AMCHAM
AMERICAN CHAMBER OF COMMERCE IN SWEDEN

Ministry of Health and Social Affairs
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Comments on public inquiry: Tydligare ansvar och regler för läkemedel (SOU 2018:89)

American Chamber of Commerce (AmCham) in Sweden works to build a stronger transatlantic business community, fostering innovation & the creation of shared value.

It is the aim of the American life science affiliates to contribute to Swedish healthcare by effectively providing solutions to improve patient outcomes, delivering scientific and societal value.

AmCham in Sweden represent more than 200 members, $ 108,7 billion in trade and investment and more than 300,000 employees.

In the area of Life Science, the following companies are represented;
3M, AbbVie, Aggrandir, Amgen, Biogen Sweden, Bristol-Myers Squibb, Celgene, GE Healthcare, Gilead, IQVIA, Janssen, Microsoft, MSD and Pfizer.

The AmCham Life Science Working Committee has identified five areas of special interest that in many ways overlap the directives of the public inquiry;

The voice of the patient *- Improve patient outcomes by accelerating access to innovation, including new treatments, early testing, early diagnosis and eHealth solutions.*

When the current system was introduced in 1998, one of the goals was to set in place a system that could meet future demands but is today perceived as complex and cumbersome.

If Sweden wants to compete for global investments in the Life Science sector a system which is easily understood from a global perspective is one prerequisite. American Life Science affiliates in Sweden see necessity for a predictable, stable system that has support in law on all levels.

The proposal from the inquiry group, that the special government subsidy for the pharmaceutical benefits scheme is to be included in the general subsidy to regions, risks becoming contra productive as the general subsidy lacks a link to actual and projected costs that include the introduction of new efficient therapies.

We see a risk that is could lead to unequal care in Sweden as there are differences in the regions in terms of tax-base and economy. The specially designated grant that the inquiry group has proposed to compensate for new efficient treatments this will not cover all new therapies, leaving the regions to prioritize.

Drive access to innovation, R&D and partnerships - *Sweden as a pilot market for life science and health technology in close collaboration with reputable universities and academia.*

Sweden has the potential to be in the forefront of the Life Science area. As stated above a complex system for introduction might be perceived as a barrier when global companies plan for clinical trials and launches of new effective therapies.

The inquiry group has proposed a new government subsidy to stimulate the introduction of new effective therapies. This is a positive signal from the Swedish government but also signal that the inquiry group sees a risk that Swedish regions might not prioritize investment in new effective therapies.

It is important to set up structures for follow-up of effective and equal introductions, to track the effects of changes in funding of medicines.

Value based healthcare - *Real World Insights and healthcare data. The Swedish Quality Registers are unique in the world and of significant added value in providing Real World Insights. Contribute to the transformation of Swedish healthcare towards value-based healthcare by improving understanding of patients, treatments, outcomes and costs.*

The price of a new therapy should reflect the value it gives to patients, the healthcare system and society. Value is a complex concept and is not created until a new technology or therapy is used. Today many treatments can reach the patients because of the three-party negotiation process. The inquiry group has proposed the type of agreements can be negotiated and that TLV should take these into account when assessing the cost-effectiveness of a specific treatment. We se the risk that this could lead to use of less effective therapies where there is a greater incentive to give discounts.

The price of a new therapy should create incentives for continued research and development. The development of new therapies is risky and with a high percentage of failures. Sweden should utilize the resources in terms of registries to allow for new therapies to be assessed and be compared to currently available treatments.

Health Economy Assessments done by TLV and price negotiations need to be separate processes. Value based pricing has been used in Sweden for a long time contributing to good patient access to new treatments and acceptable price levels compared to other European countries. Value based pricing in Sweden could be developed further to meet future unmet medical needs.

Accelerate digitalization - *Position Sweden at the forefront of the digitalization era. Swedish citizens have a high level of digital maturity with a digital presence of nearly 100%. This makes Sweden unique as a perfect testbed.*

Digitalization is a megatrend that could revolutionize the ability for patients to generate data on the value and benefits of pharmaceutical therapies.

Creating better prerequisites for follow-up can lead to a positive ecosystem in treatment and R&D. This will lead to more personalized treatments and lower costs of medicines.

Digitalization together with Sweden's registers can be of great value as complement to pivotal studies in assessing value of a therapy in Sweden. This is however dependent on that new effective therapies are introduced and used so that data can be generated.

The life science industry is a prioritized sector and high on the Swedish political agenda. *The sector benefits from a long tradition and an international reputation, including state-of-the-art care, the all-inclusive social security system and the Noble Prize.*

The Swedish government has stated a goal for a world leading healthcare system and that equal care should be guaranteed. The healthcare system is not only aimed at people currently ill but should also create the conditions necessary to ensure future investments in technologies that benefit society as a whole. In the analysis part of the proposals the inquiry group has identified several problem areas in the processes for pricing and reimbursement decisions. The proposals from the inquiry group are not enough to ensure system readiness for new types of treatment like cell- and gene therapies.

The new system proposed also manifests a negotiation-based system where a new authority (Läkemedelsrådet) will be created. It will however still be up to the regions how this new authority should work which in practice could lead to very little differences to todays NT-council. We also note that the inquiry group has not addressed the issue of an appealing process for recommendations made by the NT-council.

Other points of interest
The inquiry does not address the unreasonable demand that parallel imported products are included in agreements made with the original supplier. The proposal to limit the negotiation rights for parallel imported drugs with pharmacies is a step in the right direction, but not a sufficient measure to address the entire issue.

Stockholm, May 8, 2019

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