AmCham viser til høringforslag den 19. november 2021, om endringer i forskrift 18.desember 2009 nr. 1839 om legemidler (legemiddelforskriften) og forskrift 28. juni 2007 nr. 814 om stønad til dekning av utgifter til viktige legemidler mv. (blåreseptforskriften).

AmCham is a not-for-profit, member-led organization working to strengthen bilateral trade and business relations between Norway and the US. On behalf of our transatlantic member companies, we work to increase the attractiveness of Norway for international investment, employment, and innovation.

AmCham opposes the Government's intention to implement a tendering pilot program for select medicines within the Blue Prescriptions program, as well as the changes suggested for the associated regulations. We understand that an area assessment of the reimbursement system has indicated potential cost reduction within blue prescription medicines, but strongly advise against patients' access and doctors' autonomy being limited by a framework so heavily weighted on price alone. We respectfully encourage a more holistic view of the Blue Prescription system that takes into consideration the widespread impact that such a program may have. Alterations to regulations regarding these prescriptions, as well as the increased use of comparative measures - such as the '*technically equivalent medicines'* principle - weaken the predictability of the Norwegian healthcare market and threaten to negatively influence Norway's competitiveness internationally.

AmCham encourages the Norwegian government to carry out a thorough assessment prior to the program's implementation. We deem this vital given the foundational regulations changes the program demands, as well as the broad impact of this program both domestically and within the international ecosystem. There are considerable implications for patients, the development of new innovative treatments, and Norway's long-term goals for expansion of its healthcare sector.

Predictability & Additional System Pressure

To meet the Government's goals within the healthcare sector, it is crucial to view any changes to the pharmaceutical procurement or approval systems from an international perspective. To attract the level of clinical trials and foreign investment indicated in the *Action Plan for Clinical Trials*, *Perspektivmeldingen*, or even *Hurdalsplattformen*, multinational companies must be able to properly forecast the need for their products in the Norwegian market. If large scale tendering is implemented, Norway will undermine predictability in planning for consumption levels, stockpiling, and for providing internationally competitive standards of market access.

Tender outcomes would significantly alter demand for medicines – with wins requiring vast amounts to be quickly procured, and losses leading to supply excesses and waste. This creates supply chain strain for pharmacies and the general welfare system, with patients left without their medications, or in need of abruptly prescribed alternate treatments. Norway's import-reliant system is not suited to such variance. With the average length of validity for a prescription set at one year, it is important to assess the consequences of fluctuating tender outcomes upon patients' ability to fulfil prescriptions, and potential additional pressure on their primary care physicians.

Internationally Competitive

Central to the proposed tendering pilot program is a uniquely Norwegian concept: the principle of *technically equivalent medicines*. This approach is at the center of bilateral trade disputes, and most

recently addressed in the Evaluation of New Methods.[1] Further, this hearing consultation references both the ideas of *medically* and *therapeutically equal* - but, as with any previous mentions of these terms, does not provide a definition. There is also no consideration given to the establishment of the specialist group which will maintain responsibility for oversight of *technically equivalent medicines*, nor to the creation of a process by which these medicines will be determined. Given the lack of transparency and the pharmaceutical industry's scientifically documented position that non-generic medications cannot be exchanged in such a simplified matter, the reliance upon this method of comparison within this tendering program is concerning.

Legal Foundations

We are aware of the area assessment that has led to this proposed program, but not of reports or assessments on the impact of general regulation changes. [2] There are references to reports in both the hearing consultation and on the Ministry for Health and Care Services website, however we are unable to comment on their respective findings as we note that many of these reports have not actually been published.

This pilot program requires many changes to regulations and laws with broadly spanning application. AmCham Norway therefore argues that before these changes can be approved, this program must be properly assessed. It is critical to responsibly control the impact and possible widespread implications of these regulation alterations outside of the context of this pilot program.

Political Goals

AmCham understands that the Government must address rising welfare system costs and adhere to strict financial guidelines. However, the introduction of this tendering pilot program has a cost containment focus that heavily outweighs the three additional, equally important, political goals outlined in the Whitepaper on Pharmaceuticals.[3] With a disproportionate fixation on price as compared to enhanced quality or impact of treatment, the government is signalling a lack of value and understanding for innovation and the research phase. This will severely hamper Norway's goals of being at the cutting edge of healthcare and of attracting international clinical trials. Rather than taking a unique approach to pricing, or deepening collaboration with private sector partners to understand what makes a market attractive, an additional layer of pricing mechanisms will hamper patient access and increase inefficiency.

[1] Evaluering av Systemet for Nye Metoder
[2] Riktige Legemidler til Rett Pris
[3] Legemiddelmeldingen — Riktig bruk – bedre helse *White Paper on Pharmaceuticals*