REPUBLIC OF ESTONIA
MINISTRY OF SOCIAL AFFAIRS

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Dear Commissioner Várhelyi,

Allow me to congratulate you for taking the office as Commissioner for Health and Animal Welfare and wish you all the success in your new position. I would like to express my appreciation for the Commission's dedication to improving public health in the EU and reducing the inequalities within and across Member States. Ensuring equitable access to high-quality medicines across the EU remains one of the most important policy objectives where decisive action is needed. As we continue to refine the EU pharmaceutical reform, I seek your support in addressing the crucial issues of delayed market entry and limited availability of medicinal products in some Member States.

Despite Estonia's efficient healthcare system and streamlined national processes for the pricing and reimbursement of pharmaceuticals, our small market size often results in being overlooked by the pharmaceutical companies when launching their products in the EU, leading to significant delays for our patients in accessing essential treatments. Only around 20% of new medicines with EU central authorisation reach our market during the first four years after the authorisation. As a result, Estonian patients must often wait more than two years before the company shows interest in launching their pharmaceuticals in our country, even when these therapies are available elsewhere in the EU. For some diseases with major impact on patient´s quality of life and high unmet need (for example vitiligo, alopecia) even the proactive approach from our Health Insurance Fund has not guaranteed submission nor actual interest in price negotiations. This situation creates a troubling disparity within the Union, where healthcare access depends on market attractiveness rather than patient need.

The revision of the EU pharmaceuticals' legislation offers a unique chance to remedy this by ensuring that every EU citizen receives timely and affordable medicines, regardless of their residence. Estonia advocates for promoting equitable access throughout the EU by incentivising pharmaceutical companies and we have been strongly defending the Commission's proposal on the modulated regulatory data protection. Imposing obligations without corresponding rewards in practice could maintain current disparities, as it would not encourage companies entering less profitable markets. The Commission's initial proposal was well-balanced in terms of the goals of the EU pharmaceutical reform – more accessible, affordable and innovative medicines to all EU citizens. It is worrying to see the direction, where economic interests seem yet again to prevail over the interests of public health, which will jeopardize the initial aim for more affordable and equally accessible medicines.

Improved access to medicinal products cannot be achieved without EU level interventions, regulatory measures are needed alongside voluntary initiatives such as joint procurements. There is a clear internal market imperative that medicinal products, which have been centrally authorised should be made available throughout the EU. There are no public health

reasons that would justify the current fragmentation of the internal market for pharmaceuticals. Joint procurements can effectively pool demand and ensure supply for certain medicinal products, like orphan drugs and essential generics, but they shouldn't be the primary route for market launch. Health technology assessments (HTA) and price negotiations are often more effective in achieving competitive pricing. HTA helps to ensure that funds are allocated efficiently by identifying treatments that provide the best value for money, which results in better health outcomes for the population. The HTA Regulation introduces a new process for Member States to jointly evaluate the relative effectiveness of new pharmaceuticals, enabling efficient national cost-effectiveness analysis, but this requires companies to promptly submit their economic dossier to the Estonian Health Insurance Fund after EU-level assessments.

Since the incentives-based approach proposed by the Commission has not received sufficient support, it is necessary that clear and enforceable obligations would be set at the EU level to the marketing authorisation holders regarding the supply of medicinal products. Access to medicines should not be left only for the Member States to tackle on their own as it currently very much depends on the marketing strategies of the companies and Member States have no leverage to influence these decisions driven by economic considerations that lead to cherry picking on the internal market.

We hope for your support to tackle delayed market entry at the EU level, as national measures alone are insufficient for Member States with smaller markets. It is vital for the Commission to take a more active role in overseeing supply obligations of the pharmaceutical companies, especially regarding dominant market positions.

By focusing on practical solutions, we can reduce unnecessary bureaucracy, aligning with the EU values of fairness and solidarity. Your leadership in advancing these initiatives is crucial to ensuring every EU citizen has a fair shot at access to medicines. I appreciate the opportunity to further discuss these issues with you in person in the nearest future.

Yours sincerely,

Riina Sikkut
Minister of Health