

# 2014's Outlook on the Pharmaceutical Industry



## HELLSTRÖM

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*Peter Utterström, Senior Counsel at Hellström Advokatbyrå KB law firm, tells us how the pharmaceutical industry has fared so far this year, and what the future holds.*

### How would you describe the current business environment in your region?

Sweden has so far been fortunate in having a stronger financial situation than most countries in the western world and as a result the financial crisis has by and large passed without major effects. Unemployment is statistically high – approx. 7% – which is low from an international point of view. The recent election to Parliament creates some concern as the populist won a stronger than expected position – 13% – which will make it difficult to rule the country; two minority blocks in balance each with approx. 40% and a populist far right or brown party with a casting vote will create issues and difficulties. Top this with a new prime minister with no or little experience in politics and diplomacy Sweden is about to enter into a bumpy and risky ride!

### It is being predicted that the pharmaceutical industry could be worth nearly US\$1.6 trillion by 2020. Where in the industry will the largest and most rapid growth be seen and where will present the biggest opportunities for businesses looking to take advantage of this growth?

Based on experience one comment is that the traditional pharma companies are likely to remain but with less influence and impact. Teaming up with focused specialist companies – startups as well as well established – and acquisitions of such companies are likely to be even more frequent in the future. Furthermore, investors are likely to be more interested to risk money in the MedTech companies are likely to be very active as they are deemed to be lower risk (as compared to bio/pharma). Then, finally, we have the increasing merger between pharma and medtech, i.e. the use hardware in combination with pharma which is moving rapidly technologically, as well as the introduction of the use of smart phones as part of the health system whether to analyse status or to monitor

a patient. I assume that this latter sector will grow exponentially and will attract investors. Again, the time from idea to market is fast as compared to bringing a new drug to the market.

### What challenges (legal, operational, demand for medical services) face businesses looking to enter pharmaceuticals from another sector?

To the pharma industry the key problem is time – once you have found the “right” molecule it will take at least 10+ years and more than USD 1Bn until you have a product which can go commercial. That is if you have one – the odds are better in Russian roulette! Legally there are many regulatory hurdles to pass until there is a product to sell on the market and in addition there are a lot of IP-issues. Finally, in order to get to the market it is a necessity (at least in most European countries) to qualify for state approval for subsidy, i.e. to show that the new product is more cost efficient than the one it is intended to replace. This may also be one of the reasons why investments are going to the substitute market and to MedTech.

Finally, truly personalized medicine which will come sometime in the future is not aligned with the current regulatory environment; today such drugs can come into play when all traditional medicine and actions has been exhausted but not for “ordinary use” – at least not in countries with a highly regulated pharma R&D sector. The challenge will be how to align the development and use of “personalized medicine” with the regulatory rules.

### Tell us about the part your business has to play in the industry over the coming years. Where does your greatest expertise lie and how can this be leveraged, both for you your and your clients' benefit?

Law firms and lawyers can – in addition to the

traditional role they have played – advocate the necessary changes to further the development. The obvious areas for the commercial law firms (like Hellström) with a focus on life sciences has traditionally been in M&A, IP and product liability issues which to a certain extent are or include unique elements to the life science industry. Considering the above, I assume that this will continue, however, with more players in the market. Furthermore, it is likely that the part of the work which can be commoditized will sooner or later be picked up by organisations like Axiom Law and Elevate Services. Finally, one area is the above-mentioned personalised medicine where the rules and the regulatory bodies must adapt to the technological development and how new products are likely to be brought to the market in the future. This is an area which will require highly skilled and experienced life science lawyers who can navigate in a legal area which is not adapted to the current regulatory environment. ■

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