking cessation							
Nicotine (gum)	NP	NP	NP	NP	NP	NP	NP
Nicotine (patch)	NP	Rx	NP	NP	NP	NP	NP

NP = Non-prescription status; Rx = Prescription-only status; -- = Not registered or not marketed;
(t) = topical, (o) = oral; (v) = vaginal; (n) = nasal

1.1.2.3 Responsible self-medication

Self-medication is the selection and use of medicines by individuals to treat self-recognised illnesses or symptoms.[3] A positive position towards responsible self-medication has been adopted world-wide by different health authorities.[3,4,5,6] Responsible self-medication implies the use of medicines approved and available without prescription and the supply of the relevant information to the citizen. There are several arguments that support the trend towards responsible self-medication:

- Consumers are more and more interested in their health: they feel responsible, they seek health information that enables them to play a proactive role and take decisions affecting their health.
- Responsible self-medication is time-saving and more convenient for the citizen. It avoids the often-lengthy process of making an appointment at a doctors' surgery, it can be better fit in with the patients' working agendas and a local pharmacy or a drugstore is usually within easier reach than an out-patient clinic or GP surgery.
- Finally, the possible contribution of responsible self-medication to the containment of the public expenditure on healthcare has also been underlined, since most of the countries have expressed their concern about the ever-increasing healthcare budgets.

Consumers' behaviour also confirm the above listed arguments. Self-medication is considered the option of choice, over that of consulting a doctor, for the treatment of minor ailments such as headache (80 %), athlete's foot (79 %), heartburn (62 %), migraine (62 %), colds (60 %), cough (56 %), or acid stomach (50 %).[7] Cost and convenience seem to be major factors influencing the citizens' choice between purchasing an OTC medicine or obtaining the medicine on prescription.[8] Moreover, the provision of information about minor ailments and medicines, its easy access and comprehensiveness are key in the development of responsible self-medication practices. In this respect, the pharmacist's role as information provider is important.[8]

1.1.2.4 Self-prescription

Self-prescription can be defined as the purchase and use of prescription medicines by citizens without the required medical prescription and follow-up. In contrast to responsible self-medication, this may not be regarded as a positive option since citizens health is at risk. Available data point out that up to 13 % of consumers respond to minor ailments with the use of a prescription medicine already in the house.[9]
The existing heterogeneity among the different member states towards the prescription-only status for medicines could potentially influence this situation (table 1). Since the need for a medical prescription does not apply in the same way in all EU Member States, it is possible to circumvent national legal regulations, i.e. medicines may be purchased from a different member state, where no medical prescription is needed for the sought product. New technologies have the capability of making this situation much easier from the citizens' side.

1.1.2.5 Switching from prescription to non-prescription status

The legal process of reclassifying a medicine from prescription to non-prescription is called "switching". The arguments used to propose the switching of a medicine consider the safety profile of the particular medicine, documented through years of experience and an extensive number of uses as a prescription medicine, i.e. the lack of dangerous side effects and the lack of frequent incorrect use. Furthermore, it is argued that prescription-to-non-prescription switches offer consumers more opportunities and choices in their own healthcare and that it is a means for harmonising the pharmaceutical market, if it is applied to medicines that already have non-prescription status in other countries.[10]

In this context, an EU "Guideline on changing the classification for the supply of a medicinal product for human use", adopted in September 1998, clarifies which conditions have to be fulfilled by the manufacturers to obtain non-prescription status for a product. It is stated that scientific data on safety and efficacy must be submitted, and particular attention has to be paid to information for consumers.

Proving safety requires: (1) epidemiological evidence showing absence of risks in a long-term use, (2) limited adverse drug reaction effects that cease when administration is discontinued, (3) low prevalence of complications arising from incorrect or delayed diagnosis due to the non-prescription use.

Furthermore, the manufacturer has to provide proof of the suitability of both indication and dosage for self-medication purposes.

Finally, the product information must meet criteria for safe use, and include warnings and advice on duration of treatment and the situations when medical attention should be sought.[11]

1.1.2.6 Influence of legal classification of medicines on citizens' practical habits

The above-explained legal classification of medicines as prescription or non-prescription have different influences on consumers' habits with respect to the purchase of some medicines with a certain legal status throughout Europe for several reasons: Although the Council Directive 92/26/EEC is widely implemented into national laws, the list of active principles3 (ingredients) or other conditions (e.g. dosage or usage), which is the basis of the decision whether a medicine is prescription-only or not, varies from member state to member state (table 1). Therefore, consumers may purchase a medicine as non-prescription in one member state whereas they need a medical prescription for it in the consumer residence member state.

Furthermore, the grade of practical application of these laws has an influence on the purchase of some prescription medicines, i.e. in some countries it is common practice to sell prescription-only medicines without a medical prescription. To tackle these problems, the European Commission has endeavoured to establish a Single Market in Pharmaceuticals. The need for considering this regulation is becoming more evident because of the possible effects of electronic commerce on the pharmaceutical market.

3 Each molecule with biological activity, which administered to a living organism alters its vital characteristics, is called "active principle".

1.1.3 Information and advertisement on medicines

According to the need to fulfil legal requirements, a distinction between two broad categories of information on medicines available to citizens may be established: unregulated information and regulated information.
Unregulated information about health issues, diseases and medicines might be found in all mass communication media. In these cases, controls on the contents largely depend on the self-regulation criteria adopted by the producer or deliverer of the information. In some cases this can mean a high degree of strictness but often, the problem, from the citizens' perspective, is one of perceiving how and to which extent these control measures are carried out.
The second category, encompassing the labelling of medicines and advertising is regulated by different Council Directives:

- Council Directive 92/27/EEC regulates the labelling and the package leaflets of medicinal products for human use. The labelling, which is defined as the information on the immediate or outer packing of the medicine, has to contain particular information, e.g. the name of the medical product, the common name, a statement of the active ingredients expressed qualitatively and quantitatively per dosage unit, the special warnings, the expiry date, the name and address of the holder of the authorisation, the instructions on the use of the medicinal products (for self-medication products), etc. The most important data have to be repeated on the immediate packing. The directive covers explicit instructions about the structure and form of the obligatory information on package leaflets, i.e. all necessary details for the identification of the medicinal product, therapeutic indications, information which is necessary before using the medicinal product (e.g. contra-indications, special warnings), necessary and usual instructions for proper use (e.g. dosage, duration of treatment), a description of undesirable effects, and the expiry date. All the information has to be written in the official language (or languages) of the member state where it is marketed, and use clearly understandable terms for the patient.

- Council Directive 92/28/EEC regulates the information given in advertisements with the intention to sell a medicinal product. It establishes that advertising of non-prescription medicines to the general public is allowed in all media (therefore including the Internet). However, it strictly forbids illness-referred statements, promises of healing or improving diseases. All advertising to the general public of a medicinal product shall be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product. The advertisement must include some mandatory information (name of the medicinal product, as well as the common name if the medicinal product contains only one active ingredient, information necessary for correct use of the medicinal product, and an express, legible invitation to read carefully the instructions on the package leaflet or the outer packaging, according to the case). This Directive is further modified by national restrictions which in some cases depend on certain conditions. For example, the advertising of OTC medicines is forbidden in television in Denmark, in Belgium a special visa is necessary to receive permission to advertise, and in Ireland not all classes of non-prescription medicines can be advertised. Advertising prescription-only medicines to the public is not allowed in the EU.

The special sensitiveness associated with the information about medicinal products is well reflected by the need to clearly distinguish between information and advertising, both legal and illegal . This concern has prompted the Members of the Pharmaceutical Committee to set up an interpretative Guidance (PHARM 250a), which says that the "unmodified and unabridged publication on the Internet of information on medicinal products (prescription and OTC), which has been authorised by competent authorities, … should normally not be considered as advertising, unless the presentation of this information clearly constitutes a "hidden inducement" to promote the prescription, supply, sale or consumption of the medicinal product." By authorised information on

medicinal products, the Pharmaceutical Committee means the summary of product characteristics, the package leaflet, or the public assessment reports.
Opposite arguments can be found in relation to advertising of medicines, with respect to considering its effect on public health and on the healthcare expenditure. Supporting medicines advertising, it has been argued that it improves public knowledge of therapeutic measures and leads to a better understanding on the use of medicines and their appropriateness for the treatment of ailments. Additionally, this could imply earlier drug treatment or induce consultation with a health professional that in turn might allow diagnoses and treatment at earlier stages, therefore reducing the use of other costly health resources (hospitalisation or surgery).
On the other hand, advertisement of medicines is a licit (and to some extent necessary) but biased activity of the pharmaceutical industry, which, guided by its commercial interest, could minimise visibility of the risk of adverse reactions, be misleading with respect to efficacy, use statistics inappropriately, etc. Consequently, medicines' advertising has non-negligible risks.[12]
Further arguments against advertising of medicinal products underline the potential risks of increased consumerism of medicines and the harmful effects that self-diagnosis and self-prescription might have on public health, eventually increasing costs.[13]
Additionally, early symptomatic treatment might mask an underlying condition requiring medical attention and supervision. In this case, the use of a self-medication product might delay diagnosis and definitive and more successful treatment.
Advertising might also, as a side effect, put greater pressure on physicians to prescribe a particular drug. Information on new, and generally more expensive, treatments influences citizens and, as a consequence, physicians might find it more difficult to prescribe a different treatment without seeming to be out dated or too concerned about reducing healthcare costs.

1.2 Legal status

1.2.1 Hard law instruments

1.2.1.1 Introduction

This section deals with all the European legislation applicable to medicinal products for human use. This legislation can be divided into two main categories: the EU directives, which need to be transposed into national laws by the Member States, and the EU regulations, which are directly applicable in the internal legal order of each member state. Furthermore, other legal instruments such as treaties and case laws have to be considered as hard law instruments.
In general, existing hard law instruments dealing with the marketing and sale of medicines in the EU do not particularly address the Internet. Additionally, there is a limited number of legal instruments that regulate electronic commerce and individual data protection that could also apply in the Internet. In this study, a brief presentation of these aspects is given but more detailed information can be found elsewhere.[1]

1.2.1.2 Review of the European Union instruments

There is a number of Council Directives, Council Regulations, Commission Regulations, and Council Decisions in the European legislation which are applicable to medicinal products for human use. The present document focuses on those directives and regulations that could be related to the marketing and sale of medicines over the Internet and not on those which regulate the quality, manufacturing and marketing authorisation procedures, etc.
It has to be pointed out that all the directives and regulations, that are mentioned hereinafter, do not explicitly mention the Internet or television networks, but they may be applied to these media as well as to others. The Council Directive 65/65/EEC, which was later on amended by several directives[14] was the first step towards the single market in pharmaceuticals. These directives, along with the Council Regulation 2309/93 ("laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products") allow medicines to be commercialised only by a market authorisation and establishes the fundamental criteria for drug approval on the basis of scientific criteria of quality, safety and efficacy with the primary purpose of safeguarding public health. Council Directives regulate the legal status of medicines (their classification, 92/26/EEC, see 1.1.2), their advertising (prohibition of publicity of prescription-only medicines to the general public, 92/28/EEC, see 1.3.1), the patient information (labelling and package leaflets, the inclusion of which is compulsory, 92/27/EEC) and the wholesale distribution (92/25/EEC).The Council Directive 92/25/EEC regulates the wholesale distribution of medicinal products for human use. It ensures the exclusive distribution of medicinal products, to which a marketing authorisation has been granted in accordance with Community laws. It determines that a special authorisation is necessary to distribute medicinal products. Wholesalers have to ensure proper conservation and distribution of medicinal products. Furthermore, they must only deliver the medicinal product to authorised pharmacies or retail outlets. They must "guarantee permanently an adequate range of medicinal products to meet the

requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question". They must also contemplate emergency plans to cover urgent market requests and information supply in certain terms.
Moreover, the European Commission published a communication on parallel imports of proprietary medicinal products4 for which marketing authorisations have already been granted.[15] In this communication, the Commission emphasises its position that practices applied by Member States to parallel imports have to remain within limits compatible with Articles 30 and 36 of the EEC Treaty, i.e. the measures taken must (1) "be strictly necessary from the health standpoint," (2) "obstruct intra-Community trade as little as possible," and (3) "require Member States to adopt an active and vigilant attitude towards pharmaceutical companies."
Finally, the Directive 97/7/EC is related to consumers' protection concerning distance contracts. Article 14 allows Member States to ban within their territory the marketing of certain goods or services, particularly medicinal products, by means of distance contracts.

1.2.1.3 Review of the international instruments

Regarding the state of the regulation of the pharmaceutical market by hard law instruments at the international level (supra EU), there are clearly no hard law instruments regarding medicinal products, not even at the level of the World Trade Organisation.

1.2.1.4 Regulations in some third countries

This section considers the regulatory situation in two representative countries (USA and Switzerland) not belonging to the EU. The case of the United States of America might be especially relevant because of its leading role in the introduction of new technologies for the marketing and sale of goods.
Switzerland’s legislative framework for medicines is very similar to that of the rest of Europe. All the directives mentioned in section 1.2.1.2 were considered in the Swiss Medicines Law (*Heilmittelgesetz* or HMG). Following the national laws, and depending on toxicity, indications and active ingredient, medicines are classified into five groups (List A to E): 'restricted prescription', 'prescription-only', 'sale limited to pharmacies', 'sale limited to pharmacies and drugstores', and 'no restriction as to sales outlet'. With respect to advertisement of medicinal products, the situation is also similar to other European countries. The advertising of non-prescription medicines is generally allowed, which conforms to the EU Directive 92/28/EEC. Depending on the media and on the "sensitivity" of the product, it has to pass a check by the IKS/OICM (Intercantonal Control Body for Medicines).
Neither the distance selling of medicines, nor teleshopping, is allowed in Switzerland.
The situation that can be found in the United States of America is quite different. Alike in Europe, medicines are classified as prescription or non-prescription, but without further divisions.

4 Following the Council Directive 65/65/EEC, a proprietary medicinal product is defined as: any ready-prepared medicinal product placed on the market under a special name and in a special pack.

Following the USA Food, Drug and Cosmetic Act, medicines for human use fall under the prescription status if: (1) they are habit-forming, (2) potentially toxic, (3) may have a harmful effect or (4) the method of use (or the collateral measures) need supervision of a practitioner licensed by law to administer such drugs.[16]
OTC advertising to the public is allowed in all media. However, unlike in Europe, no mandatory text is required and comparative advertising is permitted. The responsible Federal Trade Commission (FTC) performs advertising control after publication. Additionally, advertisements for medical products are revised by several self-regulatory advertising systems (clearance departments in most mass media companies).
Also advertising of prescription-only medicines is accepted provided that it is supported by scientific arguments. This information should include details about "major" side effects and contraindications. Additional information measures are required and referred to on the package label (e.g. toll-free telephone numbers for consumers to ask for the extensive labelling, references to print ads running concurrently that include the information, distributing the information through a range of accessible locations, or a Web address with the information). The control of advertisements of prescription-only medicines falls under the jurisdiction of the Food and Drug Administration (FDA), which recommends but does not require a voluntary prepublication submission.
Non-prescription medicines may be sold in all retail outlets: pharmacies, mass merchandisers, or food stores - with some limiting exceptions, e.g. codeine-containing medicines that can be sold only in pharmacies.
The permission for mail ordering and teleshopping of non-prescription and prescription medicines is another important difference when comparing the EU and USA legislation. Remarkably, the price of medicines is unregulated, so that competition in the pharmaceutical market on the basis of the price of a medicine is a usual practice.

1.2.2 Soft law instruments

1.2.2.1 Definition

The expression “soft law” is used in this document to refer to the rules that particular groups agree to follow in a self-imposed regulatory fashion. It is also applied to the recommendations made by public institutions. These rules or recommendations may differ in nature or focus, being also named as codes of conduct, guidelines, resolutions, etc. In the case of the pharmaceutical industry, these types of self-regulatory codes are especially frequent.
It is also important to note that “soft-law” may become a vital component for a successful approach to ensure consumer confidence. The European Commission Services have explicitly recognised this point in a response[17] made to TACD.5 According to it, consumers’ confidence towards electronic commerce is likely to rest on a variety of factors including, among others, good marketing and business practices, codes of conduct and self-regulatory initiatives, especially at the international level.

1.2.2.2 Review of the instruments existing in the EU territory

In a study made by the Standing Committee of European Doctors (CP) to assess the degree of quality controls applied to the contents on health topics in the websites, it was found that there are hardly any self-regulatory instruments existing in the EU territory concerning quality assurance of the health information and health services provided through the Internet.[18]
The same study also pointed out that most websites dealing with health issues had the Health on the Net Foundation (HON) Code of Conduct as a major reference in terms of quality of contents. The HON Code of Conduct[19] was published in July 1996 to tackle the problem created by the quality of medical advices provided in the websites. It takes the form of a set of guidelines addressed to webmasters and information providers covering aspects of: authorship, information updates, data confidentiality, information sources, funding and advertising policy. In spite of its simplicity, it has become, by far, the most recognised standard world-wide. Attaching the HON logo in the website proves the adherence of a website to the HON Code of Conduct. Though not specifically addressed to the sale of medicines through the Internet, HON principle 5 establishes that “any claims relating to benefits and/or performance of a specific treatment, commercial product or service will be supported by appropriate, balanced evidence [...]“. Additionally, it should be stated if advertising is a source of funding (principle 8).
Based on the HON experience, the Official Medical College of Barcelona has launched an initiative that goes a step forward. They have created an Accredited Medical Web Seal (WMA)[20] that aims to serve as a “virtual reference point for the medical community”. To obtain the WMA seal requires submission and evaluation of the website by a delegated committee that takes into account different aspects including: (1) adherence to the Ethical Code of the Council of Medical Colleges of Catalonia, (2) full

5 TACD: The Transatlantic Consumer Dialogue is a forum of USA and EU consumer organisatons which develops and agrees on joint consumer policy recommendations to the USA government and European Union (URL: http://www.tacd.org).

identification of the owners of the website, (3) confidentiality issues, (4) acceptance of the owner to implement facilities to enable control and validation and (5) treatment given to advertising material (which should be easily recognised as such by the user) and sponsorship (declaration of conflicts of interest).
The latter approach reflects one of the first solutions given by an official health professional organisation to the concern for the potential dangers of dissemination of health information through the Internet. A different approach is that of relying more on the final user of the information by informing about the risks. The joint brochure recently produced by the Standing Committee of European Doctors (CP) and the Pharmaceutical Group of the European Union to (PGEU) seeks to create this cautious opinion among Internet users and make them aware of the risks associated to the acquisition of medicines through the Internet, discouraging this way of obtaining medicines.[21]

1.2.2.3 Review of the international instruments

Whatever European or national soft-law instruments may exist, the unique nature of the Internet calls for world-wide approaches when dealing with the problem of the sale of medicines through the net.
The World Health Organization (WHO) has recognised the problem and stated its responsibility in developing guidelines and setting regulatory standards and other norms on quality, safety, efficacy, promotion practices, and information accuracy for pharmaceuticals. A first step is the WHO Ethical Criteria on Medicinal Drug Promotion.[22]
However, WHO is also relying on user partnership to keep control. To this end, it has recently published a guide to finding reliable information about medical products on the Internet.[23] This document admits the advantages of the Internet in accessing information on health topics and conditions, treatments and health organisations. The stress is set on the need to verify the source of information and obtain pharmaceutical products through legitimate distribution channels. The key agent for such verification should be the user. Therefore, the document includes suggestions on how to look for medical information on the Internet. It also mentions the tasks being carried out by other international non-profit organisations such as Health On the Net Foundation and the Internet Health Coalition. The latter seeks to promote the benefits of the web[24] and to this end it involves health professionals, medical publishers, patient representatives, academics, lawyers and the health care industry.
The opinion of consumer organisations on this topic has been expressed through the Transatlantic Consumer Dialogue (TACD)[25] forum that is examining e-commerce from the consumer-protection point of view. Their recommendations establish the need to provide the same level of protection in the virtual marketplace as in the real one. Though they do not specifically address the topic of medicinal products, some of the recommendations might also apply.
The pharmaceutical industry has stressed the potential benefits of advertising in order to inform people about medicines that are available without prescription in a recent joint statement on Responsible Self-Medication made public by the International Pharmaceutical Federation and the World Self-Medication Industry. However, it is also mentioned that advertising should be responsible and should not discourage people from seeking pharmacist or physician advice.

In line with this idea, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) position, strongly supports the correct use of the Internet as a means of providing accurate and reliable information on medicines in a responsible manner for the benefit of citizens and healthcare professionals. The difficulties are in the different laws and regulations existing world-wide and the measures designed to regulate information access. These measures require caution: they should ensure legitimate information and communication activities while preventing and/or warning users about accessing unreliable or unregulated sources.
Based on the pharmaceutical industry's tradition of self-regulation, self-auditing and implementation of codes of Good Practice, IFPMA believes that self-regulation is the method of choice. The self-regulatory IFPMA Code of Pharmaceutical Marketing Practices sets out principals and standards for the information provided by companies about their products. These requirements are equally valid for and applicable to information made available through the Internet.

1.2.2.4 Instruments existing in some third countries

As it has been mentioned, the international nature of the Internet calls for world-wide solutions when considering soft-law instruments. However, it is worthwhile to have a look at national initiatives that have been promoted in third countries, though they might have already gained international recognition. In this respect, two important experiences from the United States of America must be mentioned.
The first corresponds to the American Medical Association (AMA) website, a resource addressed not only to health professionals but also to citizens. The AMA‘s website has been a milestone when considering the treatment of health information for citizens. Especially important is the AMA's effort to explicitly support the information that clearly identifies the producer and the validation bodies (AMA‘s seal of approval). In this way, AMA has very recently announced that they are working along with Intel in a new credential system to protect physician/patient communication on the Internet. According to the available information the system will support routine physician/patient transactions, including prescription over the Internet.[26]
The second experience is that of the successful Medscape website.[27] It has recently made public the code regulating advertising policy within this site. This policy has drawn the attention of other health-related websites because of its strict and clear distinction between the editorial line and commercial department.

1.2.3 Effectiveness of existing hard and soft law instruments

This part describes the degree of applicability and effectiveness of the above-mentioned hard and soft law instruments.
The first problem to be considered is the difficulty in assessing the success of a law. No common methods or indices measuring effectiveness of hard or soft law instruments exist. As a result, lawyers have proposed different types of success-related control tests with inconclusive results.
Another problem regarding the assessment of effectiveness is that no laws exist within the European Union focussed on the use of Internet. Though some of the aforementioned legal instruments can be, by extension, applied to the Internet, this was not their original scope and this fact further limits any analysis.
In addition, the cross-border nature of the Internet makes more evident the existence of

constraints that should also be considered. There is the case, for instance, of a country-to-country transaction scenario, where it would be not so clear which law prevails (that of the consumer or that of the manufacturer). Also, in the same type of scenario, what is legal on one side of the transaction might be illegal on the other side, while, as it is the case in the European Union, both sides are located in member states. Furthermore, it is questionable if a certain prohibition (advertising of prescription-only medicines) is really effective when the Internet user can access commercial websites for prescription-only medicines, situated in different countries outside the European Union space.
It should also be remarked that the tradition of using the Internet for health information is newer in Europe with respect to other countries (USA). This could bias the results of any measure of assessment.

1.3 Economics of the pharmaceutical sector

This section provides the basis for understanding the importance of the pharmaceutical sector and the basic forces that affect the corresponding market. It also includes some considerations on what effect can be expected of the widespread use of the Internet in the marketing and sales of pharmaceutical products.

1.3.1 Economic weight of the pharmaceutical sector. Market singularities

The economic weight of the pharmaceutical sector in the European Union, which can be defined in terms of contribution to the gross national product (GNP) and number of employees, can be regarded as significant. The pharmaceutical industry in Europe accounts for just over one per cent of GNP in the EU;[28] of this, the five largest national markets (Germany, France, United Kingdom, Italy and Spain) accounted for 89 % of the pharmaceutical industry's contribution to EU GNP in 1992. The pharmaceutical market accounts for 1.35 % of the gross domestic product (GDP) in the EU. The importance of the sector in terms of employment is shown in table 2. Distribution of employment between countries is not uniform and it is heavily concentrated again in Germany, France, Italy, United Kingdom and Spain.

Table 2: Employment in the pharmaceutical industry in European countries in 1995[29]

Country	Employment in the pharmaceutical sector (thousands of persons)	Employment in the pharmaceutical sector as percentage of the total employment
Austria	9[a]	0.25[a]
Belgium	19	0.51
Denmark	16	0.62
Finland	4	0.20
France	101[a]	0.46[a]
Germany	104[a]	0.30[a]
Greece	8	0.21
Ireland	10	0.81
Italy	94[c]	0.45[c]
Netherlands	15[b]	0.22[b]
Portugal	9	0.20
Spain	38	0.32
Sweden	15	0.35
United Kingdom	74	0.28

[a] 1994; [b] 1993; [c] 1988

The expenditure on pharmaceuticals represents 15.35 % of the total healthcare costs (see section 1.3.3 below). It is also known that the constant relative growth of healthcare costs, higher than that of the economy, is a permanent concern for EU governments, as the weight of the healthcare costs on the GDP ranges from 3 to almost 9 %, depending on the country (fig 1). Furthermore, the public expenditure on pharmaceuticals is very important, representing 61.26 % of the total expenditure on pharmaceutical goods in the EU in 1996.[29]

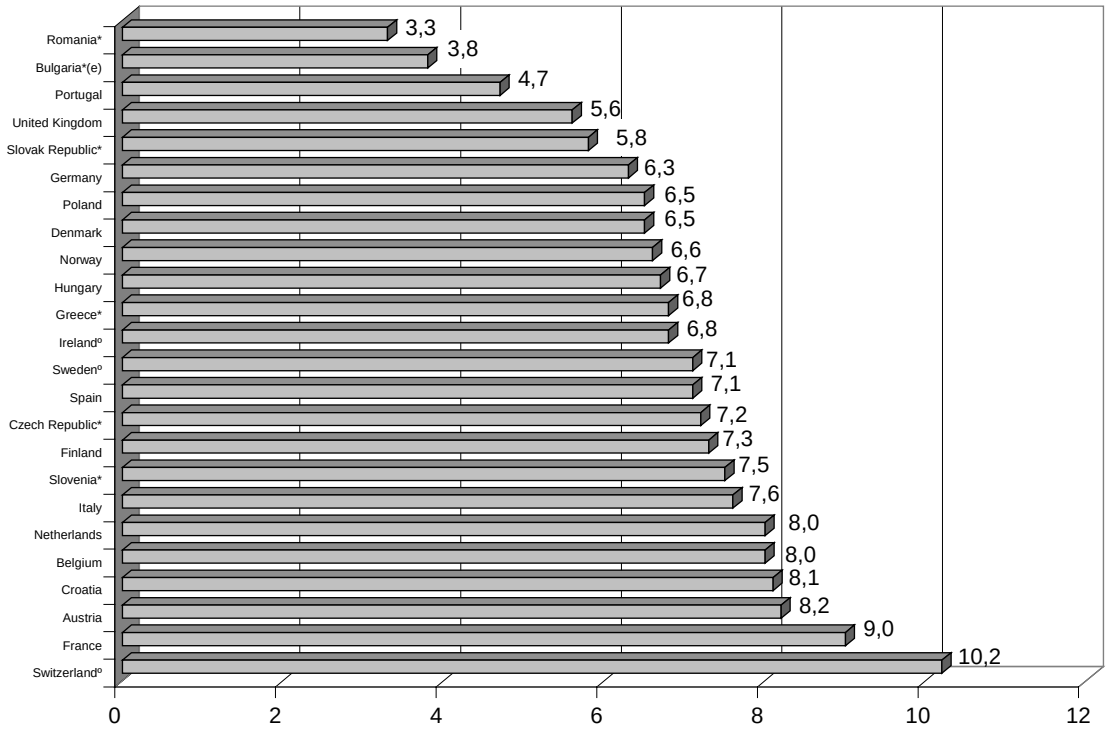

Figure 1: Healthcare costs as a percentage of GDP in European countries - 1997[30] (* = 1996, (e) = estimated, º = 1998)

The European pharmaceutical market has shown a constant growth during the last years, and its estimated value in 1998 was in excess of 90,000 Million Euro. It can be divided into two sub-markets, depending on the type of product: the prescription market and the non-prescription market (fig.2).

The analysis of the pharmaceutical market and its sub-markets reveals that the overall growth of the pharmaceutical market has been basically a consequence of the growth of the prescription market, while the non-prescription market has remained constant with only slight increases in absolute terms during the last few years (fig. 2). Consequently, the non-prescription market has lost importance in relative terms, currently representing 22 % of the total EU pharmaceutical market. The distribution among EU countries of this market structure is not uniform, ranging from a share of 10 % of the non-prescription market in Austria, Portugal or Sweden to around 30 % in Germany and France (fig. 3).

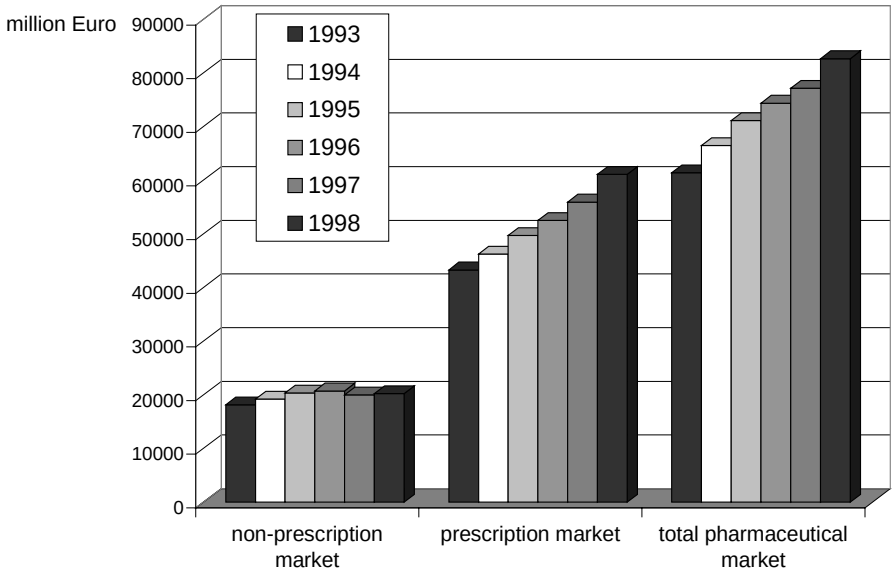

Figure 2: European Pharmaceutical Market 1993 - 1998[30]

The non-prescription part of the pharmaceutical market can be further divided into the self-medication market and the prescribed non-prescription market, depending on the initiative of the purchase act (fig. 4). Figure 5 shows how the relative magnitudes of these sub-markets vary between European countries.

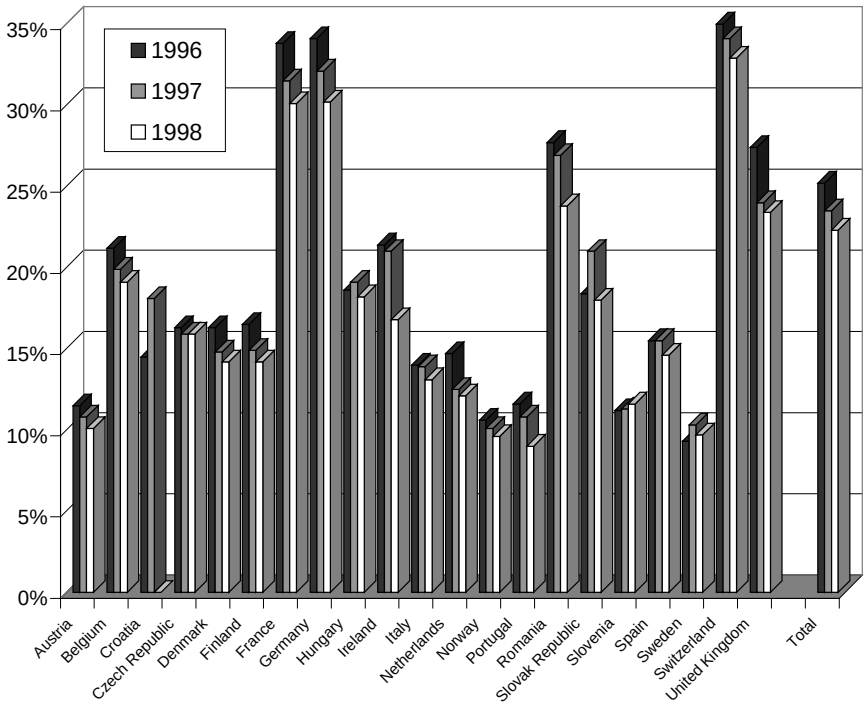

Figure 3: Non-prescription market as a percentage of the total pharmaceutical market in European countries[30]

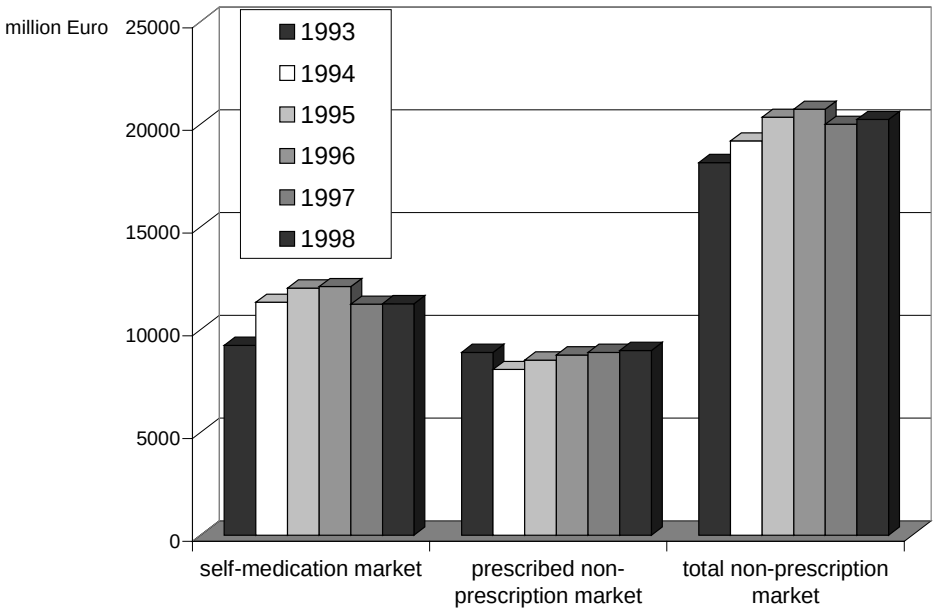

Figure 4: European non-prescription pharmaceutical market 1993-1998[30]

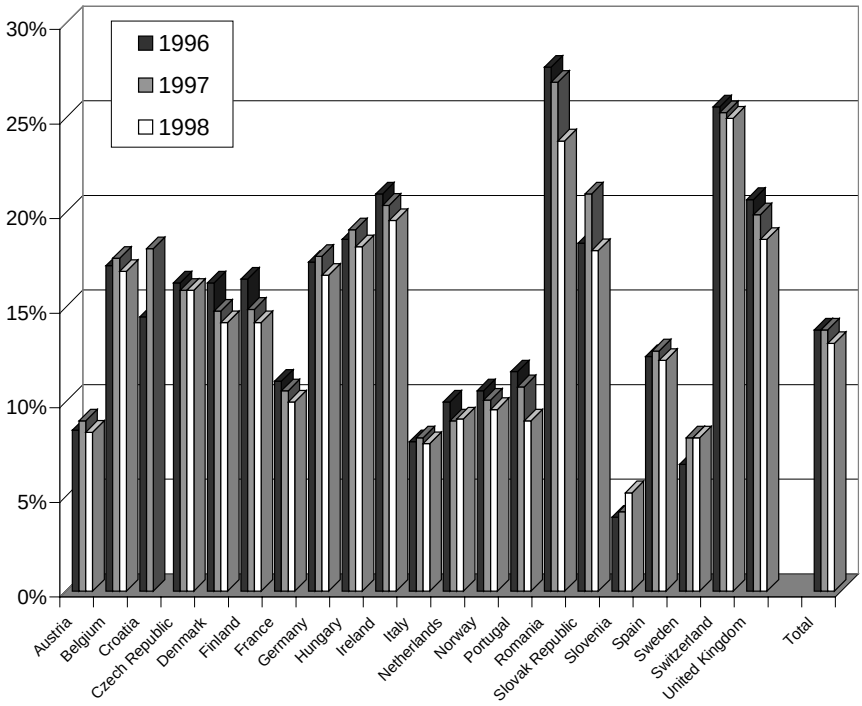

Figure 5: Self-medication market as a percentage of the total pharmaceutical market in European countries[30]

Taking a deeper look at the evolution of the non-prescription market components (fig. 4), it can be seen that the self-medication part of this market has in fact gained importance during the last six years. This increase has been however compensated by a stability or even decrease of the sales of prescribed non-prescription products. Again, this distribution varies among countries, the share of self-medication products being lower than 10 % of the total pharmaceutical market in Austria, Italy and Sweden, and around 20 % in Ireland and the UK (fig. 5).

It has been argued that one of the reasons for the relative lack of growth of the sales of

non-prescription products might be the inappropriate presentation of OTC products or insufficient information reaching the consumer.[31] Analysing the self-medication market, it can be seen that purchases are very concentrated in five major self-medication product groups related to ailments better known to the public: cough and cold, analgesics, digestives, skin treatment products, and vitamins and minerals (fig. 6). The increasing will of consumers to take decisions concerning their health (see 1.1.2.3), together with a presumed increase in the use of new technologies for the information, marketing and sale of medicines, might expand the citizens' informative background and self-medication habits, thus changing the described concentration of the market.

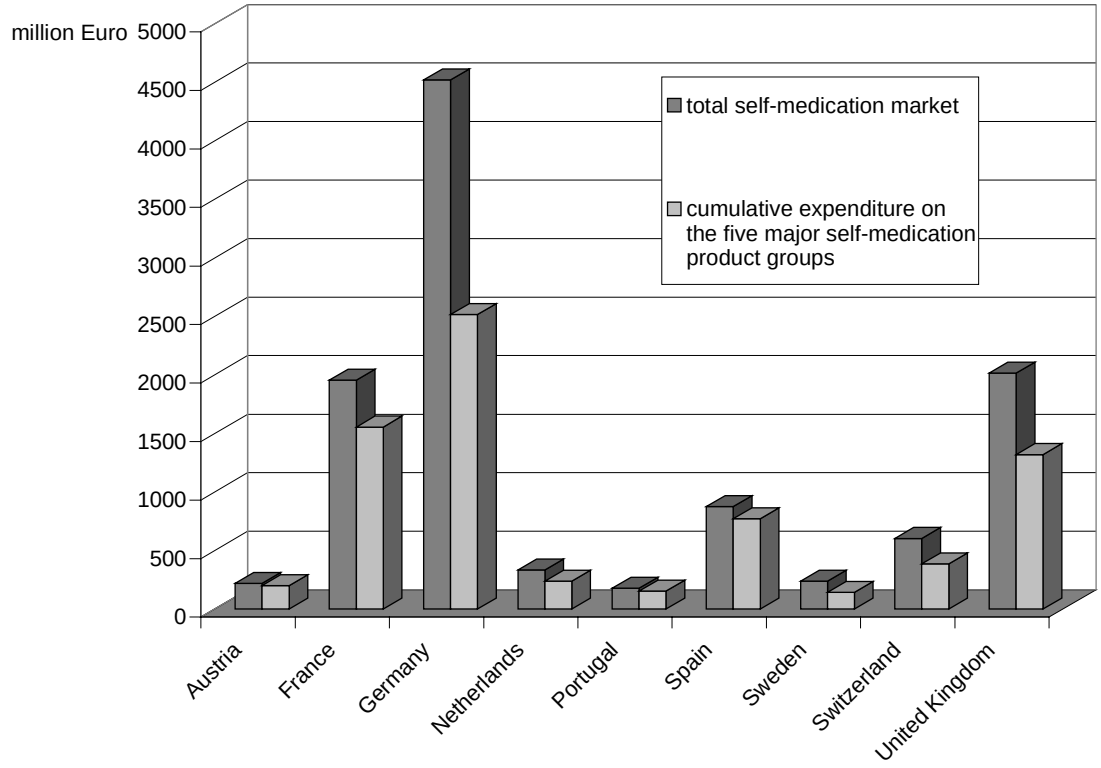

Figure 6: Total of major self-medication product groups (cough and cold, analgesics, digestives, skin treatment, and vitamins and minerals) in comparison with the total self-medication market in some European countries in 1998.[30]

There are also differences between countries regarding the approval and OTC status of some medicines, although endeavours towards harmonisation in the EU have taken place in the last years.

In addition, and as will be seen in the next section, prices differ from country to country depending on regulations and practices of manufacturers, and they are not normally visible in the marketing and sale practices as they are basically fixed within each country.

To add even more complexities to the situation, despite significant differences between member states in terms of national culture, religion, income and national health provision, and the fact that the market for pharmaceutical products in the EU is highly regulated, the pharmaceutical industry is essentially global in its marketing strategies.[32] In this context, the Internet, which is a tool that is not limited by the national boundaries allowing information to freely flow, has the potential to generate conflicts and confusion in the pharmaceutical market, as all national differences are bound to collide in a global context. To this, one must add the radically different situation of the USA and other

international markets regarding regulations, distribution networks and market functioning.

1.3.2 Pricing of pharmaceutical products. Market structure and competition

The final price of a medicinal product is, apart from the costs of its manufacture, dominantly determined by the cost of the research and development that has to be undertaken until a product can be placed on the market. It has to be taken into account that on average it takes ten to twelve years to place a medicine on the market,[32] the average cost of launching a new pharmaceutical product on the market is more than 250 million Euros[33] and that only one of about 10,000 potential new drugs actually reaches the market. Pharmaceutical companies patent the new active principles resulting from research and development (R+D) in order to protect the huge investments made. During the patent life of a new active principle, only the patent holder may market a pharmaceutical product containing the new active principle unless a license to use the patent is granted by the holder. After the expiry of patent protection, competitor companies may market essentially identical products under a generic name, so-called generics. These are normally less expensive than branded products, because developing costs were not incurred

The high level of investment needed in order to launch a new pharmaceutical product leads the pharmaceutical manufacturers to seek to market them on as wide geographic basis as possible.[32] Four of the largest world-wide pharmaceutical companies in terms of prescription sales (GlaxoWellcome, Hoechst Marion Roussel, SmithKline Beecham and Rhone-Poulenc Rorer) are from the EU. However, competition is strong in the global pharmaceutical market. Even though the ten largest pharmaceutical producers account for approximately 20 % of the world-wide pharmaceutical market, the EU market for pharmaceuticals is very fragmented, with no key player holding more than 4 % of the market.[34] Although the sector is dominated by relatively few multinational companies, there is also a large number of smaller firms operating alongside them[28] which exploit the results of their own research, usually in specialised fields.

The high costs of investment in R+D and patenting of new products make that innovation resulting in branded pharmaceutical products is easier for larger companies to achieve.[32] The fight for market shares has also produced a tendency to horizontal (such as the acquisition of Wellcome by Glaxo in 1995) as well as vertical (acquisition of distributorships by Merck and SmithKline Beecham) integration. Regarding the latter, the impact of on-line drugstores in the USA such as PlanetRx, Soma or drugstore.com has raised the competition among distributors and integration between them has also taken place when competition proved to be too painful, as in the case of the acquisition of Soma (on-line pharmacy) by CVS Corporation (USA pharmacy retailer chain) after the stock price of the latter fell by 25 % when the Internet pharmacies came on-line.[35]

The pharmaceutical products singularity has produced different types of competition in the EU market. The European Pharmaceutical Industries Association has identified four types of competition:[32]

- Innovator vs. Innovator: prices are set in anticipation of future competitors, according to the innovative properties and therapeutic advances that the products represent

- Innovator vs. Improver: improver's products are generally introduced at equal or lower prices than that of the existing treatments, leading to improvement in treatment choices and a reduction in the cost of treatment

- Innovator vs. Imitator: competition centres on prices without quality enhancement, as patents expire and generic imitations are introduced at much reduced prices

- Imitator vs. Imitator: several generic products compete on prices or promotion, and no improvement in treatment is achieved

As it has been said before, the price of medicines depends heavily on the investment made in R+D prior to its marketing and sale. In addition to the costs of development and manufacture, the final price has to cover the costs for advertising, distribution, the profit margin for wholesalers and pharmacists, and the value added tax. Prices are highly controlled in the European pharmaceutical market, and two basic situations can be described

- **Prescription market:** Member states still have exclusive authority over prescription medicines pricing and reimbursement policy, although they must ensure that any rule is compatible with the general rules of the Treaty of Rome on the free movement of goods, regardless of products' origin.[36] The majority of countries in Europe opt for either direct control of production prices or setting only reimbursement prices.[36] Whichever the case, in most member states, prices for prescription drugs are heavily regulated. The regulatory sources of price divergence of pharmaceutical products in the European countries act as a barrier to a single market for pharmaceuticals in Europe.

  As prices are mainly regulated, in the prescription market competition is initially based on improving existing medicines and developing new innovative products,. Once the patents expire, the profitability for the original manufacturer decreases rapidly as imitators enter the market competing in prices. The anxiety of the pharmaceutical companies to market their newly developed drugs in a highly regulated environment and recover the costs invested in R+D as quickly as possible, requires global marketing strategies and access to enlarged markets in search for economies of scale.

- **Non-prescription market:** for what refers to non-prescription products, it is the manufacturer that has basically the discretion to establish the final price, and prices are generally not regulated by the authorities. Therefore, it is in this latter category of pharmaceutical products that competitive market forces are at their strongest. Despite the obvious advances in the achievement of a single market for Europe since 1985, differences between countries do still exist. Figure 7 shows that the components of the final price of a medicine vary in magnitude from member state to member state. It may be expected that the upcoming macro-convergence of national economies due to the Monetary Union will also require to some extent micro-convergence of the pharmaceutical markets and reductions of the prices' divergence.

Aside from the differences between prescription and non-prescription products pricing, there are common characteristics of the whole European pharmaceutical market with regard to prices that are worth noting:

- Prices do not change between retailers within each country. The price that the citizen pays for a specific medicine in a given country is the same independent of the pharmacy where the product is acquired. However, and as it has been remarked above, significant differences between countries are still observed.

- Prices are not used as a tool for promotion

- Prices remain to a great extent "hidden" during the marketing and sale process

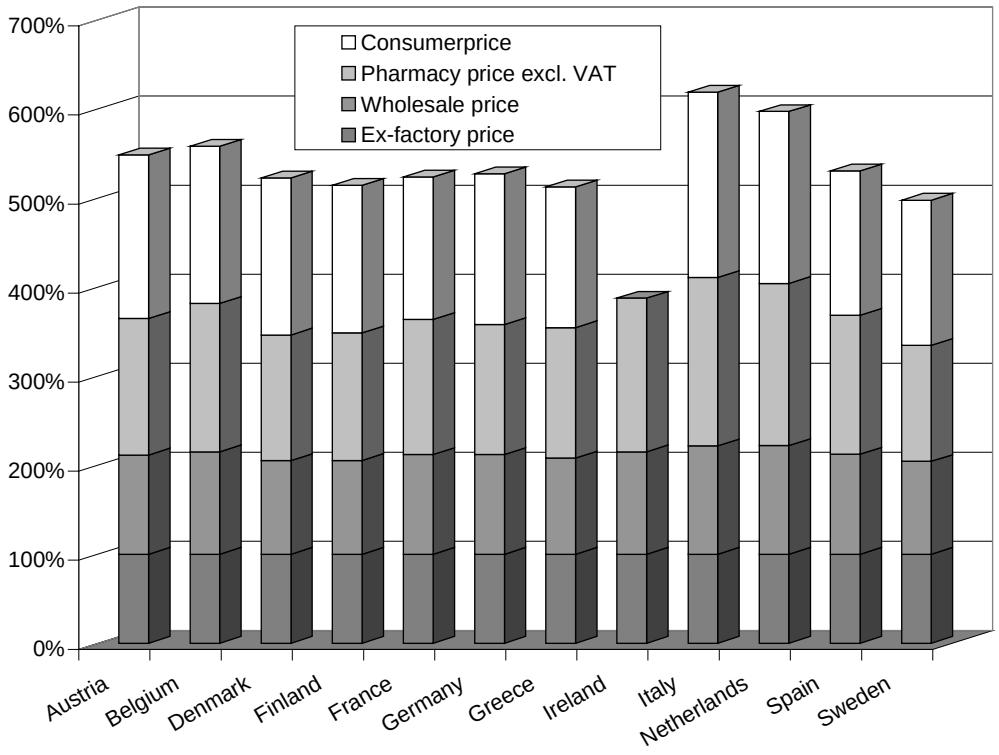

Figure 7: Manufacturers' prices, wholesalers' margins, pharmacists' margins, and VAT in member states (as percentage).[37] Manufacturers' prices are presented as 100 %.
(In Germany the mark-up depends on the ex-factory price. Here, higher priced products are considered, i.e. mark-ups are smaller; Portugal and the United Kingdom are not included, because wholesale and retail margins are not negotiated)

It is uncertain how the introduction of the Internet for marketing and sale of medicines can affect the European pharmaceutical market. Two basic uses of the Internet arise:

- **Information on pharmaceuticals -** despite all the safety measures that might be taken, it is likely that drug manufacturers will take advantage of the web's powerful characteristics for reaching a wider audience, anticipating new products' releases and stimulating the expectations of both health professionals and the general public, with a view to increasing the pressure for a swift marketing of new therapeutic possibilities. This factor is seemingly supported by the genuine interest of people in health information and the tendency in increasing the responsibility of individuals over their own health, but, as has been said before, the line between neutral information and promotion is often blurred. The spectacular growth of direct-to-consumer (DTC) advertising of prescription drugs in the USA through TV and other media seems to support this tendency. Effects of the mentioned trends on competition are uncertain, as on one side large companies have more resources for investment in new technologies and massive informative and advertising deployment, but on the other side the relative cheapness of the Internet can be very useful for small and medium enterprises (SMEs) to aim at a wider audience and improve their position in the market, although, as it has been said, the markets of reference for SMEs are normally local. This situation may change if SMEs decide to take advantage of the Internet for aiming at higher market shares abroad. Thus, two opposed effects will influence the competition degree of the market; it might be expected that, to a certain extent, one element will be compensated by the other, resulting in no changes for what refers to the market fragmentation. The existing uncertainty regarding how sales policies will be implemented and if they will affect the distribution chain doesn't presently allow for further conclusions in that respect. On the other hand, collision of information relative to different national and international environments will occur, which might produce a lot of confusion unless the information is properly labelled and even denounced if dangerous. The convergence of national practices and regulations in the EU may be accelerated for this reason. On a more general basis, increases of self-medication practices can occur if more information is disseminated throughout, but quality should be controlled.

- **On-line sale of drugs -** manufacturer's and distributors might take advantage of the e-commerce explosion that is foreseen (e-commerce volume is expected to reach over 60,000 Million USD in Europe by 2001)[38] to sell medicines on-line and lower distribution costs, while taking advantage of the perceived confidentiality that the user might experience as advantageous for the purchase of certain pharmaceutical products. However, in the case of those products that are purchased in order to obtain immediate relief, the accessibility and proximity of physical pharmacies can be an advantage. In those markets where prices are important for competition (self-medication products and generics), the Internet introduction may be a valuable competitive advantage in terms of promotion (the annual budget for drug advertising in the USA is 12.3 billion USD)[12] and/or savings on distribution costs, which may reduce the final price of pharmaceuticals. New actors in the form of on-line distributors might come into place and competition can result in advantages for the consumer in terms of convenience and reduced prices, and containment of healthcare costs might occur as the information flows and self-medication practices grow. However, vertical and horizontal integration procedures between companies in pursue of higher market shares might modulate these effects. This should be especially beneficial for large companies that have the appropriate resources to make the corresponding investments. It has to be considered that some kind of quality controls will always have to take place in order to safeguard the public health from uncontrolled, widespread information on drugs and distribution of potentially dangerous substances. As a consequence, additional public funds might be necessary in order to carry out vigilance tasks,[12] which may to some extent reduce the mentioned savings in healthcare costs.

1.3.3 Impact of the pharmaceutical expenditure for the healthcare system

The expenditure on pharmaceuticals is an important factor of the total healthcare costs. The expenditure in pharmaceuticals lies between 7.6 % and 26.6 % of the total healthcare expenditure in most European countries, as can be seen in column A of table

3 (Japan and the United States of America are included for comparison purposes). Governments assume a significant part of these costs (column B of table 3), although this contribution varies a lot between countries. Finally, column C of table 3 shows the percentage that this public expenditure in pharmaceuticals represents over the total public expenditure in healthcare, i.e. the relative importance that expenditure in medicines has within the public healthcare budget of European countries.

Table 3: Expenditure on pharmaceuticals[29]

Country	**A**: Expenditure on pharmaceuticals as % of total exp. on healthcare	**B**: Public expenditure on pharmaceuticals as % of total exp. on pharmaceuticals	**C**: Public expenditure on pharmaceuticals as % of public exp. on healthcare
Austria	14,1	59,0	11,6
Belgium	17,9	45,5	9,3
Denmark	9,2	50,5	7,1
Finland	15,2	46,5	9,0
France	17,0	61,3	12,9
Germany	12,7	72,6	11,8
Greece	26,6	16,7	5,7
Ireland	9,9	78,1	10,4
Italy	17,9	40,3	10,3
Japan	20,8	66,0	17,4
Luxembourg	11,7	80,2	10,2
Netherlands	10,9	63,9	9,7
Portugal	26,3	63,2	27,8
Spain	20,0	74,4	18,9
Sweden	13,0	71,2	11,2
Switzerland	7,6	61,1	6,6
United Kingdom	16,5	63,3	12,4
USA	8,8	14,6	2,8

The potential effects of the introduction of new information technologies on the evolution of the healthcare costs have been already discussed to some extent in the previous section. However, it is noteworthy that if prices of drugs are somewhat reduced because of cheaper promotion and distribution, the total pharmaceutical expenditure could be lowered producing the corresponding containment of the healthcare costs growth. Nevertheless, the increase of the demand generated by an enhanced visibility and accessibility could provoke a significant increase in the quantities purchased provoking an opposite effect.

2 New technologies for the information, marketing, and sale of medicines

This section provides basic concepts and definitions on new information technologies and their influence in marketing and commerce. It also presents an overview about the current implementation of such technologies in the health sector and, particularly, in the pharmaceutical one.

2.1 New information technologies and electronic commerce: introduction and basic concepts

2.1.1 Generalities

The Internet is becoming more and more important as a medium of communication and information. Though statistics about the number of estimated Internet users today and in the future show great differences depending on the market research company, the growth is impressive. Computer Industry Almanac Inc.[39] estimates nearly 320 million Internet users or 52.5 per 1,000 people world-wide at year-end 2000, and nearly 720 million users or 110 per 1,000 people by year-end 2005. For Western Europe they estimate 86,577 million Internet users and 217.5 per 1,000 people, respectively, and for Eastern Europe 9,487 million and 32.7 per 1,000 people, respectively.
Internet seems to allow new opportunities in almost any domain. Publication and access to information by anyone, anywhere and at any time, facilitates dissemination of all kinds of knowledge and promotes new environments for all kind of relationships.
This mainly affects economic areas. Electronic commerce facilitates economic growth and employment. Internet users like to use the Internet for commercial transactions. According to ComCult Research 1999, 74.5 % of the target group of Internet users visited lifestyle websites, attracted by their shopping possibilities.[40] Therefore, trends in e-commerce should be analysed (see 2.1.2).
Another remarkable characteristic of electronic commerce is its trans-boundary and world-wide nature. Consequently, national legal instruments doubtfully affect it.

2.1.2 Trends in electronic commerce

Trends in e-commerce in Europe might be extrapolated from the experience of e-commerce in the USA, where the use of the Internet is much more extended than in Europe, though Europe is making up the disparity. Although in the USA, the turnover of Internet-shops (mail order) still accounts only for up to 10 % of the total market,[41] its market share is about ten times higher than in Europe. For instance, in 1997 in Germany, companies obtained only 1% of their total turnover by electronic commerce.[42]
However, following the study on e-commerce "eEurope Takes Off", presented by Andersen Consulting in September 1999, European executives see tremendous potential in building online business capabilities: "Almost two-thirds of respondents (64 percent) see eCommerce offering a real competitive advantage in their marketplace today, compared to 51 percent a year ago, with those expressing a strong belief rising from 23 percent to 33 percent. An increased number of Europeans agree strongly that they have plans for future use of eCommerce – up to 44 percent from 31 percent in 1998.[43]

Latest statistics determine a turnover of about 16 billion Euro6 for the retail trades in Europe over the Internet in 1999,[44] which exceeds former estimates.
However, the Internet being the fastest growing medium (about seven times faster than the telephone and three times faster than television), one can expect e-commerce to grow just as fast. Several studies on Internet and/or e-commerce underline this trend. For example the current number of 9 million online-shoppers in Germany is expected to increase to up to 18 million by 2001 and 35 million by 2003.[45]

2.1.3 Business-to-business e-commerce

In the commercial field, the establishment of business-to-business electronic commerce depends on a number of conditions including company's profile, suitable infrastructure, kind of goods or services, and ancillary suppliers.
Without any doubt business-to-business activities account for the major part of the electronic commerce turnover. Forrester Research Inc. determined that nearly 90 % of total business-to-business transactions will be by electronic means in 2001.

2.1.4 Business-to-consumer e-commerce

The situation of business-to-consumer transactions in Europe is hardly developed in the case of the pharmaceutical sector because of the legal constraints to distance selling in most of the member states. However, this situation may change in the future as a combined result of international influence and the pressure of new technologies.
It has been demonstrated that users often look for information about products in the Internet, but buy them afterwards "offline".[46] A possible reason for such behaviour is the concern over privacy and safe transactions of credit card purchases. This is, however, likely to change as a result of new technical developments ensuring security over the Internet and also because of the reduction in costs for the user to 'surf' the net. An additional argument to this growing importance is the attention that is being paid by economic research institutions to the behaviour of Internet customers.[47]

2.1.5 Privacy and confidence

To reassure customers about the safety of commercial transactions through the Internet, trusted marks are being developed. The objective is to promote the principles of disclosure and informed consent. An example is the TRUSTe Program. The TRUSTe mark displayed in a website means they are obliged to notify: (1) information gathered/tracked about the user, (2) purpose of the information gathered/tracked, and (3) conditions under which the information gathered/tracked can be shared by others.[48]

2.2 New information technologies and medicinal products. Generalities

In the European pharmaceutical sector, activities using electronic data transfer can be already observed, especially a very well developed net between wholesalers and pharmacies. These activities are likely to increase and involve more participants of the distribution chain, and to expand to other electronic means as the Internet.
New information technologies affect medicinal products in several ways, e.g. the information about medicinal products as well as advertising, their selling and

6 In this study we use the American definition of "billion" (1 billion = 1000 millions).

distribution procedures, and also the process of prescription, although not all of these effects can be observed in Europe as yet. Distance sale of medicines is highly restricted in Europe. Only some countries (e.g. the Netherlands, the United Kingdom) allow some type of it.
In general, problems that hamper the e-commerce of medicines are, on the one hand, the lack of access to third party contracts and pricing, shipping fees, waiting periods, impersonality, and fears about Internet data security.[41]
On the other hand, it seems that a "wave" of online pharmacies (e.g. Drugstore.com,[49] PlanetRx.com,[50] CVS/pharmacy[51]), as can be seen in the USA, is rather unlikely in Europe at the current time.
Furthermore, pharmaceutical economical issues can only be speculated on with regard to how the Internet will affect the retail prices of medicines and whether this would imply health care cost reduction.

From the available data about trends in e-commerce in general, it is not easy to establish which should be the driving forces of e-commerce in the medicinal products domain. Clearly, e-commerce changes the way we think about value because it changes the way we obtain this value.[43] The first significant difference from the user side is, as it has been already mentioned, the increased amount of information that is exchanged with the product and service. This fact makes it easier to compare different products/services and providers. At the same time, it is possible for the provider to acquire a more comprehensive understanding of the user preferences, which can eventually imply improvements in the product or service being offered. Though the first point, information to users, specially in the case of the health care, is a clear driving force, integration of user preferences to the final product/service seems to be possible only to a limited extend, because of the particular nature of the medicinal product. Furthermore, at the current stage the profile of the e-commerce consumer that will access these services and products cannot be yet satisfactorily established. Clearly, a critical amount of users will be needed in order to establish successful services.

Besides, the experience so far in other businesses that have moved to the e-commerce arena shows, as a typical pattern, the need to create a virtual mall. In other words, a convergence among the enterprise offering the product/service, the company providing the technological platform and the financial institution supporting the economical transaction is required. Though the product/service could be offered directly by the pharmaceutical company, other possibilities are also possible and even more feasible. Wholesalers, as the experience in the USA largely demonstrates can be specially active and the same can apply to associations of retailers.

2.3 Marketing and sale of prescription medicines

Neither the advertising of prescription-only medicines in Europe is allowed, nor the sale without prescription (see section 1.1.2 and section 1.1.3). However, investigations in the United States of America show that online pharmacies do not make their profit with prescription-only medicines, as they cover only a very little volume of their turnover (IMS HEALTH statistics indicate less than USD 250,000 Rx7 volume per month through web pharmacies this year which is expected to grow to USD 966,000,000 Rx volume by 2003, and then it still will cover only 0.5%).[41]

2.4 Marketing and sale of non-prescription medicines

The use of the Internet for the marketing and sale of non-prescription medicines in Europe is very limited. Given the situation, it is worth considering the experience of the USA, where pharmaceutical e-commerce is a well-established reality. However, it is unlikely to expect the very same type of evolution in Europe, at least in the short term, since the legislation and commercial traditions are rather different.
An outstanding example of how information on medicines and their marketing and sale can be spread through the Internet is DrKoop.com website.[52] Its “Personal Drugstore” section works as a portal for accessing more than 20 Drugstores, some of which are sponsoring the website. As discussed elsewhere in this document, these websites react according to market forces, taking full advantage of the American unregulated pharmaceutical market. This implies aggressive price policies and impact advertisements together with all sort of collateral services, such as shipping facilities, convenient refill schedules, customised information or even access to drug check tools.

7 Rx = prescription-only medicines

3 Positions of key actors

3.1 Published statements of key actors

The objective presentation of opinions of identified key organisations that are bound to play a role in the issue of the use of new technologies for the marketing and sale of medicines on the Internet and television networks is one of the aims of this study. In this section, a brief summary of published statements is given; it will be completed in the next sections with the results of an *ad-hoc* conducted survey that should reflect the organisations' opinions about the discussed topic.
Several European and world-wide organisations have already expressed their concern about the marketing and sale of medicines on the Internet.
The **World Health Organization (WHO)** published the document: "Medical Products and the Internet – A guide to finding reliable information" in 1999,[53] which was requested by the 51st World Health Assembly in May 1998 and developed in consultation with drug regulatory authorities, drug information experts, consumer organisations, and the pharmaceutical industry. This guide was intended to serve as a model for member states to produce locally meaningful advice for Internet users in order to help them to obtain reliable, independent and comparable information on medicinal products.
The key points of this guide are the following:

- If used properly, the Internet allows quick and easy access to health information. It provides useful information on such topics as diseases, conditions, therapies, medical products, and health and medical organisations and institutions.
- The information you obtain from the Internet can be helpful when you consult your doctor or other health care provider about your disease or condition. But the guidance from the Internet should not replace consultation with your health care provider.
- Although it is often difficult to determine, you still need to verify the source of information available on the Internet.
- Information that sounds too good to be true, in particular, requires verification and careful assessment.
- Be cautious about buying medical products via the Internet. In many countries, selling or buying medical products via the Internet may at present be an illegal activity. You are strongly advised to obtain your medical products through legitimate distribution channels such as pharmacies.
- Consult your doctor or other health care professional before you decide to treat yourself.

The **Pharmaceutical Group of the European Union (PGEU)**, which represents the EU Member States' national professional associations of community pharmacists8, and the **Standing Committee of European Doctors (CP)**, which is an international association of national organisations of medical doctors from seventeen countries of the European Union/European Economic Area9, have jointly expressed their concern "about the increase of marketing and sales of medicines via Internet" and that "by ordering medicines over the Internet, people are exposing themselves to considerable risks" by means of:

- a letter to the Members of the European Parliament sent on May 1998;
- a leaflet addressed to the public entitled "The Internet and Medicines: Enjoy the Internet, but don't risk your health by ordering medicines over the Internet!", published on the 6th of May of 1999, which was widely distributed to European health professionals. This document was officially presented to the Committee on Environment, Public Health and Consumer Protection of the European Parliament as well as announced through a press release sent to the major European and national newspapers, and to all national magazines addressed to pharmacists and medical doctors.

Both organisations do accept the Internet as a very useful tool, but they want to warn citizens about the possible dangers that they may face if they order a medicine over the Internet. The pharmacists' organisations emphasise that the quality, safety and efficacy of European medicinal products, which results from the strict European system of authorisation, cannot be guaranteed in the case of sales of medicines through the Internet because this system might be bypassed. The medical doctors organisations are particularly interested in stressing the essential role that face-to-face contact with a physician plays for a patient.

The **International Federation of Pharmaceutical Manufacturers Associations (IFPMA)10** published its position on "The Use of the Internet for Pharmaceutical Information" in October 1998. They strongly supported the provision of accurate and scientifically reliable information on medicines on the Internet, for the benefit of both patients and healthcare professionals. Therefore, they argued that regulation of the distribution of this type of information on the Internet might impose unacceptable constraints on legitimate communication and information activities. To guarantee the quality of information, they supported self-regulation by the pharmaceutical industry, which has already proven to be very effective in other fields (e.g., codes of Good Practice, including codes governing marketing and promotional practices) They clarified that the self-regulatory IFPMA code of Pharmaceutical Marketing Practices sets out principles and standards for the information provided by companies which are equally valid for and applicable to information made available via the Internet (see 1.2.2.3). With respect to the sale of medicines over the Internet, they expressed their concern about possible misuse by the unscrupulous, selling prescription medicines without appropriate professional consultation, or supplying medicines outside regulated

8 There are approximately 125,000 community pharmacies in Europe, which employ some 600,000 people.

9 The CP represents 1.3 million European medical doctors.

10 The members of IFPMA are regional and national associations in 56 countries in both the industrialised and developing countries, representing research-based pharmaceutical companies and other manufacturers of prescription medicines.

distribution channels.
Since the strict regulation of the Internet is very difficult, they suggested to better use control mechanisms which apply to the physical movement of products via brokers, agents and dealers.
They stressed their willingness to co-operate with governments, regulatory bodies, and customs agencies to prevent the sale of medical products outside lawful distribution channels.
Finally, they recognised the problems arising from differences in national regulations on information about medicines, as well as from the differences in acceptability of "distance selling" to citizens living in remote areas, the elderly, and incapacitated people who seek better access to medicines.
They pointed out that the Internet has brought the need for harmonisation into sharp focus and that greater uniformity needs to be achieved in the international norms for disseminating accurate and reliable information on medicines.

3.2 Design of the survey

A two-step survey methodology was used to reach a satisfactory outcome. First, a questionnaire was designed to collect the information on the different topics to be considered (see Annex 1). The questionnaire included a common set of questions that were submitted to all the organisations, regardless of their specific characteristics. A complementary set of questions was customised depending on the type of organisation. The survey was conducted in an open form (free text). Additionally, respondents had the possibility of including further comments and/or statements at the end of the questionnaire. As a second step of the investigation, and after the analysis of the resulting data and the drawing of preliminary conclusions, additional contacts with some of the actors were carried out in order to collect supplementary information and refine the conclusions.
The groups asked to answer an *ad-hoc* designed questionnaire as well as those that answered, are shown in table 4.

Table 4: Answers received to the questionnaire

Organisation type	Quest. sent	Answers received																
		Total	Country[a]															
			EU	A	B	CH	CZ	D	DK	E	FIN	I	IRL	IS	NL	P	PL	S	UK
Medical doctors	32	6		✔	✔		✔	✔						✔			✔		
Pharmacists	34	9	✔	✔	✔			✔		✔		✔				✔		✔	✔
Pharmaceutical industry	48	6				✔		✔			✔				✔	✔		✔	
Wholesalers	19	3						✔					✔						✔
EU authorities[b]	2																		
Consumers	41	6		✔				✔		✔	✔				✔	✔			
Health insurance	2	1						✔											

A = Austria, B = Belgium, CH = Switzerland, CZ = Czech Republic, D = Germany, DK = Denmark, FIN = Finland, I = Italy, IRL = Ireland, IS = Iceland, NL = Netherlands, P = Portugal, PL = Poland, S = Sweden, UK = United Kingdom

[a] Only countries are listed from which answers were received.

[b] related to health and medicines

3.3 Summary of the survey results

The present section is a summary of the key actors' opinions as expressed in the answers given in the survey specifically carried out for this study. The survey was structured in four different parts according to the different issues to be explored: 1) perception of the current situation regarding the use of new technologies in the pharmaceutical sector for the marketing and sale of medicines, in comparison with "traditional" media; 2) perception of the future scenarios that can be foreseen in that respect; 3) current and planned activities of the surveyed organisations in the field; and 4) suggested policy options based on perceptions of the already existing regulations. Each of these four basic parts contained a number of specific questions with the purpose of facilitating the respondents' task and ensuring that answers were sufficiently comprehensive. For the sake of clarity, and given that the answers gathered are often based on general statements, the results of the survey are presented in a summarised form for each of the four main topics, as opposed to detailing the answers for each single question, thus avoiding repetition.

When analysing the answers, it was found that even among each type of actors significant differences were observed, which might reflect not only cultural and national differences, but also individual opinions of key representatives of the surveyed organisations. Unfortunately, the representation of specific countries among the received answers varies depending on the type of organisation, as does the actual number of answers received. Therefore the outcome of the survey is not statistically representative,

but it does give a useful overview of the variety of positions of relevant actors towards the considered topic. These different positions are summarised in the following sections. It can be said that, in general, there is a preference of pharmacists', medical doctors' and consumers' organisations towards a stronger regulation from relevant authorities on the electronic commerce of medicines in order to protect the consumer, whereas the pharmaceutical industry and wholesalers generally prefer self-regulation practices which they see as the best way to ensure consumer protection and guarantee a high quality level of health information.

3.3.1 Perception of the *current situation* on the use of new information technologies for information, marketing and sale of medicines (answers' summary)

3.3.1.1 Information

Current situation

In general the Internet is considered by the surveyed organisations as a very useful tool to disseminate information to the public and, from the users' point of view, a very powerful tool to search and receive a huge amount of information of great variety. The Internet is a medium that is rapidly developing and the quantity of information that circulates within it is increasing proportionally.

It is generally accepted that many people are using the Internet to seek information on health, including specific information on medicines. However, the perception of the quality of this information is quite diverse. Most of the organisations consider the information offered to be very mixed, ranking from the very good and objective to the bad and biased. Not only is the quality *per se* with respect to reliability is very heterogeneous, but also the level of sophistication is. Information that is dedicated to health care professionals should be more scientifically detailed than that directed to the public, and clearly labelled to avoid confusion. Finally, different types of information are also very mixed, i.e. commercial information is mixed with scientific information.

The surveyed organisations complain about the lack of quality control for information on medicines and claim for the development of some kind of quality control system, especially for that information addressed to the public, who often lacks the knowledge to discern the good from the bad, the objective from the promotional, and the scientific on-going research from the facts disseminated in press releases.

Consumers complain heavily about this lack of completeness of information, pointing out also that even if sometimes scientific information on effects of the medicine might be given, no information about its safe use and the possible consequences of repeated medication is offered. Additionally, consumers' organisations are concerned about the lack of information on the author/publisher of the web site, as well as about misleading price information (that frequently does not mention shipping costs, delivery-expenses and other fees for credit-card-paying, incomplete information about terms of the contract and conditions of the purchase and delivery, etc.).

Obviously, in countries where the use of the Internet is not too widespread, problems arising from the use of the Internet as a tool for searching and receiving information on medicines are not considered to be so important. Furthermore, in these countries language problems seem to be a remarkable obstacle to get useful information, as due to the poor development of the Internet, just few sites in the national language are available.

Perceived advantages of new technologies in comparison to "traditional" media with respect to information

- Information is (expected to be) more up-to-date.
- Information is available from any place and at any time (quicker and more easily than from a traditional library).
- Information about a particular, relevant health topic can be looked up in a more selective and targeted way.
- On-line communication is possible and gives the opportunity to solve questions faster.
- Answers can come from unexpected angles and unexpected solutions to a problem can be found by e.g. chatting.
- Information can in some cases be searched with increased anonymity.
- The great variety of information sources allows the user to choose.
- Information is more democratic and public, because it can be easily disseminated by independent and public institutions with few resources to publish, something which is seen as positive for a pluralist society.
- The Internet can be used for continuing education of health professionals and for information exchange between them in a dynamic way.
- The Internet can be easily used by citizens for their own health education and participation in healthcare.
- Possibility of organising an on-line alert system between community pharmacies to find medicines in case of shortage of normal wholesaling circuit.

Perceived disadvantages of new technologies in comparison to "traditional" media with respect to information

- Access to the Internet or other specific media is required, fees must be paid for connection and users must be familiar with electronic devices.
- No independent audit or control on the information is carried out and given to the citizen.
- Dissemination of information about medicines may not be exclusively given by qualified health professionals, i.e. pharmacists, medical doctors, etc.
- The enormous variety and amount of information makes it difficult for lay people to choose the correct information; consumers might be confused; the finding of the appropriate information depends to a great extent on coincidence and luck.
- Difficulty to distinguish between neutral and promotional information.
- Danger of misinterpretation or wrong use of medicine information found on the Internet, leading to false expectations about treatment options or misuse of drugs.
- Problems may arise due to cultural, economical or geographical differences, and also because of different healthcare systems and practices.
- Access to web pages is possible without knowledge of important context pages which contain disclaimers, warnings, etc.
- Illegal and dangerous information can be more easily disseminated because the owner of a web site can easily conceal his or her identity; difficulty to verify the source of the information given.

3.3.1.2 Marketing and advertising

Current situation

The field of marketing and advertising is also considered to be under quick development, and also the quality of the information given in advertisements is in general considered to be quite diverse. However it is – at least in Europe – perceived as much better regulated than the non-commercial information about medicines that can be found on the Internet. Nevertheless, the surveyed organisations still express concerns about advertisement practices that give incorrect or misleading information or make exaggerated health claims, or that lack the warnings and references required by law. In Europe, where advertising for prescription-only medicines is generally not allowed, and due to the cross-border characteristics of the Internet, advertisements of prescription-only medicines coming from third countries can also be accessed by citizens, being sometimes difficult to discern the country of origin or to which the information refers.
One of the surveyed pharmacists' organisation complains that although there are some good examples of advertising on the Internet, normally they offer no additional information in comparison with other "traditional" advertisements in magazines or television, although the Internet allows to do so and it would be very useful for the consumer.
Nevertheless, some industry and wholesalers' organisations remarked that advertising of medicines on the Internet is still not so widespread in Europe due to the strict regulations existing for advertisement on medicines.
Consumer organisations are more concerned by the overflow of "optimistic" information about alternative treatments and "miracle" medicinal products offered at low prices, because this will strongly confuse the consumer. This might specially affect those people urgently needing relief or under psychological pressure (e.g. overweight, hair-

loss, allergies) and those suffering from desperate situations concerning their health status, who usually feel helpless and tend to believe good news that promise to improve their situation.

Perceived advantages of new technologies in comparison to "traditional" media with respect to marketing and advertisement

- Permanent access, unlimited space, easy updating, variety of techniques and their combinations, international accessibility.
- Possibility of offering more in-depth information as an option for consumers willing to have further information on the product.

Perceived disadvantages of new technologies in comparison to "traditional" media with respect to marketing and advertisement

- Access to Internet or other specific media is required, fees must be paid for connection and users must be familiar with electronic devices.
- Ease with which a site can promote medicines in a way which is contrary to the national and European regulations and that might harm the public health.
- The authorisation and control of marketing or sales of medicinal products on Internet will be difficult due to the nature of the medium, which might endanger the safety of the consumer and the public health.
- Massive advertising of pharmaceutical products on the Internet can lead the consumers to increase consumption, misuse of drugs or exaggerate their expectations.
- Pressure on medical doctors to prescribe certain products can increase as users know more about pharmaceutical products and demand specific medicines.

3.3.1.3 Sale

Current situation

The surveyed organisations' perception of the current situation regarding the sale of medicines on the Internet is quite diverse. Whereas some organisations see a difference between non-prescription ad prescription-only medicines, others assess in the same way the situation with disregard of the type of product. In general, safety issues are underlined throughout. Some organisations see a certain potential for the sale of non-prescription medicines and other medicinal products over the Internet, if the providers of these services meet some mandatory information needs.

In general, all organisations are concerned about the sale of medicines on the Internet, when it might overcome the strict regulations and controls over sales of medicines existing in Europe. It is considered extremely dangerous that prescription-only medicines can be offered on the Internet with the possibility of obtaining a prescription by means of an "on-line doctor", or that prescription-only medicines can be supplied just assuming that the consumer has a medical prescription, with no proof requirement. Additionally, there are also some concerns about medication errors that may also occur if non-prescription medicines are available for on-line purchase, because in that case no "visible" health professionals are present to help the citizen decide on the appropriate treatment.

Another potential problem is perceived in the fact that quantitative limits of certain medicines set by national laws might not be respected with on-line sale of medicines, moreover if special prices are offered for large pack sizes. These quantitative restrictions are normally set to discourage consumers from holding large quantities at home and minimise the risk of mishap.

More importantly, pharmacists as well as consumers seem to be concerned about the lack of guarantee for the safety and authenticity of the product, and for the delivery conditions.
Some surveyed organisations express their concern about the proportion that the above-mentioned problems may reach, given the high degree of profitability for suppliers that e-commerce represents and the explosion of on-line sales that is expected in Europe in the near future.

Perceived advantages of new technologies in comparison to "traditional" media with respect to sale

- Potentially lower prices.
- Possibly helpful for housebound patients or for people who live in remote areas far away from the nearest pharmacy.
- Advantages for companies: extended markets, savings for running facilities.

Perceived disadvantages of new technologies in comparison to "traditional" media with respect to sale

- Danger of undermining the current national and European regulations.
- No guarantee of authorisation, quality, safety, efficacy, appropriate delivery and correct handling of medicines.
- Danger of medication errors because different products have the same trade name in different countries or the same products have different trade names in different countries.
- Patient leaflets may be incomplete or incorrect or they may be in a language that the consumer does not understand.
- Sale of medicines from third countries in which the ethics or regulations in health matters are questionable.
- Sale across borders of medicines not allowed in the consumers country or with different status (i.e. OTC in the country of origin, non-OTC in the country of destination).
- Danger of self-medication practices in cases where a medical doctor should be consulted.
- Offer of large package sizes for economic reasons, circumventing legal quantitative limitations.
- Lack of face-to-face contact might facilitate medication errors caused by misinterpretations of the written information provided and higher risk of interaction between different medicines, and it restricts the possibility of additional advises.
- Higher probability of misuse.
- Time delays, slowdown in distribution.
- Potential higher development of fake products: "authentic-looking" packaging but no active ingredient included.
- Difficulty to claim compensation in case of damage caused by the product, because identification of the supplier may be difficult.
- Potential delivery to persons who are not entitled to receive the ordered medicines, for instance children.
- Possible lack of privacy protection for the citizen.

3.3.2 Perception of the expected evolution of the use of new information technologies for information, marketing, and sale of medicines (answers' summary)

3.3.2.1 Information

The general surveyed organisations' perception on the expected evolution of the use of new information technologies with respect to information about medicines is that the Internet will become a more important source of information for both health professionals and consumers. Citizens have an increasing interest in health matters, and authorities promote self-care as a way to reduce healthcare costs. Furthermore, industries' interests are expected to push forward the amount of information available on health issues and medicines.
However, citizens will find problems in verifying the source of information and evaluating the quality of information itself. It will also be difficult to distinguish

between commercial and neutral information.
Consumers as well as medical doctors express their concern about an enormous uncontrolled growth and a lack of appropriate national and international legislation. Pharmacists regard the WHO paper "Medicinal Products and the Internet – A Guide to Finding Reliable Information" as a first step into the direction of helping citizens to detect objective health-related information. In addition, pharmacists think that quality labels awarded by special committees composed by medical doctors and pharmacists, or by organisations such as Medical and Pharmaceutical Societies, are needed.
Pharmaceutical manufacturers' organisations see a trend for more open provision of healthcare information that is probably going to continue, particularly to patients and the general public. They believe that they are a relevant source for this kind of information. Additionally, one organisation of the pharmaceutical industry has remarked in the survey that more information about prescription-only medicines should be given to the consumer on the Internet, as on this medium the newest information can be delivered throughout the world.

3.3.2.2 Advertising and Marketing

As perceived by the surveyed organisations, marketing and advertising of medicines on the Internet will constantly increase in the future, although (and possibly because) there is no appropriate law-suit. Therefore, some organisations pointed out that the Internet may be used for illegal purposes (both marketing and sales of drugs), and the existing rules and regulations on the market of pharmaceutical products could be circumvented. In that respect, representatives of the pharmaceutical industry think that the authorities will not be able to cope with the situation unless they go together with the industry in creating high-standard authorised web sites.
Pharmacists gave quite diverse answers to this question. On the one hand, they assume that while the possibilities to advertise medicines will remain restricted for consumer protection reasons (following the European legislation on the advertisement of medicines), the Internet will be used intensively for advertising medicines within the framework of these regulations. They do not expect electronic marketing and advertisement to step over the existing limits established by the European Directive 92/28. On the other hand, it seems to be practically impossible to safeguard the EU territory from on-line developments in the United States of America and other countries because of the own nature of the Internet. However, it is also noticed that awareness of the dangers related with the Internet seems to grow in the US.
As per the survey, the pharmaceutical industry thinks that the OTC sector will be the most affected by the new situation, at least with regards to advertising and promotion over electronic media, where the only barriers to the diffusion of information as technology becomes widespread will be languages.

3.3.2.3 Sales

In general, increase of sales of medicines via the Internet is expected, although much concern in that respect can be detected in the surveys. An urgent need for regulation arises. International regulations are expected to facilitate possibilities of health authorities to regulate this field.
However, medical doctors' argue that the magnitude of sale will also depend on the economic situation, i.e. national prices of medicines and possibility of reimbursement.

Also pharmacists state that in Europe there may be relatively small advantages to citizens in ordering medicines on-line.
Pharmaceutical industries' organisations and also pharmacists expect mail-order and trade between companies to expand. This may change the roles of some intermediaries such as wholesalers. However, the major impact will probably be to create fastest and more effective processes within the industry, which could translate into cheaper products. They do not expect major changes in the sale of prescription medicines directly to consumers over the Internet, which would probably remain the exception for quite some time. However, some pharmaceutical manufacturers seem to have a favourable attitude towards the sale of medicines on the Internet if such a distribution system will be developed once the safety, electronic prescribing and other problems regarding safety of medicines have been solved.

3.3.3 Organisations' current and future activities in the aforementioned fields (web pages, documents, commercial activities, etc.)

3.3.3.1 Current activities

The major part of the surveyed organisations are very interested in the marketing and sale of medicines using new technologies and actively search for information, participate in public debates and discussion groups, etc. A significant number of health professionals' and consumers' organisations have already initiated public campaigns to warn consumers about the dangers of on-line sale of medicines. They also encourage consumers to consult health professionals in these matters. The organisations' web sites often offer information on this topic.
Consumers' organisations provide web pages for consumers' complaints, and in some cases they provide a "black list" of web sites known by their activities in the field of sale of false or adulterated medicinal products on the Internet. Consumers' organisations also actively observe and evaluate the Internet in order to combat poor contents or illegal activities, which are denounced to competent authorities or directly initiate prosecution.
On the business-to-business field, the development of electronic communication with hospitals and care centres is to a great extent already established, so that they can order medicines electronically.

3.3.3.2 Future activities

In order to amplify the spectrum of services, telephone and e-mail services for citizens are in some cases planned.
Furthermore, electronic data collection in all community pharmacies is planed to support epidemiological and pharmaco-economy inquiries.
Finally a consumers' organisation plans to establish an initiative to implement a voluntary “good-Internet-practice”-guideline following the trends of those existing “good-clinical-practices” or “good-manufacturing-practices” to assure quality and security of the Internet, develop obligatory conditions for Internet-shopping (EU, OECD, WTO), and promote the idea for a national/EU/international board of control for Internet-shopping-sites.

3.3.4 Current regulatory framework and policy options (answers' summary)

3.3.4.1 Opinion on the current regulatory framework

Concerning the current regulatory framework two opposite positions were expressed in the survey. Some organisations pointed out that the European and national legislation with respect to marketing and sale of medicinal products is considered to provide a well-balanced framework where medicines are subject to special regulations attending to their related importance and sensitivity. Marketing and sales via Internet are limited to the professional use between industry, wholesalers and pharmacies. It was mentioned that the actual legal framework is adequate unless the Internet is used as an alternative channel for information, advertising, marketing and sale with the purpose of circumventing the current legal regulation. This might be perceived as quite easy because there is no pre-check by official control-boards of commercial information published on any web site.
From the opposite point of view, the current regulatory framework is considered to be very weak and insufficient. None of the current legal instruments regulating the framework for medicines was established with electronic commerce in mind. They are considered to be obsolete, as they are not adapted to the existence of Internet and other IT-tools.
The Directive on distance selling represents an important but small step towards better consumer protection and information, as it at least demands the identification of the salesman.
However, the cross-border and international nature of the Internet is not specifically addressed within the current regulatory framework.

3.3.4.2 Regulatory measures that should be taken

Representatives of the pharmaceutical industry as well as medical doctors argued that hard law instruments at a national level do not make much sense because of the lack of adequate control mechanisms. Medical doctors are also somehow sceptical about soft law measures at an international level.
Surveyed wholesalers believe that protection of the consumer will only be ensured through European legislation, together with treaties with other countries on a world-wide basis, and supported at a lower level by codes of good practice among industries.
Also surveyed pharmacists believe that hard law is appropriate in this case, because softer measures such as recommendations, codes of conduct, etc. are useful but not sufficient.

3.3.4.3 Possible hard law instruments at the national and European level

According to the surveyed organisations, the following legislation could be introduced at a national and European level:

- Ban of the marketing and sale of medicines on the Internet.
- Licence regulation for servers to identify the owner of websites.
- Law suits against malice activities.
- EU legislation that must set up some clear rules about the national jurisdiction for illegal activities carried out through a web site which is located in one of the European countries.
- It should be ensured that also foreign suppliers if they break national regulations will be prosecuted and sanctioned according to national law of the consumer.
- The e-commerce Directive should explicitly mention medicinal products, ensure consumer protection and contain a specific ban of the electronic sale of medicines to consumers.
- For some of the surveyed organisations, the ban on advertising of prescription-only medicines direct to the public in Directive 92/28/EEC should be extended to the Internet. However, as per some pharmaceutical industry organisations, the Directive 92/28/EEC should instead be revised into the possibility of relaxing the ban on direct-to-consumer advertising of prescription medicines.

3.3.4.4 Possible soft law instruments at the national and European level

According to the surveyed organisations, the following soft law measures could be introduced at a national and European level:

- European codes of conduct with ethical guidelines laid down by European interest groups of those who have an interest in disseminating information on medicines or advertising or selling medicines via the Internet.
- Establishment of a European board of control that regularly screens the net, traces out offences and gets the right to accuse for omission.
- Informative campaigns to the public in order to discourage the access to sites that provide information not applicable to the European reality or that are know for being dangerous.

3.3.4.5 Possible soft law instruments at the international level

According to the surveyed organisations, the following soft law measures could be introduced at an international level:

- Resolution of the WHO on medicines and the Internet, setting minimum standards for the dissemination of information as well as for the marketing and sale of medicines via the Internet.

- Agreement between the European Union and the USA in which the parties accept minimum standards for the dissemination of information as well as for the marketing and sale of medicines via the Internet and undertake to execute them.

- Establishment of an international agreement on the WTO-level that must increase the co-operation among states in order to create a regulative framework regarding liability, to ensure consumer protection, preserve consumers' health and fight against illegal activities.

- Establishment of electronic quality labels.

- Establishment of electronic systems for filtering information.

3.3.4.6 Obstacles that could be found in the application of the above proposed regulatory instruments

- Classification of medicines into prescription-only and OTC is not the same in all member states.

- Technical problems can be an obstacle for some measures that are related to Internet or customs control.

- Strict regulation will complicate usage and spreading of Internet network. Danger of over-regulation and introduction of censorship on information.

- General difficulty to reach international agreements in a short period of time.

- Hard law instruments could be circumvented, for instance by opening web sites in countries without strict legislation on these issues.

- Establishment of minimum quality standards on the information can be undermined by some suppliers of information on the Internet, which are often anonymous and difficult to identify and locate.

- Suppliers of illegal contents on the Internet could move their premises to countries that are not parties of the agreements.

- The authorities' capability for applying these regulatory instruments is limited due to the global nature of the Internet.

3.3.4.7 Practical mechanisms to guarantee the proposed legal instruments

Some practical mechanisms proposed by the surveyed organisations in order to guarantee the proposed instruments are hereunder listed:

- Public denounce of bad practices of information, marketing and sale of medicines in order to discredit the provider.
- Close co-operation between the national authorities that execute the provisions laid down in the international agreements.
- Implementation of direct phone lines to allow any citizen to publicly denounce dangerous web sites, and widespread dissemination of this information.
- In case of illegality, relevant information concerning the owner of a web site should be forwarded to the public authorities.
- Self-regulation of interested parties such as the pharmaceutical industry.
- Perhaps examination of other initiatives (such as those related to regulations and control on the Internet pornography) would assist as they, although not perfect by any means, have assisted in control measures.
- Custom controls could be enforced.
- Consumer awareness on the Internet and its implications for the marketing and sell of medicines should be raised at all possible levels.

3.3.5 Summary of the answers to the customised part of the questionnaire

In this section the answers to the questions customised depending on the type of organisation are summarised.

*3.3.5.1 Opinion on **electronic prescriptions** (medical doctors' organisations)*

One of the medical doctors' organisations voted strictly against electronic prescription without any exceptions. Another organisation argued that it could be easily introduced in hospitals, where it is already used in some places. It was mentioned that perhaps electronic prescription could be made as safe as other types of prescription on paper, by telephone or fax. However, if electronic prescription was to be allowed, there should be at least national regulations on it.
Concerning the question whether a physician without physical examination of the patient could fill out electronic prescriptions, the majority of medical doctors' organisations did not agree. However, it was acknowledged that in some exceptional cases this procedure could be possible in the same way as it is by telephone or fax.

*3.3.5.2 Possibilities to **improve services** using the Internet*

<u>Pharmacists organisations:</u>

- Providing reliable information on health care, disease prevention, medicines, self-care and healthy lifestyles on pharmacies web sites or via e-mail.
- Providing links to sources of reliable health information on the Internet.
- Regular connections with other health professionals and with local health services.
- Electronic pharmaceutical record of patients.
- Better service of community pharmacies by means of more information about the individual pharmacy and its services.
- Offering the possibility to pose questions to the pharmacist by e-mail and making appointments for personal consultation in the pharmacy.
- Enabling the pharmacies' customers to exchange information or build self-help groups by facilitating contacts between them.
- Pharmacy logistics and exchange of information among professionals could be improved to the benefit of the patients.
- Links with general practitioners to share information on patients.

Pharmaceutical industries' organisations:

- Provision of more and better information to interested consumers and professionals.

Wholesalers' organisations:

- Currently electronic communications with community pharmacies could be transferred to the Internet.

*3.3.5.3 Perception of the impact that the Internet will have on the **chain of the distribution** of medicines (pharmaceutical industry ➔ wholesaler ➔ pharmacy ➔ customer)*

Pharmacists' organisations:

- The pharmacists' organisations think that there will be impacts in the whole distribution chain. The pharmaceutical industry will probably use the Internet for disseminating information and advertising their products. Pharmaceutical companies will communicate with wholesalers and pharmacists by e-mail. Wholesalers will probably use the Internet for disseminating information and advertising their products. Maybe the Internet can facilitate the logistics of buying medicines and selling them to pharmacies. Pharmacies would in turn increasingly use the Internet as a means of advertising their goods and services within the framework of professional standards and of communicating with wholesalers and customers. Where mail order of medicinal products is allowed, citizens will probably order medicines at their local pharmacy via the Internet.

- Speeding up of the already existing distribution channels, making logistics more cost effective.

- Influence on parallel imports as e-commerce could create more links between importers and wholesalers increasing the choices of trading between them.

- The Internet might also weaken the distribution chain, what could undermine the existing system designed to ensure the quality, safety and efficacy of medicines.

Pharmaceutical industry organisations:

- Some products will go directly from the industry to the consumer, but the effect will not be important because: (1) only a small number of clients will buy their products via Internet and (2) industry will not be the only ones to open web sites, pharmacists will do so as well.

Wholesalers' organisations:

- Should the volume of medicines sold over the Internet increase significantly, it would create major problems for the industry as presently structured.

- Current arrangements for distribution of medicine are highly efficient and depend on substantial volumes for cost effectiveness. A breakdown in the system would result in a major increase in healthcare costs.

*3.3.5.4 Perception of the **need or wish of consumers** to obtain information about medicines or use mechanisms such as distance prescription or selling (consumers' organisations)*

All consumer organisations think that there is an increasing wish to obtain more information about health and medicines, especially in people who are suffering from diseases. This situation makes them weaker when faced with misleading and dubious information and "alternative therapies". On the other hand, reliable and objective information about medicines and treatments on the Internet can enhance their trust in medicine as a whole, favour their compliance to the treatment, shorten healing and improve their future prospect with the disease.
With respect to distance-selling, consumers' organisations are very concerned, but they expect an increasing demand for those so-called "life-style-drugs" (e.g. Viagra, Xenical, Propecia), as people feel very uncomfortable or ashamed to talk about them and the Internet might confer a feeling of confidentiality. Also products like analgesics or tranquillisers are expected to have an increasing potential for distance selling. All other kinds of medicines are not likely to be purchased over the Internet because of reimbursement problems.
For electronic prescription they do not expect an increasing demand, except for the aforementioned "life-style-drugs" and anti-depressive agents because of the same reasons already mentioned in connection with distance-selling of these products.

3.3.5.5 Safety measures to protect the consumers' rights (consumers' organisations)

- Very tight control over all the web sites that offer medicine information, to make sure that the information disclosed is correct, including dosage, indications, contraindications, side effects and interactions.
- Clear and whole identification of salesmen, control of business conditions (e.g. existence of insurance).
- Tight control at the customs for products coming from outside the EU.
- Possibility to identify serious sites for information and trading e.g. with “good-quality-signs”.
- Internet-sale adopted contracts.
- Confirmation of the order within one working-day – the confirmation should include all important points of order and sale, the exact price, payment- and purchase-conditions and the declaration of the right to withdraw the order within one week.
- Ban of sale of prescription-drugs via the Internet.

4 Options for EU policies

In this final chapter, a list of possible policy options is submitted to the European Parliament, taking into account all the information collected and analysed in the previous sections (singularities of the medicinal products, cross-border characteristics of the electronic marketing and sale, feasibility of control measures, positions of the key actors, etc.). When adopting any policy concerning medicines and the Internet, the global and cross-border nature of the Internet, not only across Europe but world-wide, should be taken into account. Hard law instruments on the Internet could have a very limited effectiveness if they are only applied to a confined territory (e.g. the European Union). Too restrictive European regulations could even provoke the emigration to third countries of Internet services addressed to the European market (e.g. websites containing advertisement of European medicines' brand names). This emigration, without eliminating the health problems that the regulations tried to solve, would generate difficulties to the European companies in order to participate in the potential economic benefits of the mentioned electronic services. Therefore, regulations at the world-wide level should be favoured whenever possible. However, it will surely not be feasible to adopt a world-wide ban on the sale of medicines over the Internet due to the positions of third countries (e.g. USA), where electronic distance commerce in the pharmaceutical sector is already well established.

Although the major part of the European organisations related with the pharmaceutical sector are not in favour of the development of the retail e-commerce of medicines, they consider the introduction and growth of such activities as an unavoidable phenomenon. For these reasons, they expect an active role of the European authorities in order to minimise the potential risks of these activities.

The evolution towards the European Single Market on Pharmaceuticals will be affected (accelerated) by the introduction of the electronic marketing and commerce of medicines.

According to the above mentioned points, the establishment of EU policies should consider:

- consumers' interests in terms of self-determination, economics, security and convenience,
- licit economic interests of involved enterprises, as well as
- authorities' interests in terms of public health and healthcare expenditure.

Specific policy options that we consider particularly relevant and feasible are listed below (see also section 3.3.4. for other proposals made by the surveyed organisations):

- To modify the current EU legislation on advertisement and commerce of medicines by explicitly considering the electronic media and services (taking into account their particular characteristics).

- If the EU regulation on the e-commerce of medicines was more restrictive than those existing in third countries, the possibility of confiscate medicinal products arriving to the EU borders/customs as a consequence of the mentioned e-commerce should be regulated. This possibility, even being difficult to be executed in a significant rate of the deliveries, could have discouraging effect on the potential clients.

- To support the establishment, by credible EU bodies, of quality standards and labels for health services on the Internet. These services would help the consumers to identify and filter the useful, safe and secure services.

- To support the creation (maybe in relation with the European Medicine Evaluation Agency) of an observatory devoted to the follow-up of the activities related with the marketing and commerce of medicines on the Internet. This service could contribute to the aforementioned definition of quality standards and the administration of quality labels. It would also play an important role in denouncing and even pursuing bad practices of information, marketing and sale of medicines on the Internet. In order to fight against the pernicious Internet activities on medicines, the same electronic media should be intensively used to denounce them. The mentioned observatory could play an important role also for this purpose.

- To push the pharmaceutical industry to establish agreements on "Good-Internet-marketing-practice", that should serve as a self-control instrument for the pharmaceutical industry in order to safeguard consumers' interests.

- To promote educational activities in order to provide the EU Internet users with the relevant knowledge and skills in order to obtain the maximum benefits from new information technologies incurring in the minimum risks. In the case of medicines, special emphasis should be given to the activities carried out by educational and health institutions and professionals.

5 Bibliography

1 Impact of electronic commerce on the European pharmaceutical sector by Ashurst Morris Crisp. This study was presented in November 1998 and commissioned by the European Commission.

2 Source: AESGP, status: September 1999.

3 The role of the pharmacist in self-care and self-medication. Report of the 4th WHO Consultative Group on the Role of the Pharmacist. The Hague, The Netherlands, 26-28 August 1998, Department of Essential Drugs and Other Medicines, World Health Organization

4 WHO Guidelines for Developing National Drug Policies; Statement of Dr Gro Harlem Brundtland, Director-General, World Health Organisation, 13th WSMI General Assembly & 35th AESGP Annual Meeting, Berlin, Germany 10 June 1999.

5 European Commission Communication and Proposal for a European Parliament and Council Decision adopting a Community action on health promotion, information, education and training within the framework for action in the field of public health (1 June 1994).

6 European Commission Communication to the European Parliament and Council on the outlines of an industrial policy for the pharmaceutical sector in the European Community (2 March 1994).

7 Thomas DH; Noyce PR. The interface between self medication and the NHS. BMJ 1996; **312**: 688-91.

8 Joint Statement by The International Pharmaceutical Federation and The World Self-Medication Industry: Responsible Self-Medication, 10 June 1999.

9 Lawson, D.: Treatments for common ailments. In: OTC directory 1995/96. London: Proprietary Association of Great Britain, 1995.

10 World Self-Medication Industry (WSMI): Guiding Principles in Self-Medication, 1999

11 A guideline on changing the classification for the supply of a medicinal product for human use. European commission, Directorate-General III, Industry, Industrial affairs III: Consumer goods industries, Pharmaceutical products, 28 September 1998

12 Shapiro MF. Regulating pharmaceutical advertising: what will work? Can. Med Assoc J 1997; **156**(3): 359-61.

13 Hopkins Tanne J. Direct to consumer drug advertising is billion dollar business in US. BMJ 1999, **319**: 805.

14 66/454/EEC, 75/319/EEC, 83/570/EEC, 87/21/EEC, 89/341/EEC, 89/342/EEC, 89/343/EEC, 92/27/EEC, 92/73/EEC, and 93/39/EEC.

15 OJ No C 115 of 6. 5. 1982, p. 5.

16 Federal Food, Drug and Cosmetic Act section 503(b)(1) (21 U.S.C. 353(b)(1).

17 TACD Recommendations on Food, Electronic Commerce and Trade and European Commission Services' Responses, Brussels Meeting, 23-24 April 1999.

18 MELIC (Multimedia Health Information for Citizens), Ten-Telecom program, project number 45560. Unpublished data.

19 The HON (Health on the Net Foundation) was born as an international initiative in 1996 in the field of development and application of new technologies in health and medicine. It is based in Geneva, Switzerland, and closely related to the University Hospitals of Geneva; (URL: http://www.hon.ch).

20 URL: http://www.comb.es/wma/eng/home.htm, accessed 3 Nov 1999.

21 The Internet and Medicines: Enjoy the Internet, but don't risk your health. Standing Committee of European Doctors (CP) and Pharmaceutical Group of the European Union.

22 Forty-seventh World Health Assembly geneva, 2-12 May 1994, WHA47.16 Ethical Criteria on Medicinal Drug Promotion; (URL: http://www.who.int/ism/mis/WHO-policy/index.en.html, accessed 25 Nov 1999).

23 WHO: Medical Products and the Internet. A guide to finding reliable information, Geneva 1999; (URL: http://www.who.int/dmp/Internet/InternetGuide.htm, accessed 3 Nov 1999).

24 M Boulding and J Mack. Promoting the Benefits of the Web: The Internet Health Coalition; (URL: http://www.ihc.net/content/articles_1.html, accessed 3 Nov 1999).

25 Recommendations on Electronic Commerce, TACD
(URL: http://www.tacd.org/meeting2/electronic.html, accessed 29 Nov 1999)

26 URL: http://www.ama-assn.org/ad-com/releases/1999/991012.htm, accessed 3 Nov 1999.

27 URL: http://www.medscape.com/, accessed 3 Non 1999.

28 Economist Intelligence Unit (1995) "OTC Pharmaceuticals in the European Union", London: EIU.

29 OECD Healthdata 1998.

30 Source: AESGP, national associations (URL: http://www.aesgp.be OTC Facts & Figures 1999, accessed 3 Nov 1999).

31 Bangemann, M.: The need for self-medication: an opportunity for the pharmaceutical industry. Proceedings 13th WSMI General Assembly & 35th AESGP Annual Meeting, Berlin, Germany 9-12 June 1999.

32 Matthews D; Wilson C. Pharmaceutical regulation in the single European market. Med Law 1998; **17**: 401-27.

33 Cartwright AC; Matthews BR (1991) "Pharmaceutical Product licensing Requirements for Europe", Ellis Horwood Limited.

34 Scrip Yearbook (1996).

35 Angaran DM. Telemedicine and telepharmacy: current status and future implications. Am J Health-Syst Pharm 1999; **56**: 1405-26.

36 Huttin C. Drug price divergence in Europe: regulatory aspects. Health Affairs 1999; **18**(3): 245-9.

37 AESGP: Economic and legal framework for non-prescription medicines, 1999.

38 Forrester Research Inc., Press release 1999 Sep 28; (URL: http://www.forrester.com).

39 Computer Industry Almanac Inc.; (URL: http://www.c-i-a.com).

40 ComCult Research; (URL: http://comcult.de, accessed 3 Nov 1999).

41 Brownstone, H.M., IMS HEALTH, FIP Conference, 5-10 September 1999, Barcelona.

42 KPMG's study "Electronic Commerce in German Industry- and Trade Enterprises".

43 Andersen Consulting: "eEurope Takes Off", September 1999, press release; (URL: http://www.ac.com/news/newsarchive/9.99/newsarchive_090999.html, accessed 19 Nov 1999).

44 Empirica - Communications and Technology Research: "Internet und Electronic Commerce in Europa - Wie der Internetboom den Kontinent verändert", "Die Online-Offensive der Betriebe. Zehn Länder im Vergleich inkl. Prognose für 2001"; (URL: http://www.empirica.com; summary: URL: http://www.akademie.de/news/langtext.html?id=2872, accessed 25 Oct 1999).

45 Capital-Study: "Internet und Electronic Commerce in Europa"; (URL: http://www.business-channel.de/bch/capital/index.html, accessed 10 Nov 1999).

46 Harris Interactive; (URL: http://www.ecommercepulse.com) "Only Half of Net Purchases are Paid for Online," Maryann Jones Thompson, The Industry Standard, March 1, 1999; (URL: http://www.Thestandard.com/metrics).

47 The Emerging Digital Economy I; (URL: http://www.ecommerce.gov/ede).

48 TRUSTe (URL: http://www.truste.org).

49 Drugstore.com; (URL: http://www.drugstore.com).

50 PlanetRx; (URL: http://www.planetrx.com).

51 CVS/pharmacy; (URL: http://www.cvspharmacy.com).

52 Drkoop.com, Inc.; (URL: http://www.drkoop.com).

53 World Health Organization (WHO/EDM/QSM/99.4): "Medical Products and the Internet – A guide to finding reliable information, Geneva 1999.

Annex 1 - Questionnaire

Common Part

The common part of the questionnaire was sent out as follows:

Perception of the current situation of the use of new information technologies in the pharmaceutical sector (with respect to information, marketing, and sale of medicines)

1. What is your institution's perception of the current state of information about medicines on the Internet?
2. What is your institution's perception of the current state of the electronic marketing and advertising of medicines on the Internet?
3. What is your institution's perception of the current state of the sale of medicines over the Internet?
4. What kind of specific activities do you pursue in the aforementioned fields (web pages, documents, commercial activities, etc.)?

Perception of the expected evolution of the use of new information technologies in the pharmaceutical sector (with respect to information, marketing, and sale of medicines)

5. What is your institution's perception of the expected evolution of information about medicines on the Internet?
6. What is your institution's perception of the expected evolution of the electronic marketing and advertising of medicines on the Internet?
7. What is your institution's perception of the expected evolution of the sale of medicines over the Internet?
8. What kind of future activities do you plan in the aforementioned fields (web pages, documents, commercial activities, etc.)?

Advantages and disadvantages of the electronic marketing and sale of medicines

9. What advantages and disadvantages do you see for the dissemination of information over the Internet, in comparison to "traditional" media?
10. What advantages and disadvantages do you see for the marketing and advertising of medicines over the Internet, in comparison to "traditional" media?
11. What advantages and disadvantages do you see for the sale of prescription-only medicines over the Internet, in comparison to "traditional" media?
12. What advantages and disadvantages do you see for the sale of non-prescription medicines and other medicinal products over the Internet in comparison to "traditional" media?

Opinion on the current regulatory framework

13. What is your opinion on the current regulatory framework that applies to the information on

medicines and their marketing and sale on the Internet? Please consider the national, the European Community and the international levels.

Proposals for policy options

14. What kind of regulatory measures should be taken in this field? Please consider both "hard law" instruments (e.g. legislation, treaties, case-law) and "soft law" instruments (e.g. codes of conduct, resolutions of international organisations).
15. What kind of obstacles could be found in the application of your above proposed regulatory instruments (due to the global nature of the Internet)? What practical mechanisms could guarantee their application?

Additional comments (optional)

Customised part

The customised part of the questionnaire contains two different questions, depending on the characteristics of the organisation.

A. Medical doctors

1. What is your opinion about electronic prescription?
2. Do you think that in some cases an electronic prescription could be filled out by a physician without physical examination of the patient?

B. Pharmacists

1. Do you see any opportunities for community pharmacies to use the Internet for improving their services? Please specify.
2. What is your perception of the impact that the Internet will have on the chain of the distribution of medicines (pharmaceutical industry ➔ wholesaler ➔ pharmacy ➔ customer)?

C. Pharmaceutical industry

1. Do you see any opportunities for the pharmaceutical industry to use the Internet for improving their services? Please specify.
2. What is your perception of the impact that the Internet will have on the chain of the distribution of medicines (pharmaceutical industry ➔ wholesaler ➔ pharmacy ➔ customer)?

D. Wholesalers

1. Do you see any opportunities for wholesalers to use the Internet for improving their services? Please specify.
2. What is your perception of the impact that the Internet will have on the chain of the distribution of medicines (pharmaceutical industry ➔ wholesaler ➔ pharmacy ➔ customer)?

E. EU authorities related with health and medicines

1. What is the envisaged evolution of the European pharmaceutical market, from your point of view?
2. How do you envisage the relationship between the evolution of the European pharmaceutical market and the development of new information technologies?

F. Consumers' organisations

1. Do you believe that in the consumers' community there is an increasing need or a wish for the use of the Internet to obtain information about medicines or to use mechanisms such as distance prescription or selling?
2. What kind of safety measures (i.e. precautions) should be adopted to protect the consumers' rights?

Annex 2 - List of organisations that answered the questionnaire

Medical doctors' organisations

- Austrian Medical Association, Austria
- Association Belge des Syndicats Medicaux, Belgium
- Czech Medical Association, Czech Republic
- Bundeärztekammer, Germany
- Laeknafélag Islands, Iceland
- The Polish Chamber of Physicians and Dentists, Poland

Pharmacists' organisations

- PGEU, Europa
- Österreichische Apothekerkammer, Austria
- L'Association Pharmaceutique Belge, Belgium
- Bundesvereinigung Deutscher Apothekerverbände, ABDA, Germany
- Pharmacists Federfarma, Italy
- Associaçao Naçional das Farmacias, Portugal
- Consejo General de Colegios Oficiales de Farmaceuticos, Spain
- Apoteket, Sweden
- National Pharmaceutical Association, United Kingdom

Pharmaceutical industries' organisations

- Pharmaceutical Industry Finland (PIF), Finland
- Schering, Germany
- Neprofarm, Netherlands
- Apifarma, Portugal
- Läkemedelsindustriföreningen, Lif, Sweden
- Hoffmann-La Roche Pharmaceuticals, Switzerland

Wholesalers organisations

- Bundesverband des pharmazeutischen Großhandels - PHAGRO, Germany
- Pharmaceutical Distributors Federation, Ireland
- Brittish Association of Pharmaceutical Wholesalers, United Kingdom

Consumers' organisations

- Kammer für Arbeiter und Angestellte für Wien (Abteilung Konsumentenpolitik), Austria
- Danish Consumers Council, Denmark
- National Agency for Medicines, Drug Information Centre, Finland
- Consumentenbond, Netherlands
- DECO-Associação Portuguesa para a Defesa do Consumidor, Portugal
- OCU-Organizacion de Consumidores y Usuarios, Spain

Health insurance organisations

- VdAK/AEV, Germany

STOA PROGRAMME

European Parliament
Directorate-General for Research
Directorate A

Room SCH 04 A034
Schuman Building
Kirchberg
L-2929 Luxembourg,
Tel (352) 4300.22511;
Fax (352) 4300.22418 or 24167
E-mail: gchambers@europarl.eu.int

or

RoomASP 6D46
Altiero Spinelli Building
60, rue Wiertz
B-1047 Brussels,
Tel (32-2) 284.3812
Fax (32-2) 284.49.80 or 9059
E-mail:tkarapiperis@europarl.eu.int