

Lif's positions



Lægemiddel
industri
foreningen

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1.0 Lif's positions – on healthcare policy

1.01 Denmark needs a healthcare policy

The Danish nation can have the world's best health service. If we only want to. Denmark is one of the most affluent countries in the world and Denmark has the qualifications, the necessary expertise and healthcare infrastructure needed for getting the Danish health service back into peak condition. But that requires that we are also ready to make a dedicated effort to achieving better health results.

The Danish health service is set to come under mounting pressure in the future. This should be viewed against the fact that Danish health results are already lagging behind those in the countries we usually compare ourselves with.

The Danish lifestyle has negative consequences for the general state of health. In that respect Denmark has been far too hesitant to take initiatives that would change the nation's lifestyle behaviours, to detect diseases and prevent them in time.

At the same time, Denmark has chosen to invest less in healthcare than our neighbouring countries. It is difficult to imagine how we are to improve Danish health results when we spend less money than others.

But Denmark has been far too slow to take advantage of the new health technology potentials available to the health service. The countries we usually compare ourselves with are quite simply adopting the new technologies faster. At the same time, the nation's access to state-of-the-art health technologies is unequally distributed across the different regions of Denmark. This is not consistent with the concept of equal access to treatment which previously characterised the Danish health service.

Lif believes:

- that Denmark needs a health policy. A health policy based on explicit targets for the nation's health. At the same time, health plans for how to reach the specific targets must be prepared,
- that a targeted initiative should be taken in the four areas that make up the precondition for achieving quality health results: Prevention, Early Detection, Treatment and Followup. If we know how to create a coherent health system, it will be beneficial not only for the nation's health but also for the national economy,
- that Denmark needs to be better at making the most of the benefits of new health technologies. Quality and professionalism should be the key words. We need to be better at exploiting the latest health knowledge and capabilities, while national planning and management should ensure patients of geographically equal access to the latest advances,

- that Denmark should become better at comparing our health performance in relation to other countries. We stand to learn much from how other countries are better at reaping the benefits of innovative health technology.

1.02 Remove the barriers to advances in health technology

Sustained advances in health technology are the key to achieving better preventive and therapeutic results. In relation to the countries we usually compare ourselves with, Denmark is one of the slowest to exploit such advances.

At the same time, the Danes' access to new health technologies depends on where they live in Denmark. This then results in unequal access, which is contrary to the Danish tradition and political objective of easy and equal access to the National Health Service.

Different expenditure considerations often become barriers to the new technologies. Decentralisation of the health service, with its lack of common health care objectives, has also been found to delay the introduction of new health technologies in several places of the country. The result is that public access to new health technologies and optimal treatment becomes dependent on where in Denmark, the citizens live.

Moreover, Denmark is characterised by professional disagreement in the health service often blocking patients' access to the new technology. There are several examples of disagreement halting the introduction of new technology, even in situations where internationally recognised studies have documented the effect, and in spite of the fact that the National Board of Health has issued specific recommendations regarding the adoption of the treatment.

Lif believes:

- that Denmark should implement a focused initiative aimed at defining how the technologies can be fully exploited. Responsibility should lie with a central body such as the National Board of Health and should be based on general and coherent health planning,
- that a joint national knowledge centre for assessment of health knowledge and technology should be established. At present, efforts are dispersed among many different institutions and interests, which results in inconsistent assessment of new knowledge,
- that the financial considerations currently prevailing in the healthcare system should be avoided. Accordingly, financial assessments of new knowledge and technology should be based on a broad socioeconomic perspective,
- that detailed implementation plans should be drawn up once a decision has been made to adopt a new health technology in the health service.

1.03 The principle of "No benefit, no payment"

The principle of money being refunded if a pharmaceutical product fails to have the expected effect on an individual patient is new to the Danish Health Service.

The principle cannot be extended to all types of treatment, as it presupposes that precise treatment objectives can be set.

The introduction of the principle in relation to pharmaceuticals raises a number of medical, pharmacological and technical problems that need to be clarified before a view can be taken as to its future possibilities.

The principle also presupposes support for such a system from the medical profession and the authorities, as it both requires more follow-up and monitoring of patients and their treatment, to establish whether the objectives set have been met, and places added demands on the administrative systems on which the present public reimbursement system rests.

Generally, the principle that patients can have their expenditure refunded if a given medicine does not produce the expected effect recognises the fact that the same product cannot be expected to produce the same effect in all patients.

The legal requirements as to documented clinical efficacy, quality and safety are the same for all medicinal products, and are independent of the form and strength in which a given product is introduced.

Lif believes:

- that the doctor, in consultation with the patient, should at all times choose the medicinal product that has the clinically best-documented effect in the given treatment situation,
- that generally there is a need for consistent treatment guidelines,
- that treatment ought to be planned to a greater extent on the basis of specific treatment objectives, and
- that the treatment chosen should be ongoing evaluated in relation to the objectives set, and this evaluation should include a separate assessment of whether the patient has adhered to the treatment plan.

1.04 CPD (continuing professional development) for doctors is crucial

Ensuring that doctors keep abreast of developments in the field of pharmacology is a prerequisite for rational pharmacotherapy. Rational pharmacotherapy includes research for optimal use of pharmaceuticals and a thorough knowledge of when to treat with pharmaceuticals. Knowledge of and experience with modern medicines are essential in order to be able to apply rational pharmacotherapy in practice.

Very rapid advances are happening in the health field. There is therefore an ongoing need to promote both training and continuing professional development of doctors and other health professionals.

Lif believes:

- that it is essential that doctors have maximum knowledge – not just in the pharmaceutical field but in the health field generally – of new treatments and documented new therapeutic agents,
- that the pharmaceutical industry has a natural part to play in the continuing professional development of doctors and other health professionals,
- that the authorities should increase their commitment to such CPD, to supplement the CPD offered by the pharmaceutical industry, and that the method for that should be the allocation of more funds to CPD for doctors, both those in hospitals and those working in primary care.

1.05 Health checks save lives

Many people are dying from diseases that could have been avoided if only they had been discovered in time. Today, many diseases are discovered so late that people will suffer from serious and enduring sequelae.

Characteristic of several of these diseases is that people may harbour them for many years without experiencing any symptoms. Once they are discovered, it is often too late leading to loss of quality of life or death. Several of these diseases are called 'the silent killers' or 'lifestyle disorders'.

The main causes of cardiovascular disease such as stroke and cerebral haemorrhage are hypertension and hypercholesterolaemia. Some 700,000 individuals in Denmark are currently unaware that they have hypertension and around 250,000 people currently have a cholesterol count so high that it requires treatment - and they do not know it. 300,000 people are estimated to suffer from diabetes, of whom at least half are unaware of their condition. Timely preventive and therapeutic measures will in many cases be life-prolonging for these people.

Lif believes:

- that all Danes should be offered a systematic annual health check within major disease and risk factors such as hypertension as well as elevated cholesterol and blood glucose,
- that the Danish health service should ensure targeted systematic screening of Danes within major cancer areas such as breast and bowel cancer,
- that a plan should be implemented for how systematic preventive health checks can be developed in interaction with general practitioners and municipal health centres.

1.06 Treatment should be improved

New treatment options will increase public expectations in relation to the health sector in the future. Lif considers that better accessibility, prevention, treatment and follow-up are essential to ensure a greater proportion of satisfied users – also in the long term.

The increased demands that users will be making on the health sector in the future necessitate major changes. However, Lif is aware that, in principle, the demand for healthcare services is infinite. Thus, a certain cost consciousness as regards consumption is relevant. But it is important that the cost consciousness reflects the overall economic strain within a given disease category viewed in terms of the therapeutic costs.

With the resources, both practical and financial, that the public part of the health system has at its disposal, there is a risk that the divide between the treatments offered and the demands of the users will widen. There must therefore be an ongoing debate on our expectations in relation to the health sector, including whether the funds allocated to the healthcare area in connection with the Budget negotiations are adequate.

Lif recommends that the potential divide be reduced by formulation of health policies setting specific targets. A formulated health policy will provide enhanced scope for assessing the resource requirements.

There is every indication that we already have a very efficient health service, so it might be difficult to release extra resources without jeopardising the quality of treatment. Thus, there is a current need for more resources to the health service.

Lif believes:

- that existing financial resources should be better utilised in areas with a potential for improvements in efficiency,
- that demographic trends, new treatment options and higher expectations will increase the need for more resources in the health service and that, for many years now, the health service has been subject to “under-investment” by international standards,
- that it is possible to improve diagnosis, prevention and treatment if health professionals are given opportunities for better training and access to using the steadily improving medicines,
- that diagnosed cases of illness should be followed up by rapid and effective prevention or treatment,
- that there should be stronger coordination of courses of treatment that have been initiated.

1.07 Patients have a right to be better informed

Patients and the public in general have become, and are continuing to become, far more active in seeking information from the press, electronic media, the internet and other sources. As a result, patients more often now have clear expectations and ideas when they come into contact with the health system.

The internet affords new opportunities both for users and for suppliers of information. This means that patients will be using the internet to an increasing extent to find information and obtain an insight into

prevention, illness and therapeutic options as applied to their own situation, both before they contact the health system and during the course of their treatment. It must therefore be recognised that the internet is internationalising patients, so that the latest information from abroad will be known in Denmark too. It will also be apparent what treatments are possible in other countries – and perhaps still not available in Denmark.

In this new information landscape, all parties – the authorities, the medical profession, patient associations, pharmacies and the pharmaceutical industry – have a natural role as sources of information about diseases and treatments. Such information will equip patients better to use their medicines correctly, and help to make people aware of symptoms of undiagnosed illnesses. All parties should have the right and duty to make accessible information available.

Lif believes:

- that all patients have the right to easy access to all unbiased, factual and authoritative information about their illness and about the treatment options that exist,
- that Denmark should take the lead in ensuring that patients have access to and are aware of reliable websites for good-quality factual information – websites that satisfy a set of impartiality criteria and which are ongoing monitored,
- that the Danish public should have access to information about medicines on the Danish pharmaceutical companies' websites in exactly the same way as they can now find corresponding information on foreign pharmaceutical companies' websites.

1.08 Roles in the healthcare system

The patient's role

In the event of any symptoms or other suspicion of disease the patient is personally responsible for seeking medical advice to get a diagnosis. The patient should pay attention to own health and regularly consult a doctor to have general health checks performed. It is positive that more and more patients today seek information on prevention, diseases and therapies – e.g. on the Internet. It is therefore important that the patients' access to all unbiased, factual and authoritative information about prevention, diseases and therapeutic options is strengthened and facilitated.

When the patient has been diagnosed and started treatment, the patient him/herself is responsible for following the correct treatment, including medication. If any doubt arises about the treatment, the patient should seek factual information and medical advice. The patient should not stop the treatment without prior consultation with his or her doctor. Untoward events and adverse reactions to the medicine should immediately be notified to the doctor.

The doctor's role

The doctor is, based on his or her professional competencies and talks with the patient, responsible for making a diagnosis. Thus, doctors play - through their medical competencies and direct contact with the patients - a key role in the health service. The doctor shall also be responsible for ensuring that

from a medical viewpoint the patient is always offered optimal treatment. The doctor is therefore obliged, on an ongoing basis, to seek new knowledge about prevention, diseases and treatments.

It is important that the doctor's free right of prescription is not limited, neither directly nor indirectly.

Such limitations would adversely affect medico-professional considerations and the possibility to adapt the treatment to the individual needs of the patients. Thus, a restricted free right of prescription may have a negative impact on patient treatment.

Today, the health service has implemented initiatives aimed at regulating the doctor's choice of treatment, through for instance the individual reimbursement system and through regional and national recommendation lists. In general, the health service should use such regulating initiatives with great caution and regularly assess whether their use has a negative impact on patient treatment.

It is the doctor's responsibility to give the patient information about prevention, the relevant disease, treatment and any side effects. It is important that the doctor involves the patient in his or her treatment, and that the two parties have a real dialogue so that the patient's knowledge and experience will also be included in the planning of the treatment.

The pharmacy's role

The pharmacy is the distributor of medicines. Thus, the pharmacy is responsible for dispensing prescription drugs to patients. Besides, the pharmacy has an information responsibility supplementing the information given by the doctor. The pharmacy gives the patient information about the drug, its correct use and any side effects. In case of substitution between products, the pharmacy has a particular information responsibility to the patient.

It is absolutely crucial that the pharmacies' dispensing of medicines as well as the information imparted by the pharmacy are completely fair and independent of own financial interests. Therefore, in the pharmacy sector no financial incentive models - such as the extensive use of discounts - should exist which may question the pharmacies' professionalism and financial independence.

Lif believes:

- that the patients themselves are responsible for seeking medical advice in the event of suspicion of disease and responsible for following the doctor's directions with respect to treatment,
- that patients should have clear and easy access to all relevant specialist information on prevention, diseases and treatments,
- that the doctor's free right of prescription should not be restricted – neither directly nor indirectly,
- that the doctor shall involve the patient in a real dialogue, so that knowledge, experience and expectations can be adapted,

- that financial incentive models raising doubts about the independence of pharmacies - such as discounts - must be abolished.

2.0 Lif's positions – on research policy

2.01 Trials must be registered and results published

The research results of clinical trials and tests of the effect and action on the human body of medicinal products (pharmacodynamic trials) must be made public, irrespective of whether they show positive or negative results.

However, the results of trials to describe how a medicinal product is absorbed and excreted by the body (pharmacokinetic trials) is a part of the confidential material the firms make available to the authorities in connection with marketing authorisations and safety reporting.

Since 1 July 2005, the pharmaceutical industry has registered trials when they are initiated and, together with the results from the completed trials, the information will be published in electronic databases open to the public. The electronic databases are a supplement to the requirements laid down by law. The statutory requirements entail that irrespective of the nature of the clinical trial it must be approved by a scientific ethical committee as well as the Danish Medicines Agency.

Besides, Lif prepares and publishes a list of databases used by Lif members for registration of trials and publication of trial results.

The principle of the Declaration of Helsinki to the effect that both positive and negative results must be published is now enshrined in the Danish Act on a Scientific Ethical Committee System since the scientific ethical committee may only grant permission if the results of the trial are published. The same provision is included in the cooperation agreement which the Danish Medical Association (DADL) and the Danish Association of the Pharmaceutical Industry (Lif) have signed concerning the conduct of clinical trials.

Lif sees it as crucial that the aim of the DADL-Lif cooperation agreement to ensure that there is no conceivable doubt as to the independence of the parties and the quality of the experimental work, is respected and sustained. Thus, it is important that there is a clear task and role sharing between companies, researchers and authorities. This task sharing will not be changed by the decision concerning public access to trial results.

Companies and researchers must submit all knowledge gathered in clinical trials to the Danish Medicines Agency which together with the scientific ethical committee have authorised the conduct of the trial. The reason for this is to protect patients and the general public from any knowledge being kept secret – with or without intention – and, at the same time, the authorities may stop trials or ask for supplementary information or investigations.

Lif supports the work of the scientific ethical committees because they ensure that the trials are

meaningful before patients are subjected to new treatments or new trials.

Lif believes:

- that clinical trials must be registered and the trial results be made public,
- that each individual enterprise should draw up the required internal guidelines to ensure that the international guidelines are observed,
- that it is up to the enterprises to decide which databases to use for registration and publication.

2.02 Clinical research – the foundation for future therapies

Clinical research is trials on humans. The aim of the trials is to test new forms of treatment. Preclinical trials (for instance animal experiments) precede the clinical trials.

Clinical research is essential if patients are to receive the best treatment including the latest medicines.

Apart from actual clinical trials, clinical research includes other systematic observations of a medicine's action, efficacy and side effects. At the same time, clinical research is a regulatory requirement associated with the approval of a new medicinal product.

Pharmaceutical manufacturers play a natural part in this process.

Clinical trials are thus the link between the preclinical studies (animal experiments, etc.) and the treatment of patients. Clinical trials are often carried out on the initiative of pharmaceutical manufacturers, but there is always a researcher (the investigator), typically a doctor, who is responsible for the conduct of the trial and the trial protocol (the detailed description of the trial).

Lif recognises the international guidelines for good clinical practice (ICH GCP), and supports the continuing collaboration between Europe, the US and Japan.

Ethical considerations have to be assessed by a scientific ethical committee system. The system includes professional and non-professional people who shall judge on the ethical correctness of asking patients to participate in trials.

The rights of participants must be explained in the patient information sheet, which is produced jointly by the investigator and the manufacturer. It is the investigator's responsibility to ensure that the patient receives this information.

The participant's written consent must be obtained, and the consent form must contain a clause stating that the participant can withdraw from the trial at any time without giving any reason and without that having any effect on the continued course of his or her treatment.

Patient's data are confidential, i.e. all parties, including representatives of the sponsoring pharmaceutical industry, must have obtained the patient's written consent in order to have access to information that can be linked to the individual.

Lif has signed an agreement with the Danish Medical Association that clarifies the division of responsibility between medical researchers and the pharmaceutical industry.

Lif is in favour of openness surrounding the financial agreements that underlie the relationship between the investigator and the sponsoring company.

All research results of clinical trials are published on IFPMA's (International Federation of Pharmaceutical Manufacturers & Associations) Clinical Trials Portal on the Internet. The publication ensures openness about industry research and patient safety.

Lif believes:

- that clinical trials are a prerequisite for the marketing of a medicinal product. Society also makes that demand,
- that doctors should be offered training in the quality assurance of clinical trials (GCP),
- that the rules governing doctors' duty of disclosure with regard to their financial links with the pharmaceutical industry should be made explicit.

2.03 Use of non-intervention studies

A non-intervention study is a scientific study where one or more doctors monitor one or more patients being treated with the same drug. During this monitoring process, no »medical intervention« takes place.

Thus, the doctor does not change the treatment or his/her treatment behaviour, makes no surgical intervention or takes any blood samples apart from samples normally taken in connection with the treatment concerned, etc.

Non-intervention studies are not subject to any reporting obligation (except for the general obligation to notify the Danish Data Protection Agency), nor to any supervision by the Danish Medicines Agency, the scientific ethical committees or any other authority.

Besides, the GCP directive (see "Position 2.03") entails that it is not possible to introduce a mandatory obligation to report non-intervention studies to the Danish Medicines Agency.

Lif has therefore urged the Danish Medicines Agency to establish a voluntary system for reporting of nonintervention studies. If an enterprise chooses to report a non-intervention study, the Danish Medicines Agency shall assess whether the specific study is to be considered a non-intervention study and whether it complies with the existing advertising rules, including in particular the fees paid to the doctors conducting the non-intervention study.

Lif believes:

- that non-intervention studies contribute valuable knowledge about the clinical practice in patient treatment,
- that a voluntary system for reporting of non-intervention studies should be established,
- that in the absence of a voluntary system for reporting, the enterprises should submit a description of specific non-intervention studies to the Danish Medicines Agency to have confirmed that the Agency agrees that they are indeed non-intervention studies,
- that the enterprise at the same time asks the Agency to assess whether the study complies with the existing advertising rules.

2.04 Make the most of Denmark's position of strength

Denmark must concentrate on established fields of research in which we already have a global position of strength. Denmark is a small country, and cannot be a leader in all areas. We must therefore concentrate our resources on those areas of strength where we have the potential for continued success. We have that potential in the pharmaceutical and biotechnological field, but we must act to use it.

Health research is approaching a number of future breakthroughs in the understanding of why diseases arise and of their prevention and treatment. Denmark has the potential to be first with the answers to some of these questions.

But future success in the healthcare field will not happen automatically. It requires that Denmark seizes its opportunity. If the pharmaceutical industry, the biotech industry, decision-makers, hospitals and universities are able to work together with a view to embracing the challenges in health research, a beneficial spiral will be initiated. That will contribute to more knowledge, growth and new jobs in our society.

Accordingly, a strong partnership between enterprises, hospitals, universities and politicians is essential if Denmark wishes to remain an attractive place for research. At the same time, continued success requires that we have proper and competitive framework conditions.

Lif believes:

- that authorities, universities and enterprises should draw up a strategy for how to improve health research and drug development in Denmark,
- that the university structure should be developed, on an ongoing basis, with a view to creating the best possible conditions for science and excellence in each of its disciplines,
- that more PhD graduates should be produced in the natural and health sciences,

- that new international researchers should be attracted by making it more desirable to work in Denmark,
- that long-term framework programmes targeted at the generation of new health science breakthroughs should be established.

2.05 Improved conditions for research

The pharmaceutical industry is one of Denmark's areas of strength, and it makes a considerable contribution of growth to our society. Its contribution to society is the result of massive investment in R&D. It is on such investment that innovation, knowledge and growth – the very lifeblood of Denmark in a globalised future – depend.

However, the private sector pharmaceutical companies cannot meet this challenge alone. It is through the interplay of public and private research that results in health science are achieved. Necessary basic research must be conducted before pharmaceutical companies can develop new treatments.

Denmark is lagging considerably behind the rest of Europe and the US in its level of public investment in research. Other things being equal, over time this would erode Denmark's ability to maintain its leading position in the pharmaceutical and biotechnological sphere. There is therefore a need for a considerable boost to public basic research in the area of health science.

A continued prioritised drive and more funds are needed to retain and improve the competitive position that Denmark still has. The whole foundation for a continued strong Danish position in pharmaceutical and biotechnological innovation is precisely public investment in education and research.

Lif believes:

- that more public funds should be allocated to research so that Denmark will achieve the Barcelona target of 1 per cent of GDP for public research,
- that basic research in health science in Denmark should be strengthened. Investment in basic research should be long term and should give space to the logic of the research itself so that it will not be limited by a short-sighted focus on commercialisation,
- that public investment should be strategically prioritised to target and support research that is already of high quality and represents positions of research strength,
- that allocation of public research funds should prioritise research environments engaging in targeted collaboration on extending our knowledge of why diseases arise and how to prevent and treat them,
- that resources will be allocated, with more funds generally being made available per research project, and projects being allowed to run for longer periods.

2.06 Training of researchers should be developed

Pharmaceutical research is to a large extent based on the knowledge and ability to make use of the requisite technologies in medicine, chemistry, biology pharmacology, and genetics and biotechnology.

To ensure that the persons who are to apply the research technologies have the necessary skills, MSc programmes of a high academic standard must be available in the health and natural sciences.

Moreover, an MSc programme of a high standard is often a necessary prerequisite to arouse the interest of potential Master-level graduates in going on to train as researchers.

It is therefore satisfying to see that in recent years the number of PhD programmes in the health and natural sciences has been rising.

Lif holds the view that it would be appropriate for the involvement of companies in the design and implementation of PhD courses to be considerably increased, in order to promote collaboration between private and public research and thereby contribute to an overall strengthening of research in Denmark.

Increased corporate involvement would also contribute to encouraging foreign investment in Denmark. More Danish support for research would contribute to stimulating research and economic growth in the whole of the Øresund Region.

Lif believes:

- that greater interest should be generated in training as a researcher in a range of the health and natural sciences, by allocating more public funds to researcher training,
- that the state should promote the training of researchers by allocating more funds to PhD programmes in the health and natural sciences,
- that more internationally recognised training programmes and research faculties should be established in Denmark, and
- that it should be made attractive for Danish and foreign researchers to work in Denmark.

2.07 Basic research is short of funds

The pharmaceutical industry accounts for a third of all industrial research and development activities in Denmark, which makes it the most innovative sector in the country's economy.

The greater part of the research effort takes place within individual companies. However, an increasing amount of research is being carried out as collaborations between various partners, including university research programmes.

For the pharmaceutical industry, it is particularly important that hospitals have sufficient research funding. Here, research must be seen as a prerequisite for the ability to continually improve treatment.

Collaboration between the industry and public research establishments ought therefore to be further expanded, while the state should promote opportunities for collaboration by allocating more funds to relevant public research establishments.

It must be ensured that publicly funded basic research is independent of special interests. It is therefore important to ensure that there are clear rules governing the use of the results produced by such research.

But an innovation is no good to anyone if it is not put to use. Therefore increased incentives ought to be created for the public sector to exploit the results of research in partnership with private-sector companies. That would enhance the companies' competitiveness and ensure that society gained from the research results.

Lif believes:

- that the greatest possible quality and competence should be ensured in Danish university research,
- that augmenting the finances and quality of public basic research is essential if Denmark is to continue to be an attractive place to carry out research and engage in collaboration with public research establishments, and
- that boosting public basic research, especially university research, is a prerequisite for achieving a higher level of training amongst Master-level graduates and researchers. This could also contribute to encouraging greater interest in the health and natural sciences amongst young people.

3.0 Lif's positions – on market conditions

3.01 Unit-dose dispensing should be correctly used

In connection with unit-dose dispensing the medicine to be taken at a specific time is packed in a small plastic bag. A bag is packed for each time medicine is to be taken. The bags are suspended in chronological order in a long line so that it will be easy to see when the next portion of medicine is to be taken.

Lif finds that unit-dose dispensing is a good tool which for some groups of patients can contribute to ensuring a rational use of medicine so that "the right medicine is taken at the right time".

It is essential that unit-dose dispensing is backed up by thorough information to each patient.

If unit-dose dispensing is used, it is important that the shelf life of the packed products is tested. The documentation hereof must reflect the current status with respect to storage, manufacturing and filling so that the result is in compliance with the demands placed on industry as regards changes in manufacturing conditions.

Lif believes:

- that the authorities should spot check that the quality of the various unit doses is satisfactory,
- that unit-dose packing for more than two weeks' consumption is only possible if the documentation of the shelf life of the unit-dose dispensed medicines reflects the actual conditions to which the products have been subject,
- that the workload connected with unit-dose dispensing of medicines is fully covered by fees,
- that reimbursement for the unit-dose packed medicines follows the current reimbursement rules governing substitution rules, reimbursement prices, etc.

3.02 Information about side effects is important

It is important that the individual user of a medicine is given comprehensive information about the side effects and risks that may be connected with using that particular medicinal product.

It is in the pharmaceutical industry's interest to have as complete a picture as possible of the usage of individual products and to receive the most comprehensive information possible about the product, including its side effects, from authorities, doctors, patients and other health professionals.

It is also in the pharmaceutical industry's interest that the information in package leaflets reflects the most recently updated knowledge about the use of the products which the companies have received concerning their products and consider relevant to pass on.

Therefore Lif fully endorses the augmented duty to report adverse events that has been introduced in respect of medicinal products during their first years on the market, and Lif also welcomes the fact that the user can now report adverse events directly to the authorities

Lif believes:

- that it is essential that patients who experience adverse reactions to a pharmaceutical product inform their doctor, the authorities or the company concerned. Only in this way can the authorities and the company concerned become aware of new adverse reactions,
- that, to ensure the quality of the individual adverse drug reaction reports, it is important that the company, if necessary, will have the opportunity to follow up on all types of reports submitted,

- that it is the responsibility of the company to gather and assess information about adverse reactions and together with the authorities to assess whether the product information needs to be changed,
- that it is essential that Danish industry complies with the EU requirements and that special national requirements are not imposed on the industry.

3.03 The doctor's prescription should be respected

It is the doctor who bears the responsibility for the patient's treatment, and it is therefore the doctor who acts on behalf of the patient. In view of this, it is important that the doctor has the right to choose the optimal treatment in consultation with the patient and in consideration of the patient's autonomy. Where medicines are concerned, this implies the right to be able freely to prescribe the product that is most suited to the patient.

Precisely this choice of a specific treatment strategy in the interest of the patient will ensure the best possible treatment outcome.

Public expenditure considerations should not be taken separately from the overall treatment implications.

Initiatives aimed at influencing the doctors' prescription habits should always be broadly assessed, taking patient-specific aspects into account. The doctors' decisions should always be viewed in light of each patient's specific situation.

Lif believes:

- that the regulation of the doctors' prescription habits through the use of recommendation lists (regionally as well as nationally) will diminish the doctors' authority to prescribe and responsibility for the treatment,
- that information to the doctors should be formulated as general treatment guidelines making an individual adaptation to each patient possible.

3.04 Substitution of drugs

Substitution means that the pharmacy must inform the patient about the cheapest substitutable medicinal product which in terms of content is identical with the product prescribed by the doctor. The current rules for substitution of medicinal products in Denmark have contributed to Denmark having one of the largest markets for generic medicines (me-too drugs) in Europe, which facilitates ongoing introduction of new therapies for the benefit of both patients and the Danish National Health Service.

On the other hand, general substitution schemes should not be introduced without discrimination.

Each and every medicinal product needs a specific healthcare assessment based on stringent scientific documentation before it can be decided whether the product is substitutable. Such assessments must be taken a step further than the current bioequivalence evaluations which only concern the body's absorption of the medicine.

The aim of bioequivalence evaluations is to document that the medicine is absorbed to the same extent and at the same rate as both the original and the generic product and to document that generic products do not differ markedly from the original. The results of bioequivalence represent - like all other clinical documentation - an average for the population. Thus, some might experience differences between the generic product and the original product.

Lif believes:

- that generic substitution increases the risk of poor compliance due to frequent product switches and, therefore, the rules should be followed closely,
- that costs associated with the increased uncertainty due to extra consultations with the doctor and/or pharmacy staff should be further analysed,
- that the introduction of analogue substitution will diminish the doctor's treatment options, and conflicts with patients' interests.

3.05 There should be no VAT on medicines

VAT on medicines means that Danes pay more for their medicines than the inhabitants of other European countries – even though the companies' prices are the same in the countries.

Medicine usage being composed as it is, the 25 per cent VAT charged on the sale of medicines in Denmark means that pensioners and the chronically ill pay the greater part of the VAT revenue. This fact conflicts with the latest amendment to the law on reimbursement, which was made precisely to accommodate sections of the population with a heavy use of medicines.

There are no sustainable economic arguments for keeping VAT on medicines – apart from maintaining public revenue. On the contrary, there are actually important social and health considerations that speak for medicines being free of VAT.

Lif believes:

- that VAT on medicines should be abolished, or, failing that, reduced as much as possible.

3.06 Public calls for tenders inappropriate, especially for the primary care sector

Lif essentially believes that dynamic competition ensures the best possible conditions for all involved in healthcare. Therefore, Lif does not believe that public calls for tenders in healthcare will ensure the right market conditions.

Lif acknowledges the fact that the hospital sector can expect to obtain "economies" through bulk purchasing within the framework of the EU's public procurement directives, but also notes that they of course are granted under the very special conditions characterising that part of the pharmaceutical market.

Lif opposes the idea of medicines in the primary care sector being the subject of calls for tenders, with only the winner of the tender round being awarded the right to sell or to be included on the list of drugs that are reimbursable from public funds. Lif believes that this model is an unfortunate confounding of price setting and the reimbursement system, and also considers such an arrangement to be in conflict with EU legislation.

Such a model will in the long term exclude any form of competition. Once a product has been sidelined, it is extremely doubtful whether it will continue to be marketed. In the end the result is a long succession of temporary product monopolies.

In addition, there is a considerable risk of unfortunate implications for public health when patients for various reasons cannot use the winning product, and there are considerably fewer products to choose from or the others have perhaps been withdrawn from the market.

Lif believes:

- that public calls for tenders for medicines in the primary care sector, where only the winner of the tender round is awarded the right to sell the products, are distorting competition and the price setting,
- that the patients' state of health will be threatened if they do not tolerate the prescribed drug and the supply on the market is limited.

3.07 Rational pharmacotherapy should have a holistic outlook

Rational pharmacotherapy is to be understood as "the right medicine, to the right patient, at the right time".

Lif's view of rational pharmacotherapy is based on a holistic picture which takes into account many of the indirect economic benefits such as fewer sick days, fewer or shorter hospitalisations, lesser use of other health-related services, etc.

Rational use of medicinal products must be seen in relation to relevant treatment alternatives or prevention initiatives, and not merely in relation to the price of the drug therapy concerned.

Lif is working actively to promote rational pharmacotherapy by participating in a special steering group for the Institute for Rational Pharmacotherapy. Lif also holds regular meetings with Denmark's clinical pharmacologists and relevant scientific societies.

Lif believes:

- that rational pharmacotherapy ought to include the compliance aspect, especially with regard to new pharmaceutical forms, dispensing forms, preparations, etc.
- that it would be appropriate to establish (primarily electronic) decision support systems (group level), for the doctor to use in choosing the particular medicinal product for a particular situation,
- that when therapeutic effects are evaluated and assessed, the views of a wider circle of stakeholders, for example, patient organisations, ought to be taken into account, and
- that health economics analyses and considerations should be taken into account in the choice of medicinal product.

3.08 Lif's opinion on medicine prices in Denmark

Lif finds it essential that medicine prices reflect the research and development activities. This is the only way to maintain the incentives for a continued development of future therapies.

The medicine prices in Denmark should also reflect the general level of prices and income.

Lif does not exert and cannot exert any influence on companies' pricing policies, but as a responsible player in the health sector Lif finds that the general level of medicinal prices in Denmark should not differ significantly from the level in other comparable European countries.

Lif believes:

- that the current reimbursement system will entail more frequent price adjustments and fluctuations as a result of fiercer price competition,
- that the terms of competition in the individual sub segments may lead to relatively large price fluctuations in both directions,
- that overall, prices will still fall due to the continued expiry of patents and the resulting competition from generic products.

3.09 Dialogue on animal experiments important

Lif supports the publication of applications and authorisations to conduct animal experiments. Lif is of the opinion that openness is the foundation for a good dialogue on animal experiments.

Lif wants to ensure the best possible conditions for the laboratory animals and has contributed to the Danish requirements regarding animal welfare being tightened relative to the current European requirements.

Today, animal experiments are necessary for the development of new medicines. They are still necessary because cell cultures and computer models cannot as yet imitate the complicated interaction occurring in live animals.

Besides, certain types of animal experiments are a regulatory requirement and a precondition for allowing new medicine to be tested on humans and later on to be used by patients.

Lif's member companies are spending many resources on developing alternative methods to replace animal experiments or methods using fewer animals. At the same time, the existing animal models are being developed on an ongoing basis so that they will cause less distress to the animals.

Lif supports the international efforts to improve the conditions and welfare of laboratory animals, for instance in the Council of Europe and the EU, and the work carried out via the international harmonisation process for medicines between authorities and the industry (ICH).

Lif believes:

- that the development of alternatives and improvements of existing methods should be coordinated internationally. Therefore Lif is represented in DACOPA which is internationally anchored in ECOPA where animal welfare associations, authorities, universities and the industry are represented,
- that it is important to allocate sufficient resources to DACOPA,
- Initiatives should be taken to make more advice available in the field of animal experimentation, including the development of methods that cause less distress to the animals and alternatives to animal experiments.

3.10 Efficient regulatory data protection necessary

Licensing by the authorities of new medicinal products, new administration forms and new indications requires the production of very comprehensive documentation establishing a product's efficacy and safety. Efficient documentation protection is essential for protecting this research.

The new legislation, which generally provides a 10-year protection, creates new possibilities for data protection. Thus, it is now possible to obtain one year's data protection for new indications, both in relation to new medicinal products and for well-known medicinal products. It is also possible to obtain one year's data protection for switch to OTC.

However, the new rules create a need for transparency and explicit definitions as well as a need for the rights obtained by the companies being efficiently enforced.

Lif believes:

- that clear rules should be established for how the enterprises are to be informed of the new data protection legislation,
- that there should be transparent and explicit definitions with respect to the criteria for obtaining the new data protection,

- that the new scope provided by the act for data protection should be enforced in such a way that it is clear at all points when the possibility for substitution is limited and when full reimbursement is feasible.

3.11 Efficient licensing of pharmaceutical products

New medicines should become available to patients as rapidly as possible. Lif urges that the new available possibilities to get a medicine fast on the market for the benefit of the patients are used.

Therefore the licensing process for medicines ought to take as little time as possible and be of the highest possible quality, whether carried out by the Danish authorities (the Danish Medicines Agency), the European Medicines Agency (EMA) or an authority in one of the other EU countries.

It is also important that the Danish Medicines Agency plays a central role in the European work in this area, including the continued development of the body of rules, to ensure the highest possible degree of competence within the Danish Medicines Agency, so that it is among the most frequently used of the European licensing authorities.

Lif supports the harmonisation process that the Danish Medicines Agency has initiated with regard to product information relating to identical medicinal products, so that the information on the package leaflet will be the same for products with the same active ingredient.

Lif believes:

- that applications constitute part of a company's intellectual property, and should therefore be exempted from the Danish Act on Access to Public Information Files,
- that an open and ongoing dialogue with the authorities is necessary in order to obtain rapid, efficient and safe processing of applications and service to the industry,
- that it is important that the Danish Medicines Agency gives priority to the international world and has sufficient professional resources to take an proactive part in the international work,
- that the Danish Medicines Agency has sufficient resources to process all types of applications within the set deadlines,
- that medicinal product licence fees should be negotiated with the industry and should reflect the actual costs associated with the application under consideration,
- that the procedures of the Danish Medicines Agency's procedures conform with EU procedures and that national special demands should be avoided,
- that there is a need for further simplification of the procedures for processing variations.

3.12 Ethical agreements should be formulated

Lif works closely with a number of organisations and authorities. The mutual cooperation is based on openness and trust, and as far as possible the terms on which it is conducted are laid down in writing.

Cooperation between the medical profession and patient organisations, for example, is essential if new and more effective medicines are to be developed. Cooperation is also essential to ensure that use of existing drug therapies is incorporated into the treatment of patients in the best possible way.

Therefore Lif wishes to enter into ethical agreements with all involved parties, and thereby ensure that no doubt arises as to their mutual independence. Lif has signed agreements with the Danish Medical Association and the Danish Pharmaceutical Association, and has drawn up a set of internal guidelines for member companies' relations with patient organisations.

Lif supports a competent and independent self-regulation, controlled by The Danish Board of Drug Advertising as far as the industry's compliance with the agreements is concerned.

Lif believes:

- that cooperation should always be conducted in such a way that all possibility of pressure or dependency is excluded,
- that non-compliance reprimanded by the Danish Board of Drug Advertising should be made public.

3.13 Medicines for developing countries is a complex problem

The supply of medicines to developing countries to combat the many serious diseases prevalent there demands special provisions.

The pharmaceutical industry carries a share of the joint responsibility to develop effective medicines to combat such diseases, and also shares the duty to cooperate in financial initiatives to combat acute and epidemic-like diseases in those countries.

Situations can arise in connection with combating serious diseases in developing countries that demand exceptional action. Lif recognises that in such situations the pharmaceutical industry too has a duty to play a part.

Lif believes:

- that if the pharmaceutical industry is to be able to contribute to solving the problem of the supply of medicines to developing countries, it is a prerequisite that there exist the
- necessary incentives for investment in the development of drugs to treat diseases specific to those countries – that is to say, effective protection of patents, trademarks and other industrial property as well as a tight control of reimport,

- that the pharmaceutical industry nationally and internationally shares in the responsibility to assist in solving the supply problems, and
- that the rules laid down in the WTO TRIPS agreement should be respected and complied with by all participant countries, and the agreed timetable for the implementation of the agreed provisions in developing countries should be maintained.

3.14 Production and quality assurance are crucial

The high quality of medicinal products must be ensured and maintained, primarily by the companies' own measures, and secondarily through supervision by the authorities.

Lif considers it important that the Danish authorities are amongst the leading national authorities for quality assurance and supervision of medicinal products, so that inspections by authorities from other countries are minimised.

Quality assurance of medicinal products should in future be affected more and more by assuring the various production processes rather than by analyses of the finished product.

Lif believes:

- that it is important that the necessary confidentiality and safety is maintained around the data to which the authorities have access in consequence of their supervision of the companies, and
- that it is important that all aspects of quality assurance have a key place in the teaching at higher education establishments and universities.

3.15 Change of the enforcement court system

Lawsuits owing to patent or trademark infringements are lengthy and very costly to an enterprise. The set of rules on which such lawsuits are based is extremely complicated. Therefore, it is important that each case is handled by experts experienced in such lawsuits. This will ensure a more consistent handling of the case and, thus, greater predictability as to the outcome of the case. By consolidating the cases a qualified and faster handling of the individual case will be achieved.

Lif supports the recent amendments of the Danish Administration of Justice Act that were effected as part of the reform of the courts of law in Denmark. According to these amendments cases concerning patents, trademarks, etc. are now consolidated in the Commercial Court (previously the Maritime and Commercial Court). However, Lif is of the opinion that the Danish Ministry of Justice should take it a step further.

Enforcement cases are still decided in local district courts, but should also be gathered in the Commercial Court to improve the quality of the legal procedure.

Lif believes:

- that enforcement cases concerning infringement of patents and trademarks should also be consolidated in the Commercial Court so that all infringement cases will be subject to highly qualified proceedings.

3.16 Patents are a basis for new medicinal products

During the recent century medicinal products have had an enormous importance to peoples' health. The average life expectancy has increased by 30 years in Europe, and many diseases that previously were incurable, we are able to cure today. There is still a large unmet need for development of new medicinal products, because several diseases exist which we are not able to cure with present medicinal products. The incidence of the diseases has changed in a way that diseases requiring special treatment exist today that we did not focus on previously.

The patent system is a basis for development of new medical treatments. The patent system stimulates the innovative competition. Within the pharmaceutical industry the patent system contributes to innovation of medicinal products as regards first-in-class, diversified follow-up on existing medicinal products and stepwise improvement of existing products. The patent system encourages to innovation, and then it is the "market" (patients and doctors) who decide which products achieve success.

The patent system stimulates new innovation and is the direct reason to the fact that knowledge on new innovation spreads quickly within the society and among competitors, because applications for patents typically are published 18 months after the time of application.

Patents have an encouraging effect on innovation by securing the possibility for a fair return that balance the financial risks and investments. Research and development of new medicinal products is a very cost-intensive and long process (typically 10-12 years) which also implies significant commercial risks for the companies. The patent is a basis for a successful pharmaceutical industry that through innovations creates value and welfare for the society as well as the patients.

The patent system is developed over a long period of time. The patent system has proven its worth, because it has secured considerable technological improvements. The patent interacts with legislation on competition.

It is possible to improve the patent system as every other system. Effective handling of disputes on patents has a great importance to future innovations and by this also the generation of new improved therapeutic options in the future.

Lif believes:

- that a joint European patent (EU patent) is to be established and a joint EU Court of Patents in order to secure equal and effective access to patent protection in the EU, and secure joint and high standards for the enforcement,
- that patents have an encouraging effect on research and development of new medicinal products which benefit the patient treatment,

- that patents stimulate innovation and result in increased wealth and welfare in society.

3.17 Patenting stem cells and genes

Patents are an important and imperative tool to promote research and development and are therefore an indirect incentive to conduct research in gene technology. For many enterprises performing such research and development it is crucial to obtain patenting in order to protect their research results from being utilised by others. At the same time, it constitutes the financial basis on which the enterprises build their continued research which, ultimately, will also benefit society.

When it comes to patents on human genes and stem cells, some special ethical aspects must be considered apart from the purely practical ones. It concerns the dignity of each human being. In this connection it is important to have clear rules about what is patentable. It is in the borderland between patent expertise and ethics that misunderstandings arise.

Among the various stakeholders there is today no clear and unambiguous understanding of the scope within the present patent system to patent human genes and stem cells. Thus, a consensus is required in order that the needs and concerns of the various stakeholders can be met. The pharmaceutical industry bears a large responsibility in the process of establishing balanced solutions.

Stem cells

Today stem cell research involving cell transplant options presents a promising opportunity to find the best treatment for patients. Human stem cell research is an important step towards developing new forms of treatment for such diseases as type 1 diabetes and Parkinson's disease.

Lif believes:

- that human embryonic stem cells should only be used if the same scientific results cannot be reached by using human adult stem cells,
- that only human embryonic stem cells should be used which come from surplus embryos (fertilised eggs) from infertility treatment and which have been collected after voluntary informed consent,
- that multipotent/coherent stem cells from embryos should not be subject to patenting. Methods and processes for transformation of unmodified cells into modified cells for therapeutic use, adult cells and their precursors or tissues developed by using research protocols should be patentable.

Human genes

Human genes (DNA sequences) are important tools for the development and manufacture of new medicines for the treatment of previously untreatable diseases or for the development of better medicines for existing treatments. An example would be that the insertion of the human growth hormone gene into a bacteria cell has made it safe to manufacture growth hormone without any risk of Creutzfeld-Jacob's disease.

Another example is the identification of variations of human genes which are important to the development of a disease and its treatment and which are expected to become a breakthrough in treatment adapted to the individual.

Another promising, future medical treatment is gene therapy where healthy DNA from a human being is inserted into a patient's body in order to repair the dysfunctional gene, for instance in a haemophilic patient who cannot produce coagulation factor VIII, or a patient with type 1 diabetes who is unable to produce insulin. Thus, the use of DNA from humans is important to treat patients.

In this connection it is important to stress that the discovery of the gene cannot be patented, whereas the results achieved from the research based on the gene can. The gene is isolated outside the body – by for instance blood or tissue samples. It can then be manufactured synthetically so that it will be possible to mass produce the gene and develop a medicinal product. The patent as such does not give any rights whatsoever to the gene which is inside the individual human being.

Lif believes:

- that the human body as well as precursors to the human body should not be patented,
- that the simple discovery of parts of the human body, including genes (DNA sequences) and subsequences, should not be a patentable invention per se,
- that patents on isolated human genes (DNA sequences) should only be obtained if the patentee has demonstrated a practical and commercial use of the invention,
- that patents on human genes should not be used to inhibit research and development and prevent free, non-commercial research. Gene patents should not be used to the detriment of the common good or stand in the way of using new diagnosis and treatment methods,
- that DNA sequences from humans should be available for non-commercial purposes in accordance with the development of biomedical research. In case of licence agreements for research purposes, the licence should be available on a non-exclusive and nondiscriminatory basis and be based on fair conditions in accordance with biomedical research,
- that the regulation of gene technology should be effected by the scientific ethical committee system.

3.18 Counterfeit medicines – a threat against the patient safety

In large parts of the world, patients experience problems with counterfeit medicines. Counterfeit medicines are also called pirated copies or just counterfeits. Counterfeit medicines are often products with too much, too little, wrong or no active substance at all. At best, counterfeits have no serious consequences for the patient, but at worst their use might lead to death.

According to WHO the official definition of a counterfeit medicine is: "Deliberately and fraudulently mislabelled with respect to identity and/or source". This means that a counterfeit medicine is produced without the consent of the original licensee, but will be sold as if it was the original product.

Until now no counterfeits are identified in the Danish authorized distribution channels e.g. at the pharmacy or other authorized distributors of medicinal products, but counterfeits have been found among products at pharmacies in our neighbouring countries in e.g. England, Germany and the Netherlands.

To buy products at Internet outlets is easy, quick and discrete. That is the reason why it is so popular to buy medicinal products on the Internet, but it might present a significant risk to your health. Very few distributors who sell pharmaceuticals on the internet are serious. WHO estimates that about 50 per cent of the pharmaceuticals that are sold at Internet outlets are counterfeit medicines. This trade is in the nature of organized crime, often with the same backers who manage the traffic with narcotics. It is very easy to buy pharmaceuticals on the Internet but also the same as gambling with your own life and money.

The trade of pharmaceuticals is often organized by use of spam mails. The American company MarkMonitor - the global leader in Internet fraud prevention and brand protection has examined 60 million spam mails offering the most popular products. In addition to products for men with erectile dysfunction (ED), they offered tranquilizers and antidepressant medicines. These spam mails were traced back to 110,000 advertisements that were showed on 11,000 web sites that were ran by 3,160 online pharmacies. Only four of these turned out to be to legal distributors of medicinal products.

The trade with counterfeit medicines is an increasing problem both internationally and in Europe.

Therefore Lif takes actively part in national and international initiatives in order to secure that it is safe for patients to buy medicine through the authorized channels in the future. Lif thinks that we need an improved legislation, a close cooperation between stakeholders, an intensified supply chain and a safe identification of pharmaceuticals and safe traceability through the distribution network.

Lif believes:

- that it is important to maintain a safe supply chain for distribution of medicines, so that patients can buy medicine safely.
- that internet commerce of medicinal products must be allowed only through certified Internet outlets.
- that patients are informed, on an ongoing basis, about the health risks associated with buying medicines on the Internet.
- High patient safety is provided on the condition that the authenticity of pharmaceuticals is verifiable in a safe way and that all links in the distribution chain should be traced back to the manufacturer. This is only obtainable through a prohibition of repacking of pharmaceuticals

and use of a more safe and standardized coding of pharmaceuticals in Europe (2D matrix bar codes).

- that counterfeit medicines must be fought in close cooperation between authorities, pharmaceutical companies and distributors.
- A central unit should be established within the public sector. All stakeholders, also consumers communicate to this unit and all information about counterfeit medicines is available here.
- that regular spot checking is introduced in the authorized supply chain.
- That the maximum penalty for manufacturing and selling counterfeit medicines should be harmonised within the EU and be the same as for infringement of the Copyright Act. A more severe penalty will better reflect the health risks to which the citizens might be exposed and give the police access to personal data, letters, e-mails, telephone calls etc.
- The original licensee should demand a compensation corresponding to the violator's profits from the sales of the medicinal product (instead of proving his/hers own loss) just as the rules for legal venue should be changed in order to be used in injunctions also (e.g. hawker's markets and fitness centres).

3.19 Generic medicines occupy a natural place on the market

Generic medicine is a copy of an original medicinal product. The generic product can be manufactured and sold when the patent on the original product expires.

Patented medicinal products are newly developed medicines and are often referred to as original medicines. This means that the medicine is the first of its kind (new active substance) used for treatment of a given disease and will, therefore, usually be subject to patent protection.

The foundation for the development of new medicines and therapies is adequate patent protection.

When a patent expires, it is equally natural that the product can be legally copied, manufactured and distributed by other authorised manufacturers. Generic medicines are also called me-too drugs. Often several companies will copy the original medicines at the same time. Generic products must not be confused with counterfeits. Generic medicine contains the same active substance, and in the same quantity, as the original medicine, but since the development costs have already been defrayed, generic products will typically be considerably cheaper than the original products. Since medicines contain various additives and excipients apart from the active substance, patients may experience a different effect and/or adverse reaction from use of generic medicine.

As a general rule, pharmacies must dispense the cheapest medicinal product, original or generic, unless the doctor has stated otherwise on the prescription. The structure of the reimbursement system, combined with the keen competition in the field of medicines, means that patients will

experience that, time and again, they have to switch between generic medicines from different generic producers.

According to the reimbursement rules, patients who do not tolerate the cheapest medicinal product are able to obtain increased reimbursement after application to the Danish Medicines Agency.

Lif believes:

- that it is only natural that generic medicine will take over a substantial part of the market share after expiry of the patent,
- that the use of the cheapest generic medicine will increase the financial scope to introduce new medicines and therapies,
- that unnecessary switches between various medicines should actively be restrained with new rules against negligible price changes and higher requirements as to the delivery performance of the enterprises.

4.0 Lif's positions – on distribution of medicine

4.01 Distribution of pharmaceutical products

The distribution of medicinal products from manufacturer to patient must comply with the safety requirements concerning the handling of pharmaceuticals.

Safety in the entire chain of distribution combined with accurate, impartial and independent information should always be the primary aims behind the dispensing of medicines to the user.

4.02 The pharmacy sector should be modernised on an ongoing basis

In order to get access to most medicinal products the patients have to visit the pharmacy. The pharmacy play an important role in the treatment of patients in the primary health sector, and therefore it is extremely important that the pharmacy sector is organised in order to meet the patients' expectations and needs.

The pharmacy sector has a very special position as a business based on private economy with a monopoly given by the authorities in a healthcare sector that is mainly established on the basis of a public health service. Basically, this means that the pharmacies have two large customers – the public authorities and the users/patients who both make demands to the pharmacy sector's offers and services.

The pharmacy must as all other sectors " be up to date", and the pharmacists' monopolistic position oblige them in a wide extent to modernise the pharmacies on an ongoing basis in order to have a patient-centric health service.

Lif believes:

- that a need for an up-to-date pharmacy sector exists, and therefore the pharmacy sector should be modernised on an ongoing basis in order to meet the population's expectations and needs,
- that a need exists for a special comprehensive regulation of the sale of medicinal products for the users in order to guarantee a safe dispensing of medicinal products to the patients,
- that the demands may need to be changed as well as the regulation and/or the financial structure of incentives for the pharmacy sector, if the pharmacies themselves do not provide offers and services that live up to the patients' and the society's reasonable wishes and needs,
- that the pharmacy sector must focus on delivery of services of high quality and safety,
- that the pharmacy personnel must provide unbiased information about medicinal products, correct use of medicinal products and other information on healthcare of a high professional quality. Information on healthcare in connection with dispensing of medicinal products must be given as a minimum when it is considered necessary and is requested,
- that the professional resources of the pharmacy personnel must be used better than they generally are today,
- that the level of service at the pharmacies must be adjusted according to the users' reasonable expectations, including the waiting time must be reduced as much as possible, and advice must be given with appropriate discretion,
- that availability of pharmacy services must be regularly adjusted the consumers' wishes and needs. The number of pharmacy units, their location and opening hours must, on an ongoing basis, be adjusted to the customers' expectations and demands in the same way as applying for the other retail trade and other service providers,
- that the pharmacies must offer e-trading services that are adapted to the users' needs and wishes. All pharmacies should as a minimum offer sale of both prescription medicines and over-the-counter products via Internet solutions.

4.03 Pharmaceutical products freely traded

Today, it is possible to buy selected OTC products from other outlets than Danish pharmacies. Lif considers this to be a natural development extending the availability for the benefit of Danish consumers as well as increasing competition.

Freely traded pharmaceuticals are a good and important alternative for the consumers who are wellinformed and who do not need access to specialist information and advice from trained pharmacy staff.

Lif sees a number of advantages in a liberalised pharmacy sector. However, that presupposes a free right of establishment without restrictions as to ownership. It also presupposes a more liberal pricing system, in the form of free price setting with maximum resale prices.

Lif believes:

- that liberalisation of some OTC products must not ease the general requirements regarding the safe use of medicines,
- that increased access to more OTC products may contribute to improving public health in general.

4.04 Flexible medicine prices

The retail prices of the individual pharmacy-only medicinal products are uniform at all pharmacies in Denmark. This reflects the general healthcare policy principles behind the public health service that offers easy and equal access to healthcare services. The uniform prices are today secured through complex regulations of the pharmacy sector's economy.

Lif believes:

- that the retail prices of pharmacy-only medicinal products should be uniform across the whole of Denmark in the future,
- that in the future the regulation of the pharmacy sector should ensure that expenses in connection with retail distribution of medicinal products are not unnecessary high e.g. ensure a cost-effective distribution structure.

4.05 Wholesale distribution prices should be negotiable

Wholesale distribution should take place in the realm of the private sector, and wholesalers' mark-ups should be set by means of negotiations between the individual wholesaler and the individual manufacturer.

It must at all times be ensured that the distribution costs reflect a rational and appropriate supply of all marketed packages to Danish pharmacies. In this way we will avoid that patients and the public sector are subjected to unnecessary additional expenses.

4.06 Discounts should be abolished

Discounts between producer and pharmacy place the consumers in an unfortunate situation. If pharmacies favour certain pharmaceuticals with discounts over other alternatives, the consumers will not get the independent advice, they have a right to.

According to current legislation, cost-linked discounts are permissible. In this way, wholesalers have a possibility of changing the purchasing behaviour of the pharmacies by offering discounts through cost

reduction in previous links of the distribution chain. Experience shows that by an large it is impossible to delimit cost-linked discounts from marketing discounts.

Under the present system with cost-linked discounts, only about half of the discounts obtained benefit the users and the health insurance system through reductions in pharmacy profits. The other half remain in the pharmacy sector.

The discounts given by manufacturers thus have a limited effect on the price of medicines. As the system is designed, the effect is not on the price of the particular product, but instead on the price level generally through reductions in pharmacy profits.

The price reductions ought, in Lif's opinion, to apply directly to those products on which the reductions are made.

Lif believes:

- that discounts to pharmacists should be abolished, as price reductions would then directly benefit users and public funds,
- that the principle of cost-linked discounts is not appropriate,
- that safeguarding the mutual independence of the parties should be regarded as crucially important and that that can only be ensured by abolishing the possibility of discounts.

4.07 Statens Serum Institut should face competition

Today, virtually all vaccines for the Danish market are distributed via Statens Seruminstitut (the Danish National Serum Institute). The reason for this is that the Institute has a monopoly on distribution. Lif sees no rational grounds for this, as the distribution of vaccines could certainly take place via existing distribution channels.

Lif is certain that the existing distribution channels would be fully able to ensure safe and economically efficient distribution.

Lif believes:

- that the vaccine distribution monopoly should be abolished, giving private manufacturers equal access to the market,
- that a more free competition must be expected to lead to lower prices for county councils/consumers.

5.0 Lif's positions – on public production

5.01 Statens Serum Institut ought to have competition

Statens Serum Institut has today a monopolistic role in relation to vaccines. It combines the functions of manufacturer, wholesaler, distributor and exporter.

Moreover, the Institute also acts as adviser to the government. This is a cause of serious distortion of competition in relation to the conditions applying to all other medicinal products and pharmaceutical companies. For example, the Danish child vaccination programme is based entirely on the Institute's products. In many other countries, several manufacturers' products are used, with beneficial competition as a consequence.

Lif is working for a solution to be found whereby the Institute's supervisory and advisory functions are maintained, but its production of vaccines takes place on a competitive basis, with all manufacturers having equal conditions of competition.

Lif believes:

- that there no longer exist supply, health or economic arguments to justify the maintenance of the monopoly status that Statens Serum Institut has today, and
- that the Institute's distribution monopoly should be abolished, so that all manufacturers can freely market and sell vaccines in Denmark.

5.02 The role of hospital pharmacies should be analysed

It is Lif's view that an unfortunate competition between private companies and hospital pharmacies exists today.

Medicine should only to a very limited extent and only under special circumstances be given from the hospital pharmacies instead of from the private pharmacies. Hospital pharmacies and medicine depots should only supply the hospitals in the regions to which they are linked.

Production at hospital pharmacies and in the private sector ought to be put on an equal footing. That means that production at hospital pharmacies must not be allowed to distort competition through hidden subsidies from public funds or cross-subsidising from other activities. Therefore, hospital pharmacies' accounts should show all the costs associated with their activities. Moreover, the cost calculations must be accessible and transparent.

The hospitals-sector supplier Amgros is responsible for a large proportion of the supply of medicines to hospitals. Since in principle Amgros is acting on behalf of the hospital pharmacies, there is an unfortunate conflict of interests.

The hospital pharmacies' own production of medicines might possibly gain a favourable position in Amgros's tender rounds thanks to knowledge of bids received, and it cannot be excluded that it is in fact the hospital pharmacies' own production to which calls for tenders are matched. Also, the hospital

pharmacies' own production is maintained, even if those product groups are simultaneously the subject of a public call for tenders.

Lif believes:

- that it is unfortunate that the hospital pharmacies produce medicine in many of the areas that are the subject of Amgros public calls for tenders without themselves participating in this form of price competition.

6.0 Lif's position - on reimbursement

6.01 Reimbursement must support and improve the optimal patient treatment

Reimbursement is granted to the patients, not to medicinal products. At the same time it is important to be aware that reimbursement is important for the use of medicines and the quality of treatment. Therefore the public reimbursements are important health and allocation policy instruments.

The medical treatment at public hospitals is free of charge for patients in Denmark, but as a main rule, this is not the case when the treatment takes place outside the hospitals in the primary healthcare sector. Actually, the most healthcare services are free for the patients – also outside the hospitals. But as a patient you must contribute financially when the health service's treatment offerings include the use of medicinal products.

The public reimbursement system implies that the patient when buying some medicinal products is granted a public reimbursement. The size of the reimbursement depends on the individual person's consumption of medicinal products entitled to reimbursement, and is granted only when the consumption is above a certain level (in 2009 DKK 820 for persons older than 18 years of age).

Not all medicinal products are eligible for reimbursement. Approximately 40 per cent of the new medicinal products are not reimbursed automatically ("General reimbursement"). The Danish Medicines Agency decides if a medicinal product is entitled to reimbursement. The Danish Medicines Agency also has the opportunity to favour special patient groups that the agency for some reason finds especially relevant to grant a reimbursement ("general conditional reimbursement"). The Danish Medicines Agency makes use of this possibility very rarely. Instead the Danish Medicines Agency to a wide extent chooses to base the reimbursement system on individual reimbursement ("single reimbursement"), this necessitate that the doctor on behalf of the patient submit an application for reimbursement for the individual patient to the Danish Medicines Agency.

Lif believes:

- that the reimbursement system should support an optimal patient treatment, including a optimal use of medicinal products in the Danish health service,
- that general conditional reimbursement for specific diseases is a reasonable way to support an optimal use of medicinal products in cases where the authorities find no basis for granting reimbursement to all persons who take the individual medicinal product,

- that it must be possible for companies to apply for general reimbursement as well as general conditional reimbursement,
- that the single reimbursement scheme should be used as a safety net for the very special patients. To be used in exceptional cases, as intended, the single reimbursement scheme may be a useful tool,
- that the Reimbursement Committee must be enlarged with representatives with special financial expertise seen in the light of the crucial importance that the financial considerations have in reimbursement cases,
- that reimbursement decisions must be taken on the basis of objective and controllable criteria. The authorities' decision-making process and procedures have to be transparent, and both companies and patients must have the opportunity to trial all parts of the Danish Medicines Agency's decisions at another complaints board,
- that the public reimbursements for Danish patients due to safety and market reasons have to be reserved for purchase of medicinal products in Denmark,

6.02 The value of pharmaceuticals for the society should always be assessed

A better effect of the treatment and consequently less sickness may generally be regarded to have some financial advantages such as fewer hospitalisations and doctor's call, just as some financial advantages may be achieved because of a quicker resumption of work and daily tasks. An analysis of expenses and benefits of the new medicinal products, therefore cannot automatically be limited to the immediate expenses and benefits of medicinal products, just as an analysis cannot be limited by more or less casual planned sector limits ("boxes"). On the contrary, a need exists for including all relevant expenses and benefits in- and outside the health service, including considering the consequences of many different elements such as differences in the patients' compliance, differences in services offered by the primary healthcare sector, the hospital sector and the social sector, and the implication of family relations and other social relations. The point is that the delimitation must happen on the basis of relevance.

The above-mentioned conditions may be described in so-called healthcare or cost benefit analyses. It should be a matter of course, that authorities, which make decisions on behalf of us all, disclose all relevant conditions.

Today we have an arrangement where the pharmaceutical companies voluntarily can submit a cost benefit analysis in connection with an application for reimbursement. The fact that the arrangement is voluntary and aims at the companies, do not exempt the authorities from making a qualitative assessment of the same elements when decisions are made on reimbursement based on financial considerations. Today, according to the regular practice the Danish Medicines Agency's decisions often are based on a simple comparison of prices of the new medicinal products and previous treatment procedures combined with a more or less implicit assumption that there are no significant differences in the results of the treatment.

Lif believes:

- Decisions on reimbursement for use of new medicines must take into consideration all health economic aspects of the use of the medicinal product. The financial considerations have to include relevant advantages in connection with expenses inside and outside the health service,
- that the health economic method and analysis must be used better and broader than we do today when we assess medicinal products' rational use in the Danish health service,
- that the assessment of a medicinal product's importance to the treatment of diseases or the prevention of disease should be based on the same principles that are included in a medical technology assessment – the technology itself, the importance to the patients, the organisational frames and the financial conditions,
- that the assessment of medicinal products should be carried out on the same terms and according to the same principles as other healthcare technologies are assessed. It should be the same organisational unit that assesses the societal importance of the use of all new technologies in the Danish health service.

Read more in the leaflet: "Lif's views on reimbursement"