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“Innovative people need room to breathe”

How Roche addresses innovation and new drug launches.

An interview with Dr Severin Schwan, CEO Roche.

Arthur D. Little What does innovation mean for Roche?

Schwan For us, innovation means focusing on creating medically differentiated products, diagnostic tests and therapies that improve patients' quality of life and extend lives. This innovation strategy, however, is only sustainable if we succeed in continuously renewing our research and development pipeline with novel products. So for us, staying innovative – and ahead of the competition – also means exploring new, unknown paths, taking risks, trying out new ideas and constantly reinventing ourselves.

Arthur D. Little How important is the protection of intellectual property to sustaining innovation in your business?

Schwan Without patents there would be no innovation in our industry. Patents are the backbone of our business model. Today, it takes between eight and twelve years and costs on average more than a billion Swiss francs to bring a new medicine to the market. For investments in drug research and development to pay off, the industry depends on a temporary market exclusivity for its products. Once off-patent, these products can be copied by generic manufacturers and made available to patients at very low cost in perpetuity. Therefore, in the long term, patent protection pays off many times for society.

Arthur D. Little How well are patents protected globally?

Schwan The good news is that the global status of patent protection is better than ever before. Countries like Brazil and China have now accepted the nature and necessity of patent protection by joining the World Trade Organization (WTO). All major markets have a patent protection system in place and most countries enforce it strictly, as there is increasing recognition that patents are extremely important for the future of their own economies. China, for example, has a strategic goal to establish Chinese global players in a number of high-value, knowledge-based industries, and patent protection is key to achieving this goal.

Arthur D. Little And which markets are problematic?

Schwan The situation is difficult in India: It improved with the country's entry into the WTO in 1995 and the introduction of patent law, but enforcement remains a problem. Just recently, the Indian government has allowed some local generic companies to produce patented medicines without the consent of the patent owner. Despite this setback, I still hope that in the long run, when it wants to

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About Roche

Roche is a global leader in the life sciences industry and generated joint sales of CHF 45.5 billion from its pharmaceutical and diagnostics divisions in 2012. The company mainly focuses on five disease areas: oncology, inflammation, infectious disease, metabolism, and the central nervous system. Roche is the largest biotech company in the world, the number one supplier of cancer treatments and the global leader in in vitro diagnostics, which are used for the early detection, evaluation and monitoring of disease.

Roche operates 18 research centers around the world and is fully committed to becoming a leader in personalized healthcare, which is about developing and providing personalized treatments by taking patients' individual conditions into account. Some 60% of the projects in Roche's pharmaceuticals pipeline are being developed in conjunction with companion

diagnostic tests, something which uniquely positions Roche to improve healthcare with increasingly innovative treatment solutions. These companion diagnostics are used to select the right treatment for the right group of patients, thereby substantially improving effectiveness.

This strategy relies heavily on a long-term commitment to R&D, which is reflected in Roche's above industry average R&D spending. However, the cost of developing new medicines has increased significantly over the last decade. At the same time, governments and health insurers – under considerable budget pressure – are increasingly stipulating the advances in treatment they are looking for and the prices they are willing to pay. These and other factors have increased the risks inherent in the pharmaceutical business. How is Roche responding to these challenges?

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protect its own domestic intellectual property, India will eventually follow international standards.

Arthur D. Little There seems to be an increasing conflict between tighter healthcare budgets and more expensive drug development. How are you responding to this?

Schwan The tremendous pressure that the financial crisis put on government budgets remains universal. The healthcare industry in particular is affected at the moment by the price cuts and austerity measures being imposed in Europe. But, I'm absolutely convinced that as pricing pressure continues to increase, payers will channel available funding into options offering the greatest incremental benefits for patients. Innovative companies are in a much stronger position to negotiate with payers. The era of “me-too” products with marginal clinical benefits is definitely over. More than ever, we have to set high standards for developing medicines with real clinical benefit over existing therapies. Hurdles in R&D to be overcome are getting higher.

Arthur D. Little Some insiders claim that generating patented drugs is no longer enough and that other options need to be considered – for example, offering a com-

plete solution for a disease area. What are your thoughts on this?

Schwan I can clearly see there is a market for disease management, but we see this to be outside our core competence – every company has different strengths. The key question for us is: Where can we make a difference? We are in a unique position to leverage our strengths in pharmaceuticals and diagnostics to develop high-value targeted treatments, for example, in personalized medicine.

Arthur D. Little Can you tell us more about this concept of personalized healthcare and how Roche is developing it?

Schwan On average only 50% of patients respond to any given medicine. For some treatments this figure is higher, like in anesthetics where almost all patients respond, and in some areas much less, like psychiatric disorders where only 20-30% of patients are likely to respond. At Roche, developing medicines and companion diagnostics which can identify patients more receptive to certain treatments is a critical part of our strategy. Take one of our breast cancer medicines, Herceptin, for example. This drug is only effective in patients whose tumours carry a particular genetic defect,



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causing them to overproduce a protein called HER2. HER2-positive tumours are highly aggressive, fast-growing, and likely to relapse. Around 15-20% of all women with breast cancer have HER2-positive tumours, which means Herceptin can only be used in conjunction with a companion diagnostic test. We have over 200 development programs in our pipeline which have both a medicine and a diagnostic test.

Arthur D. Little Payers often argue that personalized healthcare actually increases the cost of care. Can it really save healthcare costs?

Schwan Personalized healthcare certainly contributes to more cost-efficient healthcare delivery. Although the cost of biological medicines is high, diagnosing patients properly and treating only those likely to respond to the treatment takes away considerable wastage. What is also important to consider is that the most significant part of healthcare budget spending is allocated to other areas like hospital care. In total, drugs usually only amount to 10% of any country's healthcare budget. Innovation can also help reduce costs in other areas of care. Let me give you an example: 80% of cancer patients used to be treated in hospitals, with all the additional cost that entails. Today this number has fallen to 20%, and

the effectiveness of our drugs has been a major factor in this development.

Arthur D. Little So where does the real problem lie in the cost of healthcare?

Schwan First of all, in many countries we not only spend a lot on our healthcare, we also get a lot in return: good hospitals, good doctors, good care with new treatments, and long life expectancy in good health. I believe that it makes little sense to focus exclusively on a country's health expenditures – we have to consider healthcare efficiency instead. The value you get for your money. Today, healthcare spending is mostly looked at through a set of segmented budgets – medicines, hospital care, outpatient care, etc. – rather than as a whole. And this means that the fact that an expensive medicine could, for example, reduce hospital time and make the treatment cheaper overall, is often overlooked. I believe healthcare authorities should take a more holistic view of budgeting and total treatment costs.

Arthur D. Little Realistically, do you see a way forward to improving global healthcare standards?

Schwan Healthcare has, for a long time, been taking an increasing share of national

income – health expenditure and prosperity are actually intertwined. Wealthier countries can afford – and wealthier people want – to spend more on healthcare. At the end of the day, it's a political question how much a society wants to spend on healthcare. However much or little that may be, though, it's up to governments, politicians, and industry to ensure that the money is spent wisely.

Arthur D. Little What could be the way forward in defining the societal value of medicines which prolong or even save lives?

Schwan Tell me, what would you pay for living one more year in good health: EUR 10 000, EUR 100 000, EUR 1 000 000? I believe it depends on many individual factors, such as your family life, perhaps your age, certainly also your ability to pay. Nobody can objectively determine the value of life. At societal level there is a need for consensus among all healthcare stakeholders – doctors, payers, patients and industry – in order to ensure that as many people as possible can have access to good healthcare. When we are able to sit around the table and discuss these issues with all stakeholders, we are more effective in achieving this goal of defining a “fair” price for the value of medicines.

Arthur D. Little Are we making progress in this globally?

Schwan The fundamental issue is that today, not only at Roche, but across our industry, by and large there is uniform global pricing for innovative medicines. As a

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consequence, many patients don't have access to medicines. This has to change. I see more creative pricing models as we go forward, and these pricing models will always be specific to the individual countries because the needs, resources and healthcare delivery systems are very specific to those countries. We are prepared to go for not only differentiated pricing across countries, but also within countries. We have piloted different pricing for different therapeutic indications, or even for patients depending on their income levels. But for this kind of system to work, solidarity between rich and poor countries is needed.

Arthur D. Little How do you improve access to medicines in countries where affordability is an issue?

Schwan We look at all markets individually – local management has a high degree of freedom to tailor solutions to local conditions. In Brazil, for example, we have entered a private-public partnership to improve access to modern therapies. And in China, insurance coverage for cancer

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was extremely limited, so we work with SwissRe and local private health insurance companies to support them with data to develop cancer insurance packages that cover treatment. As of today, this scheme has enabled more than 12 million people in China to receive insurance coverage for cancer treatment.

Arthur D. Little Closer to home, do you still see Europe an interesting location for Roche?

Schwan No doubt, we are facing a tougher market environment here. But we still believe in Europe as a good location for innovation. We just recently invested EUR 200 million in our R&D site in Penzberg, Bavaria. Countries like Germany still have a competitive advantage in terms of industrial know-how and high-level qualifications. I'm deeply convinced that Europe's long-term prosperity is directly linked to innovation. And pharma is certainly one of the main drivers of innovation – in the EU no other industry spends more on R&D. However, Europe is increasingly losing its competitive edge to the US, Asia and Latin America. Healthcare is primarily seen as a cost factor rather than an important pillar for growth and wealth. Europe will only remain one of the best places in the world for investments

in science if we maintain and strengthen our innovation-promoting advantages. Innovation needs a suitable macroclimate to help it flourish — such as a regulatory framework that provides the right incentives, adequate financial resources, and social acceptance.

Arthur D. Little What do you see as the key success factors for innovation from a company perspective?

Schwan In our industry, you cannot program innovation at will. But there are ways of improving the odds. Innovation is by definition always outside the mainstream: If you have an innovative idea, 99 out of 100 people think you are mad. So, what we are striving for at Roche is to create the conditions for innovative thinking by providing the right environment and the right attitudes. When I talk to retired employees who made important discoveries during their careers at Roche and ask them how they did it, many of them give answers such as: "My boss gave me a lot of freedom to make decisions on my own, and to follow up on my own thoughts or projects." Some of them even tell me that they used the lab over the weekend or researched an idea in secret. Innovative people need room to breathe. If you tell someone exactly what to do, you



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Dr Severin Schwan

Dr Severin Schwan is the Chief Executive Officer of Roche Group. He joined Roche in 1993 as a trainee at Corporate Finance in Basel. In 1995 he became Head of Finance & Administration for Roche in Brussels. From 1998 to 2000 he was Head of Finance & Informatics at Roche Grenzach, Germany and Member of the Executive Board of Roche Deutschland Holding GmbH. He then held the position of Head of Global Finance & Services, Roche Diagnostics in Basel until 2004. In 2004 he was appointed Head of Region Asia Pacific, Roche Diagnostics in Singapore. From 2006 to 2008 he was Chief Executive Officer of the Division Roche Diagnostics.

Dr Schwan studied Economics at the University of Innsbruck, the University of York and the University of Oxford and holds a Mag. rer.soc.oec. and a Mag. iur in Law, both from the University of Innsbruck. He received his Doctorate in Law at the University of Innsbruck in 1993. He was born in Austria in 1967.

shouldn't be surprised if this doesn't lead to anything new. Another key success factor is openness to what happens outside of Roche. I always tell my people that probably 99% of all discoveries happen outside of Roche, so we need to stay open and bring in external expertise to the company. We do not differentiate between what has been invented outside or inside Roche.

Arthur D. Little How do you keep the entrepreneurial spirit in the company alive?

Schwan I am convinced that innovation needs a diversity of approaches and perspectives. Our decentralized approach to management at Roche creates the necessary space within clearly defined responsibilities. I am in favor of lean structures and minimal central functions. Our key research

units operate as autonomous centers: They have their own budgets and run their own external networks. For example, when we bought Genentech, we chose not to integrate its R&D function into Roche and now only have the reporting line directly to me as the global CEO. We did this to preserve their unique research culture. Providing a working environment that encourages diversity is a managerial imperative, so that different teams have the freedom to do it “their way”.

Arthur D. Little What does failure mean for Roche? What role does it play in developing successful new drugs?

Schwan Accepting failure is critical to the success of innovation in our industry. Nine out of ten innovation projects fail. When we find out that a project has failed, we meet up with everybody involved, because it is my strong belief that we should celebrate our failures just as we celebrate our successes. I personally congratulate all participants and thank them for their hard work – because innovation is about taking risks and accepting failure.

Arthur D. Little How do you balance the time needed for innovation with the pressure to develop new drugs quickly?

Schwan Innovation in pharmaceuticals takes time and it usually happens in incremental steps, only rarely in leaps. One of Roche’s great strengths is our ability and willingness to build strategy over the long term. The backing we receive from the

founding families who still own the majority of Roche gives management the security and confidence to take decisions which do not just need to produce results in the following few quarters. The majority shareholders’ enduring commitment to Roche’s independence has a very important bearing on our ability to pursue our long-term strategy and to shape our own future.

Arthur D. Little If you had to sum up Roche’s innovation philosophy in one sentence – what would this sentence be?

Schwan I think it is about pursuing a common purpose – putting the patient first – and living our values every day by sharing high standards of integrity, showing the courage to take entrepreneurial risks, and having a passion for our business.

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