

The background of the slide features two petri dishes. The top dish contains a red agar medium with several small, dark, circular bacterial colonies. The bottom dish contains a yellow agar medium with various bacterial growth patterns, including streaks and clusters of small, dark colonies.

Pharmaceuticals, biotechnology and medical technology

– an Integral Part of Innovative Sweden



Produced by The Ministry of Industry, Employment and Communications, Sweden

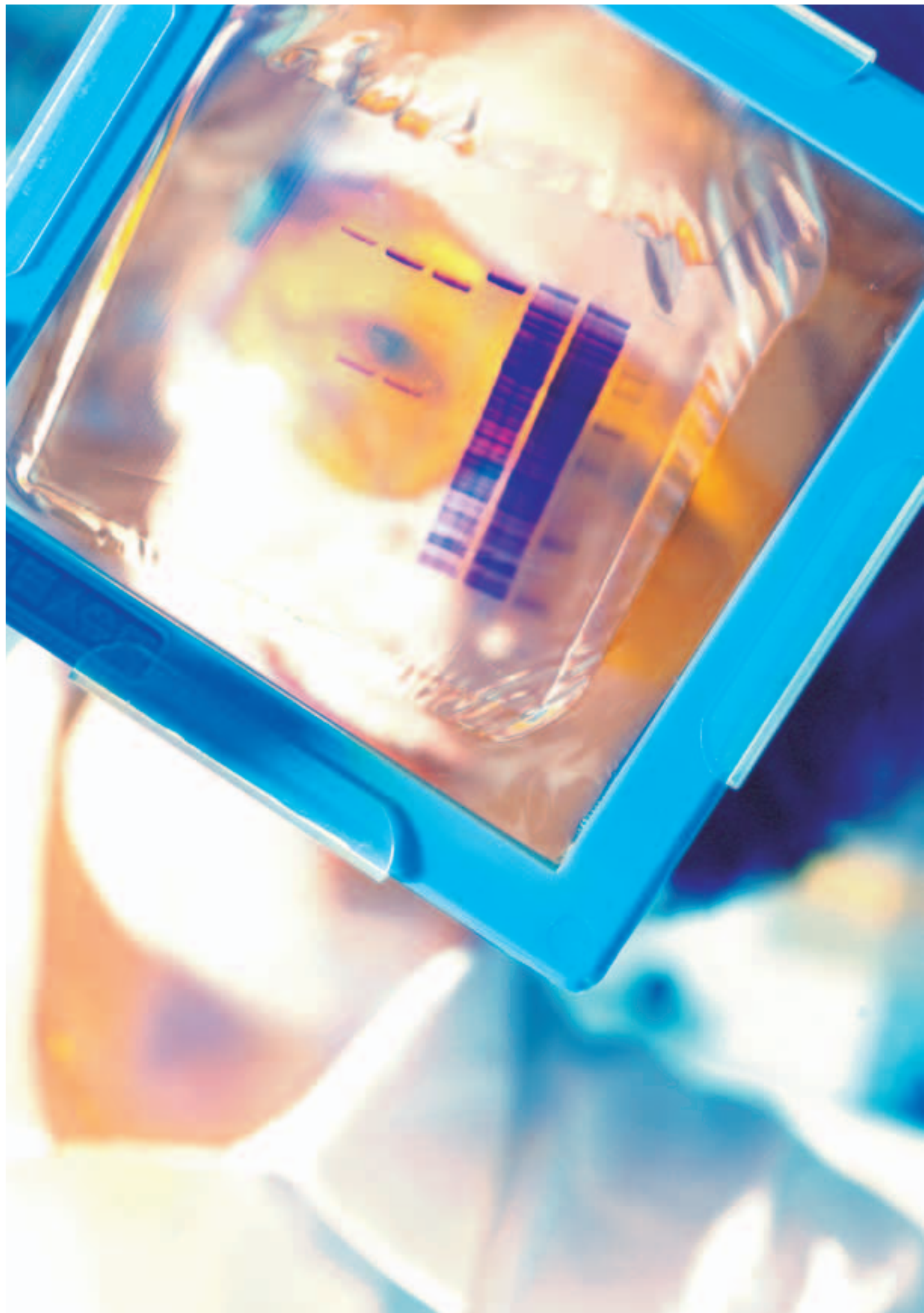
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Preface

The Government's perception of how we should meet international competition is clear. Sweden shall compete through knowledge, innovation and renewal. We shall not compete on the basis of low wages and deteriorated working conditions. We shall continue to occupy a position high up in the value-added chain and develop on the basis of high technology and international markets.

Central government's role is to create the preconditions for Sweden to have the world's best research and education, a stable social economy, a first-class climate for enterprise and a well-functioning innovation system. In order to develop the preconditions for innovation, production and enterprise, it is crucial for Sweden to continue to be successful in the face of the ever-tougher international competition which characterises the global life science industry.

In June 2004, the Government presented its innovation strategy *Innovative Sweden – a strategy for growth through renewal* (Ds 2004:36). The strategy acts as a platform for strengthening Sweden as a knowledge-based nation. The vision is clear. Sweden shall be Europe's most competitive, dynamic and knowledge-based economy, and the Swedish pharmaceuticals, biotechnology and medical technology industry shall be the most competitive in Europe.

Following the Prime Minister's invitation in the 2004 Statement of Government Policy for joint discussions with a number of business sectors, work began on developing a strategy programme for them. A modern industrial policy is based on a well-functioning dialogue between central government and the business sector. This strategic programme for the Swedish pharmaceutical, biotechnology and medical technology industry is part of a series now being developed, which also includes strategy programmes for the aerospace, automotive, metallurgy, IT/telecom and forest-products industries.

The Swedish pharmaceuticals, biotechnology and medical technology industry is one of the most important sectors of the economy and plays an important role in promoting innovation, employment and exports. The industry provides Sweden with research findings and infrastructure, skills, technology and health. Through cooperation between central government and the business sector, authorities and non-governmental organisations (NGOs), we can improve the competitiveness of the pharmaceuticals, biotechnology and medical technology industry as well as Swedish welfare.

The publication presents the strategy programme *Pharmaceuticals, biotechnology and medical technology – an integral part of Innovative Sweden*.

Stockholm, 6 December, 2005



Thomas Östros
Minister for Industry and Trade





Introduction

This strategy programme encompasses all actors operating within the fields of pharmaceuticals, biotechnology and medical technology. These fields have many points in common, including research and development (R&D). An internationally unifying concept for these sectors, which are intertwined and derive benefit from one other, is "life science industry". In this strategy programme, "life sciences" is used as a collective concept to describe the knowledge field that is the basis for the three sectors.

Sweden's biotechnology industry is Europe's fourth largest and the world's ninth largest as regards the number of enterprises. In relation to our population, the pharmaceuticals and medical technology industries are also very extensive. Sweden has great potential to continue to be one of the world's leading nations in enterprise based on life science research. Sweden has a long tradition of internationally competitive life science research with effective collaboration between researchers at universities and university colleges, the industry, the authorities and the health service. This has led to many world-leading innovations of Swedish origin, e.g. gastric ulcer drugs, diagnostic allergy tests, the pacemaker, titanium dental implants and equipment for protein separation.

Some 800 Swedish and international enterprises are currently active in Sweden in the development of products and services in the field of pharmaceuticals, biotechnology and medical technology and about 50,000 people work in them. There is major potential for growth in these fields and through the increasing impact of life science in other sectors such as the food, chemical and forest industries, as well as in plant-breeding and energy production based on renewable raw materials.

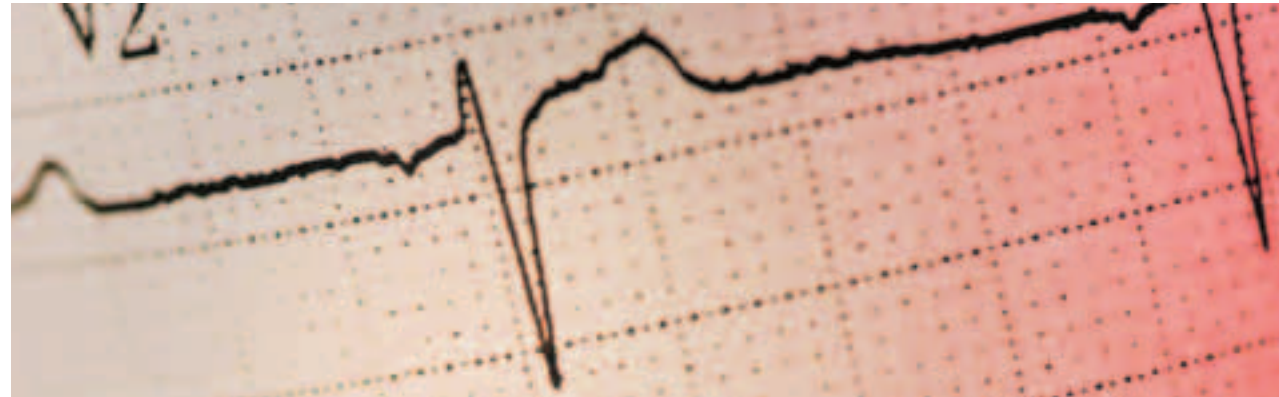
The pharmaceuticals, biotechnology and medical technology industry has developed to a large extent as a result of seamless contact with scientific research. Government investment in research at Swedish universities and university colleges helps to develop the Swedish economy and create growth. Internationally speaking, Swedish life science research maintains very high quality. The transfer of knowledge from advanced research to enterprise has hitherto been successful. This can inter alia be illustrated by the fact that net exports of pharmaceuticals and medical technology equipment have during the last 25 years advanced from an almost negligible figure to around SEK 40 billion in 2003.

Despite the hitherto very positive development in the industry, how well Sweden can continue to assert itself in the face of future competition remains an open question. In many countries, attention has been paid to the potential of life science to contribute to economic growth and greater employment, as well as to improved health and the development of new environmentally-friendly products from renewable raw materials. That has led to a great increase in international competition which results from the fact that many countries are investing substantially in research, development and commercialisation in the pharmaceuticals, biotechnology and medical technology field. Globally speaking, this is a very dynamic field. Research is increasingly being conducted as part of large-scale projects and based on very costly technology platforms. A wave of mergers in the industry has resulted in the emergence of large multinational enterprises. At the same time, many new enterprises have been formed, inter alia as spin offs from the academic world and the industry. Good conditions for innovation, development and growth, measured in international terms, are needed if enterprises in Sweden are to grow and remain in the country, as well as in order to attract the establishment of new firms and investment. These conditions include:

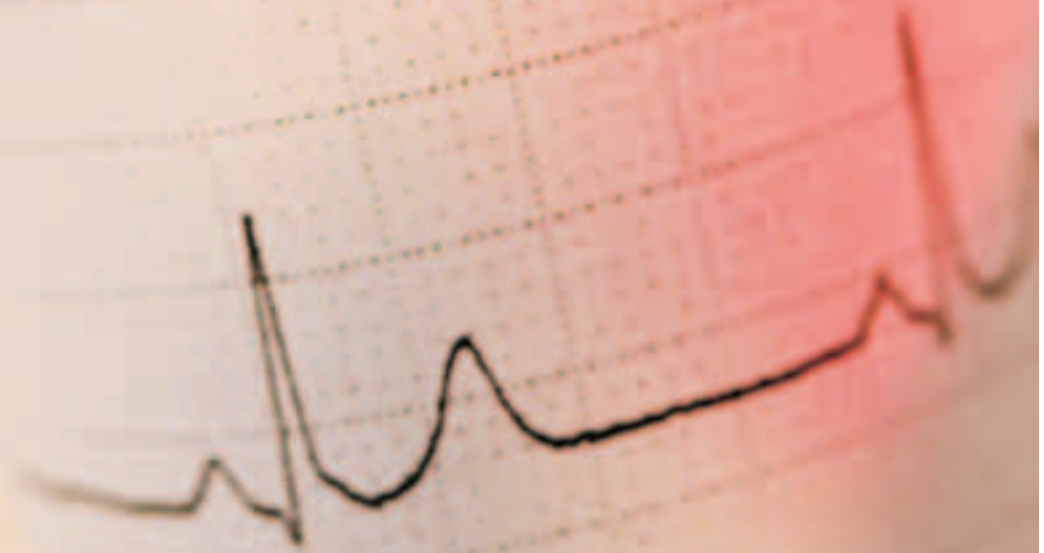
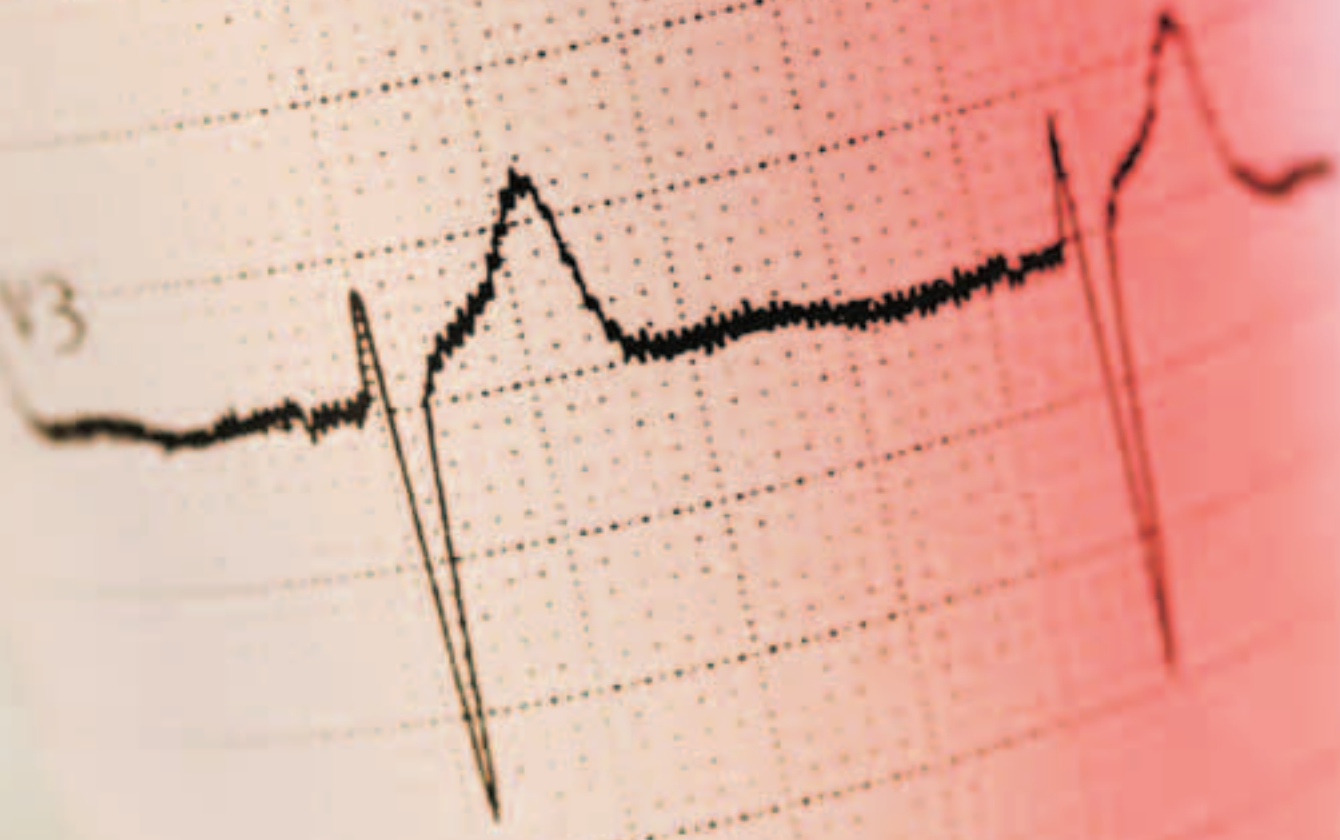
- ▶▶ Good interaction between the industry, the health service, researchers at universities and university colleges and the authorities
- ▶▶ Internationally competitive life science research in both established and new fields
- ▶▶ Strong research and innovation environments with international collaboration providing access to complementary resources and skills
- ▶▶ An effective system for refining ideas from research leading to long-term growth
- ▶▶ Specialised business knowledge and financing in all phases of development from initial commercialisation to international deals, competitive conditions for enterprises and long-term owners
- ▶▶ A health service which is quality-oriented, cost-effective and which both demands and adopts innovations.



V2



V3



In the summer of 2005, Thomas Östros, the Minister for Industry and Trade, met leading representatives of the pharmaceuticals, biotechnology and medical technology industry, as well as representatives of the research community, public authorities and trade union organisations, in order to discuss conditions in the sector and its future. The parties agreed to cooperate in developing a strategy programme. A strategy group was appointed for this task with representatives of various ministries, the business sector, academia, the authorities and trade union organisations, under the leadership of State Secretary Sven-Eric Söder. A secretariat, made up of stakeholder representatives, was appointed to support the strategy group.

This strategy programme presents a common vision for the Swedish pharmaceuticals, biotechnology and medical technology industry, along with an action plan to enable enterprises, central agencies and other stakeholders to realise the vision. Concrete measures from all stakeholders will improve the conditions in those fields where the need for input can already be identified. The discussions that have taken place serve as a starting-point for a longer-term dialogue between the sector, central government and other stakeholders. Activities already in progress partly fulfil the demands that have been identified but new efforts and initiatives are required in a number of cases. To provide some background, we describe the challenges and opportunities facing the sector.





Vision and Strategies

“Swedish industry in the field of pharmaceuticals, biotechnology and medical technology is one of the most important driving forces for innovation, renewal and sustainable growth in Sweden. The strength of development rests on effective, trustful cooperation between the business sector, politics, research at universities and university colleges, the authorities and the health service in order to ensure research, development, production and trade in products and services based on world-class life science research.”

Efforts in the field of biotechnology, pharmaceuticals and medical technology contribute to innovations which improve human health and the quality of Swedish healthcare. In addition, they lead to an increased use of renewable raw materials, environmentally friendly production processes and new tools for R&D. The industry also contributes to growth and greater employment. Life science-oriented industry and research in Sweden face major challenges as well as obvious opportunities for a continuing positive development. The overarching question is how the conditions for life science research and enterprises can be improved and continue to be internationally competitive. In the discussions which have been held within the framework of this work, the following key questions have been identified:

- ▶▶ How can the dialogue in the life science innovation system and the interaction between the industry, the health service, universities and university colleges as well as the authorities be developed in order to cope better with international trends, events and initiatives?
- ▶▶ How can clinical research be stimulated and the system for clinical trials be improved?
- ▶▶ How can a quality-oriented health service which demands and adopts innovations be developed?
- ▶▶ How can the commercialisation of life science research be put into effective practice?
- ▶▶ How can skills provision in the pharmaceuticals, biotechnology and medical technology fields be ensured?
- ▶▶ How are cooperation and the mobility of personnel between the academic world and the industry to be encouraged?

- ▶▶ How are international alliances within Europe and with the rest of the world to be encouraged?

Dealing with these key questions effectively requires a common strategy followed up with concrete initiatives and measures.

Improved dialogue and interaction

In order better to meet increasing international competition, continued good dialogue within the life science innovation system is required. This will enhance Sweden's opportunities to benefit from international development by being well-prepared for new trends, events and initiatives. Sweden has been characterised by effective interaction between political decision-makers, the industry, trade union organisations, the health service, universities and university colleges, as well as other public authorities.

To encourage future investments and sustainable growth in Sweden, it is important for the organisations in the innovation system, as well as the political decision-makers, to have access to up-to-date information about how the sector is developing in relation to international comparisons and international trends. It is important for changes in the innovation system to be based on up-to-date background information, in which scope is provided for the enterprises' own assessments. Furthermore, background information of this kind is necessary in order to market Sweden as a leading nation in research and enterprise based on life science. The industry, the authorities and other actors all have an active role to play in helping to formulate the background information, which sheds light on different aspects of international events,



initiatives and trends that have an impact on the conditions for research and enterprise. The industry, the Government, the authorities and other actors all have a responsibility to market Sweden.

Life science has brought with it major expectations for the development of new products and services which contribute to better health, environment and economic growth. The rapid development has also resulted in a certain anxiety about what other consequences research and applications may have. It is therefore important to conduct an open dialogue among researchers, experts, politicians, the business sector and the general public on developments within the field.

Preconditions for development and competitiveness

Strong and internationally competitive national research and a good business climate are the basic preconditions for continued expansion of an internationally competitive pharmaceuticals, biotechnology and medical technology industry in Sweden. In its latest research policy bill, *Research for a better life* (2004/05:80), the Government has made a strategic investment in both medical and technical research, whilst life science and biotechnology were given priority in the last research policy bill. Investments of this kind in research are a precondition for future development. The development of knowledge in life science has been very intensive in recent decades and development is still continuing at a fast pace. The new knowledge leads inter alia to new treatments for diseases, new diagnostics and better use of biological natural resources. Sweden today occupies a leading position in several life science fields and there is therefore major potential for future research, product development and production in the country. At the same time, many countries are rapidly expanding their life science research. This promotes the global development of knowledge but has also led to a considerable intensification in international competition in recent years. This can be observed in the statistics of scientific publications. The Swedish research community has expressed anxiety over what it perceives as the increasing difficulty in keeping step with leading international research environments.

The pharmaceuticals, biotechnology and medical technology industry is globally very dynamic, with mergers leading to ever-larger international enterprises, as well as the setting up of many new enterprises. Venture capitalists are also operating more and more globally. Swedish enterprises must go out onto the international market because the domestic Swedish market for their products and services is often small. Sales on the home market are nonetheless important since they function as a reference-point in international marketing and affect the enterprises' chances of getting their products out onto the international market. In

this international environment, it is essential that Sweden, by offering good conditions for research and enterprise, can be an attractive alternative site in which enterprises can establish themselves and operate. Through good conditions for enterprise and research, the emergence of innovative and competitive enterprises is encouraged. A world-class business climate is needed if ambitious growth targets are to be realised. This presupposes, for example, taxation rules which encourage growing research-intensive enterprises, good access to venture capital, a minimised administrative burden, rapid administrative procedures and clear, appropriate rules that enable enterprises to adapt quickly to new conditions. In those countries with which Swedish enterprises in pharmaceuticals, biotechnology and medical technology compete, growth in research-intensive sectors is encouraged by a variety of measures, e.g. as regards taxes and tax allowances. In Sweden, there are a number of proposals and on-going processes which show that this is also being given priority.

Importance of clinical research and a good system for clinical trials

The high quality of Swedish clinical research is intimately connected with support for an efficient, high-quality, health service. The high quality of research has contributed to good healthcare, facilitated recruitment, led to innovations and new enterprise based on research, attracted clinical trials of new drugs and treatments, and facilitated cooperation with the industry. The general public's openness to participation in the development of new therapies has also contributed to successful clinical research, as has Sweden's national patient and disease registers and biobanks. It is important for research to continue to be encouraged and prioritised in the health service. There are signs that clinical research in recent years has not been given the same scope in the health service, at the same time as the outside world's efforts in clinical research have increased. The investment in medical research pledged in the most recent research policy bill is spread by Sweden's state research funders. Decisions on a more detailed allocation of resources are taken on the basis of a competitive quality assessment. In recent years the Swedish Research Council has elected to make special investments in clinical research. The new ALF Agreement (An agreement regulating government disbursements to county councils to cover their costs for doctors' education and clinical research) also strengthens the conditions for clinical research as it enhances research collaboration between universities and university colleges and county councils. Furthermore, the investments made by individual county councils in clinical research centres and nodal points to attract clinical trials and research cooperation with the industry are important.



The quality-oriented Swedish health service's demand for and adoption of innovations is important

A quality-oriented health service is a fundamental precondition for an innovative pharmaceuticals industry in Sweden. Actors involved in the innovation system often maintain that one reason for Sweden's capacity to develop internationally successful products within the field of pharmaceuticals, medical technology and diagnostics is that the Swedish health service has been a demanding customer with close contact with the enterprises supplying new healthcare products. The industry is of the view that the circumstances in this regard are today no longer as good as they were in the past. If innovations are to be developed, it is important that there should be scope for such activity in the health service.

The prescription of new drugs is characterised by the need to strike a balance. On the one hand, we have the county councils cost-efficiency assessments of new drugs, their endeavours to attain rational drug use and their responsibility for patient safety. On the other hand, the industry has an interest in seeing that drugs in the development of which they have made investments, and which have been found to be suitable by the authorities responsible for the control and approval of drugs, are used in the health service and generate revenue for enterprises. A continuing and intensified dialogue about how work on quality can be developed is very important. Against that background, discussions have been conducted with the sector about the need for further developed quality work aimed at making holistic assessments of the effect and value of different treatments.

The commercialisation of life science research

Many enterprises which are spin offs from universities and university colleges have been set up in Sweden. The innovations in the industry often have their origin in research at universities and university colleges, as well as in the health service. It is therefore important that the system for absorbing and developing research findings into commercial products and services is effective, businesslike and technically professional. This can be particularly urgent given that the system as regards intellectual property rights to research findings from universities and university colleges is currently being reviewed. Access to early financing is also important. At the same time the systems for the commercialisation of research results are often perceived as difficult for the individual researcher to grasp, with many actors and limited coordination.

Guaranteed skills provision

Fundamental to a competitive pharmaceuticals, biotechnology and medical technology industry is sufficient access to

skilled personnel for research, development, production and trade. The public sector has a key role, being responsible for the education system and the regulatory framework governing foreign labour. Enterprises also have a part to play, e.g. in reaching out into the education system to inform and thereby arouse interest in training and education in the relevant fields with a view to a possible future career within the sector. It is also essential for the industry to provide work practice positions and provide staff with scope to improve their skills. The requirements for various skills and the preconditions for skills provision change over time. The industry should constantly monitor these issues in order to assess and convey their personnel requirements within different skill categories and different levels of education to universities and university colleges.

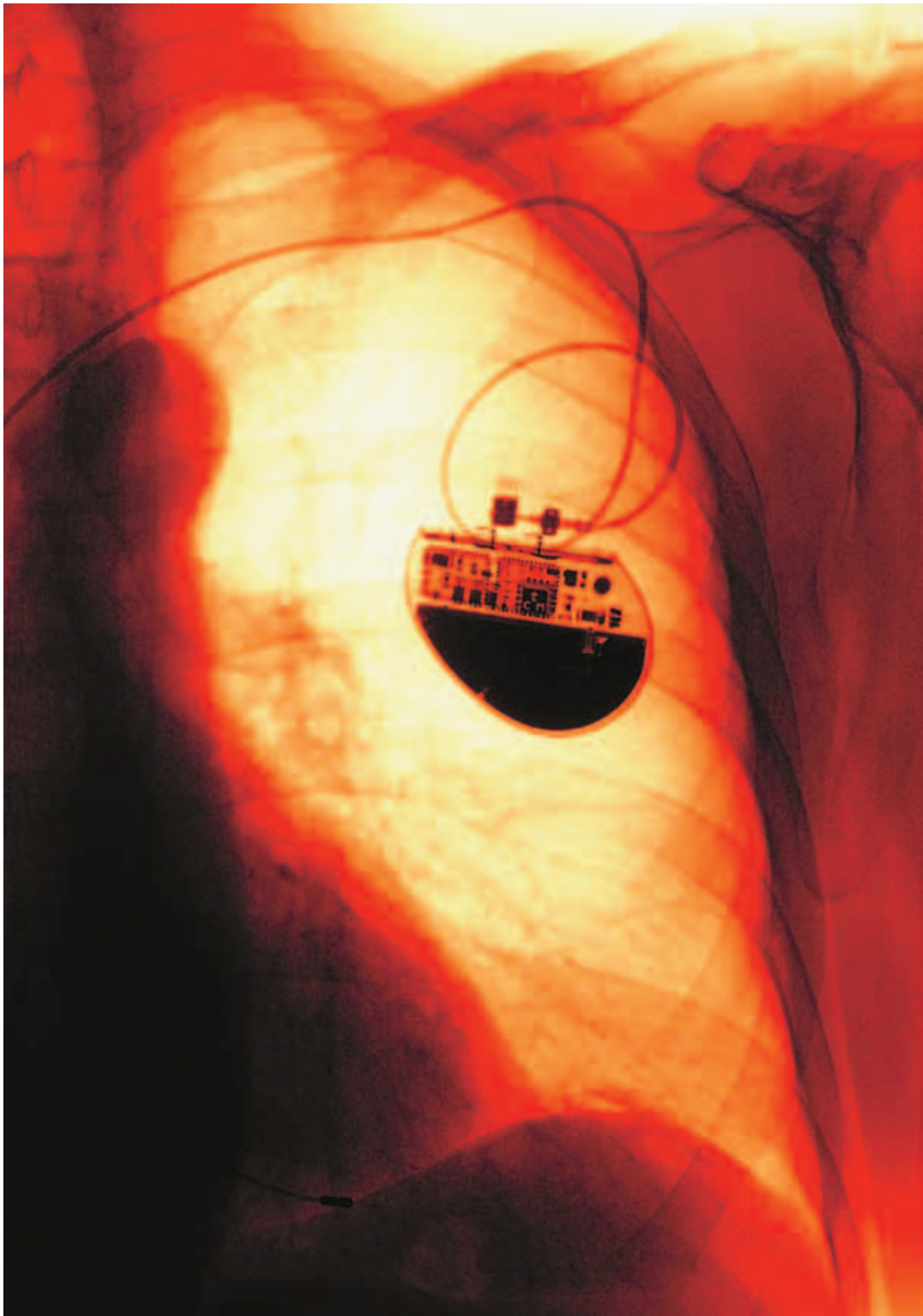
Within life science, fundamental research is very close to the applications being developed. It is therefore important for there to be good cooperation between researchers at universities and university colleges and the industry in order to generate and develop ideas which form the basis for industrial growth. Cooperation also helps to improve awareness at the universities and university colleges about the way in which projects are carried out in the industry, as well as to maintain this research-intensive industry's knowledge as regards the latest scientific developments. One of the main arguments of the industry for establishing itself and staying in Sweden is access to well-qualified and skilled labour. Achieving this requires good cooperation and increased mobility of personnel between academia and the industry.

Development in pharmaceuticals, biotechnology and medical technology takes place in interaction with other sectors. Examples of important subcontractors, cooperation partners and clients are the engineering, electronics, IT and food industries. IT development provides new tools for research, development, production and products. The engineering industry's process innovations affect the medical technology industry and more life science applications in, for example, the chemicals, food and forest industries can lead to more biotechnology enterprises focused on developing products and services for these industries. The conditions for and development of these subcontractors, cooperation partners and clients thus also influence the pharmaceuticals, biotechnology and medical technology industry.

Efforts to achieve international alliances

Both research and enterprises in pharmaceuticals, biotechnology and medical technology are global in character. Within life science research, the development of knowledge often occurs in major international projects and collaboration on new technology platforms, which are often expensive to build up and maintain, is becoming ever-more important. The research-intensive enterprises in these sectors also seek cooperation and alliances with academic research groups internationally. The





Swedish domestic market for these enterprises is small so that, irrespective of their size, they must make an early entrance on to the international market. Good opportunities for forming international alliances and partnerships are thus very important in order not only to have access to knowledge, skills and technical platforms, but also to attract investments and reach out into international markets. Cooperation within the EU and the opportunities which the EU Framework Programme

for research and technical development provides, as well as the cooperation agreements which have been concluded with individual countries, are important in this context, as are the activities of the Invest in Sweden Agency (ISA) and the Swedish Trade Council. The initiatives to improve cooperation and infrastructure regionally and to strengthen and market regional clusters are also important.





The Strategy Programme

The participating parties have identified a number of sectors where cooperation between the actors can be further improved and where efforts can be made to reinforce and develop the competitiveness of the Swedish industry in pharmaceuticals, biotechnology and medical technology.

The following main areas have been identified:

1. **Develop interaction between central government, the business sector and other stakeholders**
2. **Further develop world-class life science R&D within strategic areas**
3. **Promote commercialisation of research findings**
4. **Guarantee skills provision and develop dialogue**
5. **Improve the conditions for sector-specific production**
6. **Safeguard quality in the health service**
7. **Ensure competitive framework conditions**
8. **Meet the challenges of internationalisation**

The objective is for concrete measures carried out by all stakeholders to improve the long-term conditions in those sectors where the need for action can already be identified. The discussions that have taken place serve as a starting-point for a longer-term dialogue between the sector, central

government and other stakeholders. Activities already in progress partly meet the demands identified but fresh efforts and initiatives are required in a number of cases.

The design of concrete measures must be constantly updated and evaluated, which presupposes contacts between, among others, the authorities, enterprises, trade union organisations, research funders and research institutes, in the form of universities and university colleges. External factors such as new EC directives, changes in economic trends, environmental legislation and market demands can necessitate a constant change of focus as regards the measures being designed.

The measures proposed have a strong mutual interdependence and a holistic approach must also be adopted when deciding on their implementation. The proposals must be seen as a framework of measures. Several of the proposals require further preparation as regards their form, content and funding. New concrete measures may later be drawn up and implemented as needs are identified and any necessary funding becomes available.

The parties are agreed that there is a common responsibility to carry out these measures appropriately. This presupposes active participation and in certain instances co-financing by the parties. Each measure has been appointed a lead actor whose task is to take the process forward with the support of the other parties.

It is essential that the value of a well-balanced sex distribution should be observed in any groups which may be organised as part of the monitoring work.



1. Develop interaction between central government, the business sector and other stakeholders

» *Establishment of a forum for life science dialogue*

Continued dialogue in which the stakeholders and central government participate is an important tool for implementing and monitoring the strategy programme. A forum for dialogue is to be established creating the opportunity to discuss the development of the sector, as well as other topical proposals, issues and initiatives.

The strategy programme will be implemented gradually and will involve the industry and trade union organisations, as well as the Government, central agencies, universities and university colleges and other representatives of the research community as well as municipalities and county councils. Changes in the surrounding world have been taken into account when designing the programme. This applies inter alia to the demands for renewal made on the business sector by the ongoing globalisation process and by developments in the IT field. This is, however, a process in which new features are constantly appearing. It affects not only the business sector but also public life and the interaction between them. It is thus important for stakeholders to be able to carry on a constructive dialogue. Follow-up should take place at both the senior management and white-collar levels. It is intended that the work should follow a predetermined order and be continuously evaluated. This dialogue forum shall inter alia contribute to an understanding on the part of the authorities of the potential effects of their proposed measures on the conditions for different business activities in a broad growth perspective. It should also increase the industry's understanding of measures proposed by central government. Mutual, trustful exchange of information between stakeholders also increases the opportunities for constructive dialogue.

The focal point of this work should be issues which particularly affect the long-term international competitiveness of enterprises and other stakeholders within the pharmaceuticals, biotechnology and medical technology sectors. Other important issues for the pharmaceuticals, biotechnology and medical technology sectors can also be discussed. The general business climate, including e.g. tax issues, infrastructure, environmental and energy policy, as well as ethics, ought also to be permanently on the agenda. By way of introduction, a special working group in the field of medical technology will be assembled, with the industry acting as convener.

It should also be possible to discuss possible synergies in the various proposals by the authorities, both on the national and international level. With respect to the competition to which the industry is exposed on the global market, it is also of importance that the discussion should include international

harmonisation of regulations. That will give the Government and public authorities a better basis for drawing up Swedish positions in various fora such as the EU, WTO, UN-ECE and OECD. Increased cooperation should strengthen and bind together the networks which the representatives of public authorities and the business sector already have and in the future should help the Swedish pharmaceuticals, biotechnology and medical technology industry in its long-term planning. This will pave the way for favourable future development.

The Ministry of Industry, Employment and Communications shall act as convener

» *The Swedish innovation system for pharmaceuticals, biotechnology and medical technology in an international context (international benchmarking)*

The Swedish pharmaceuticals, biotechnology and medical technology industry and life science research are well-placed to meet international competition. Global changes and active measures by other countries aimed at strengthening their competitiveness must be met by measures on the part of enterprises, the research community and other actors in Sweden. For this to happen effectively, good factual information on the conditions and potential of the industry and the research community in an international perspective is required. This information should then be assimilated by stakeholders and be the subject of discussion within the framework of the dialogue forum described above. The Ministry of Industry, Employment and Communications should initiate a commission, the task of which should be to shed light on the international competitive conditions of the industry and research, by means of a comparative study of innovation systems.

The Ministry of Industry, Employment and Communications

2. Further develop world-class life science R&D within strategic areas

Internationally competitive life science research, an efficient infrastructure for the commercialisation of research findings and good cooperation between universities and university colleges, the health service and the industry are the preconditions for continued innovations, increased employment and growth in the field of pharmaceuticals, biotechnology and medical technology. This applies to technological, medical and natural science research aimed at increasing knowledge about biological systems. If there is to be continuing positive development, Swedish research environments must be among the world's best in their respective fields. Important new knowledge will then be developed, the most outstanding researchers can be recruited, innovations can be generated and investments in research and enterprise will



be attracted. The pharmaceuticals, biotechnology and medical technology industry is characterised by a uniquely strong link and interaction between research, the health service and innovative activities in enterprises. Collaboration between the business sector, universities and university colleges, the health service, public authorities and funders is something to build on further and to safeguard.

Medical research encompasses both pre-clinical and clinical research and is of great importance for the development of the pharmaceuticals, biotechnology and medical technology industry in Sweden. Good conditions for conducting medical research are also of vital importance for the investment decisions of individual enterprises. Swedish medical research has long been internationally prominent and has played an important role in the development of high quality healthcare. When medical research is now being expanded in other countries, Sweden is faced by new challenges. It is therefore important that measures should be taken to create a good basis for the continued development of medical research in Sweden. Within the design framework of this strategy programme, the importance of improved conditions for clinical research has been particularly emphasised, i.e. research which is primarily conducted in association with the health service.

The research policy bill *Research for a better life* (2004/05:80), put forward by the Government in the spring of 2005, makes reference to the major efforts in medical research made by several countries in recent years. In accordance with the proposals put forward in the bill, the Government has made a strategic investment in both medical and technological research. The level of funding for medical research is being gradually raised. This increase began in 2005 and with effect from 2008, the cumulative increase will amount to SEK 400 million per annum. By way of comparison, a total of SEK 4.2 billion was allocated from the national budget to general scientific development in medicine in 2005, according to figures from Statistics Sweden. In its Statement of Policy of September 2005, the Government announced a target of one per cent of annual GDP for public funds devoted to research.

Clinical research

A new agreement on the training of doctors and research, known as the ALF Agreement, was concluded in June 2003 between the Swedish Government and those county councils in which universities with medical science faculties are located. The agreement is of great importance since it governs central government disbursements to the county councils to cover the costs associated with the basic training of doctors in county council health service establishments and with clinical research.

Under the new ALF agreement, cooperation between central government and the respective county councils on

training, R&D will be extended. Furthermore, the agreement underlines the common responsibility of the parties for these activities. Thanks to the new agreement, the system has become clearer since disbursements to the county councils are now divided up into funds for research and funds for doctors' training respectively.

The situation for clinical research is nevertheless complex and will therefore be the subject of a forthcoming commission as announced in the research policy bill.

As regards the development of patient-oriented clinical research and the conditions for cooperation between clinical research environments and the industry, the dialogue in progress between the county councils and the pharmaceutical industry is of central importance. It is important for it to continue in order to develop the sector in a manner which is satisfactory for both parties.

» *Regional investment in skills development*

Within the framework of the ALF agreement, a special programme has been developed in order to combine clinical and scientific training at the Sahlgrenska University Hospital in the Västra Götaland Region. This investment in skills development has led to the programme participants going on to more qualified posts and tasks. The Västra Götaland Region intends to redress the lack of in-service training for clinically active doctors holding postgraduate qualifications, in order to safeguard continued skills development. This initiative will be subject to external evaluation so that the experiences can be disseminated to other county councils in the best possible way. In addition, the Västra Götaland Region intends to ensure that clinical active doctors who also conduct research are looked upon in a much more positive light.

The Västra Götaland Region

» *Opportunities for research and its career merit value*

A very significant incentive for an individual to conduct research is that it should enhance career prospects. It is important to create a culture which encourages healthcare personnel to carry out research and in which skills development is an integral part. The opportunity for research and its career merit value are central to this. Health service authorities and trade union organisations are responsible for designing suitable working methods.

Health service authorities and trade union organisations

» *The conditions for clinical research*

The strategic points of departure make it important for Sweden to continue to occupy a leading position in clinical re-



search. The necessary conditions for further development of clinical research should be investigated further. The Swedish Research Council should arrange a workshop with a view to taking a broad look at clinical research from both the national and international perspective.

The Swedish Research Council

» **Continued dialogue on the conditions for clinical research and clinical trials**

Clinical research environments of high scientific quality and cooperation projects between them and the industry have been identified in the sector discussions as important fields for further efforts. Sweden has for example outstanding skills in epidemiology with unique opportunities for monitoring the effects and safety of drugs, diagnostics and medical technology. The situation for clinical research is complex. For the sake of future work, it will be valuable to study the issue in greater detail in order to generate more fact-based background information. Seminars will therefore be held on clinical research and clinical trials, among other matters. The results of these seminars will increase the knowledge base and generate some of the background information for future work and discussions in the dialogue forum.

The dialogue forum

Clinical trials

The conditions for conducting clinical trials of new drugs in Sweden are good. The number of trials carried out in Sweden has however diminished in recent years according to information from the Swedish Medical Products Agency. This trend was broken in 2004, however, when more trials were carried out compared to 2003. The diminishing extent of clinical drug trials in Sweden and other EU countries is of central importance, in light of the increased international competition in this area. Through an EC Directive (2001/20/EC), the aim of which is to reduce the time it takes for a new drug to be approved, a first step towards meeting this competition has been taken.

It is important that initiatives be taken to attract clinical trials, at the same time as the health service must also be effectively managed. Having high-quality clinical research in Sweden enhances skills and improves the conditions for conducting clinical trials. This underlines the importance of the investments made by individual county councils in clinical research centres and nodes, in order to attract clinical trials and deepen research cooperation with the industry. A case in point is Östergötland County Council, which is working actively to expand clinical research activities by creating the Berzelius Clinical Research Center.

» **The conditions for clinical trials**

Good opportunities for conducting clinical trials are very important for the industry. A process should therefore be initiated by the pharmaceuticals industry, with the participation of other stakeholders, including the Medical Products Agency, the Swedish Research Council and the health service. The objective should be to examine the conditions for developing clinical trialling in Sweden. Various individual initiatives should also be studied aimed at exchanging experiences and taking advantage of best practice. For example, experiences gained in establishing centres for pharmaceutical epidemiology should be discussed, taking the initiatives of Karolinska Institutet's initiative in this area into account.

The industry in collaboration with other actors such as the Medical Products Agency, the Swedish Research Council and the health service

A new strategic R&D programme

A strategic R&D programme in the field of pharmaceuticals, biotechnology and medical technology should be drawn up. It can include subsidiary programmes and focus on skills and product areas in which Sweden already has a leading position and high quality research. Possible priority initiatives are described under the headings below.

» **Cooperation projects between universities and university colleges and the industry**

Important R&D fields, in which cooperation projects between universities and university colleges and the industry would produce major added-value, have been identified during the sector discussion. These include life science R&D in, for example, biotechnological tools, industrial biotechnology, diagnostics, medical technology, drug development and innovative foodstuffs. In the selection process, the project's relevance for the needs of the industry and society as well as its scientific quality should be considered. It is envisaged that the Swedish Agency for Innovation Systems, Vinnova, would be given the task of putting forward proposals for such a programme in cooperation with other actors and the industry.

Vinnova

» **Mobility of personnel between universities and university colleges and the industry**

More extensive exchange of knowledge between the universities and university colleges, the health service and the industry is essential. One way of achieving this is through greater mobility of personnel between the two sectors. One initia-



tive is the system of visiting assistant professors who, with their specialist skills and experience of the business sector and society in general, bring an extra dimension to universities and university colleges. Opportunities for PhD students to divide their time between academia and the industry also help to exchange knowledge between the sectors.

One proposal to increase the mobility of personnel is to give researchers who have already been awarded a PhD the chance to take up temporary appointments in the business sector.

Vinnova will be given the task of putting forward proposals for a staff mobility programme in consultation with other actors and the industry. The programme shall be based on common funding by Vinnova and the industry.

Vinnova

3. Promote the commercialisation of research findings

A sound and effective structure for the supply of venture capital is of fundamental importance for a country's capacity to create increased growth and employment and for an EU Member State to contribute to achieving the objectives of the Lisbon Process. It is moreover important that the first link in the chain, the emergence of new activities and new products, has access to appropriate forms of funding in the early stages.

In Sweden, an average of about twenty biotechnology enterprises have been started every year since 1997 and a number of them are growing rapidly, recruiting personnel and expanding internationally. The great majority of these enterprises are spin-offs from research environments at universities and university colleges, but there are also spin-offs from established enterprises disposals of entire business units by such enterprises.

Support for university-based environments which develop research-related business ideas is often provided in what are known as incubators. These are environments which verify and identify the business idea, assess its commercial potential, examine the possibility of obtaining protection for intellectual property rights etc., and take active steps to develop the business idea.

To widen the scope for commercialisation of research-related business ideas and innovations, the Government has set aside funding to ensure access to capital and business skills in the early stages of development. The main focus of this initiative is the creation of Innovationsbron AB. Responsibility for the national incubator programme initiated by Vinnova has been assumed by Innovationsbron AB, which now has the resources to fund incubators, in which early verification, business-coaching and commercial growth take place, and to contribute early seed-capital. Innovationsbron also has a uniquely strong structure, combining regionally experienced businesses, presence and professionalism in a national group, one of the aims of which is

the achievement of better coordination between different actors, regionally and nationally.

» *Support for development projects in academic research environments prior to enterprises being established*

There is a great need to be able to take projects further within the universities and university colleges before an expensive and time-consuming process of setting up an enterprise has been set in motion, i.e. before seed-financing which Innovationsbron, for example, can provide. The majority of projects in the life science sector involve high risk, long gestation periods and major costs. Life science business skills are therefore needed to identify projects which have the potential to develop future products and eventually lead to growth. The purpose of providing business skills and the opportunity for additional technical verification is to guard against premature enterprises, set up before the idea has been fully verified. Innovationsbron should, in consultation with Vinnova and other actors, analyse the preconditions for deepening and improving this form of development project, as well as submitting proposals for such a project.

Innovationsbron and Vinnova

4. Guarantee skills provision and develop dialogue

» *Access to labour and future skills provision*

Access to skilled personnel for research, development, production and trade is vital to a competitive pharmaceuticals, biotechnology and medical technology industry. The public sector has a key role given its responsibility for the education system. The industry also has a responsibility for skills development of its personnel. The industry's view of its future requirements for personnel with different skills and qualifications is part of the information on which the universities and university colleges base their priorities.

Interaction between the business sector and the education system is an important factor in achieving employment policy goals. The business sector needs skilled labour in order to meet the market's requirements for higher productivity, improved logistics and higher quality. A well-educated labour force also provides greater scope for rapid changes of direction in production and for improving the working environment with a view to reducing industrial injury and increasing worker motivation. An example of measures within this framework is the establishment of teknikcollege¹ and

¹ Teknikcollege is a municipal independent school in cooperation with the business sector which has more similarities with a workplace than a traditional school.



advanced vocational training in places where enterprises and education providers create joint training programmes aimed directly at the needs of the industry.

The need for skilled personnel varies over time. These issues should be constantly monitored by the industry, in order to assess and convey its future requirement for skilled and educated personnel to the universities and university colleges. The universities and university colleges are responsible for deciding on the design and volume of education. The industry will also assume a responsibility by, for example, arranging work practices, study visits and, when appropriate, participating in educational programmes by giving lectures or providing laboratory material.

A working group with representatives from the industry and the trade union organisations is to be formed. The purpose of the working group is to monitor the skills requirements in the sector and then discuss its findings with the universities and university colleges. The work done by the group will be discussed in the dialogue forum.

The industry, via the organisation SwedenBio, will act as convener

» **Dialogue with the general public**

Another important issue as regards the conditions for the industry is public opinion. This opinion influences, for example, how attractive the industry is for young people when choosing their education and future careers. It is also important for the general public to have a basic awareness of life science because the knowledge generated, both today and still more so in future, will result in applications which will affect everyone's daily lives. Well-founded standpoints on bioethical issues require basic knowledge. This applies not only to decision-makers and politicians at various levels but also to the general public at large. All actors in the life science innovation system have a role to play in this respect and many initiatives to promote effective dialogue with the general public are already being taken by universities and university colleges, the authorities, NGO's and enterprises. A working group with representatives from the industry and the trade union organisations is to be formed. One task for the group is to identify possible efforts to develop the dialogue with the general public and to disseminate information about activities in the sector. That can take place in cooperation with universities and university colleges, public authorities and non-profit-making associations. Work in the group will be discussed in the dialogue forum.

The industry, via SwedenBio, will act as convener

» **Stakeholder dialogues**

The activities of the pharmaceutical industry affect many stakeholders, including patients, doctors, co-workers, share-owners and public authorities. Enterprises must operate in a

responsible manner in order to retain stakeholder confidence. Responsible enterprise is based on acting in accordance with high ethical standards and running a trustworthy business.

In order to help achieve these objectives, stakeholder dialogues were initiated by certain enterprises in the pharmaceutical industry some years ago. Various stakeholders meet in this forum to develop action plans and to find a balance between the economic, environmental and social aspects which are part of a sustainable development. In addition, there are the demands of society and customers which include ethical standards and high product quality.

The concept of stakeholder dialogue should be extended to include more enterprises in the pharmaceutical industry. A proposal for developing stakeholder dialogues will be drawn up by the industry in consultation with the relevant parties.

The pharmaceutical industry

» **Mentor programme for contracting enterprises**

The purpose of this programme is to provide mentors for contracting enterprises and their top-level managers in particular. Mentors can be outsiders, such as consultants or senior people who have been or are active in the industry concerned, and who support the enterprises in their business development. Similar projects in other sectors have given company executives support from outsiders who have brought with them both skills and different attitudes.

The areas in which such mentors can be most effective are company strategy, company board audits, contacts with venture capitalists for investments, marketing, internationalisation or as go-betweens both in Sweden and abroad.

The industry and Nutek

5. Improve the conditions for sector-specific production

» **Industrial biotechnology**

Industrial biotechnology is defined as the use of enzymes and micro-organisms in order to produce chemicals, material and energy. Industrial biotechnology is based on the use of renewable raw materials and helps reduce dependence on fossil raw materials for industrial production.

Today the forest industry is responsible for approximately half of Sweden's net export value (more than SEK 80 billion), the biggest contribution to Swedish net exports by a single sector. Within this and other industries, such as the chemical industry, the food industry and the engineering industry, as well as regarding energy supply, there is major potential for growth through increased use of the knowledge developed through life science research, as well as for



increased use of biotechnological applications. Research in industrial biotechnology in Sweden is strong in the areas of genetic engineering (micro-organisms and plants), enzyme technology and separation technology/bioprocess technology. The issue of renewal in the forest industry is also being broached in another sector discussion.

The food industry is a traditional purchaser of biochemical methodology. One example is the development of functional food based on certain types of bacteria.

Research in industrial biotechnology is being financed by, for example, MISTRA (the Foundation for Strategic Environmental Research), Vinnova and Formas (the Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning). Vinnova and MISTRA are performing an analysis of Swedish industrial biotechnology, focusing on growth potential and environmental relevance.

Vinnova and MISTRA

▶▶ **Opportunities for more biotechnological production of pharmaceuticals in Sweden**

The industry has emphasised the importance of studying the need of small pharmaceutical enterprises for quality-assured biotechnological production of pharmaceuticals. This complex of questions relates to the possibility of scaling up production of biotechnologically produced substances from the laboratory level to volumes sufficient for carrying out early-phase clinical trials. If this scale-up is successful, it will provide small biotechnology enterprises with a better chance of taking their product development further before entering into cooperation/licensing agreements with major pharmaceutical enterprises, as well as increase the likelihood of future large-scale production being located in Sweden. There should be further analysis and discussion on this subject, one step being to hold a workshop to investigate the current situation. It should also cover the topic of initiatives in other countries including, for example, Ireland and the United Kingdom. The industry is to be responsible for organising this workshop in collaboration with Vinnova and other stakeholders.

The industry and Vinnova in collaboration with other stakeholders

▶▶ **Information about the environmental impact of pharmaceuticals**

EU legislation on pharmaceuticals was tightened in 2004 and requirements for an assessment of the environmental risks of a pharmaceutical product have been introduced and made more specific. On the other hand, environmental requirements must not play a decisive role in the approval of drugs intended for human beings. The Swedish Association of the Pharmaceutical Industry (LIF), Apoteket (the Swedish state pharmacy chain) and the Swedish Medical Products

Agency, together with Stockholm County Council and the Swedish Association of Local Authorities and Regions, have developed a method for surveying and presenting environmental risks and hazards associated with pharmaceuticals. This information is accessible through the FASS website for patients, doctors and the general public. Work is in progress on producing environmental information about all pharmaceuticals and this information will be published in stages on the FASS website (www.fass.se). This is an example of the power of initiative to accept environmental responsibility voluntarily despite the fact that under EU legislation environmental aspects cannot yet be taken into account in the approval of pharmaceuticals for human use. This initiative is the first of its kind.

The pharmaceuticals industry, Apoteket, the Medical Products Agency, Stockholm County Council and the Swedish Association of Local Authorities and Regions

▶▶ **The Medical Products Agency reviews environmental information**

The Medical Products Agency has a particular sector responsibility as regards the Swedish environmental quality objectives (*Swedish environmental objectives – a common task*, Government Bill 2004/05:150). In accordance with this responsibility, the Agency must endeavour to achieve all relevant environmental objectives in its sector. The Medical Products Agency is also developing a basis to assist the Government in making an assessment of what might be involved in the Agency's new task of reviewing environmental information.

The Medical Products Agency

6. Safeguard quality in the health service

▶▶ **Quality work in the health service**

An important factor in the development of the health service and for the healthcare industry is for the care service to adopt quality-oriented working methods. The concept of quality means, among other things, that healthcare must as far as possible be evidence-based, i.e. designed in accordance with the best available scientific evidence. To ensure that the care creates the maximum possible benefit both for the individual patient and the society in general, it is also important for the results of administered treatments to be systematically followed up on the individual, group and societal level. It is very important that the health service is given adequate scope to carry out such follow-up tasks. Such follow-up constitute the basis of evidence-based healthcare. The concept of quality also includes each patient being entitled to an individual assessment and treatment that is as far as possible customised to fit his/her individual needs and conditions.



Increased focus on quality in the health service constitutes an important incentive for the development of new and innovative pharmaceuticals and forms of treatment. Quality work in the health service has thereby a direct impact on the development and competitiveness of the pharmaceutical industry. Conversely, a competitive pharmaceutical industry is important for quality work in the health service.

For number of years, a considerable number of measures have been adopted to improve quality work in the health service. These have been implemented in county councils and municipalities as well as at the national level, through central agencies and also in various collaboration projects between central government and health authorities. For the development of both the Swedish health service and the industry, it is important for quality-oriented and evidence-based working method to be further intensified. This can be achieved not only through the structured development of working practice and methods, but also through incentive measures.

The Government ascertains that a quality-oriented health service is a fundamental precondition for an innovative pharmaceutical industry in Sweden. The Government therefore intends to assist in bringing about a continued and intensified dialogue between the National Board of Health and Welfare, the Medical Products Agency, the Pharmaceutical Benefits Board, the Swedish Council on Technology Assessment in Healthcare (SBU), the Swedish Association of Local Authorities and Regions and the Swedish Association of the Pharmaceutical Industry on how work on quality can be further improved. Given the financial situation of the county councils, initiatives aimed at stimulating quality development are to be given priority. This aspect will be an important part of the dialogue described above. Within the framework of this dialogue, it is anticipated that the actors concerned will analyse this issue more closely and put forward constructive proposals for how quality aspects can be encouraged in the local health service. Particular attention should be paid to the issue of quality in the form of achieved treatment results and how the concept of evidence-based medicine can be concretised in various disease groups. In this way, the impact of evidence-based guidelines etc., can be accelerated at the local level. Quality-enhancing efforts in healthcare should further be a constant subject for discussion in the dialogue forum proposed in this strategy programme.

The Ministry of Health and Social Affairs, the Ministry of Industry, Employment and Communications, the Swedish Association of Local Authorities and Regions, plus the industry

» **Financing of pharmaceuticals in relation to the discussion on quality in the health service**

The Government' statement in its autumn 2004 budget bill took its starting-point in the funding model applied since 1998

and according to which the health authorities must themselves take responsibility for the costs of the pharmaceuticals used in inpatient care, while they receive special Government funding for pharmaceuticals on prescription, the amount of which is governed by agreement between the Government and the Association of Local Authorities and Regions. The present agreement runs for the period 2005–2007. In light of the observed need for further quality improvements in the health service, the Government intends, prior to the next agreement period, to analyse ways of financing pharmaceuticals, linked to the discussion about quality in the health service. This issue should also be discussed in the forthcoming dialogue forum, in which representatives of the Association of Local Authorities and Regions and of the industry will be included. The issue of future financing is, however, a question for joint decision by the Government and the health service authorities.

The Ministry of Health and Social Affairs, the Ministry of Finance, the Ministry of Industry, Employment and Communications, the Association of Local Authorities and Regions and the industry

» **IT in healthcare**

The chief task of the National Executive for IT in Healthcare and Social Services is to draw up and monitor a national IT policy for health and social care. The executive, coordinated by the Ministry of Health and Social Affairs, is to present a national IT policy at the beginning of 2006 and thereafter be responsible for its dissemination and monitoring. The executive includes representatives of the authorities and enterprises concerned, as well as the Association of Local Authorities and Regions. It is working to establish a national consensus on how various forms of IT support best can be utilised in order to create more accessible, reliable and effective healthcare of high quality. The aim is to establish a common vision for the future use of IT in the sector, to report on what efforts and concrete decisions are required to achieve this vision, and to allocate responsibility and lay down a time-table for future work. The importance of a unified IT structure, developed terminology and standardisation work, and measures to promote accessibility are some examples of areas which will be dealt with in the national IT policy. Information contained in healthcare and social services documentation shall primarily promote the health and social care of the individual, but it must be of sufficiently high quality to be of use for other purposes, such as matching with health data and quality registers. With greater exchange of information between different healthcare units, it is essential to be able to safeguard personal integrity and data protection. A comprehensive legislative review is currently in progress to consider how these questions are to be regulated. The starting-point of the review is that all patient records must in future be in electronic form (The patient records commission S2003:03).

The Ministry of Health and Social Affairs



» **Regional pilot-study on a coordinated IT structure**

As far as clinical research studies are concerned, it is often important to identify and be able to follow up a sufficiently large and appropriate patient population. Purpose-designed IT systems can in this respect facilitate the effective follow-up of the patient-population in the study, e.g. as regards treatment outcomes. Taking the intensified quality work in the health service a stage further, the Västra Götaland Region has undertaken to conduct a pilot-study in which it will analyse how an improved and better coordinated IT structure can be designed. The conditions for carrying out such development work are good in the Västra Götaland Region, since it has a large patient base. The purpose is to improve the conditions for clinical research and the development of new diagnostics, treatments and therapies. This initiative is intended to be a subject of external assessment, so that the experiences can be disseminated in the best possible way to other county councils.

The Västra Götaland Region

7. Ensure competitive framework conditions

A world-class business climate is a precondition for continued investments in research, development and production in Sweden. Ambitious growth objectives can then be achieved. This implies, for example, tax regulations which stimulate growth in research-intensive enterprises, good access to venture capital, good conditions for research, a minimal administrative burden, rapid official procedures and clear rules which allow enterprises to adapt quickly to new conditions.

» **Tax incentives for R&D investments**

For many research-intensive enterprises in the sector, it takes a long time before research investments produce a profit. For this reason, enterprises have a major need for capital during the period before a product or service can be commercialised. It is therefore of importance for the measures taken to be designed so that they take account of the special requirements of research-intensive enterprises for capital. SEK 100 million will be made available in 2006 for new support to R&D in small and medium-sized enterprises and, as from 2007, SEK 200 million will be allocated to an annual tax credit for the same purpose. Within the Swedish Government Offices, a working group has been appointed to formulate the conditions for the tax credit for small and medium-sized R&D enterprises.

The Ministry of Industry, Employment and Communications

» **Increased opportunities for skills provision through foreign expertise**

The opportunities for the industry to recruit personnel are not just affected by factors related to education and train-

ing. The scope for commuting to major workplaces either by private or by public transport can increase the catchment area. The design of social and medical services has a bearing on to what extent employees can adapt their private lives and effectively participate in production. Particular emphasis should be put on measures to create equal working conditions for both women and men. The conditions for foreign personnel, especially those in key positions, are also important for global enterprises.

The industry needs to be able to recruit expertise from other countries to work in Sweden. Enterprises can currently offer foreign workers time-limited contracts with specific conditions. Employees then work in Sweden but under the terms and conditions (e.g. regarding salary and taxes) which prevail in their home country. This is an expensive method of remuneration for the enterprises. Local employment can be offered as an alternative, i.e. standard Swedish salary and taxation levels. More often than not, this form of employment offers significantly worse terms for the employee than in the home country. Improved scope for being able to classify posts as "expert" entitling holders to a tax reduction, would make the local form of employment a more attractive alternative and provide enterprises with greater access to important specialist expertise. Making it easier for the pharmaceutical industry to attract foreign expertise was one of the reasons for introducing a special "expert tax" in 2001. The parties in the sector discussion agree that application of the expert tax will make it easier for the industry to recruit the expertise they require. The Government will continue to ensure that the objectives of the expert tax are met.

Within the dialogue forum, stakeholders are to promote better skills provision, for example by facilitating the employment of foreign experts.

The Ministry of Industry, Employment and Communications

» **Reduced administrative burden for enterprises**

The Government is working to reduce the administrative burden on enterprises. Part of this initiative is the Government action programme for reduced administration for enterprises, including 300 planned or already implemented measures. In addition, a method is being developed and applied to assess the costs for enterprises of complying with laws and regulations. This has been carried out in the taxation field, where the objective of a 20 per cent reduction in tax administration by 2010 has been established. The Government will develop similar objectives for environmental legislation and labour law. Within the Swedish Government Offices, work is currently also in progress to develop an improved system for impact analysis and on more coordinated efforts to improve the quality of regulations. This work is being carried out on a general basis and hence also has a



bearing on legal frameworks linked to the life science sectors. The Government will also ask the OECD to assess the sector-specific regulatory burden for the life science industry. In addition, Nutek, the Swedish Agency for Economic and Regional Growth, has been given prime responsibility for issues relating to regulatory improvement.

The Ministry of Industry, Employment and Communications and Nutek

» **Stable conditions for animal experiments**

The pharmaceutical and biotechnology industry is very research-intensive and is dependent on animal experiments in order to develop effective and safe medicines. This is also a precondition for certain life science research, particularly medical research. Providing research with stable operating conditions is of vital significance for pharmaceutical and biotechnological activities in Sweden. By backing the research policy goal, the Riksdag has shown commitment to making Sweden a leading research nation, where research of high scientific quality is conducted. The Government intends to work to establish stable conditions for research while also ensuring strong animal protection.

Ministry of Agriculture, Food and Consumer Affairs, Ministry of Education, Research and Culture and Ministry of Industry, Employment and Communications

8. Meet the challenges of internationalisation

Life science research, like the pharmaceuticals, biotechnology and medical technology industry is international in character. Cooperation between research environments in different countries is intensive and often takes place through co-financing between countries or through bilateral agreements. In this context, the EU Framework Programme for research and technological development is very important. For enterprises, the possibility of attracting investment and reaching out onto international markets is a precondition for their growth. The international harmonisation of regulations, standards and approval processes has a major effect on enterprises. The Government and those central agencies with a sector responsibility intend to continue to be active in design and monitoring of these processes, as well as in negotiations aimed at eliminating trade barriers. The dialogue with the industry in this context is of great significance.

Efforts to promote exports and investment are important for this industry, both because the Swedish domestic market for the industry's products and services is small, and because much of the capital which is invested in Swedish enterprises in the sector comes from abroad. It is therefore also impor-

tant that all actors in the innovation system actively market Sweden as a country with good conditions for research, development, production and trade in this sector. This will lead to new investment and enterprise establishments in Sweden and hence promote Swedish growth.

» **Efforts aimed at increased internationalisation**

Special measures to facilitate exports have been highlighted during the sector discussion as an important investment area to meet globalisation and in particular to increase the export opportunities for Swedish small and medium-sized enterprises. In light of this, a number of measures are planned during 2006.

- Special 'business promoters' will be stationed at Swedish embassies and consulates-general in some 30 strategic markets.
- The Government is commissioning the Swedish Export Council to station a regional export adviser in every county.

The Government has also given the Export Council the task of conducting a targeted export initiative for small and medium-sized enterprises in the biotechnology field. This initiative goes under the name of the Swedish Life science Programme. The Programme is now being reviewed with the aim of broadening its focus to include medical technology and other closely related market segments.

The Swedish Export Council and the Ministry for Foreign Affairs

» **Competence groups for international business development**

In order to meet the need for business development in medical technology enterprises more effectively, the Swedish Export Council has established an internal global competence group to bind together and reinforce the Council's expertise in the field of medical technology. Based on this competence group, more detailed studies, including proposals for market activities, are now being performed on markets to which enterprises attach priority. During 2006, the Export Council intends to establish a special competence group for biotechnology, pharmaceuticals and healthcare.

The Swedish Export Council and the Ministry for Foreign Affairs

» **Export of Swedish expertise in healthcare and social care**

Swedish cutting-edge healthcare and social care expertise is being highlighted in export promotion initiatives. The



Export Council's healthcare collaboration group, Swecare AB, is to have a new organisation with the Swedish Medical Suppliers Association (SLF), SwedenBIO and the Swedish Association of the Pharmaceutical Industry (LIF) as its main pillars, together with the Government (Ministry of Health and Social Affairs, Ministry of Industry, Employment and Communications and the Ministry of Foreign Affairs), Swedish Association of Local Authorities and Regions and the Export Council. Its activities are to be given a more specialised direction with clear areas of focus.

Swedish Care Institute AB (SCI), which is owned by the Swedish Handicap Institute (HI) and Swecare AB, specialises in the export of Swedish expertise in healthcare, elderly care and care of disabled persons, particularly to Japan. SCI operates through its own network of Swedish and Japanese stakeholders and through close cooperation with HI, the Swedish Export Council and the Ministry of Health and Social Affairs and the Ministry of Foreign Affairs. After five years of operating in Japan, an extensive contact network and expertise have been built up on the Japanese market. SCI runs courses and training in Sweden for visiting Japanese, as well as a major seminar programme. Starting in the spring of 2006, it will also run extensive training activities in Japan. SCI has an office with two employees at the Swedish Export Council's Business Support Office in Tokyo.

*The Swedish Export Council
and the Ministry for Foreign Affairs*

▶▶ **Initiatives to increase foreign direct investment in Sweden**

Investment-promotion measures are important to increase the inflow of foreign R&D investment. Particular initiatives are needed in the life science sector.

The Invest in Sweden Agency (ISA) will this year conclude a follow-up initiative as part of the international marketing project of Swedish biotechnology clusters. During 2006, ISA intends to launch a new, more advanced project to market Swedish biotechnology clusters internationally. ISA will develop and increase cooperation between the industry, sector associations and the relevant authorities, in order to increase the long-term flow of investments in the form of establishments and skills. This is taking place with a view to achieving greater impact and attractiveness in the face of increasing international competition, in which Sweden's unique scope for collaboration will be exploited. Pharmaceuticals, biotechnology and medical technology, as well as life science research, will continue to be allocated priority in the Government's trade and investment promotion programmes, and further efforts to increase international competitiveness within Swedish profile sectors are judged to be necessary.

In view of its developed client base, ISA's continued efforts are considered to have a positive influence on the conditions for future direct investments in the pharmaceuticals, biotechnology and medical technology sectors in Sweden, and should continue.

In order to further strengthen Swedish biotechnology clusters and to reinforce efforts within Swedish profile sectors, the Government intends to instruct the ISA to make special efforts in the neuroscience sector.

The Ministry for Foreign Affairs and ISA

▶▶ **Trade cooperation with the US**

A cooperation project between the Swedish Government and American Administration, known as the Informal Commercial Exchange (ICE), has been running for the last two years. This exchange is aimed at further development of the conditions for economic cooperation as regards both trade and investment. Bilateral issues relating to market access and procurements are also covered, as are the effects of EU enlargement and the WTO Round. A specially identified sector of cooperation is innovation and entrepreneurship. Biotechnology is mentioned as a priority field for cooperation and aspects discussed include research cooperation and the promotion of contacts between enterprises. The scope for facilitating contacts and cooperation with the American society, for example through the US.

Department of Commerce, via the present inter-governmental cooperation, must be exploited in issues of importance for the life sciences.

*The Ministry of Industry, Employment and
Communications and the Ministry for Foreign Affairs*

▶▶ **Bilateral cooperation agreements**

For many years Sweden has had strong research contacts with the US and these can be expected to be developed further in future. Japan, China and other countries in Asia are also playing an increasing role both as sources of knowledge and technology and as markets in the field of pharmaceuticals, biotechnology and medical technology. In addition, Vinnova has cooperative programmes with countries outside the EU. A research programme between Japan and Sweden and a Structural Genomics Centre with the United Kingdom and Canada are noteworthy examples.

The Government enters into special agreements on cooperation in science and technology and currently has such agreements with Japan, China and South Africa. Negotiations are in progress also with the US and India for similar agreements. The agreements assist authorities involved in funding and conducting research in their cooperation with their counterparts in the respective countries. This kind of cooperation also has positive effects for both established and recently started research-inten-



sive enterprises. The opportunities provided by these research agreements must be exploited in the life sciences.

Ministry of Education, Research and Culture and the Ministry of Industry, Employment and Communications

» **Cooperation on projects in developing countries**

Enterprises in the pharmaceuticals, biotechnology and medical technology industry have considerable expertise in sectors affecting developing countries. They include Astra-Zeneca, which is running a project in Bangalore in India that can potentially help to combat tuberculosis and to develop the skills of Indian researchers in this field. Other enterprises and researchers in universities and university colleges, and certain authorities, are also conducting research on diseases which only exist in developing countries.

Infectious diseases cause more than a quarter of the deaths in the world. As diseases of poverty they represent a threat to the individual, to society and to societal development. The Government has decided that a strategic action plan is to be drawn up for the period 2006–2008. Within the framework of this action plan, development assistance efforts will be initiated to combat HIV/AIDS, malaria, tuberculosis, measles and antimicrobial resistance, as well as for other strategically important measures in connection with the Government's policy for global development. In certain cases, development assistance funds can partly finance efforts which contain an element of making a global common benefit available to partner countries.

A strategically important sector for the Swedish contribution to the fight against infectious diseases is support which makes it possible for poor countries to train and retain educated personnel in healthcare and associated research fields. In many cases, this is a question of various ways of enabling personnel who have left their own country to return to it. Both national and international efforts are needed to reinforce health systems in developing countries. In the long term, these efforts contribute to their struggle against poverty and to the achievement of their own development objectives in many fields, particularly in the important health sector.

In order for Sweden to be able to implement its policy for Swedish international cooperation for global development, it is important to find new forms of collaboration between different actors in Sweden. The business sector plays an important role in this context. The Government is positive towards various forms of public and private cooperation in which the resources and skills of the business sector can be exploited to achieve the objectives of Swedish policy for global, just and sustainable development. It is the common ambition of the Government and the business sector to extend their cooperation in fields which can be of advantage for Sweden's objectives for global development.

The Ministry for Foreign Affairs and the industry

» **Research cooperation within the EU framework programme**

The goal of the Lisbon strategy is to reinforce Europe's competitiveness and to create the most dynamic knowledge-based economy in the world. The EU Framework Programme for research and development represents the largest budget item for implementing the Lisbon strategy and aims to create a European Research Area. The Framework Programme has run in four-year periods and the current Sixth Framework Programme, amounting to EUR 17.5 billion, covers the period 2002–2006. Sweden has hitherto been successful in achieving extensive participation in the Framework Programme. Taking the EU as a whole, industrial participation has diminished during the present Framework Programme.

In the proposal for the Seventh Framework Programme, which is to start in 2007, biotechnology and pharmaceutical research will primarily be dealt with in the thematic area of health and in the thematic areas of food, agriculture and biotechnology. New forms of cooperation are also proposed in the programme, such as a European Research Council and Joint Technology Initiatives (JTI). The latter type of initiative has emerged in order to promote increased industrial participation in the Framework Programme. For projects which are to receive support from the European Research Council, it is proposed that scientific excellence should constitute the primary criterion. Within the framework for JTI, industrial competitiveness is highlighted as a significant criterion. A JTI currently under discussion, which has importance for the pharmaceutical industry, is the Innovative Medicines Initiative. Other types of cooperation projects are also proposed.

Continued strong Swedish participation in the Framework Programme requires readiness from the Swedish research community and business sector. Vinnova, in consultation with the Swedish Research Council and the industry, should be given the task of drawing up a strategy for how Swedish actors should proceed in order to derive optimum benefit from the efforts currently being made at the European level.

Vinnova

» **Regional co-financing of projects within the EU Framework Programme**

Projects in the EU Framework Programme are sometimes co-financed using regional resources. One example is the Västra Götaland Region which is to co-finance regionally relevant medical technology and healthcare projects, if the projects are granted funds in the forthcoming Seventh Framework Programme.

The Västra Götaland Region



» *Follow-up of G10 work*

The G10 High Level Group on Innovation and Provision of Medicines was appointed in 2001 to examine to what extent pharmaceutical, health and industrial policy can contribute to encouraging innovation and increase the competitiveness of the European pharmaceuticals industry, while also meeting health and social objectives. In the spring of 2002, the G10 agreed on 14 recommendations linked with the conditions for innovation, the supply of pharmaceuticals and the regulatory framework of the internal market. In addition, the development of indicators for international comparisons and monitoring were proposed. These indicators should cover research, use of pharmaceuticals and development of the industry.

EU Member States, on the initiative primarily of the European Commission and the industry, have tried to concretise and implement the G10 Report recommendations in national legislation. During the autumn of 2005, the Commission initiated a Pharmaceutical Forum which, in line with the Lis-

bon strategy, has the objective of absorbing three important sectors not covered by the G10. These are patient data, the issue of objective compliance compared with existing therapies, and price and subsidy systems. The forum will include representatives from all member states as well as other key actors with the objective of developing concrete measures to stimulate the development and growth of the pharmaceutical industry. The first meeting can be expected to be held during the first half of 2006. The British Presidency of the EU intends to initiate a process to monitor G10 work. It is important for Sweden, both public bodies and the business sector, to take an active part in these monitoring activities. The monitoring results should be assimilated by stakeholders and be the subject of discussion in the dialogue forum described above.

*Ministry of Health and Social Affairs,
the Ministry of Industry, Employment and
Communications and the industry*





The Global Picture

Sweden has a very strong position in the field of pharmaceuticals, biotechnology and medical technology, despite the fact that the domestic market for the products of most of the enterprises concerned is small. The industry that operates in Sweden is global in nature and highly influenced by international trends, initiatives and events. The industry is very dynamic and the biggest changes that have occurred or are ongoing include:

- ▶▶ International consolidation of the industry which has changed the competitive situation and affected the close ties between Sweden and certain enterprises, the major decision-makers of which had previously been located in the country.
- ▶▶ Major investments in life science research contribute to a rapid increase in the volume of knowledge and increased competition for Swedish research environments.
- ▶▶ Increased focus on research in major projects and with advanced technology platforms.
- ▶▶ New knowledge and technology creates scope for new products, services and production processes which have yet to make a major impact.

The major specific trends for the sectors involved include:

- ▶▶ A diminishing number of totally new approved medicinal substances.
- ▶▶ Major medical technology enterprises are investing in uniform systems which integrate different functions.
- ▶▶ Increased demands from major pharmaceutical companies for biotechnology companies in the field of drug development to take their drug candidates further in clinical trials before cooperation agreements are concluded.

The pharmaceutical industry

During the last 10 years there has been a wave of mergers in the global pharmaceutical industry leading to ever larger pharmaceutical enterprises. The new major players can still be found to a great extent in the countries in which the companies party to the mergers existed historically. Most enterprises have extensive business in the US which is by far the

largest market and where the prices which industry obtains for pharmaceuticals are highest. Companies also choose to invest in the US largely because of the powerful research environments there. A number of factors have led to pharmaceutical industry investments in R&D being currently greater in the US than in Europe, which was not previously the case. Companies also increasingly set up in growth markets such as China and India. According to the European Commission, approximately 38 per cent of all pharmaceuticals are produced in Europe (the equivalent of EUR 160 billion), 30 per cent in the US and 20 per cent in Japan.

The global pharmaceutical enterprises need to increase their innovative capacity in order to safeguard their future competitiveness. One sign of diminishing innovative capacity in the pharmaceutical industry is the dwindling number of applications for the registration of new drugs which reach the regulatory bodies in the EU and the US. The number of approvals of totally new pharmaceutical substances is also diminishing. That can partly be explained by the increasing costs of pharmaceutical development, which can be as much as USD 1 billion per drug. It often takes more than 10 years to develop a new drug, while less than one tenth of projects entering clinical trials result in a new drug. The enterprises are currently reviewing their organisation in order to increase internal innovative capacity and also to improve cooperation with researchers at universities and university colleges and biotechnology enterprises.

With its long tradition of clinical research, Sweden has been attractive for investment by the pharmaceutical industry in clinical research and clinical trials. But competition in this field from for example the Baltic Countries and South-East Asia, as well as from China and India, is now growing.

The medical technology industry

Medical technology products (MTP) comprise e.g. pacemakers, X-ray equipment, orthopaedic implants, dental implants, mobility aids (wheelchairs, walkers, crutches etc.), laboratory medicine, self-test kits, dialysis equipment, respirators, ECG apparatus, certain means of birth control, syringes, cannulae and dressings/bandages. During the last decade, the medical technology industry has also undergone extensive international consolidation. Major multinational companies have



bought up smaller enterprises in order to enter new markets, add to their product range or buy up competitors.

The industry trend is increasingly towards selling uniform systems that integrate different functions, making it more difficult for smaller players who sell only parts of such a system. The medical technology industry in Sweden is of the view that the regulatory demands relating to its products have been tightened in recent years. In order to enter international markets, products must both prove their value in clinical trials and demonstrate that investment in them is cost-effective. Close familiarity with the health service organisation in different countries and the different systems of reimbursement for existing products in the field of medical technology is a necessity for both large and small companies trying to reach the international market.

The biotechnology industry

Biotechnology can be defined as the technological exploitation of cells and their component parts in order to analyse, produce or modify products. The biggest industrial breakthrough in biotechnology has been in the development of new drugs, different medical treatments and diagnostics, as well as in plant-breeding and as regards equipment and instruments for biotechnology research, development and production. Both environmental arguments and the scope for developing new functionality and hence greater added-value lead to more business sectors benefiting from developments in life sciences. In this context, the application of biotechnology in forestry is of particular interest for Sweden. Life science research will also play an increasing role in the development and production of chemicals, new materials and energy production based on renewable raw materials.

Biotechnology enterprises that develop new pharmaceuticals and other medical applications

The traditional pharmaceutical industry uses biotechnology to a significant extent for R&D. In parallel with the development of major global pharmaceutical enterprises, many new biotechnology companies focusing on pharmaceuticals have also been set up, mainly in the US and Europe. The business idea of these companies is most frequently to sell the knowledge they build up to larger drug companies – either through licences, cooperation agreements or through being bought up. In the field of drug development, biotechnology enterprises therefore play a complementary role in relation to the major drug companies. Some of the enterprises also have a strategy to build up sales organisations for their own rights, or rights which they have obtained through licences, to what are known as niche-drugs.

The number of approved drugs based exclusively on the use of biotechnology, from cloning of the right genes to production with the aid of suitable host cells, is increasing. The

fact that biomolecular drugs are currently relatively expensive to produce and more complicated to administer to the patient is causing the pharmaceutical industry in a number of cases to drop such lines of development. However, there is a trend towards lower production costs and for products to be targeted at new patient groups and also treatments for which there are already existing drugs. The value of the global market for biotechnologically produced drugs is estimated to be in the order of USD 30–36 billion according to a study from Biotech Valley, which is approximately seven per cent of the global drug market.

Green chemistry using biotechnology

Industrial biotechnology, known as “white biotechnology”, involves the use of biotechnology applications in the production of chemicals, materials, paper, pulp, food, animal feed, fuel and propellants. It is carried out using enzymes or micro-organisms. According to the European Commission, Europe is bigger than both the US and Asia when it comes to chemical industrial products. In future, it is most likely that a large proportion of the products and goods we buy will have originated in renewable raw materials. The most important driving forces are the high price, and the expected future shortage of oil (oil is currently the raw material for most organic chemicals). A more effective and more diversified use of renewable raw materials is therefore highlighted as a necessary development by most industrial nations. The initiative known as the “European Technology Platform for Sustainable Chemistry” has identified the industry’s difficulty in integrating new life science knowledge into its activities as the chief obstacle to the breakthrough of biotechnology in the European chemical industry.

The forestry, pulp and paper industry

In recent years, a merger and consolidation trend among enterprises in the forestry, pulp and paper industry has created ever-larger multinational enterprises, and their links with Sweden are weaker than they used to be. The raw material is still to be found in Sweden but its further processing can be carried out wherever the conditions are best. Biotechnology has so far not made any major impact on this sector but expectations for the future are considerable, chiefly as regards increased use of enzymes in production processes, finishing, coating and the development of new fibre composites.

Agrobiotechnology

The world market for biopesticides is estimated at approximately USD 600 million, increasing annually by 10–20 per cent. This can be compared to the total world market for conventional pesticides, which is estimated to be between USD 30 and 35 billion with an expected growth rate of 1–2 per cent.

Genetically modified (GM) crops are cultivated in large parts of the world, chiefly in the US (approximately two-



thirds of the GM-cultivated area in 2003), Argentina, Canada, Brazil and China. Genetic modification relates chiefly to improving the crops' resistance to insect attack and tolerance of herbicide application and has led to bigger harvests compared with conventional crops. The cultivation of GM crops in 2003 amounted to about 20 per cent of the total global crop cultivation area (primarily soya, maize, cotton and rape-seed) and the proportion has increased over the last decade. R&D is currently in progress regarding for example GM crops which yield non-allergenic foods, the medicinal substances from GM crops or GM livestock, GM fish for food production and GM trees for the production of special products.

Research, development and trade – initiatives, cooperation and agreements

The European Union

In April 2005 the European Commission put forward a proposal for the Seventh Framework Programme which is planned for the period 2007–2013. Swedish researchers in the field of life science achieved a high rate of participation in the EU's Sixth Framework Programme for research and development. In the sub-sector 'Life Science, genomics and biotechnology', about five per cent of the available funds have gone to Swedish participants, the majority of whom are university and university college researchers.

To encourage the industry's research efforts, the Commission has invited the industry to form what are known as European Technology Platforms, the objective of which is to draw up programmes in support of the industry's long-term requirements for research. The Commission wants to identify sectors which have made particular progress and have the ambition to set up so-called Joint Technology Initiatives (JTI) which can be a future new tool in the Seventh Framework Programme. One such area identified by the Commission is Innovative Medicines. The purpose is to identify and over time remove bottlenecks in European drug discovery and development. Together with the industry and other actors in the life science sector, the Government should work towards successful participation in the life science-relevant sectors of the EU Seventh Framework Programme, including the Innovative Medicines Initiative, if it is implemented.

The G10 High Level Group on Innovation and Provision of Medicines agreed in the spring of 2002 on 14 recommendations related to conditions for innovation, the supply of pharmaceuticals and the functioning, competition and regulation of the internal market. A number of measures were dealt with in the context of the review of European pharmaceutical legislation in 2004, which in turn influences legislation in individual Member States. In addition, the development of indicators for international comparisons and monitoring was proposed. These indicators should cover research, use of pharmaceuticals and development of the industry. The G10

work was formally concluded during the summer of 2004. On the initiative of, chiefly, the Commission and the industry, EU Member States have tried to concretise and implement the 14 recommendations in the G10 report.

A bill drafted by the Ministry of Health and Social Affairs is to be presented to the Riksdag at the beginning of 2006. Its purpose is to implement four EC directives in the pharmaceutical sector. These relate to traditional plant-based medicines, the institution of Community regulations both for human medicines and for veterinary medicines, and the marketing of drugs. It is proposed to give legislative effect to the relevant parts of the directives primarily through amendments to the Medicinal Products Act (1992: 859).

During the autumn of 2005, the Commission initiated a Pharmaceutical Forum, the object of which, in line with the Lisbon strategy, is to absorb three important sectors not covered by the G10 work. These are patient data, the issue of objective compliance compared with existing therapies, and price and subsidy systems. The Forum will include representatives from all Member States, as well as other key actors, with a view to developing specific measures to stimulate the development and growth of the pharmaceutical industry. The first meeting is expected to be held during the first half of 2006.

As regards stimulating company investments in R&D, a number of European countries employ various forms of tax incentives. In France a special taxation status, "Young Innovative Company" (YIC), has been introduced and in the UK there is a tax allowance of 150 per cent for costs related to R&D. The UK aims to increase the ratio of R&D investments/GDP by 40 per cent between 2004 and 2014.

Cooperation, agreements and efforts on the global level

Both research and enterprise in life science are global in character. Within the framework of GATT, now reconstructed as the WTO, a number of sector agreements were reached, for example for pharmaceuticals and medical equipment. Under these agreements, the signatory countries levy no customs tariff on stipulated pharmaceuticals and medical equipment. In 2003, approximately 81 per cent of Swedish pharmaceutical exports and approximately 77 per cent of medical equipment exports went to countries which are party to sector agreements (this relates to exports to countries outside the EU). All WTO members, including those that have not adopted the agreements, are entitled to exemption from customs duty when pharmaceuticals or medical equipment are imported into one of the signatory countries. However, the principle does not apply conversely. Discussions on these sectors are in progress in the current negotiating round in Geneva.

Sweden has had strong research contacts with the US and they can be expected to continue and develop. Japan, China and other countries in Asia also play a growing role both as sources of knowledge and technology and as markets



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for drugs, biotechnology and medical technology. The US and Japan are investing major resources in building up the technological platforms for large-scale biology and currently command a number of the most advanced facilities in the world. It is important that Swedish researchers should strive to develop cooperation with the leading research environments globally, irrespective of where they are. A further reason why R&D cooperation with the US and Japan is of interest, is that companies in these countries can be expected to account for the major part of the foreign direct investment in Sweden in the fields of pharmaceuticals, biotechnology and medical technology.

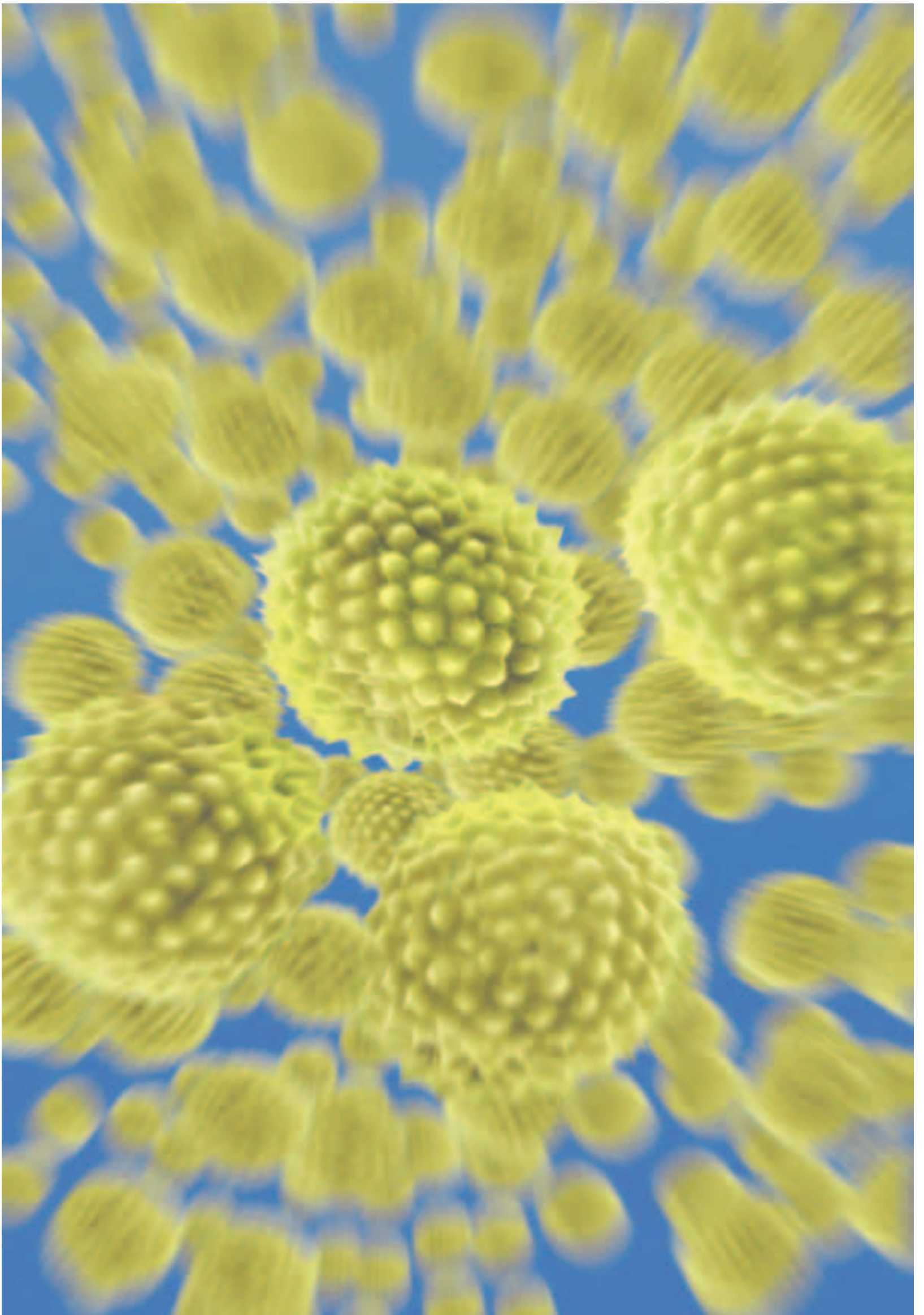
In many countries, major investments have been made in the life science sector. That is particularly evident in the US. For example, the budget for the National Institute of Health (NIH) has doubled in the last decade and now amounts to approximately SEK 200 billion per annum. The NIH places great emphasis on appointing researchers from non-life science disciplines to work on life science questions. Another trend is for the NIH to implement major projects with combined expertise from many different research groups spread over the whole country and with offshoots abroad. In addition to the changes which have taken place within the NIH, private foundations and donations have also played an important role.

After having played a relatively modest role in the international "Human Genome" project, Japan instituted a national

campaign at the end of the 1990s, with a view to playing a significantly more central role in functional genomics and related sectors. One of the consequences of this is that the Institute for Chemical and Physical Research (RIKEN) now is being completely dominated by life science. The UK, Canada, Australia, France and the Netherlands are other countries which have made major efforts in life science research and in genome research in particular. "Genome Canada" is an investment in genomics and proteomics which the Canadian Government has contributed CAD 600 billion in support. This investment is co-financed by industry and the participating regions. Several countries which have not previously focused on life science such as Singapore and South Korea, have also in recent years given priority to this sector. Among the Nordic countries, Finland and Norway have increased funding on a per capita basis, while Denmark has reduced it.

As regards the situation in clinical research in different countries, examples can be cited from the UK where active discussion and work has been in progress for a relatively long time. This has resulted in measures and programmes of cooperation between research councils, industry, researchers at universities and university colleges, central government and county councils, in the form of "Public – Private Partnership" programmes. In the US, the National Institute of Health (NIH) has a key role in clinical research, as reflected also in the "NIH Roadmap". Several similar activities also exist in other countries, such as the Netherlands.





The Outlook for Sweden

The Swedish pharmaceutical, biotechnology and medical technology industry

There are approximately 800 enterprises in Sweden, the core skills of which are within the field of pharmaceuticals, biotechnology and/or medical technology. The largest enterprises are AstraZeneca, Pfizer, GE Healthcare, Gambro, Siemens-Elema, Fresenius Kabi, Getinge, AstraTech, Pharmacia Diagnostics, Biovitrum and Octapharma. These 800 enterprises have just over 40,000 employees², more than 15,000 of whom work in production. Enterprises within this field hence create many highly qualified research jobs. In addition to these 40,000, there are a large number of consultants and subcontractors indirectly active within the pharmaceutical, biotechnology and medical technology industry. If these professions are included, the number of people employed within the sector is considerably greater.

The enterprises are to be found almost exclusively in regions that have universities and university colleges with strong life science research. Nearly 60 per cent of the employees are found in the Stockholm-Uppsala region. Other strong regions are Skåne and western Sweden close to Göteborg. The industry is also experiencing growth around Umeå University and in Linköping. All these regions have different profiles and strengths and each of them employs various initiatives to stimulate a positive development of the industry.

In terms of the number of employees in the industry, the largest regional initiative is Medicon Valley, which includes Skåne and the Copenhagen region. Other cluster initiatives are UppsalaBIO, Stockholm Bioregion, GöteborgBIO and MedCoast Scandinavia including the Göteborg-Oslo Region, Biotech Valley within biotechnological production in Mälardalen, Biotech Umeå and BioMedley in Östergötland.

² Number of direct employees has been converted into the number of full-year jobs, resulting in the actual number of employees being approximately 20-30 per cent higher, i.e. about 50,000.

³ Enterprises working exclusively in marketing and sales.

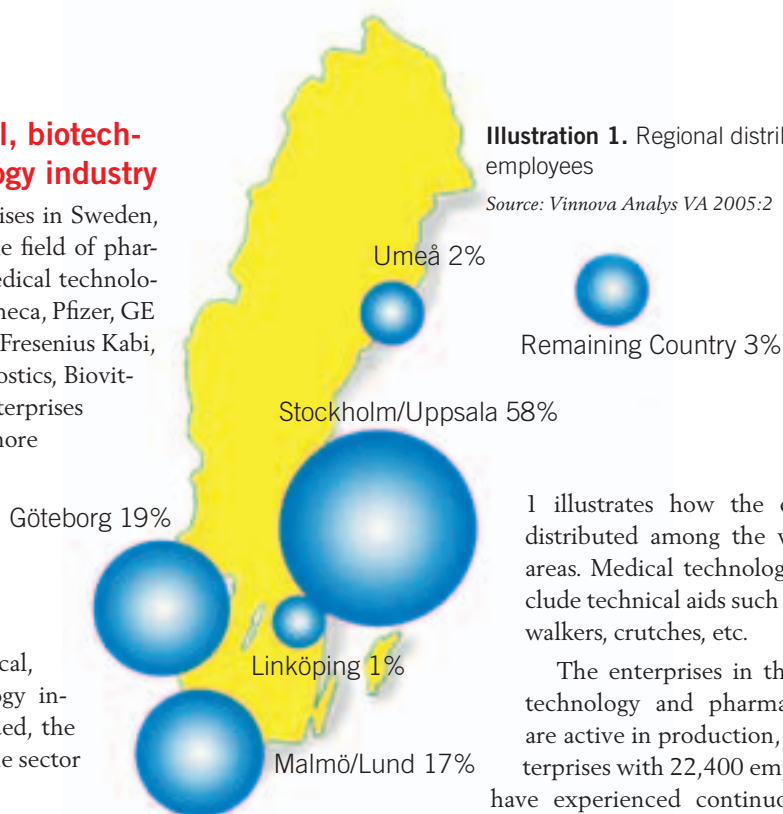


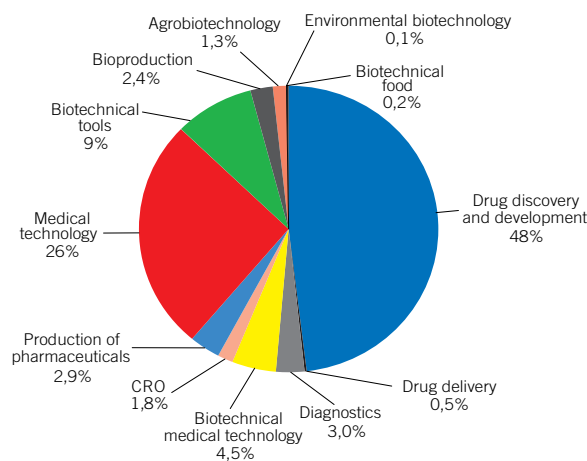
Illustration 1. Regional distribution of employees

Source: Vinnova Analys VA 2005:2

Diagram 1 illustrates how the employees are distributed among the various subject areas. Medical technology does not include technical aids such as wheelchairs, walkers, crutches, etc.

The enterprises in the field of biotechnology and pharmaceuticals that are active in production, R&D (216 enterprises with 22,400 employees 2003)³ have experienced continuous growth in the number of employees between 1997 and 2003. The total increase was 31 per cent or 5,300 new jobs, which corresponds to an annual growth rate of just under 5 per cent. The former Pharmacia enterprise has been sold to various owners since 1995 and now consists of 9 different enterprises. Between 1997 and 2003, however, the

Diagram 1. Distribution of the number of employees within various fields



enterprises combined has grown by 19 per cent in terms of number of employees, corresponding to an annual growth rate of three per cent. During the same period, AstraZeneca has increased its workforce in Sweden by just under 5.5 per cent per year. Biotechnology enterprises outside the AstraZeneca and the Pharmacia group as a group show the largest percentage growth in the number of employees between 1997 and 2003, 6.2 per cent per year, corresponding to an increase of 1,300 employees during the period. The greatest growth in the group of enterprises, both in terms of the number of enterprises and the number of employees, has occurred in pharmaceuticals and biotechnical tools and supplies. In a questionnaire survey conducted by the sector association SwedenBio in 2005, industrial leaders say that they have the potential to triple their revenue and increase the number of employees by nearly 40 per cent within three years.

In the longer term, biotechnology will also increase its importance for other Swedish industries such as the food, forest and chemical sectors. The integration of life science research has progressed furthest in the food sector but in just 5–10 years time, it may well have an impact on the development of high value added products in the paper and pulp industry.

In Sweden, exports made up about 43 per cent of GDP in 2004 and this share has increased since 1990 when the corresponding figure was 30 per cent of GDP. In international comparisons, Sweden is therefore a country heavily dependent on exports. The greatest share of revenue comes from the forest, pharmaceutical and telecom industries. Exports from high value-added sectors, such as the telecom and pharmaceutical industries, have grown dramatically during the 1990s. The pharmaceutical and diagnostics sector is a shining example of the growth in knowledge-intensive industries

in Sweden. Net exports of pharmaceuticals⁴ have risen from about SEK 0.4 billion to SEK 35 billion during the period, a remarkable development unmatched by any other product group. Pharmaceuticals⁵ currently make up about 20 per cent of Sweden's total net exports and medical technology⁶ is responsible for just over 2 per cent.

The Swedish business structure, with both large, global multinationals as well as small and medium-sized research enterprises, combined with their well-developed international networks and alliances, has considerable development potential. For major sections of industry, the consolidation trend as a consequence of globalisation has led to former Swedish enterprises becoming multinational and subsequently less well-rooted in Sweden. The likelihood of these enterprises making R&D investments and locating their production facilities in Sweden will increase if the efforts are concentrated to strengthen Swedish research environments and make the economic incentives for such investment more competitive.

AstraZeneca

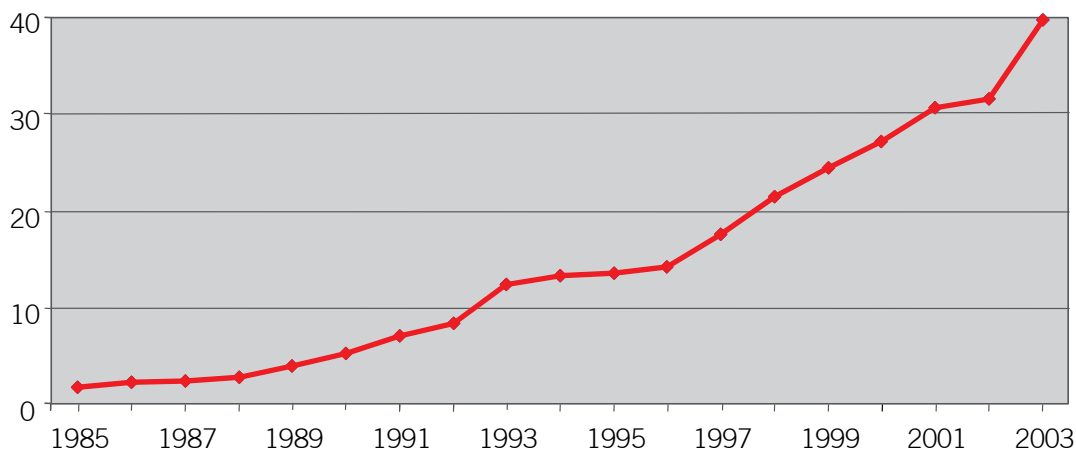
AstraZeneca is responsible for more than a quarter of the employees in the Swedish biotechnology, pharmaceutical and medical technology industry. The enterprise is a global pharmaceuticals group with its head office in the United Kingdom. Its R&D headquarters is still located in Sweden, however. 36 per cent of AstraZeneca's total R&D investment – the equivalent of more than SEK 10 billion per year – is made in Sweden. Only about 1.5 per cent of AstraZeneca's total sales revenue is generated on the Swedish market. The latter is however important for AstraZeneca as a reference market prior to the international marketing of its products. Since the merger between Astra and Zeneca in 1998, the enterprise has invested SEK 17.7 billion in Sweden and increased its workforce by 3,500, to about 13,000 in total in 2004. Around 5,500 of these are employed in R&D and about 1,100 hold a PhD. The number of employees has mostly increased in Södertälje and Mölndal, whilst the workforce in Lund has decreased slightly. Most new jobs have been gener-

⁴ Source: Statistics Sweden, Product classification 54, medical and pharmaceutical products, in accordance with SITCrev3.

⁵ Source: Statistics Sweden, Product classification 24.41, pharmaceutical base products and 24.42, pharmaceuticals; other pharmaceutical products, in accordance with Product-SNI97.

⁶ Product classification 33.10, medical, surgical and orthopaedic equipment.

Diagram 2.
Trend in Swedish net exports of pharmaceuticals and medical technology products 1985–2003 [SEK billion, current prices]



ated in R&D, although approximately the same number has been added in production. AstraZeneca's drug tablet factory in Södertälje is the largest of its kind in the world. The enterprise also generates large export revenue and in 2004, its gross exports totalled SEK 39 billion. License revenue coming into Sweden totalled another SEK 8 billion in addition to gross exports. AstraZeneca's contribution to total Swedish net exports in 2004 was approximately 20 per cent. It currently has 59 ongoing clinical trial projects, just under half of which are in their latter stages.

Biotechnical tools and supplies

Sweden has had an internationally competitive industry for products used in life science research, development and production for a long time. GE Healthcare (previously Amersham Biosciences) is one of the world's leading suppliers of these types of products. Biacore, an enterprise spin off from Pharmacia, has developed a successful and unique method of analysing biomolecular interactions. Many new enterprises have released their innovative products onto the international market relatively recently. Much of the innovation leading to new products is generated by academic research environments and multidisciplinary efforts are a key factor in this area.

Industrial biotechnology and pharmaceuticals production

The field of industrial biotechnology is expected to grow in Sweden. A case in point is a Swedish pilot facility outside the northern town of Örnsköldsvik, where cellulose is broken down into sugar and then fermented to make ethanol. Regulatory requirements and legislation can accelerate the process of replacing fossil raw materials with biomass. Sweden has access to raw materials but substantial investment is required for an increased use of biomass. Public-private financing of such investment is a way of spurring development in industrial biotechnology. Biotechnical methods for processing renewable raw materials compete with chemical technologies. Both of these are constantly being improved as regards productivity and environmental performance. The biotechnical production of pharmaceuticals is the sub-sector of industrial biotechnology that has progressed the furthest in Sweden. Sweden was among the first countries in the world to use genetically modified bacteria in the manufacture of pharmaceuticals. Large-scale production is underway at Pfizer in Strängnäs, for example.

Production constitutes just a fraction of the total costs involved in developing a new drug. When global pharmaceutical and biotechnology enterprises seek to optimise these costs, low-cost countries are seldom an option since the savings made on production have little effect on the total cost calculation. Sweden's strengths are advanced R&D and efficient, safe and high-tech production. The interaction

between the development of new drugs and their production is very strong, making it advantageous to have research, development and production in close geographical proximity. Positive examples of investment in production facilities in Sweden in 2005 include Pfizer's planning of an extension to its Strängnäs plant and AstraZeneca's investment in Mölndal. Another example is Advanced Medical Outputs, who, having bought Pfizer's production plant for Healon (a product used in eye surgery), is now investing in R&D in Uppsala. These investments benefit Sweden in two ways: firstly, production that is not so sensitive to competition from low-cost countries is established, and secondly, it strengthens the ties between R&D and the country.

Food, agrobiotechnology and environment biotechnology

Biotechnology is expected to be utilised to an ever-greater extent in all industries working with biological raw materials. Quality and safety are profile areas for the Swedish food industry and life science research can, for example, provide new knowledge as to the connection between diet and health and help develop new methods of analysing food quality.

There is currently only a handful of biotechnology enterprises (including Probi and Biogaia) within this field and a few mature companies have been part of this development as active customers and cooperation partners (e.g. Skåne-mejerier and Karlshamn). In the food industry, technical development is often based on interdisciplinary efforts combining food development with medical research, nutrition, new packaging and material, microtechnology and sensors.

Swedish research into genetically modified forests is currently conducted mostly at universities and university colleges. Regarding the increased use of biotechnology for forest industry purposes, there is innovative Swedish research linked to the commercial activities of SweTree Technologies AB. Concerning agricultural products for purposes other than food, there is Plant Science Sweden AB, a subsidiary of Svalöf Weibull and BASF in Germany. As regards the potential for genetically modified plants in agriculture and forestry, both the economic potential and the ongoing discussion on the benefits and drawbacks of the technology should be considered.

Biotechnology can potentially help to improve environmental quality in a number of different ways. Environmental measurement technology, bioremediation and the development and production of new materials based on renewable sources from forestry or agriculture are examples of this. Research is also being conducted into the use of biological processes in waste management.

Other applications

It is difficult to predict what impact knowledge of biological systems will have on industries not currently associated with life science. Internationally, both the automotive industry



and the electronics industry, have started using biologically degradable plastics manufactured using biotechnical methods from renewable raw materials. There is also development potential linking the construction of robots, cognitive science, brain research and biomechanics and for being able to mimic biological systems artificially. The foundation for widespread use of life science needs to be laid now, even though the financial effects will not be felt by Sweden for at least another ten years.

Corporate financing and investment in Sweden

Many of the enterprises are relatively young. Long development phases and high R&D costs mean that many of them are dependent on risk capital for a relatively long period of time. There are currently several specialised venture capitalists in this field in Sweden. Venture capitalists and international capital work in countries where the best objects of investment are available. There is considerable foreign capital invested in some of the funds managed by Swedish venture capitalists as well as substantial direct foreign investment. Since 2000, national and international venture capitalists have invested about SEK 10 billion to develop Swedish enterprises in the pharmaceutical, biotechnology and medical technology industry. The venture capitalists assess the potential for being able to divest their holdings at a profit further down the line. This assessment includes a technical appraisal of whether the idea is economically sound, an evaluation of the product's potential markets as well as a review of the prevailing investment climate in the country in which the object of investment operates. Volatile venture capital is affected by terms and conditions under which the enterprises operate, since these in turn affect their potential for becoming an attractive object that can be divested at a later stage. The investment can be divested either by floating the enterprise on the stock market or selling it to industrial owners.

Many enterprises found it difficult to acquire venture capital during 2001-2003, but there are signs that this is beginning to change for the better. In addition to early financing, long-term ownership and access to expansion capital are very important to this industry. Expansion capital may be needed when it is time for a big market launch or when the enterprise wishes to take its clinical trials a step further. Few enterprises in this sector have been floated on the Swedish stockmarket in recent years, but a number of Swedish enterprises have been sold to foreign owners.

Medium-term growth is determined by already successful enterprises, especially AstraZeneca. Development of the industry also depends on whether there is an efficient and professional infrastructure for commercialisation in place at universities and university colleges. This in turn determines whether new robust enterprises will emerge and grow. As regards the small enterprises, there are likely to be a certain

amount of consolidation over the next few years. In order for the sector to achieve a certain critical mass, the small and medium-sized enterprises must develop their business and grow.

In partnership with regional investment bodies, authorities and institutes, the Invest in Sweden Agency (ISA) has been running a three-year project for proactive international marketing, Bio Sciences, the aim of which has been to increase direct foreign investment in Sweden. The project was concluded in June 2005. The project has resulted in the setting-up of over 30 enterprises and just over 800 active enquiries about establishment. The project has also focused on strengthening already established enterprises.

Swedish life science research

A unique aspect of pharmaceuticals, biotechnology and medical technology is the strong link and interaction between scientific research, innovative enterprise and the health service. Specialised, modern biotechnology enterprises, which first emerged in the US during the 1970s, have been almost exclusively established in close collaboration with leading researchers, among them several Nobel prize winners. Many pharmaceutical enterprises have entered into major research agreements with research groups at universities and university colleges, a step seldom taken in other industries.

The fact that the pharmaceutical industry employed 30 per cent of all qualified researchers in private companies in Sweden in 2003 illustrates the strong position of research in the industry. The corresponding figure for female qualified researchers was 44 per cent. In contrast, for example, with the telecom and transport industries, where only 4-6 per cent of R&D work is performed by qualified researchers, the corresponding figure for the pharmaceutical industry is 25 per cent.

Sweden has been at the forefront of life science research for a long time. This has resulted in many world-leading innovations being of Swedish origin. The country has many internationally oriented scientists in research environments that are less hierarchical than in other countries and that are characterised by strong interdisciplinary collaboration. World-leading research has emerged through the efficient use of resources. Research in certain biomedical areas and into the development of biotechnology research methodology is particularly strong. An example of the quality of Swedish research environments in the biomedical field is Karolinska Institutet, which is number four on the list of the world's one hundred best biomedical universities according to the new rankings published by The Times Higher Education Supplement. Karolinska Institutet was behind Harvard, Cambridge and Oxford but in front of Stanford, Imperial College and John Hopkins University in the field of biomedicine. Sweden is also in the vanguard of public health and infection control research, which has led the heads of state and government of the European Union chosen Sweden as the site for the new European authority for infectious disease control. This



new authority will, when fully operational, have around 100 employees. It will also help the EU to improve coordination in the event of serious outbreaks of infectious diseases.

Successful medical research has helped build up a good international reputation, which facilitates the recruitment and retention of highly qualified personnel in both the health service and the research community. As far as the health service is concerned, the findings of clinical research can improve the standard of patient care. Access to high-quality clinical research is needed if the healthcare provided is to be evidence-based. Access to qualified researchers is also a precondition for new scientific discoveries and for new methodology to be integratable into healthcare. It is also needed in order to critically evaluate the methods and processes currently in use. Sweden's successful clinical research is also the product of the general public's openness towards participating in the development of new treatments, as well as the country's extensive patient and disease registers and biobanks. Investment in an efficient, high-quality health service has been a precondition of this development.

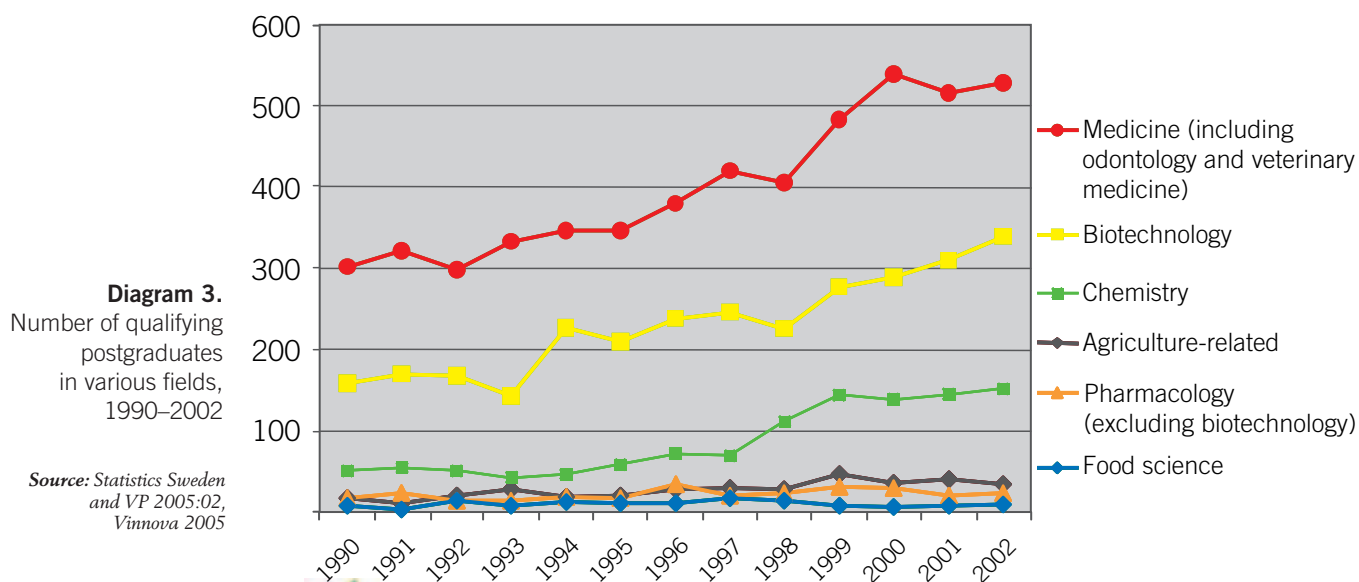
Within the field of pharmaceuticals, biotechnology and medical technology, there is a long tradition of collaboration between universities/university colleges and the business sector, which has laid the foundation for the successful products of many enterprises, including AstraZeneca, Pharmacia and Nobel Biocare. Many new enterprises have started as spin offs from research conducted at universities and university colleges. There has been good collaboration between the business sector, researchers at universities/university colleges, the health service, authorities and financiers, which in many respects has led to efficient innovation systems. Furthermore, there is increasing interest, especially among younger researchers, for the commercialisation of research findings and greater innovative thinking. The development unit DS Innovation at Danderyd Hospital in Stockholm is an example of how skills can be utilised within the health

service. Here, product ideas from healthcare personnel in the field of medical technology are harnessed with the aim of creating new products for the business sector.

Sweden is still very prominent in the field of life science as regards the publication of articles in scientific journals. Sweden is among the world-leaders when it comes to the number of articles published per capita. Over the last twenty years, however, many countries have advanced their positions considerably regarding the publication of articles in scientific journals. The US and the UK continue to be in the forefront whilst countries like the Netherlands and Finland have been catching Sweden up. A frequently employed quality indicator for articles is how often they are cited (referred to in scientific literature) by the research community after publication. In a study published in the Biomedical Journal, Sweden came top both regarding citation level and publication volume in relation to population and GDP in the field of biomedicine between 1994 and 2004.

The Swedish Research Council has performed a study (2005) of the conditions for Swedish clinical research compared with other countries. It shows, among other things, that the number of Swedish publications in clinical fields per capita has decreased over a ten-year period, whilst Japan, Italy, Germany, Austria, the Netherlands and Switzerland have all increased their relative share of this type of publication. Sweden's citation level has dropped during the period whilst those of Japan, Germany, Austria and Italy have all risen. In previous publications, the Swedish Research Council has indicated that the same downward trend is apparent regarding quotations of what is known as pre-clinical medicine.

For a number of years, the Swedish Society of Medicine has recorded the number of qualified doctors going on to gain PhDs in medicine. In 1988, 70 per cent of those gaining PhDs in medicine were qualified doctors, compared to 20 per cent in 2004. Modern clinical research demands skills from other fields such as molecular biology, cell biology, bioinfor-



matics and mathematics, which partly explains the increase in the number of students gaining PhDs in medicine who are not qualified doctors and the corresponding decrease in the number of those who are. However, the number of doctors gaining PhDs is also falling in absolute terms. In 2000, 306 qualified doctors gained PhDs whilst the corresponding number in 2004 was 217, a decrease of 30 per cent. Medicine is one of the fields with the highest relevance for the pharmaceutical, biotechnology and medical technology sector, although there are other important areas. The diagram below shows the number of people gaining postgraduate qualifications in a selection of relevant fields.

As diagram 3 shows (page 41), the increase in medical fields is 75 per cent; the number of people gaining postgraduate qualifications in biotechnology has more than doubled and in chemistry it has tripled, albeit from a considerably lower level. At the same time, it is important to increase the scope for recent PhD graduates to gain additional qualifications. In its 2006 budget bill, the Government has stated that a certain adjustment to the volume of postgraduate education might be appropriate from this perspective but that the number of graduates should remain high.

From the point of view of life science oriented enterprises, high-quality Swedish research is:

- ▶▶ A source of commercialisable ideas
- ▶▶ A necessary admission ticket to international research networks, which provide early and effective access to the knowledge and research findings being built up around the world

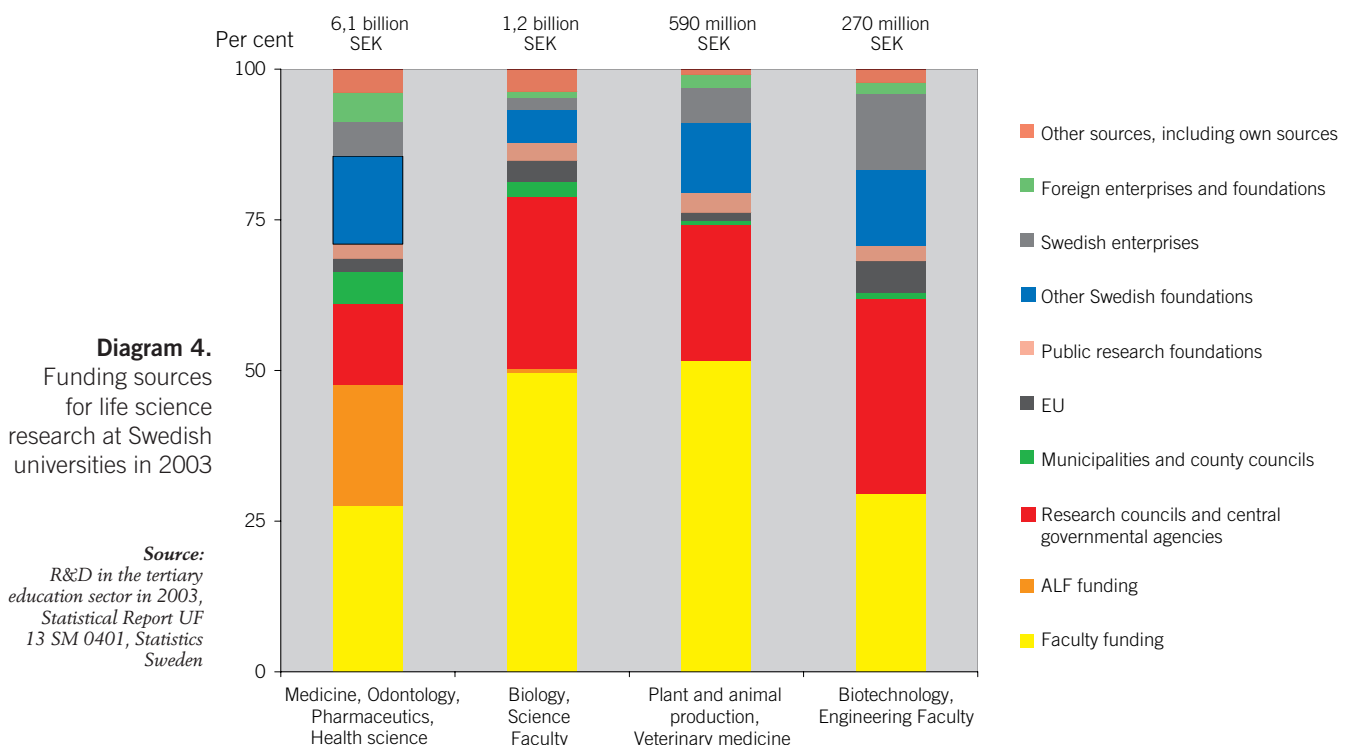
- ▶▶ A recruitment source for Swedish enterprises
- ▶▶ A reason for enterprises in the subject field to be in Sweden.

Research funding

Diagram 4 illustrates the funding sources for life science research at Swedish universities and university colleges, according to statistics from Statistics Sweden (SCB). For departments of medicine and biology at science faculties, government appropriations make up about 50 per cent of total funding (now allocated to specific scientific fields rather than to individual faculties and departments). The corresponding proportion for biotechnology at technical faculties is about 30 per cent, which is slightly less than average for technical faculties. Private foundations, such as the Swedish Cancer Society and the Knut and Alice Wallenberg Foundation, are an important source of funding for life science research in Sweden, and made up 13 per cent of total funding in 2003. This can be compared to 17 per cent from research councils and government agencies. Funding from public research foundations such as the Swedish Foundation for Strategic Research made up 3 per cent of total funding for life science research.

Funding from foreign enterprises to medical schools made up 58 per cent of total funding from foreign enterprises to life science in Sweden. In total, life science was responsible for two-thirds of all funding from foreign enterprises.

Diagram 4 refers to revenue for all types of research-related running costs within specified faculties and subject areas at



the universities. Since some of the costs are for premises or common facilities at the university, faculty or department level, most individual research groups feel their financial situation is considerably more dependent on project financing than is evident from the diagram.

In its research policy bill *Research for a better life* (2004/5:80), the Government presents a series of powerful initiatives for Swedish research that is important for welfare, growth and sustainable development. As a result of the proposals in the bill, government appropriations for research and postgraduate education have increased by SEK 2.34 billion during the 2005–2008 period. In the bill, the Government presents special investment initiatives for research into medicine, technology and sustainable development. Furthermore, resources for strong internationally competitive research environments have increased and the transfer of knowledge from universities/university colleges to the business sector have been strengthened. To meet the increasing demand for qualified postgraduates, the Government has announced investments in postgraduate education and more jobs for young researchers at universities and university colleges.

Strong research environments

The above-mentioned research policy bill also contains an initiative for major, long-term research appropriations to strong internationally competitive research environments. As a result of the bill, special funding has been allocated to the research councils and Vinnova (Governmental Agency for Innovation Systems) for this purpose. The initiative will cover both research environments where basic research is being pursued and research and innovation environments for needs-driven research. It should be possible to give up to SEK 10 million in support to a strong research environment for up to ten years. In addition to this support, universities and university colleges, research institutes, enterprises and other stakeholders are expected to contribute substantially with their own resources to support strong research environments. The Swedish Research Council and Vinnova currently collaborate on the allocation of funding to strong research environments, which they call Berzeli Centers. One aim is to stimulate the establishment of environments characterised by scientific excellence with innovation potential, i.e. basic research environments with a strong link to development of knowledge that can lead to new processes and products. For a research environment to be designated a Berzeli Center, participation from the business sector and the public sector is required. Representatives of the business sector are also involved in assessing applications.

Several other Swedish actors have already invested in strong research environments. These include the research councils, Vinnova and the Foundation for Strategic Research.

Research centres and institutes

There has been little major investment in the establishment of research centres or in equipment-intensive life science research in Sweden, the exception being the major investment (at least in Swedish terms) made by the Knut and Alice Research Foundation (KAW Foundation) in the field of functional genomics and bioinformatics and in the Human Proteome Resource. The extent of these five-year investment initiatives amounts to about SEK 1.75 billion.

Research at the Swedish Defence Research Agency (FOI) is aimed at expertise that deals with holistic solutions and complex issues based on the individual's need for protection against e.g. biological threats. Life science research can help find solutions to combat such threats. Examples of areas in which FOI is involved include environmental medicine, medical protection, toxicology and simulation.

Education and skills provision

In 2004, the National Labour Market Board performed a questionnaire study of the future skills requirement of Sweden's biotechnology enterprises. The majority of enterprises say that they will recruit more personnel over the next three years. They intend primarily to recruit personnel with more than three-years of tertiary education or postgraduate qualifications. It is also clear from the questionnaire study that the enterprises mostly require personnel with experience of the industry and preferably people who combine specialist skills with at least some knowledge of economics, marketing and the like. The enterprises also point to a lack of people in Sweden with skills and experience of international business development in this field. There is a particular lack of people with this expertise regarding the business development of smaller enterprises.

One of the priorities of Swedish research policy over the last decade has been to expand postgraduate education. The expansion in postgraduate education in life science subjects is clear from the statistics on the number of people gaining qualifications.

Quality work in the health service

An important factor in the development of the health service and for the healthcare industry is for the care service to adopt quality-oriented working methods. The concept of quality means, among other things, that healthcare must as far as possible be evidence-based. To ensure that the care creates the maximum possible benefit both for the individual patient and the society in general, it is also important for the results of administered treatments to be systematically followed-up on the individual, group and societal level. It is very important that the health service is given adequate scope to carry out such follow-up tasks. Such follow-up constitute the basis of evidence-based healthcare. The concept





of quality also includes each patient being entitled to an individual assessment and treatment that is as far as possible customised to fit his/her individual needs and conditions. Quality can also be enhanced by creating new knowledge in the form of research findings.

Various measures have been implemented over a number of years to try to reinforce quality efforts in the health service. On the central level, many of these measures have been aimed at putting evidence-based medicine into effect in Sweden. The Swedish Council on Technology Assessment in Health Care and its work on systematic knowledge banks, the National Board of Health and Welfare and its work on state-of-the-art documents and national guidelines, etc., and the establishment of the Pharmaceutical Benefits Board and its application of the concept of cost efficiency in order to make price and subsidy decisions are all worth mentioning in this context. On the county council level, we can also mention the work on designing and implementing various healthcare programmes and different measures aimed at improving the monitoring of healthcare activities and presenting the monitoring results openly. Databases used to monitor activities include Sjukvårdsdata i fokus (Healthcare data in focus), Vårdbarometern (The Healthcare Barometer) and Väntetider i vården (Health Service Waiting-lists). Initiatives are being taken to develop the methods and knowledge of the professional healthcare organisation. These include local change management and efficiency drives, modernisation of the fundamental structure, leadership and management of the health service.

An important source of quality improvement in the health service is the emergence and further development of what are known as quality registers. These registers contain information such as data on individual patients, their treatment and results thereof. The National Board of Health and Welfare has a coordinating responsibility to maintain the quality registers, of which there are currently 60 or so nationwide. The Board also has the supervisory responsibility for the registers. The Patient Data Commission is considering how the quality registers should be regulated by law as well as how they should interact with other registers and with how personal data is otherwise handled within the health service. In addition to quality registers linked to different diagnoses, it is also important for the county councils to be able to guarantee the quality of their medical prescription activities.

Central government, the municipalities and county councils have been working for a number of years to improve the quality of the health service and increase patient security. Two of the most important projects are the "InfoVU Project" run by the National Board of Health and Welfare in close cooperation with the Swedish Association of Local Authorities and Regions and the establishment of a National executive for IT in the health and community care services. In order to create a common structure for information transfer and open reporting of results (as part of the InfoVU project), the National

Board of Health and Welfare is developing quality indicators for healthcare and medical product use. These indicators are intended for use both to describe what is considered 'good healthcare' and to monitor and measure the results attained by the health service. Reporting the side-effects of medical products may also be included as a quality indicator.

The health service has a responsibility to ensure that the healthcare it administers is appropriate and cost-effective based on current knowledge, thereby creating the conditions for the future introduction of new, more expensive, but more cost-effective for society as a whole, treatments.

In its autumn 2004 budget bill, the Government brought attention to the issue of quality in the health service as follows: "The county councils have been making active efforts during the period to achieve rational and cost-conscious use of pharmaceuticals. These efforts have also helped to curb the rate of cost increases. It is important, however, that the county councils allow new, more expensive medical products, which are adjudged to be cost-effective by the Pharmaceutical Benefits Board, to be prescribed to and used by patients who need them."

Regarding the prescription of new drugs, the current situation is somewhat of a balancing act. On the one hand, we have the county councils cost-efficiency assessments of new drugs, their endeavours to attain rational drug use and their responsibility for patient safety. On the other, we have the interests of the pharmaceutical industry, who want the products in which they have invested money to develop and which have been found to be suitable by the authorities responsible for the control and approval of drugs, to be used in the health service and generate revenue for enterprises. A third important factor in this context is the patient's expectation of receiving the best possible treatment.

There are regional initiatives aimed at increasing collaboration between the business sector, researchers and the public sector. The region of Västra Götaland is a case in point. It has recently initiated a project called "More effective healthcare and economic growth". The first phase of the project includes sector discussions well attended by representatives of the business sector, academia, the health service, venture capitalists and politicians.

Regulatory frameworks

Pharmaceuticals and medical technology products – from clinical trials to sales

The Medicinal Products Act contains the fundamental provisions governing pharmaceuticals. It also contains special provisions governing clinical trials of pharmaceuticals. In order to conduct clinical trials of a pharmaceutical product, both approval from the Medical Products Agency and from an ethics committee is needed, see illustration 2 (page 46).



The aim of a clinical trial is to comprehensively test a trial drug out on humans in order to guarantee its safety and/or effect. A potentially new medical product undergoes clinical trials for several years. It is normally first tested on healthy people, then on a small group of patients who suffer from the disease in question and thereafter on large groups of patients in major comparative studies. The aim of a trial can be to discover or verify clinical, pharmacological and/or pharmacodynamic effects, and/or to identify possible side-effects and/or to study absorption, distribution, metabolism and secretion of one or more trial drugs.

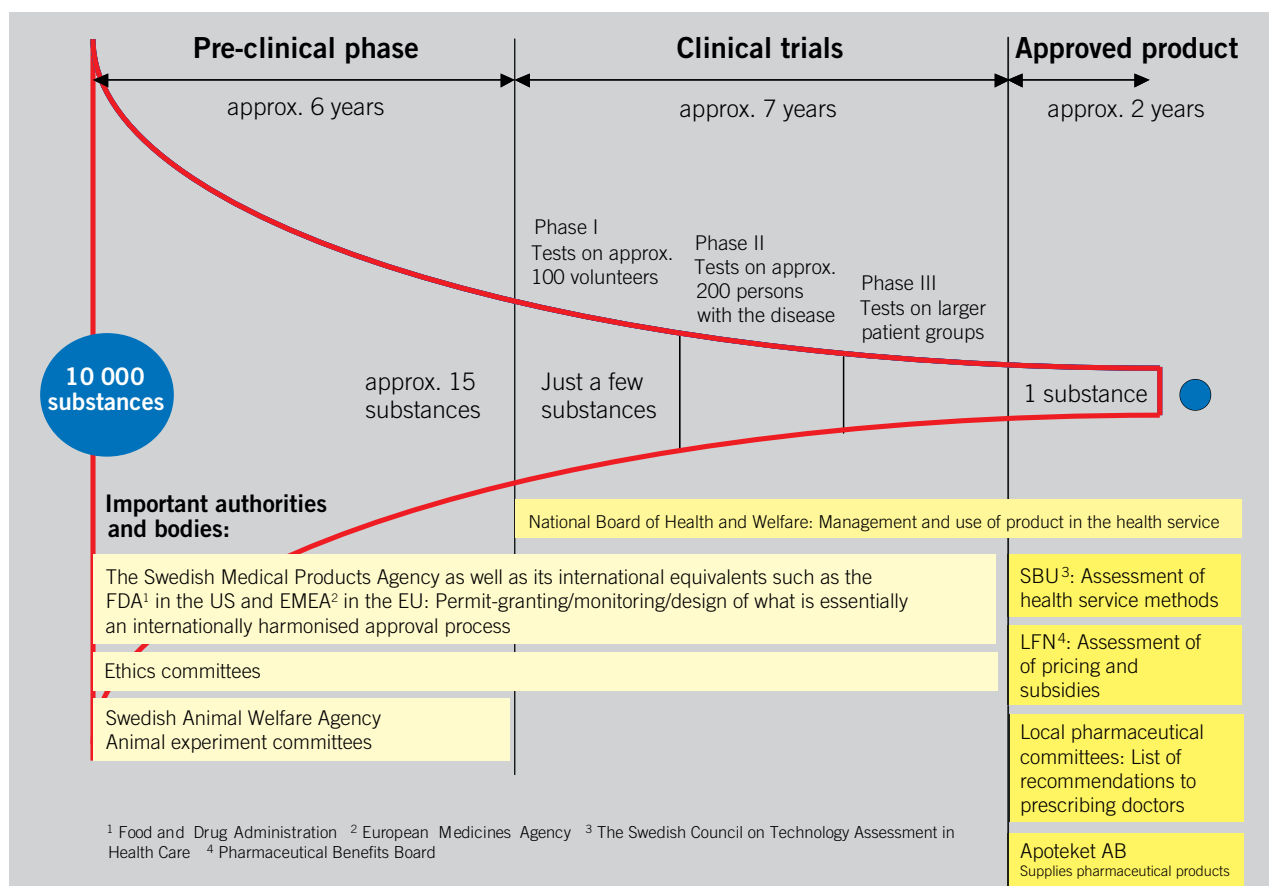
When a drug has been approved for sale by the Medical Products Agency, the enterprise in question may apply for the drug to be included in the Pharmaceutical Benefits Programme, i.e. be subsidised. This application is submitted to the Pharmaceutical Benefits Board, which decides on price and subsidy. Apoteket AB (The state pharmacy monopoly) must stock all medical products approved for sale. A precondition of this, however, is that the enterprise in question keeps the drug in stock itself.

When the drug has reached the market, the Medical Products Agency tracks its use and provides prescribers within

the health service with information and treatment recommendations. It is particularly important to constantly monitor a drug's side-effect profile and take action where necessary. There is well-developed cooperation within the EU as regards monitoring the side-effects of medicinal products. Through their medical product committees, the county councils assist prescribers by collecting, evaluating, disseminating and monitoring knowledge about medicinal products. The Swedish Council on Technology Assessment in Healthcare (SBU) evaluates healthcare methods and works to provide scientifically reliable answers to questions such as: What is the best treatment? How can the diagnosis best be established? How can the resources of the health service be utilised to create the best possible benefit? SBU evaluations also cover non-medicinal treatment methods.

Effective medicinal product use presupposes that there is an incentive for enterprises to choose to invest in the R&D of new pharmaceuticals as the costs involved can be quite considerable. A patent guarantees the holder exclusive rights to the developed drug for a period of 20 years calculated from the date of patent application. In the EU, a patent can be extended for a maximum of a further five years (known as supplementary

Illustration 2. From clinical research to sales



protection). There is parallel trade of patented pharmaceutical products within the EU as a result of varying price levels in different member states. When the patent or supplementary protection has expired on a pharmaceutical product, other enterprises are free to produce their own generic copies of it. About 25 per cent of the approved medicinal products on the Swedish market are currently generic copies.

Estimates indicate that there are around 500,000 different medical technology products (MTP) on the market. The Medical Products Agency deals with applications for clinical trials of MTP and maintains MTP registers. Prior to a MTP being released onto the market, a manufacturer must submit a signed affidavit that the product's properties are in accordance with the formulated requirements, along with CE-labelling for the product. When a MTP has reached the market, the Medical Product Agency monitors how the manufacturer deals with accidents and near-accidents and inspects manufacturers and national notified bodies.

Statutory regulation governing the ethical assessment of research involving humans came into force on 1 January 2004. This regulation is primarily incorporated in the act concerning the ethical assessment of research involving humans, but there are also certain ordinances establishing the framework for how trials are to be performed and containing instructions for the responsible ethics committees. Under the above-mentioned act, research covered by it may only be conducted pursuant to approval by an ethics committee. Ethical assessment procedure is based to a considerable degree on the Convention on Human Rights and Biomedicine of the Council of Europe. The act also contains detailed provisions governing information and consent.

Genetically modified crops

Genetically modified organisms (GMO) are regulated in the EU by a regulatory framework comprising Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, Regulation (EC) no. 1829/2003 on genetically modified food and feed and Regulation (EC) concerning the traceability and labelling of GMO. This regulatory framework shall among other things guarantee that the GMO on the market constitute no risk to human and animal health nor to the environment and that the consumer has a free choice between a GMO product and a conventional counterpart. It shall be possible to trace GMO products along basically the entire feed and food supply chain. In Sweden, the Swedish Board of Agriculture is the competent authority regarding genetically modified (GM) crop applications.

Up until 1998, 13 GM crops had been approved (including variants) in the EU and GM maize that was approved before 1998 is still cultivated in Spain and Portugal. During 2001–2003, European legislation governing the permit procedure for cultivating genetically modified organisms

(GMO) was revised (Directive 2001/18/EC). New EU regulations governing GMO for food and feed and for traceability and labelling were also drawn up. The new regulations place tough requirements on health and environmental safety, labelling and traceability along the entire food and feed supply chain. Up until the summer of 2005, about 20 applications concerning GM-crops have been approved in the EU. These have primarily concerned the import and processing of animal feed. The first cultivation cases after the legislative revision are expected to be voted on during 2006. Swedish enterprises have applied for GM-crop approval in the EU, including one concerning potatoes for industrial use.

Animal experiments

Fundamental research is a precondition for the development of society. As far as the Swedish business sector is concerned, investment in R&D is crucial to international success. The pharmaceuticals sector is one of the industries that has invested the most in R&D in Sweden. The pharmaceutical industry, like those pursuing research at universities and university colleges, is endeavouring to restrict the use of animal experiments by developing alternative methods, such as computer simulation or cell-based systems for e.g. toxicological studies. In addition to the alternative methods currently used, it is often necessary to have the option of animal experiments when pursuing life science research.

It is important to restrict the use of animals in experiments as much as possible and to guarantee their welfare and protection in cases where they are used. Swedish animal welfare legislation expresses a basically restrictive attitude to the use of animals in experiments and considers on the one hand the need for such experiments and on the other our responsibility towards animals and their health and well-being. Provisions governing the use of vivisection are to be found in the Swedish Animal Welfare Act (1988:534), the Animal Welfare Ordinance (1988:539) and in regulations enacted by the national agency responsible. Under the basic provisions, animals may be used in experiments only if the purpose of their use cannot be achieved through any other satisfactory method; as few animals as possible must be used; experiments must be designed so as not to subject the animals to more suffering than is absolutely necessary; and no animals other than those explicitly bred for the purpose may be used.

A new provision in the Animal Welfare Ordinance (49 a §) has been incorporated in order to clarify the content of the legislation. The import of the new provision is that animal experiment ethics committees may approve experiments that deviate from the provisions in the Animal Welfare Ordinance and regulations issued pursuant to the ordinance. A political agreement has since been struck between the Government and its coalition partners. Under this agreement, the provision in 49 a § shall be abolished no later than 15 March 2006 and be replaced by new provisions.





Patents

Patents play a crucial role regarding innovations and economic actions. Patent protection provides the conditions for enterprises to be able to exploit and commercialise their innovations to a greater degree both nationally and internationally. Within the field of life science which is in an expansive stage and playing an ever-greater role in a number of industrial sectors, the patent system is of crucial importance for development.

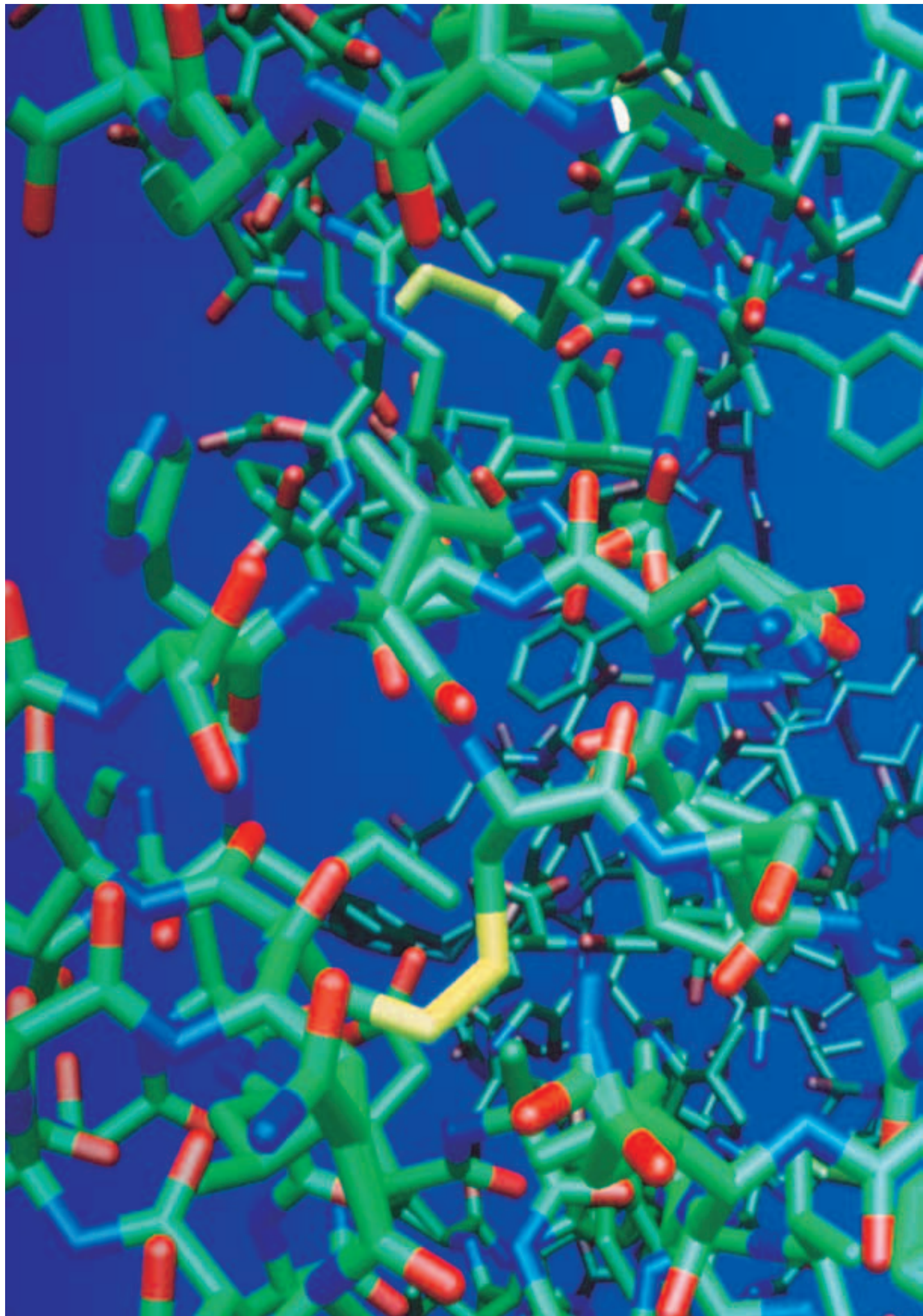
Opportunities for protecting biotechnical discoveries by patent have been available for quite some time. As a result of developments in the life science field in recent years, the number of patent applications has risen dramatically, not least in the area of genetic engineering.

There is broad consensus that effective protection, regarding genetic patents for example, is a necessary precondition for the development of new pharmaceutical products. The claim that patent protection as a whole fulfils its function within the life science field also has widespread

support. At the same time, however, there are misgivings that the protection, if it becomes too broad and strong, may be counterproductive and hamper development and access to new knowledge and technology. These issues are currently the subject of an ongoing commission, *Follow-up on patents for biotechnology inventions* (directive 2005:2). The idea is to follow the development of practices and the effects of patents in the field of biotechnology on healthcare and research. Patents for genetic inventions shall receive particular attention. Regarding the application of what is known as "unlimited product protection", the assignment is to be reported no later than 1 July 2006.

A second ongoing commission concerning patent issues and which should be mentioned in this context is *Review of the economic aspects of patenting for company growth* (directive 2004:55). The idea is to review the economic aspects of patenting for company growth in Sweden, the Nordic countries and Europe. The commission will report on 31 December 2005.





Strategy Group and Secretariat

The following people have participated in the strategy group:

Sven-Eric Söder	Ministry of Industry, Employment and Communications (Chair)
Lars-Olof Lindgren	Ministry of Industry, Employment and Communications
Mikael Sjöberg/Kent Waltersson	Ministry of Health and Social Affairs
Kerstin Eliasson	Ministry of Education, Research and Culture
Jan Herin	Swedish Industrial and Chemical Employers Association
Richard Bergström	The Swedish Association of the Pharmaceutical Industry
Håkan Mandahl	The Swedish Association of the Pharmaceutical Industry
Kjell Alenius	Swedish Medtech
Per-Erik Sandlund	SwedenBIO
Björn Nilsson	SwedenBIO
Hans Sievertsson	Swedish Academy of Pharmaceutical Sciences (SAPS) /SwedenBIO
Mattias Kalén	AngioGenetics
Stefan Carlsson	The Swedish pharmacy Apoteket
Steinar Höeg	AstraZeneca
Robert Ström	Baxter
Cristina Glad	BioInvent
Akbar Seddigh	Elektra, Ortivus
Paula Treutiger	Gambro
Lars Olofsson	Merck Sharp & Dohme
Magnus Lundberg	Pharmacia Diagnostics
Lars Gunneflo/Niklas Prager	Pfizer
Hans Nyctelius	Q-Med AB
Erik Adolfsson	IF Metall
Jörgen Ohlsson	The Swedish Association of Scientists
Mari-Ann Krantz	SIF
Håkan Sörman	The Swedish Association of Local Authorities and Regions (SALAR)
Anders Wenström	The Swedish Trade Council
Kai Hammerich	Invest in Sweden Agency (ISA)
Harriet Wallberg-Henriksson	Karolinska Institutet
Ann-Christin Tauberman	The Pharmaceutical Benefits Board (LFN),
Gunnar Alvan	The Medical Products Agency
Per Eriksson/Katarina Nordqvist	Swedish Governmental Agency for Innovation Systems (Vinnova)
Håkan Billig	The Swedish Research Council
Sven Sjögren	Ministry of Industry, Employment and Communications
Ulrica Dyrke	Ministry of Industry, Employment and Communications
Johan Lannering	Ministry of Industry, Employment and Communications
Sofia Medin	Ministry of Industry, Employment and Communications
Anna Sandström	Ministry of Industry, Employment and Communications
Charlotte Hall	Ministry of Education, Research and Culture
Cecilia Nordling	Ministry of Education, Research and Culture
Birgitta Bratthall	Ministry of Health and Social Affairs
Claes Debourg	Ministry of Agriculture, Food and Consumer Affairs
Henrik Gorbow	Ministry for Foreign Affairs



The following people have participated in the strategy group:

Sven Sjögren	Ministry of Industry, Employment and Communications (Chair)
Håkan Mandahl	The Swedish Association of the Pharmaceutical Industry
Anders Blanck	The Swedish Association of the Pharmaceutical Industry
Kjell Alenius	Swedish Medtech
Per-Erik Sandlund	SwedenBIO
Mats Berggren	SwedenBIO
David S Andersson	AstraZeneca
Per Vretblad	The Swedish Institute for Food and Biotechnology (SIK), and BioteknikForum
Gunilla Thörnwall Bergendahl	The Swedish Association of Local Authorities and Regions (SALAR)
Erik Adolfsson	IF Metall
Frida Lawenius	The Swedish Association of Scientists
Emma Åberg/Nils-Åke Carlsson	SIF
Anders Wenström	The Swedish Trade Council
David Ernstsson	The Swedish Trade Council
Ylva Williams/Rolf Rising	Invest in Sweden Agency (ISA)
Anna Renman	The National Board of Trade
Christina Graffner	The Medical Products Agency
Katarina Nordqvist	Swedish Governmental Agency for Innovation Systems (Vinnova)
Håkan Billig	The Swedish Research Council
Ulrica Dyrke	Ministry of Industry, Employment and Communications
Johan Lannerling	Ministry of Industry, Employment and Communications
Sofia Medin	Ministry of Industry, Employment and Communications
Anna Sandström	Ministry of Industry, Employment and Communications
Anders Hedberg	Ministry of Finance
Sara Kilander	Ministry of Finance
Per Bergman	Ministry of Agriculture, Food and Consumer Affairs
Claes Debourg	Ministry of Agriculture, Food and Consumer Affairs
Maria Åhs	The Ministry of Sustainable Development
Birgitta Bratthall	Ministry of Health and Social Affairs
Charlotte Hall	Ministry of Education, Research and Culture
Cecilia Nordling	Ministry of Education, Research and Culture
Henrik Gorbow	Ministry for Foreign Affairs
Johan Bäverbrant	Ministry for Foreign Affairs





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and Communications, Sweden**

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