

Rolf Krebs discusses the pharma industry past, present and future

Interview by Joanne Clough

Rolf Krebs, Chairman of the Board of Managing Directors, Boehringer Ingelheim

Professor Rolf Krebs was interviewed at the Boehringer Ingelheim (BI) Annual Press Conference, held in Ingelheim, Germany, 9 April 2002. Krebs has been Chairman of the Board of Managing Directors at BI since January 2001; before that, he held the position of Vice Chairman. Appointed President of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) in May 2000, he was the first German to assume the Presidency of the World Pharmaceutical Associations, which alternates between US and European leaders every two years. From 1996–1998, Krebs was President of the European Federation of Pharmaceutical Industries and Associations (EFPIA), and was a member of the Board of Verband Forschender Arzneimittelhersteller (VFA) (Association of Research-based Pharmaceutical Manufacturers) from its foundation in 1994 until 1995. He had a university career as Professor of Pharmacology and Toxicology at the Johannes Gutenberg University of Mainz from 1973–1976, before which he studied Medicine in Germany (Frankfurt/Main, Erlangen and Mainz; 1959–1966).

Briefly describe your career, from obtaining a Professorship to joining Boehringer Ingelheim

After my university career as Professor of Pharmacology and Toxicology, I joined Bayer AG in 1976, where I was Head of Medical, then Head of R&D. I then went for a short period (two years) to the United States to do some business development work with Miles/Cutter. From there, I went to Italy as Vice CEO of Bayer Italy, which not only focusses on pharmaceuticals but is also related to other business areas, such as chemicals and plastics. Then I decided to return to Germany, where I joined BI in 1989 as a member of the Board of Managing Directors.

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What is your day-to-day role within the company?

In my day-to-day activities I deal with the most diverse topics. Preparing for, and attending, the board meetings takes a

considerable amount of time. Also, the job involves looking after PR, IT and auditing. I furthermore have to represent the company. At the same time, I am President of the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA), which is also time-consuming because it means maintaining contacts to the UN organizations in Geneva. My job is really everything; it goes beyond one broad area.

Can you briefly describe the business plan of the company [BI] for the next five years? In the next five years, we expect to grow, on average, between 10 and 11% in sales, and we have programs running that support the profitability of the company. Although profits will be stagnant next year, taking into account our investments in our new drug Spiriva® [for chronic obstructive pulmonary disease (COPD)], we expect them to rise again soon. It is also important for BI to strengthen its sales infrastructure and gain market share. We are also preparing ourselves for the period beyond 2006: we are looking at the pipeline, development of our compounds

and licensing products, and also cooperations with other companies – questions we intend to pursue more intensively than during the 1990s.

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How has BI been so successful when all around companies are going into mergers and acquisitions? Do you see this success continuing?

Maybe the fact that we didn't go into a merger or acquisition has been our success! If I look at the bigger merger and acquisitions, I can't think of an example where value was improved by using synergies. Companies say that synergies bring profitability and more productivity but it never happens. It's a question of culture; when two cultures merge, the different organizations are bound to operate differently. Companies have different systems and procedures as well as different decision-making processes. It is not the dedication that is under question but the communication and, very importantly, new products. BI doesn't have this problem.

'Companies say that synergies bring profitability and more productivity but it never happens.'

Is there anything that can be done to avoid the recent spate of patents being lost to generic competition in several large pharmaceutical companies?

This is the advantage of generic companies, of that there is no doubt, because it puts more pressure on the research-based companies. In the next five years, a sales volume of 30-50 billion US dollars will go off patent. We [at BI] see that as a challenge: it forces us into registering more and more patentable drugs with appropriate prices that make further investments into R&D possible. The low prices in Europe is one of the reasons why the European pharmaceutical industry is losing competitiveness compared to US companies. In a way, the pharmaceutical industry should become more Americanized - that means good prices for innovative drugs.

What are the difficulties that the industry faces in Europe and how are these being overcome?

Europe has a particular weakness. First, there are the healthcare systems, which are too cost-driven. Second, there are only really four countries in Europe that are major players in the pharma export: Germany, the UK, Denmark and France. But the rest of the European countries are not really interested, because they have no major pharmaceutical companies and no lobby there. This makes it difficult to overcome the growth problems of the pharma industry in Europe. In the UK, Tony Blair has started an initiative, which is quite remarkable because he saw that the pharma industry is very important for the UK. I think the UK is the only country [in Europe] where the involvement of this industry is positively perceived.

'In a way, the pharmaceutical industry should become more Americanized.'

Do you see the development cycle time successfully managed with your products Micardis® and Viramune® [for the treatment of HIV] being continued in the foreseeable future?

In the development cycle, there are two distinct processes. The development time is shrinking but this is counterbalanced by the amount of additional documentation required by authorities to approve and register compounds. This leads to a competitive disadvantage in Europe, as we don't have the equivalent of the FDA. In the United States, it takes 18 months or so to approve new products, whereas in Europe you then have to wait for approval by all member states in the mutual recognition procedure, which can take another nine months. Then you have to discuss reimbursement, which can take up to a year. So, in Europe you have double the time from submission to the market compared with the USA. For this reason, companies with bigger sites in the USA use the advantage of the reduced registration times over there. But as we [BI] formerly used to develop mainly in Europe, our structure has had to change. BI first introduced new products in Europe, then in the USA, then the same compounds in Japan: this process cost a

lot of money. With Micardis® [for the treatment of hypertension] this was changed: we first developed internationally and were on the market in Europe and the United States within one week or so, [and] it will be introduced in Japan this year.

How do you see business in Japan taking off in the next five years? (In 2001, the Triple-A market accounted for 18% of BI's turnover worldwide.)

It improved very much for BI and it is going to improve further, with 4-5 new compounds getting to the market within the next 3-4 years. In Japan, with SSP [a major Japanese pharmaceutical company] having been added [to BI], we now have a sizeable OTC (over-the-counter) business, bringing the Japanese net sales this year [2002] to over 1.3 billion Euro. As we move into Japan, improving our marketing and positioning, we will increase the fieldforce there, as well as in the USA. In other parts of the world we don't need such an increase in fieldforce - we are as strong as we need to be in the European. South American and South East Asian markets. The two markets we still need to do something about are Japan and the US - a challenge for the next few years. We have approximately 1300 fieldforce people in the USA, but only about 500 in Japan. This has to be improved.

What are the current drugs in BI's pipeline?

We added a new indication to Pramipexole (Sifrol®, Mirapex®; Phase IIb/III), which is a dopamine agonist for Parkinson's disease. The indication being explored now is restless legs syndrome [RLS]; RLS is a disorder with an agedependent prevalence of up to 10% affected in the elderly. Also, Tipranavir [a first non-peptidic protease inhibitor for HIV therapy] could make a difference as a combination therapy for those with multiple anti-viral drug experience [currently in Phase IIb/III]. There is no official data, but up to 25% of people living with AIDS already suffer from resistance [to anti-HIV drugs]. There will also be a protease inhibitor for hepatitis C.

Is there a blockbuster among them?

We have Spiriva® for the treatment of COPD, which will make at least two billion Euro by 2005. This product was launched in the first European countries and in the Philippines in June this year [2002].

What do you think will radically reshape the pharma industry in the next 10–20 years?

I foresee a big change! This is primarily because of the nature of healthcare budgets and a lack of clear definition of what society wants. It is clear from statements from politicians that the quality of treatment is there if people ask for it. If that is the guiding principle, then innovations will be increasingly important. The research-based pharmaceutical industry, particularly those who are productive in new compounds, will progress nicely - of that there is no doubt! There is another type of industry, that is the generic industry, which will take off dramatically, especially in the USA, as patents run out. Competition in the free market will be an important element to this business. I see the innovative researchbased pharmaceutical industry, as well as the generic industry, to be winners. But I see companies in between, who used to be innovative companies but are presently not putting much money into R&D. As a consequence, they have no innovative products; those may be the losers.

'Two-thirds of all diseases don't have any medication as yet. This is quite striking – there is a long way to go.'

How do you see the future of the pharmaceutical industry?

The future of the pharma industry is most promising; it is high-tech, and there is still much to discover in biology. Biology is in a revolution at present and will be for several hundred years. Two-thirds of all diseases don't have any medication as yet. This is quite striking – there is a long way to go!

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