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Full Length Research Paper

Review of the biotechnology research and development (R and D) in OECD countries concerning biological drugs

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The pharmaceutical industry is among high technology industries that needs considerable attention in research and development. Overall, the processes that a drug must go through from its production in the laboratory, to clinical trials on certain groups, to the drug being licensed and finally planning for its marketing makes it different to any other product. Boosting research and development capability in this industry as well as saving patients' lives is also essential in controlling the costs of importing drugs. According to this point of view, having suitable R and D strategies in the pharmaceutical sector becomes very important for every country. In this study, we aimed to review several studies concerning biological drugs R and D in selected countries. Since the discussions in relation to the R and D within the pharmaceutical sector about biological drugs come under the umbrella of innovation system of each country. By reviewing the pharmaceutical innovation system studies of selected OECD countries including Norway, Germany and Japan, we aimed to look at the main factors in national R and D system, the trading system conditions, R and D co-operations, human resources, financial matters, entrepreneurship, the market, R and D policy making and coordination of different organizations and main support policies within the biological drugs system.

Key words: R and D, biotechnology, biological drugs.

INTRODUCTION

During the recent years, developing countries such as Iran have not achieved noticeable success in the modern biotechnology field (Soleimani, 1997). This observation applies to different pharmaceutical sectors not just the biological drug sector. These products have a direct relationship to public health and are important within society (Hamzeh-Pour, 1997). Access to new drugs is an expensive process; the main cost is incurred in carrying out trials (Gale and Clark, 2000). According to statistics, one of the main barriers to success in the biological drugs industry is lack of systematic attention to R and D in this sector (Behboodi, 1997). It is not that difficult to hold a systemic view in the pharmaceutical industry (McKelvey and Orsenigo, 2001). In this point of view, attention is paid to different elements and their relationship to each other (Nejad and Sasan-gohar, 2002). Among countries that have carried out reliable studies in this field are members of the OECD (Noori-Hekmat, 2009). The main aim of these studies was to review the innovation system of biological drugs in these countries. The R and D discussion was also included in the report (Esmailzadeh

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and Dehnavieh, 2004). Japan, Germany and Norway were chosen as a sample and the main factors affecting the R and D of biological drugs were reviewed. A review of these countries' experiences has important lessons for developing countries such as Iran. References have been made to these experiences.

MATERIALS AND METHODS

The method of this study (carried out in 2010) was cross-sectional and comparative study. The research society consisted of all OECD countries and 3 countries were selected as study sample. This study was conducted in three stages. Research literature in the first stage was investigated. In the next stage, the biotechnology research and development (R and D) situation concerning biological drugs was reviewed in Japan, Germany and Norway. Data collection was done through documents reviewing. Finally, tried to providing useful strategies for other countries, especially developing countries in this area.

RESULTS AND DISCUSSION

Japan

R and D system

Universities, public research centres and private research centres form important elements of the biological drugs R and D system in Japan. The most important organization in the field of biological drugs in Japan is the national cancer research centre which is supervised by the Ministry of Health, Work and Welfare. The Agency for Industrial Science and Technology (AISI) is part of the economics, trade and industry ministry and plays an important role in biotechnology research. The physical and chemical research institute and university hospitals such as Tokyo University Hospital carry out considerable research activity in the field.

Trading system

In 2003, there were 334 biotechnology companies in Japan. In recent years, the number of these companies has grown rapidly. However, in comparison to 2000 companies in the US and 2500 in Europe, Japan has few biotechnology companies. The relative size of these companies is also small.

Cooperation

Billions of yens are assigned to new drugs R and D and it takes more than ten years to develop and produce. Since the drugs industry needs intensive R and D and the relative R and D costs to production and sales are high; cooperation with international organizations is vital for effective and efficient R and D to produce new drugs.

Human resources

The number of qualifications relevant to biotechnology in Japan is relatively low.

Financial considerations

The cost of biotechnology R and D within public research centres and universities is almost entirely met by the government, more than half of all biotechnology costs is also paid by the government. The costs of biotechnology R and D is always increasing and is rising faster than other R and D. In order to boost the market, it is necessary to encourage industry to support joint investment companies, financial institutions and similar organizations.

Entrepreneurship

In recent years, the number of biotechnology companies has increased. In the past 2 to 3 years, approximately 50 new companies have been incorporated.

The market

An increase in pharmaceutical product imports and participation of foreign companies in the Japanese market has made a competitive environment even more competitive. Despite Japan's gradual shrinking in the world market, it has managed to keep a sizeable portion of the world market (15%) and it is still an attractive market for international corporations. The most influential factors in Japan's pharmaceutical industry include: Reforms in the pharmaceutical management system and a review of government regulatory supervision in clinical trials and new drugs. New drugs pricing is based on the price of a similar product, plus a certain percentage depending on innovation, the drug's effectiveness and market tolerance. In 2003, the fix price regulation came into force to control prices (only exclusive, non-generic drugs that made major improvement to patients were exempt from the requirements).

Japanese pharmaceutical companies have slowly formed R and D partnerships with international companies and have achieved good results (biological drugs). Japanese pharmaceutical companies have realized that in order to make progress in many fields, they cannot just rely on their own human resources and technology. Therefore, they supported joint co-operations. Opinion poll showed pharmaceutical companies favour supporting co-operations with other companies, especially Japanese universities as well as public research organizations and international investment companies. On the other hand, further studies into these co-operations made it clear that the goal of most co-operations with universities and

national research organizations was to obtain public knowledge and meanwhile, development of new drugs was reliant on international investment.

R and D policy making

In Japan, different organizations are involved in biotechnology R and D and biotechnology innovation. The most important are: Ministry of Health, Work and Welfare (medical), The Ministry of Economy Trade and Industry (industrial goods) and the Ministry of Agriculture Forestry and Fishing (agricultural products). In addition, the Ministry of Education Culture, Sport and Science and Technology is responsible for higher education and public research organizations. These four ministries work together and are responsible for Japan's policy making.

Recently, the prime minister's cabinet office set up the Biotechnology Strategy Council (BTSC) to further develop biotechnology in Japan. BTSC is responsible for coordinating policy making in different departments. BTSC's biotechnology strategy instructions include three vital strategies to make technology accessible and available, to strengthen the industrial process and understanding the public needs. The Council for Science and Technology Policy (CSTP) based on prime minister's office coordinates various ministries' technology policies. CSTP's main responsibility is to publish the science and technology plan every five years to clarify government's future science and technology policy. Recently, government corporations have undertaken the following policies to further develop biotechnology.

Policies: Base science support policies: One of the key policies for expansion of base sciences in biotechnology is to increase biotechnology R and D budget. Besides, budgets that have been allocated to public projects researchers in universities or public research organizations can access budgets that have been dedicated to increase competitiveness.

Another helpful measure adopted is the favourable change in the R and D taxation system. R and D tax credit system was reviewed recently that resulted in further tax incentives. In the new system, a tax incentive for investment in pharmaceutical R and D was increased. This law can have a major influence on large pharmaceutical companies' R&D.

Policies in support of commercialization

As far as universities are concerned, the technology transfer (development law) from universities to industry plays an important role in commercialization. In 1998, this law was passed to enable technology licensing offices (TLOs) to support public research institutes.

During the 1987 financial year, joint research centres were set up in universities to promote industrial co-operation. These centres create an environment to carry out joint research between universities and private corporations. These organizations are used as places by industry and university representatives to interact. Existence of a suitable system to protect intellectual property rights motivates researchers to commercialize their research results. To protect intellectual property rights concerning university internal research, the Ministry of Science and Technology has established regulations in state universities (Noori-Hekmat, 2009).

Germany

R and D system

The main factor in the German pharmaceutical R and D industry is the universities. As well as universities, public sector research organizations (PORO s) are also active in biological drugs field.

Alongside these key factors, some federal ministries' research organizations departments are active in this system. For example, the German federation of industrial research association can be referred to. The European molecular biology laboratory (EMBL) not only carries out basic bio-molecular research, but also transfers research results to industrial applications. In addition, the EMBL runs educational courses in molecular biology.

Trading system

Key organizations in the pharmaceutical industry include active biotechnology pharmaceutical companies, specialized biotechnology companies, supplier companies and clinical research organizations. The mergers and company purchases is among the interesting facts that can be referred to. In the majority of these cases, one of the partners has been an international corporation. This proves that the security of the world markets can be a major incentive to join them.

R and D co-operation

Internally, German pharmaceutical companies co-operate with the PSROs. The main aim of this co-operation is to gain base knowledge. In relation to international co-operation, international collaborators tend to co-operate with American companies. This shows that German companies find US companies' attractive partners to co-operate with. The most important achievements of these co-operations are to develop products and marketing, and to get assistance in product distribution. Repeated co-operations take the form of research projects contractual research. In some cases, exchange of employees takes place.

Human resources

Except in certain specific areas such as clinical medical research on patients, currently there are no shortages in the German biological drugs sector. Nevertheless, the approval of the development plan for future university graduates shows that planners are concerned about human resources in engineering and biological sciences.

Financial matters (considerations)

On the whole, there has been stability in investments in biotechnology in comparison with other sectors. Offering shares is an important strategy for investment companies.

Entrepreneurship

Although, in the past ten years, entrepreneurship in Germany has had good growth and the lack of entrepreneurship cannot be an important barrier in innovation in the biological drugs sector, the promotion of necessary expertise for innovation within university courses must be expanded.

Market

Briefly, statistics show there is a strong trend towards the American market and an improvement in the position of US corporations in the German market. German pharmaceutical companies are under competitive pressure in world markets as well as in the German market. Despite the fact that the growth in German pharmaceutical market has been significantly less than the US or other markets, Germany is still an attractive market for innovative drugs in general and biological drugs in particular.

R and D policy making

The German innovative policy system is relatively complicated and includes a large number of factors (organizations) and ministries involved in federal and state level. In addition, different tools have been used to support innovation in biotechnology.

The main quality of the German R and D system is the division of political responsibility between the federal government and the states (Lander). State (Lander) is generally responsible for education. As a result, the state provides the majority of university budgets. In addition, the state supports research organizations in the state. Some states have started special programmes for biotechnology that provide the capital for industry and research organizations. Federal ministries that are involved in biotechnology innovation system have also several research units that receive the main organizational supports to carry out research activity to satisfy the respective needs of their ministry and to discharge their political duties.

Between investment organizations and organizations carrying out research, there are intermediary organizations known as project management organizations (PMO). The duty of these units include: supporting development related to the federal government, analysis and evaluation of research projects, to offer consultation to investment applicants, evaluation of proposals, executive and financial management of current projects and publication of research results through workshops and publishers.

Policies: Knowledge base support policies: In Germany, biotechnology and pharmaceutical knowledge base is supported horizontally and vertically. Political tools (horizontal support) play the key role in supporting biotechnology base sciences. Through this kind of investment, research organizations can protect their independence and plan and carry out their research projects without worrying about political trends or ministries' priorities.

In relation to vertical policies, during the implementation of 4 structural plans major investment in important fields such as tissue engineering and genomic micro-organism research were undertaken. The groups that benefited from these investments were mainly universities, PSROs and industry. These activities particularly emphasised joint research between universities, PSROs and industry.

Policies in support of commercialization

Supporting technological commercialization and industrial research investment is the responsibility of the ministry of economy. Dedicated support for biotechnology commercialization follows two major approaches. The first approach has been attempted to use mechanisms to promote biotechnology within the industrial sector. In other words, industrial partners have been encouraged to cooperate with public research organizations in carrying out biotechnology research.

In the second approach, support programmes for biotechnology commercialization have included plans to form research units and industrial partnership groups. Accordingly, policymakers have tried to transfer biotechnology knowledge and its conversion to products, processes and services by supporting competition in regional research units, investment institutions and industrial partners (Noori-Hekmat, 2009).

Norway

R and D system

One of the most important elements of the research

system in Norway is the high percentage of government investment. Universities play a minor role in R and D in Norway, it is only 15%. Public and partially public institutions are among other organizations active in the national R&D system. These institutions are categorized according to their research area such as genome, nutritional research, marine research and other subjects. Among the most important aspects of the Norwegian system is the lack of large foreign pharmaceutical corporations.

Trading system

While the attention of world pharmaceutical companies is focused on therapeutic treatments, many Norwegian companies are paying attention to marine biotechnology and medical diagnoses. These companies have two main reasons for this. Firstly, the development of human medical sciences needs larger human resources and takes longer in comparison with the development of diagnostic tools. Therefore, it is more profitable and less risky for Norwegian companies to invest in the diagnostics market. Secondly, these companies can resolve difficulties/challenges in their chosen fields without the involvement of human bodies.

On average, specialized biotechnology companies in Norway have just over ten employees. A recent opinion poll indicates that a large number of Norwegian pharmaceutical companies have stated that in the next three years cooperating with foreign biotechnology companies or university researchers is one of their priorities.

R and D cooperation

Norwegian pharmaceutical companies (80%) are more in favour of joint cooperation with universities and other higher institutions. Depending on the research, R and D cooperation in the Norwegian pharmaceutical industry varies. Most of it relates to joint R and D (30%), 26% relates to R and D contracts, 23% relates to licensing and R and D purchases from foreign companies, joint investment and exchange of employees is less than 10%.

Human resources

It seems access to specialist human resources has been a major stumbling block to the Norwegian pharmaceutical industry's progress. It has been one of the main barriers to growth in the industry in Norway. Smaller biotechnology companies experience more difficulties in employing staff than larger pharmaceutical companies.

Financial matters (considerations)

The main investment organizations in biological drugs research in Norway are the Ministry Of Education and Research, the Health Ministry, the Environment Ministry and the Ministry Of Trade and Industry. The ministries of agriculture and fisheries also play a role in this area. Research Council of Norway (RCN) funds most of the investment in basic research in Norway. The investment is allocated by RCN between different organizations and universities. The two main strategies relating to R and D financial matters in this industry are individual and joint investment.

Entrepreneurship

The specialised biological drugs companies' speedy growth in Norway shows that entrepreneurship is booming in this industry. Nevertheless, entrepreneurship has not found its rightful place. One way to resolve this difficulty is to grant awards to entrepreneurs.

The market

Growth in demand for healthcare can play an important role in the development of the pharmaceutical industry. The pharmaceutical industry is constantly seeking new drugs. This trend is more obvious in the Norwegian drugs industry as in 2002 more than 37% of products sold in Norway were new products.

In Norway, hospitals are owned by the government, investment is also government's responsibility. In 2002, these hospitals became semi-independent. This meant that the government became more sensitive to the development, production, marketing and sales of pharmaceutical products. One of the most important factors under supervision was the price of drugs. To combat monopolization and reduce healthcare costs, the Norwegian drugs agency determines the price of prescription drugs based on prices in Austria, Belgium, Denmark, Finland, Germany, Ireland and some other countries. From the beginning of 2001, the price of prescription drugs must not exceed the average price in three countries with the lowest prices.

R and D policymaking

Other than the Ministry of Education and Research and the Trade and Industry Ministry, the Research Council of Norway (RCN) and the Norwegian Industrial and Regional Development Fund are two other key government R and D policymaking organizations. RCN plays the most important role in determining research policies in Norway. This organization is sponsored by the Ministry of Education and Research and is the government's main policy advisor and according to instructions received, determines research budgets. RCN as well as being responsible for investment management is also the

government's advisor in research policies.

NIRDF provides the specialists and the investment for companies in the initial development stages and develops new and innovative business by finding, improving and investing and following up interesting projects. NIRDF is decentralized and has 17 regional offices in different states. The head office is based in Oslo and has management responsibility and is in charge of the NIRDF system. As well as the organizations mentioned earlier, there are other institutions that act as advisors in policymaking to the government.

Policies: Policies for supporting base sciences: To support biotechnology knowledge bases as well as investment by RCN in research programmes, the Norwegian government has chosen the functional genome, the Prosbio research programme and a programme to establish a molecular biology and neurology quality control centre to support.

Policies to support commercialization: To achieve commercialization in Norway, a wide range of policies are in place for supporting newly established companies to issuing invention licence rights in universities. START agency for investment is among organizations that are active in this field. START is a private investment company and was established in 1998. START invests in companies that are in their initial stages of their activity and have extensive potential for growth and expansion at the global level. Among other developments related to this category we can point to the increasing trend towards commercialization within Norwegian universities (Noori-Hekmat, 2009).

Conclusion

Although, the biological drugs industry in developing countries is less experienced and operate under different conditions than OECD countries, paying attention to R and D which is the most important factor in this field can be helpful. On the whole, before undertaking biological drugs R and D system studies; different parts of the R and D system must be identified and their roles clarified. The most influential elements in selected countries are government organizations and institutions.

Specialist human resources play a very important role biological drugs R and D activities. In most OECD countries, there is a shortage that needs suitable solutions. Due to brain drain in the developing countries, the problem is more severe (Noori Hekmat 2009).

In selected OECD countries, biotechnology R and D policy is made at the highest levels of national policy making. At this level, responsibility for different policies from macro policies, to supporting the biological drugs industry, to consultation, to investment, to international cooperation, etc has to be completely cleared and without interference.

In the biological drugs industry, the majority of R and D costs are met by the government in selected countries. In recent years with R and D costs rising, there has been a tendency towards joint investments and share offering. It is important not to forget that allocation of resources to R and D needs planning and this task should be up to specialised organizations.

In selected countries, adequate attention has been paid to entrepreneurial factor within the biological drugs industry. Despite this, at some levels and especially in the contents of university courses, further attention is needed.

Within the biological drugs market, it must be acknowledged that its most important property is the existence of strong competition. For governments, one of most important concerns in this competitive market is the price of drugs; in fact, all countries under review have clear and well defined instructions. An important point in the biological drugs market is its attractiveness for the commercial sector which means increasing number of companies is entering this industrial sector.

The essential point that must always be considered is the attention to commercialization. In selected countries, among the most important steps to support commercial-lisation is the establishment of joint university/industry research centres within universities. Legislations to enhance technology transfer from universities to industry, support for newly established companies, attention to intellectual property rights and the establishment of privately funded incubators are among solutions that can be pointed to (Esmail-Zadeh, 2003). In order to protect and develop researches related to base knowledge/ sciences, different solutions are in practice in selected countries. Among these solutions, an increase in budget for government research centres, increased investment in the field, dedicated budgets to increase competition in the field and the creation of motivation in the taxation system can be pointed to.

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