Ann. Ist. Super. Sanità
Vol. 21, N. 4 (1985), pp. 543-546

BIOMEDICAL RESEARCH POLICY OF THE EUROPEAN COMMUNITY

P. FASELLA

Director General for Science, Research and Development, European Community Commission (EEC), Bruxelles, Belgium

Mr Chairman, President Chagas, dear colleagues, it is a great pleasure to be here, although it feels strange to be addressing you in English here in Rome. I suppose Latin would be more appropriate, but perhaps even less understandable than my English.

The European Community has been active in medical research for some time, but I would not spend much time on the past. Many of you have actually been involved in programmes, such as Radioprotection, the Medical Research Concerted Action Programme and — more recently — the programme for medical problems related to developing countries. I will therefore concentrate on our new Biotechnology programme which we have now to discuss with government officials and industry, but especially with scientists. This opportunity to discuss it with you seems to me particularly appropriate. At this state, we can take advantage of the feedback which can come from you either directly through questions, or later on through contacts, letters, etc.

Why a biotechnology policy in the European Community? Before doing something it is worth asking ourselves why; if we do not, somebody else will.

I can see three different sets of reasons, which are contained in the very words I mentioned. The first is inherent to biotechnology itself. It is a rapidly expanding field; definitely multidisciplinary; it can provide a number of different options for the solution of different problems. For instance, one cannot tell from the start if, for the production of a given protein, it is preferable to do genetic engineering in yeast rather than *Subtilis* or *Escherichia coli*, or whether for the purification of a very diluted high value product one should use monoclonal antibodies rather than other high-affinity techniques. It is clear then, that in order to make certain that you make the best use of resources, you have to maximise the chance of matching the solutions to the problem and, therefore, to integrate offer and demand over a wider area. Otherwise if you pursue one technical solution for one problem approach, the probability that you guess right is not so high. At a geophisical level this means that a larger than national integration is needed. For European countries, the European dimension, and in particular that provided by the Common Market, is obvious. For historical reasons, one or more years abroad, mostly in the United States, are part of the *curriculum vitae* of many European scientists, at least of my generation. Traditionally, therefore, interactions are easier with the United States than with other European countries. Interaction with the United States should be continued, but contacts within Europe should also be developed.

The second set of reasons is related with the situation of Europe itself, in particular in the area of biomedical research. Economic considerations must bear very strongly on the mind of a civil servant who works, as I do, for an "Economic" Community. Let us look shortly at the situation in Europe. Although biotechnologies can be used in many areas such as industrial production and agriculture, my main concern here are the biomedical applications. For instance, if one considers the development of new pharmaceutical products over a 20-year period, in various parts of the world, Europe has altogether been doing quite well. An analysis of the distribution of the pharmaceutical interchange for the years in question shows that imports from Europe were larger than exports to Europe. Europe, from the strictly commercial point of view, is in a pretty good position.

If we consider the present years' production, again Europe is at the top. However, if you take the production per employee, Europe comes out worse than the US and much worse than Japan. Exports from Europe are still — as we saw before — very important, but drug consumption is actually higher in Japan than in Europe. This proves that Japanese industry has a large internal market, which is a very good basis for the penetration of external markets.

If you come to consider the future, it should be remembered that in the drug field there is a very large time lag — roughly ten years — between the conception and the marketing of a product. One must therefore look at what is happening today in research in order to predict what will happen on the market ten years from now. In recent years Japanese production has been growing more rapidly than that of its competitors. Moreover, Japan has been investing in biomedical and pharmaceutical research more than the US or Europe. If the research investment of today gives an indication of production ten years from now, I think that Europe should react and increase its efforts. The situation can be summarised as follows: we are in a good position, but we have to prepare new developments because the rest of the world is progressing and if we do not invest now in R&D, we will not have fruit to harvest in the future.

When you come from general pharmaceutical developments to specific biotechnology, the situation in Europe is less favourable. It is sometimes useful — although not always pleasant — to look at ourselves in the way in which others look at us. A recent study of the commercial applications of biotechnology issued by the Office of Technological assessment of the United States House of Representatives in 1984 states that the United States are in the forefront and that Japan is likely to be the leading competitor. The European countries are not moving as rapidly towards commercialisation of biotechnology as either the US or Japan. In this volume there are some very useful pieces of information on views on what is going wrong in Europe: the lack of qualified scientists and engineers, inadequate cooperation between industries and universities and delayed and insufficient funding by industries and governments are the biggest obstacles to commercial competitiveness in western European countries. Governments as well as industries and all research people must be aware of these obstacles and keep on their toes in order to remain competitive, taking into account the big time lag between research and commercial exploitation.

The financial effort of the United States government in support of research should also be considered. 1984 budget authorisations for various departments amount to 50 billion dollars and are increasing. On health the US government spend about 5 billion dollars per year. As Dr Wyngaarden (Director of the National Institutes of Health, NIH) has previously stated, this represents an enourmous effort in the field of fundamental and applied research in the health sector, and provides a powerful basis for the US industrial development in this sector.

This is the situation in the United States. What is happening in Europe? In Europe, most governments have realised the importance of biotechnology and have launched *ad hoc* programmes. Prof. Ernesto Quagliariello mentioned the "Programmi Finalizzati" in Italy. In Germany the Research Ministry has financed programmes for 60 million DM per year. In the UK something of the order of 13 million pounds is devoted to biotechnology, by the Department of Industry. Almost all other European countries have also launched programmes in support of biotechnology R&D. So the total European effort is not negligible.

But — and we come to the third set of considerations — besides the national efforts something should be done at Community level, which, in some areas such as information technology, requires a continental approach. In general, the European Community must create a really European, internal market for European products. Moreover, the Community should get involved in a number of areas in which there is mutual interaction between biotechnology and existing Community policies. There are some of these areas which I shall just mention here without going into details. There is certainly the interaction with the Community Agricultural Policy, which as you may know, is quite expensive and risks wrecking the Community finances. A specific case concerns the price policy for sugar and starch which, at present, is too high to allow their use as raw material for biotechnological developments. Proposals to modify the situation have been made by the Commission but have not yet been approved by the Member States.

There is the problem of Community regulations, which is certainly familiar to this audience. I think you all agree that if a really common market is to be established, the Community must issue regulations which promote its development rather than hindering it. These regulations concern various aspects including safety, standards and testing methods. It is very important that in this activity the Community authorities, when preparing the proposals, are well informed as to the present trends in biotechnology so that the proposals are coherent with the expectations of this promising new technology.

There is the problem of intellectual property, including the definition of "discovery" and "invention", as applied to "biotechnology — a question that conventional patent policy is not equipped to answer. Another aspect is the duration of validity of patents. As the time required for testing and bringing to the market a new product increases, the owners of the patents have an even shorter time during which they can exploit their invention. We do not have any contractual work in this area but we organise meetings in order to persuade the persons interested in patent policy to work together and possibly reach a common orientation. To this end, we have a consultation unit for biotechnolgy which meets regularly, involving people from different Community directions as well as national experts.

Then there are a number of technical supporting measures which biotechnology needs. One such measure which is crucial and should be developed at Community rather than national level is data banks. Forty or fifty years ago nuclear physics became so "energy" intensive that big multinational centres, such as CERN, had to be developed to provide adequate facilities. Modern biology is very "information" intensive. For instance, we have all seen information about new sequence structures of proteins or nucleic acid presented in a conventional form in various scientific journals. Such presentation is not convenient for information in new biology. What can you do with three, four or five pages of sequence in a printed paper? To handle such a lot of information you need advanced computing. Data banks become a necessary tool and it would not make sense to set up ten systems of independent data banks for ten different countries. We have already begun an action aimed at creating a network of data banks in Europe, connected through Euronet or similar lines and which would be in periodic contact with the United States and Japan. However, a single integrated data bank is not enough: we need to develop systems for data capture. And it is important to do it together so that you have compatible inputs from the various users and contributors. Besides the problem of data collection and storage, there is the problem of treatment and intelligent retrieval which needs sophisticated software. This is an important part of our programme.

Among the biological data banks, which should be extensively computerised, those concerning toxicology deserve special attention. The European Community is certainly interested because of its reponsibility in the field. It as a pleasure to recognise here the very important work carried out by the Istituto Superiore di Sanità in this field.

Another area which requires European attention is the utilisation and completion of the existing collection of biotic materials. Here we propose a European network connecting existing and future centres.

We are aware that in order to be successful we have to intergrate our European effort in a world effort. This we do both through collaboration with CODATA, a committee established by the International Council of Scientific Unions, and the "Technology Growth and Employment" working group established upon Mr Mitterand's suggestion by the Summit of Industrialised Countries.

Finally, let us have a quick look at the research part of our programme. It includes: technology for bioreactors, genetic engineering, physiology of microorganisms, technology of tissue cultures, screening methods of toxicology and biology, assessment of risks, etc. This is a sort of shopping list that you could find in any book, including high-school textbooks. Our problem is to identify within this list what can be done at Community level which is a useful and sometimes necessary complement to — and not a duplication of — what is already being done at national level. This we do in various ways, such as the promotion of the use of "unique» national resources (*e.g.* large machinery such as synchrotrons of neutron sources), by other countries, or a common approach to common problems, such as concerted epidemiological studies. One very large problem, common to all western countries, is the soaring costs of health assistance which in western Europe is eventually paid for by the taxpayers. A possible approach to the solution of this problem, could start from the classification of health expenses by disease, a sort of nosography of health expenditure in order to select the areas in which efforts have to be made to reduce the costs. To solve this, and many of the problems discussed, the European Community will count on the continuing contribution of the ISS.

Thank you for your attention.