



Association of
Pharmaceutical Manufacturers
in Estonia

Positions of the Association of Pharmaceutical Manufacturers in Estonia in developing the national pharmaceutical policy

To ensure the availability
of pharmaceuticals to patients in Estonia
at the European Union average level
by 2015

2011



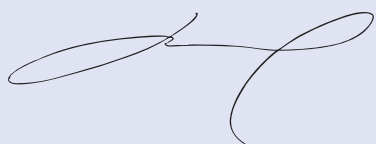
Estonia has established extending the life expectancy and improving the quality of life of the population as a priority. In 2008, the state adopted the Public Health Development Plan for 2009-2020, which links various development plans and strategies in the health area and with other areas. The overall objective of the Development Plan is to extend the expectancy of life lived healthily through reducing premature mortality and illness. The objective of the Development Plan is that by 2020, the average expectancy of life lived healthily has increased to 60 for men and 65 for women and the average life expectancy has increased to 75 for men and 84 for women.

The Association of Pharmaceutical Manufacturers is of the opinion that the said objective can only be fulfilled, if all those in need of assistance are ensured high-quality healthcare services, one of the integral parts of which is guaranteeing the availability of up-to-date pharmaceuticals to the public. Reasonable and safe use of pharmaceuticals increases the welfare of the population and improves the overall public health situation, while also reducing treatment costs and often the costs of the social area as a whole. We consider it important to develop and facilitate ambulatory medical care with modern and efficient pharmaceuticals, which ensure the most cost-effective results. In order to achieve the established objectives, the proportion of expenditure on healthcare of the gross domestic product should reach the average level of OECD countries.

Pharmaceutical policy developments have so far been directed by the Bases of Estonian Pharmaceutical Policy until 2010 – a document, which was prepared in 2002 and focuses on the basic pharmaceuticals and the safety and reasonable use thereof. The period of time defined by that document is over. In that time, Estonia has undergone considerable development, become a member of the European Union and OECD and is currently one of the economically most rapidly growing European countries.

The Association of Pharmaceutical Manufacturers is glad to note that the Government Coalition Agreement for 2011-2015 establishes the development of a new pharmaceutical policy as an objective. The Coalition Agreements aims at ensuring a wider selection of pharmaceuticals, a lower level of co-payment by people, and a fairer business environment more open to competition – which match the vision of a sustainable pharmaceutical policy held by the Association of Pharmaceutical Manufacturers.

Our aim is to stimulate a wide-based discussion of pharmaceutical policy dialogue in the society and we believe that the presented positions and proposals are helpful in the implementation of significant changes.



Piret Sell
Chairman of Supervisory Board
Association of Pharmaceutical Manufacturers



Riho Tapfer
Director
Association of Pharmaceutical Manufacturers

Association of Pharmaceutical Manufacturers in Estonia

The Association of Pharmaceutical Manufacturers in Estonia (APME) represents the manufacturers of research-based original medicinal products, companies manufacturing generic medicines and companies engaged in pharmaceutical research in Estonia. APME is a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA), which connects 2,200 companies through 32 national associations and 43 leading pharmaceutical companies in the European Union and follows a common code of ethics.

The investments of bio-pharmaceutical companies in scientific research and development in Estonia by estimation amount to approximately 25 million EUR a year. Through investments into research and development activities, 200 highly qualified jobs have been created together with the necessary infrastructure.

In addition to scientific research investments, pharmaceutical manufacturers have initiated various charity projects, the most important one of which was the compensation of the co-payment part of medicines, aimed at the unemployed during the peak of the economic recession in 2009-2010 with the objective of reducing the negative effect of health risks on employment.

1 Objectives

In Estonia, pharmaceuticals have in recent years been mainly subject to reimbursements on the basis of the lowest possible cost. That has created a situation where older and non-patent medicines are available, but the availability of new and efficient medicines is one of the lowest in Europe.

Pharmaceutical manufacturers consider it important to change the long-term strategic perspective in providing reimbursements for pharmaceuticals and to aim at ensuring the following 5 basic areas:

- availability and reimbursement of necessary medicines;
- quality, efficiency and safety of medicines;
- reasonable use of medicines;
- availability of pharmaceutical information to patients;
- protection of intellectual property and equal treatment.

Pharmaceutical policy has an impact on the welfare and health of the population. The successful implementation of the policy is ensured by efficient cooperation between the public, pharmaceutical and medical scientists, doctors, companies engaged in pharmaceutical business, government agencies and the media.

The objectives of these parties are both common and contrary. Limited resources and contrary interests require understanding, tolerance, compromises and agreements.

A wider involvement of the parties and the consideration of various interest groups will ensure that decisions are more transparent and common objectives are achieved more rapidly.

Availability and reimbursement of necessary medicines

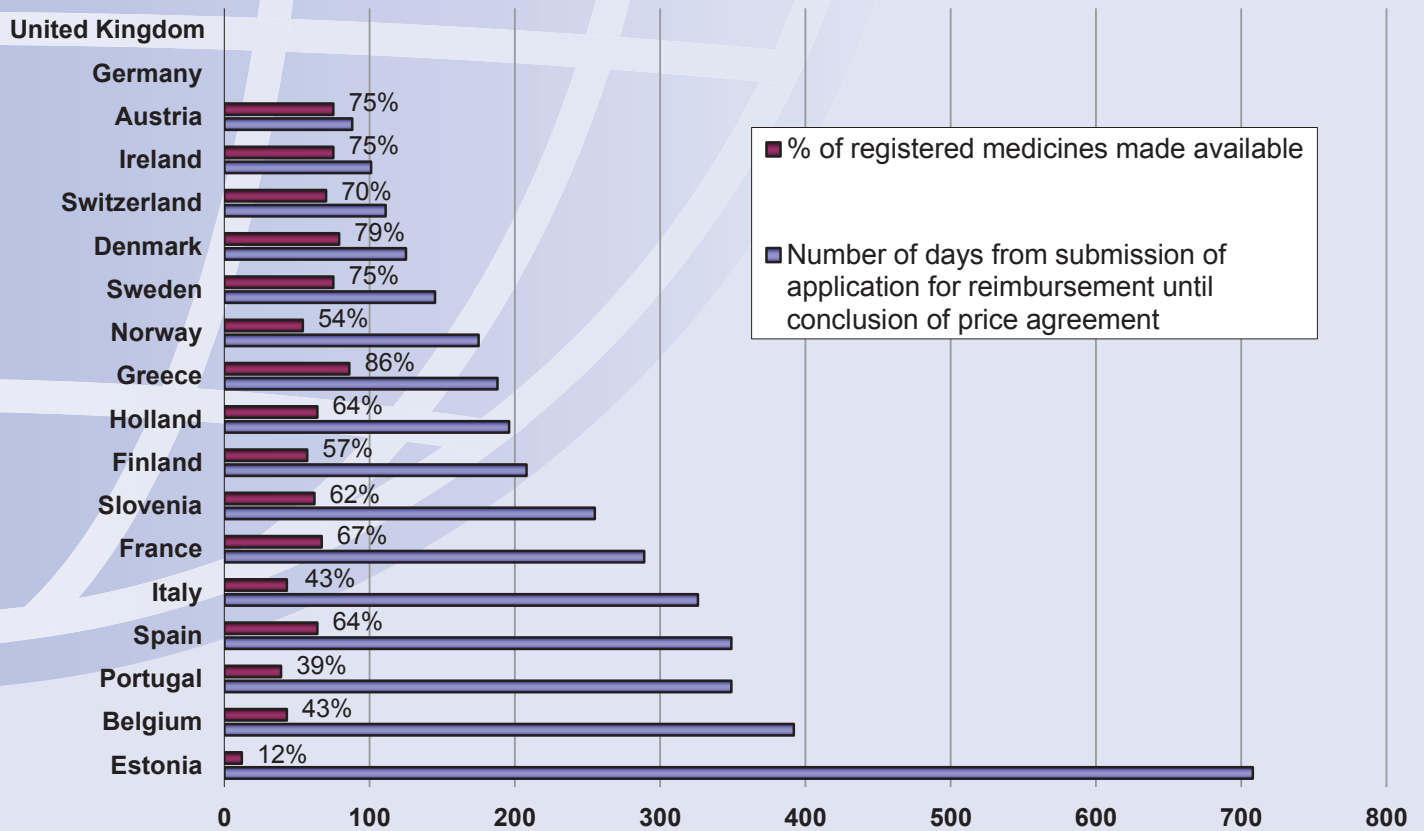
In Estonia, the availability of pharmaceuticals is considerably below the average level of European countries. The provision of reimbursements for medicines cannot be aimed at the minimum selection of pharmaceuticals, as that is not characteristic of a developed country. At the same time, the real availability of medicines compensated by the state has to be ensured at the pharmacy level. Decisions concerning the compensation of medicines should be made on the basis of the needs of patients, only then assessing their impact on the budget.

Estonia needs clear and rapid changes in order to improve the availability of new medicines. According to the 2010 data of the State Agency of Medicines, 63% centrally authorised medicines and 85% decentrally authorised medicines, 54% of medicines authorised via mutual recognition procedure and 12% of nationally authorised medicines have not been marketed in Estonia in the past three years. The main factors restricting availability are the small size of the Estonian pharmaceutical market and the highly complicated process of adding medicines to the list of compensated medicines.

In Europe, the availability of medicines to the public in individual countries is assessed on the basis of the W.A.I.T. indicator (*waiting to access innovative therapies*). The W.A.I.T. indicator analysis published by the European Federation of Pharmaceutical Industries and Associations (EFPIA) in November took into account the new medicines that were for the first time centrally registered at the European Medicines Agency between 1 January 2007 to 31 December 2009 (84 new medicines in total). As at 31 March 2010, 24 of these medicines had been submitted for reimbursement and 10 of these medicines (12%) had price agreements concluded and reimbursements valid. The average time from registration of these medicines to the conclusion of price agreements for these medicines was 708 days and the duration of the official procedure from the receipt of an application to the conclusion of a price agreement was 443 days.

Figure 1: W.A.I.T. indicator data for European countries compared to Estonia

Availability of new medicines



Source: EFPIA, homepage of the Ministry of Social Affairs

4 Co-payment by patients

In the area of payment for medicines, Estonia is characterised by a high level of co-payment by patients. The national pharmaceutical policy places priority in preferring cheaper medicines, which is implemented through three measures:

- active substance based prescriptions;
- pharmacists' obligation to offer medicines with the lowest price;
- extensive national media campaign.

The highest level of co-payment by patients in regards to prescription medicines as compared to other European countries is due to two important factors:

- the reimbursement rates do not sufficiently cover the cost of medicines (the upper level of 12.78 EUR for 50% reimbursement medicines);
- the non-reimbursement of new medicines of proven efficiency increases the level of co-payment by patients, raising it to 42% according to the 2009 data; therefore, the level of co-payment increased by nearly 5% according to the 2009 data due to the use of prescription medicines not subject to reimbursements.

Table 1: Co-payment by patients across years

	2001	2002	2003	2004	2005	2006	2007	2008	2009
Prescription medicines	37,9%	36,3%	43%	41,9%	43,3%	43,6%	43,5%	43%	41,7%
Medicines subject to reimbursements	31,9%	30,7%	36,6%	35,6%	36,6%	37,1%	37,6%	37,7%	37%

Sources: WHO 2009 "Review of the Estonian Pharmaceutical Sector: Towards the Development of a National Medicines Policy"; homepage of the State Agency of Medicines; homepage of the Estonian Health Insurance Fund

Proposals for reducing the level of co-payment:

- to increase the number of medicines subject to reimbursement by 2015, so that the impact on the level of co-payment by patients would correspond to the co-payment of prescription medicines;
- to annul the 12.75 EUR upper limit of compensation of 50% reimbursement medicines.

Innovative medicines 5

Innovative medicines are understood to be medicines or methods of treatment, which satisfy the unaddressed clinical needs of a certain group of patients or do that in a manner different to existing medicines/methods of treatment. An innovative medicine/method of treatment may differ from existing ones by the active mechanism, efficiency, safety, form of treatment and method of administration.

Innovative medicines are also considered to include medicines of the same class added to first class medicines, if the former have been developed independently.

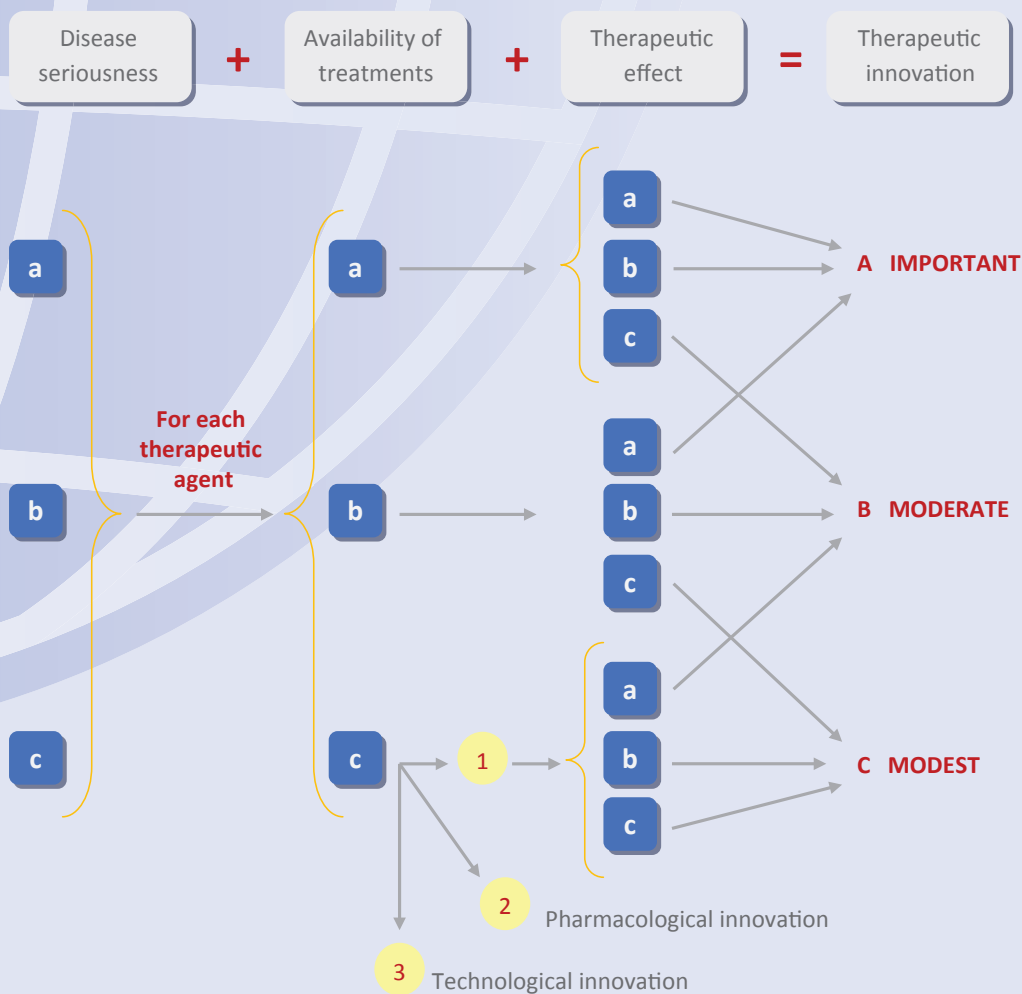
The European Federation of Pharmaceutical Industries and Associations (EFPIA) has initiated a wide-based discussion concerning the promotion of innovative development activities in the European pharmaceutical industry. Estonia's indicators in regards to the availability of innovative medicines are considerably lower than those of our neighbouring countries. In 2007–2009, sales licences were granted to 84 new medicines in Europe, of which only 10 (or 12%) are available in Estonia under reimbursement terms. This situation should be compared to Germany and the UK, where all the medicines are included in the list of compensated medicines from the moment of their registration. It is also worth pointing out our neighbouring country Finland, where 57% of the new medicines were made available to the public within the aforementioned period (see Figure 1).

It is important to emphasise that a novel medicine or method of treatment becomes innovative and potentially beneficial only on the condition that it is available to at least a certain number of patients. In other cases, these are just inventions, the practical benefits of which are not realised.

Proposals for improving the availability of innovative medicines:

- to increase the level of providing reimbursement for new medicines in Estonia to the average level of European countries by 2015. The calculation is based on the ratio of new medicines registered at the European Medicines Agency (EMA) to the number of medicines subject to reimbursement;
- to aim at bringing the duration of the administrative procedure of providing reimbursements to the European average level by 2015. The calculation is based on the time taken from the submission of an application for reimbursement to the conclusion of a price agreement.

Figure 2: Innovation assessment algorithm



Source: Domenico Motola, Fabrizio De Ponti, Elisabetta Poluzzi, Nello Martini, Pasqualino Rossi, Maria Chiara Silvani, Alberto Vaccheri & Nicola Montanaro. An update on the first decade of the European centralized procedure: how many innovative drugs? *British Journal of Clinical Pharmacology*. 2006)

Algorithm used to assign the overall score for innovation:

Disease seriousness:

- a) drugs for serious diseases;
- b) drugs for risk factors for serious diseases;
- c) drugs for nonserious diseases.

Availability of treatment:

- a) drugs for diseases without recognised standard treatment;
- b) drugs for diseases where subsets of patients are less responsive to marketed drugs and/or other medical intervention;
- c) drugs for diseases responsive to marketed drugs or other medical interventions (c_1 – more effective or safer or with a better kinetics than existing drugs; c_2 – mere pharmacological innovation, i.e. drugs with a new active mechanism of action; c_3 – mere technological innovation, i.e. a new chemical or biotechnological product with a therapeutic role similar to already existing medicine).

Therapeutic effect:

- a) major benefit or clinical end-points (e.g. increased survival rate and/or quality of life) or validated surrogate end-points;
- b) partial benefit on the disease (on clinical or validated surrogate end-points) or limited evidence of a major benefit (inconsistent results);
- c) minor or temporary benefit on some aspects of the disease (e.g. only partial symptomatic relief of a serious disease).

5.1 Orphan-drugs

The status of an orphan-drug is granted to a medicine used for treating rare diseases, i.e. life-threatening or chronic diseases, from which 1 person in 2,000 suffer. A separate model of compensation needs to be developed for medicines used for rare diseases, taking into account the individual needs of patients and the nature of the disease. It would be expedient to establish a separate fund in the health insurance budget for the treatment of rare diseases, similarly to the majority of European Union countries. Decisions concerning the compensation of treatment should, above all, be based on the needs of the particular patient and not the usual pharmaco-economic analysis, as there are generally no input data for the analysis in Estonia, only a few patients would need treatment and the cost per patient is high. As at February 2011, 61 medicines with the states of orphan-drugs had been registered in the European Union. In Estonia, 8 of these (10 indications) are available (subject to reimbursement).

Proposal for improving the availability of orphan-drugs:

- a separate compensation model needs to be developed for medicines used for treating rare diseases, taking into account the individual needs of the patients and the nature of the disease.

Committee for Medicines Subject to Reimbursement (Medicines Committee)

6

The Committee for Medicines Subject to Reimbursement has been formed for the purpose of preparing a wide-based public and expert opinion on the provision of reimbursements for medicines. Unfortunately, the members of the Committee are not equally informed of the impacts of their decisions. The decision-making process is often not transparent and unambiguous and does not sufficiently take into account the opinions of professional specialists and patients.

In order to increase the transparency of the decision-making process, we consider the following changes important:

- to develop clear assessment criteria for the inclusion of medicines in the list of compensated medicines;
- to add to the process a written opinion of a professional association (area-specific advisor) on an entire application (not only on specific issues);
- to add to the process a written opinion of an organisation representing patients;
- to create possibilities for further training for organisations representing patients in cooperation with the state and the University of Tartu;
- the explanation of the decisions of the Medicines Committee and the explanation of the impacts thereof in a transparent manner;
- taking into consideration the European Union context and the practices of other Member States;
- to include in the work of the Medicines Committee a representative of the Association of Pharmaceutical Manufacturers.

7 Price formation of medicines

The prices of medicines are regulated nationally, in order to guarantee the most optimum price possible. At the same time, all the possible measures should be taken to facilitate the availability of as many medicines as possible in Estonia, free competition, the freedom of choice of patients and the protection of intellectual property rights.

In regards to price formation, we deem it important to consider the following principles:

- **innovation should be valued;**
- **competition should be facilitated, while preserving the freedom of choice of patients and doctors and the availability of medicines;**
- **price formation should be flexible, i.e. the price of medicines with the same active substance may differ depending on the method of administration (e.g. inhalation), dosage (e.g. children's doses), form of treatment (e.g. pills, powders, aerosols with prolonged effect), combination of medicines (combination of active substances) or indications (e.g. doses differing by orders of magnitude in the case of different indications);**
- **price formation should take into consideration the European Union context.**

8 Medicine sales channels and business restrictions

The implementation of digital prescriptions in 2010 has created good preconditions for ordering and delivering medicines via the Internet and postal services. The implementation of the additional possibilities of the digital prescription system would considerably contribute to improving the availability of medicines.

The Association of Pharmaceutical Manufacturers considers very important the implementation and maintenance of the principles of free competition in Estonia. The provision of pharmacy services is subject to founding restrictions, which have not fulfilled their objective. The currently applicable restrictions on the foundation of pharmacies have not increased the number of pharmacies in rural areas and do not facilitate the provision of more favourable prices for consumers through reasonable competition.

In the case of non-prescription medicines, the principles applied are good availability and the best possible safety upon independent use. Decisions to purchase non-prescription medicines are made by patients themselves and therefore it is important that information about non-prescription medicines is well-available.

Proposals for improving the availability of non-prescription medicines and developing e-services:

- **to establish legislative regulation for the creation of possibilities for the electronic ordering and postal delivery of prescription and non-prescription medicines during 2011;**
- **to facilitate free competition and eliminate the legislative restrictions on the foundation of pharmacies;**
- **to find possibilities for using additional sales channels in order to improve the availability of non-prescription medicines.**

Vaccination is an important part of prophylactics in the area of public health and therefore we consider it important to increase the overall awareness of vaccination among the population and the doctors with the objective of improving the general interest towards vaccination as one of the most efficient ways of avoiding diseases (particularly communicable diseases). In order to achieve this objective, it is important to develop a long-term strategy in cooperation with national organisations, professional associations and the Association of Pharmaceutical Manufacturers. International organisations (WHO, CDC, ECDC) recommend ensuring comprehensive access to vaccines and increasing the coverage of the population. In Estonia, only the vaccines included in the national vaccination calendar are subject to reimbursements, and therefore many efficient vaccines are not available.

Proposals for improving the availability of vaccines:

- **to develop a long-term vaccination strategy in cooperation with professional specialists, national organisations and pharmaceutical manufacturers;**
- **in addition to the national vaccination plan, to make efficient vaccines more affordable and available to the public by providing additional reimbursements from the state budget;**
- **the review of the national immunisation calendar should be regular and transparent.**

The medicines used in Estonia are registered by the Estonian State Agency of Medicines and/or the European Medicines Agency (EMA) and sold under sales licences issued by the Estonian State Agency of Medicines or the European Commission, which guarantees their quality and, upon purposeful use, safety and efficiency.

10.1 Biological medicines

In the case of biological medicines, competent authorities are authorised to demand that the holders of sales licences exercise additional supervision in regards to safety and efficiency in everyday medical practices, incl. the organisation of surveys after obtaining a sales licence.

In line with the supervision requirements of EMA, many EC Member States recommend the prescription of biological medicines on the basis of the commercial name (and not active substance). Substituting a biological medicine with another biological medicine may cause a release of undesired immune reactions.

A decision to substitute a medicine should be medicinally justified and made under medical supervision, not on the basis of economic considerations and/or at the pharmacy level. Compliance with EMA's recommendations is also important in protecting the interests of patients in Estonia.

Mechanisms need to be created in Estonian legislation to exclude the substitution of biological and biologically similar medicines at the pharmacy level due to price pressure. Possibilities should also be found to establish reasonable price and limit price regulations, e.g. substituting and replacing biological medicines according to limit prices changed on a quarterly basis is unthinkable due to the possible immunogenicity risks.

As these issues have not as yet been adequately addressed in Estonian regulations, cooperation between different parties (competent institutions, professional doctors, pharmaceutical manufacturers and patient representatives) is needed in order to ensure the appropriate, efficient and safe use of biological medicines.

10.2 Reasonable use of medicines

One of the underlying principles of evidence-based medicine is that in order to use a method of treatment, sufficient up-to-date information should be available concerning the efficiency and risks of the method of treatment, or the risk and benefit ratio should be scientifically determined. Reasonable use of medicines requires the integration of such information with economic considerations. To implement that approach, the relevant reliable information should be readily available at the moment it is needed and the decision-maker should be competent and motivated to use the information.

10.3 Availability of medicine information to patients

The European Parliament holds that patients should to have easier access to accurate information concerning prescription medicines in the future. Emphasis should be placed on the patients' right to receive information they need and wish to receive. The aim is to improve the quality and extent of information provided to patients. In the opinion of the members of the European Parliament, it is namely the pharmaceutical companies that have to make an overview of the characteristics of a medicine, the designation and packaging information sheets as well as assessment reports available to the public. In addition, pharmaceutical companies should be allowed to provide other information not related to advertising, for instance, information concerning the price, the possible changes of packaging and the instructions of use, but that requires the prior approval of a competent authority of Member States. Information should be available both electronically (on a topical website) and in printed form as well as in a form accessible to disabled people.

In order to ensure fair and free competition, it is important to take into consideration the following principles:

- the reference of prices in determining reimbursements should take into consideration the protection of intellectual property;
- the reference of prices should be performed in groups of medicines, which do not include a medicine under the protection of intellectual property;
- molecules in the same ATC group should be ensured compensation at an equal reimbursement rate, which would ensure the freedom of choice for doctors and patients and be in conformity with the requirements of the Competition Act.

The implementation of the pharmaceutical policy has extensive micro-economic and macro-economic impacts. The fulfilment of the established objectives would help improve the availability of medicines and facilitate the reasonable use of medicines.

12.1 Healthcare

The timely use of modern and efficient medicines helps use resources in the healthcare area in a more economical manner, which on a whole would have a positive impact on the general economic capability of the state. At the same time, activities to continue raising the awareness of the medical community of the role of economics in making medicine-related choices, which in turn would help ensure the reasonable use of medicines in a manner most favourable for patients role.

Although the ageing of the population and the increased readiness to use medicines causes a need for additional resources in the healthcare system, the resources for the faster introduction of innovative medicines also have to be increased. More effective medicines extend the working capability of the population, which in turn benefits the entire society. From the patients' point of view, a very important place for receiving health and medicine related information is the pharmacy service, which has to conform to uniform professional standards in all the pharmacies.

The Association of Pharmaceutical Manufacturers considers it necessary to consider the partial allocation of the alcohol and tobacco excise duty to the healthcare sector. Both alcohol and tobacco are the highest risk factors in health behaviour and therefore the taxes collected on the use thereof should facilitate the development of healthcare.

12.2 Satisfaction and awareness of the public

The successful implementation of the pharmaceutical policy would increase the awareness of the public of the use and risks of medicines and improve the readiness for treatment. Important information related to medicine would become more available to the population, which would increase the awareness of non-use or misuse of medicines. A successfully implemented pharmaceutical policy supports the objectives established for the development of public health through increasing both the average life expectancy and the number of years lived healthily.

12.3 Economy

The maximum rate of employment is a precondition to the development of the economy. Upon the reasonable use and sufficient availability of medicines, working-age people can participate in the maximum employment. The life quality of people on incapacity-for-work pension or old-age pension would improve, thereby reducing the financial risks arising from their health. Unemployment must not increase health risks due to the fact that the necessary healthcare services and medicines are unaffordable due to the high level of co-payment.



