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Dr Göran A. Ando, former chairman of Novo Nordisk and a Swedish life sciences industry veteran, recently moved back to his home country after over 35 years abroad. He shares his view on Swedish healthcare today, which is striving to continue its strong tradition of collaboration. Although Sweden is struggling to increase the number of clinical trials it hosts, Ando truly believes that the country has vast amounts of potential to become a front-runner in implementing the new generation of therapies and remain one of the best healthcare ecosystems in the world.

Can you start with informing our readers if there is a Swedish model of success for life sciences, and if so, what are its attributes?

The Swedish have a long tradition of working well together, and this dates right back to the early fifties and sixties. During that time, there was already a strong collaboration between companies and academia, which had developed naturally over time. Everyone involved saw the dual benefits of the situation. A number of inventions from the Swedish powerhouses, including Astra, Pharmacia and Kabi, were a result of basic research and long collaborations with scientists and institutes before they developed them into commercial successes. A good example of this collaborative relationship includes the discovery of a local anaesthetic called Xylocaine (Lidocaine), discovered at the Institute of Chemistry at Stockholm University, and then moved further along by the industry

to achieve commercial success, and still used to this day. Although not every discovery became fruitful, this exemplifies the concept of a working Swedish model for many industries, including life sciences.

Looking more in depth into the national healthcare system, there are advantages and disadvantages of this model. Although our healthcare is funded regionally, there is no post-code lottery and there is a strong focus to ensure that patients are treated equally regardless of location. Also, we can capitalize on being a small country to ensure no patient is lost in the system, especially when it comes to treatment follow up, due to personal ID numbers which are used throughout the healthcare system and across the society.

From a research standpoint, this system is extremely valuable and ensures the triangle of communication between hospitals and clinics, academic research and commercial companies is strong. This triple-helix existed very early on and is of benefit to all three parties.

What are some of the main pressure points in Sweden's healthcare system?

The problem now in Sweden, and in many other mature countries, is the financial pressure on the hospitals and out-patient clinics. A growing population and variety of treatment options equate to financial pressure and an employment strain on the system, resulting in less time available for classical clinical research.

Sweden was an early pioneer in large clinical studies, examining fundamental treatment options and some resulting in global changes of practice in the treatment of MI and other cardiovascular diseases. If we have ambitions to keep this, physicians and nurses need to be able to allocate much more time to conduct studies, reversing some of the current pressures in the system.

Typically, clinical research in Sweden has an incredible reputation, which has not disappeared. Unfortunately, the large, ground-breaking studies have diminished year on year for a while now, and that needs to change. My feeling is that the government is very open to improving clinical studies in the country. The committee I sit on for the government will follow this change very carefully and see what can be done from all sides to change it.

The real crunch sits with the regions, who have the financing responsibilities and thus have to find the money to fund them. Everyone is on board with finding a solution, and if money wasn't a problem, there would be no objection and the physicians would love to participate more. The main struggle is the financing, and Sweden needs to find a way forward to allocate more time to

scientific research and get the country back into the world leading role it can have.

Looking at the internationalization strategy of Swedish companies, we see that the majority of them are very outward looking. So why is it so important to have a domestic regulatory and pricing agency of such high-quality when you are targeting the outside world?

An important point to remember is that Sweden is small and almost nobody speaks Swedish unless they are born here. If you have ambitions, you have to look globally very quickly, and this is exactly what many Swedish industries did. They started with Northern Europe, then expanded further overseas to ensure there are no boundaries when it comes to reaching people and patients. Companies became very comfortable with this method, typically because you will rarely find an employee who does not speak English, and many will also command another language. This skill of cross-country communication has been the real driver of internationalization.

However, it is important to have a strong, domestic healthcare landscape and progressive regulatory system. This is evident when you begin conducting early-stage clinical trials. It is important to be as close as possible to these, so you can have the opportunity to interact with every single volunteer and analyze every detail carefully to ensure the best result possible. This is equally as imperative when conducting comparative clinical trials, and having a top-quality domestic system ensures you have the best comparator drug possible.

In my opinion, Sweden’s Medical Products Agency (MPA) has been extremely progressive in every aspect. The EMA farms out its reviews to a rapporteur and co-rapporteur, and Sweden, alongside the UK, has been the most proliferate due to the ability to recruit and retain high-quality scientists and physicians at the local regulatory agency. The MPA’s work on a local basis sees the agency remaining very open to meetings. Although they are tough, they share their views and key information effortlessly and are striving to bring better medicines to the country. For small companies, this is invaluable, and the MPA is seen as a good partner in Sweden’s healthcare ecosystem.

The Dental and Pharmaceutical Benefits Agency (TLV) is another vital player in positioning Sweden as a world-class healthcare system. They have shown a superb balance of prioritizing essential drugs at the right compromise for the companies and pushing these through onto the market quickly and efficiently.

All of the local agencies and players have been essential in creating a strong domestic healthcare system, which sets the foundation for producing the next AstraZeneca of the world.

There is now a “new generation” of therapies entering the global markets, like cell and gene therapies, with no healthcare model ready to embrace them yet. Does Sweden have the potential to be a front-runner in integrating these new innovations into its healthcare model?

Sweden definitely has the potential, which is augmented when you look at the different healthcare models in the world. One of the biggest problems for an insurer in the US is that they typically have the same patient only for two years. So, unless the insurer can be guaranteed pay-back for treatment in these two years, they have little interest in paying. So, these new therapies are exceedingly difficult to integrate into current healthcare models, especially when it comes to pricing.

In Sweden, the difficulties aforementioned are not of consequence, because we have the same payer that takes care of you throughout your treatment. This makes it easier for our system to make an economic calculus and ensure that a decision on your healthcare is made efficiently. Looking at an extreme, if it is between whether you go blind at an early age or not, the decision is easy.

Working out the benefit ratio for the patient and society can be achieved fairly easily in a country like Sweden due to our current healthcare system. However, this will not be as straightforward in other complex markets around the world, so definitely Sweden can lead in this.

As an industry executive on the board of many biotech companies around the world, can you share some commonly made mistakes by CEOs during the drug development process that you have witnessed?

There are some traits of management that do not have national boundaries, especially in small biotech companies. One of the most obvious, and most frustrating, is the design and development of clinical trials orchestrated around their financing as opposed to the optimal scientific answer you wish to see. This means trials are underpowered often, leading to an end result in the “grey zone” which is of no use! A lot of time has been wasted and an enormous amount of money frittered away when you have no clear answer. As a result, you do not know if the drug is effective, and if it

is not effective how to rectify this. Unfortunately, this is still a common mistake and is driven by insufficient funding at that stage of the company.

Research and development is both scientific and experience based. It is paramount that a company has access to industry veterans, even if it's through consultancy or members of your board, who have had experience and seen the highs and the lows of this part of the process because they hold the knowledge that is most helpful to avoid unnecessary errors and setbacks.

Another, which is fundamental for a small company, is the inability to attract enough competent talent. We see that scientific competence and knowledge is always present, as this is how many companies are started and thus funded. The pitfall is on the side of the development competence and the understanding of the business landscape. A common error is a presumption that the world is standing still whilst you develop your drug. The best biotech companies and most successful are those who know exactly what is happening on the ground in their therapeutic area now, whilst in parallel visualizing the market in six to seven years' time, when their drug is at the commercial stage. It is about knowing the competition and seeing potential scenarios of whether your drug can withstand its competitors on the market. R&D is all about the hurdles of the future, and this requires a lot of skill and even more data.

In parallel, what do you see achieved in smaller organizations that can inspire bigger companies?

I think the ability to quickly pick up a trend and move forward with it is a great advantage for a small biotech company. In bigger organizations, they will do a variety of reports, committee meetings and so on. By the time they have reached a consensus agreement, typically that opportunity or trend is no longer available. Small companies should really work hard to protect their nimbleness because, if used well, it has tremendous power.

There have been a number of attempts to mimic this from big companies, for example splitting up departments into their own mini-organizations. The devil in this is that each compartment within the same organization is fighting for funding and resources. For me, this creates the enemy from within and produces a mindset of "as long as I am better than my counterpart I am fine". This does not always result in the desired behaviours.

The industry landscape is moving from an in-house model to a collaboration mindset, with big companies sourcing innovation through M&A. Do you believe this model is here for the long term?

The best model of success stems from significant amounts of collaborations, with big multinationals working together with 20 to 30 small biotech companies. I urge that it remains a collaboration and that they do not try to integrate them into their big and complex system because the collaboration falls apart and the biotechs are then structured to the bigger company's model and bureaucracy. Moreover, in an ideal situation, I would like the M&A aspect to be avoided, as this wipes out the company. Especially if their science is of good nature and quality.

However, for this model to continue, we need more investment and VC funds to really drive the life sciences industry, and this is an area of improvement for Sweden. What I see is that early stage financing is pretty good but lacking in mid to late stage funding. The investment that exists within Europe either stays within the boundaries of its country or moves away over to the US, bypassing the other countries within the union.

This lack of investment is forcing our small start-ups to out-license too early or fold altogether because they cannot access the essential funds. This is a tragedy for the local industry. Everyone knows the best way to build value of a company is to hold on to assets for as long as possible and their value curve becomes very steep towards the end.

A major dream of mine is to see more intelligent investment from some of the large investment funds, i.e. the pension funds, that exist in Sweden.

To conclude, please share your final message for our audience of industry leaders about Sweden.

Sweden has a tradition of world-class science. The government invests very heavily in the life sciences landscape and this is evident in our universities, research institutes and hospitals. Every political party agrees that the Swedish life sciences are very good, and totally independent from politics because these investments are long-term.

Although we do not have many universities, they are large and sophisticated establishments. We are able to commercialize academic discoveries because the universities have been structured to handle this from the offset. Moreover, there is a positive attitude towards creating both new companies and driving the ones that already exist, especially when the science is very good. The

Swedish healthcare system is accustomed to innovation, from pharmaceuticals to medical devices. In terms of the ecosystem, Sweden’s overall regulatory framework and commercialization focus is structured to ensure that new inventions are integrated into Swedish healthcare efficiently. This absolutely exemplifies that Sweden can be one of the best healthcare systems in the world.

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