

- **Statement Nordic Pharmaceutical Forum and the Beneluxa initiative**

- In recent years, efforts to enhance international payer collaboration and the willingness to exchange expertise and knowledge have increased substantially. The need for international exchange intensifies due to the challenges that authorities, including payers face concerning pricing, reimbursement and procurement of medicines and therapies. In order to ensure access to new medicines for patients these issues are essential to solve in an effective and rational way. The efforts have materialised in the form of international platforms such as the Nordic Pharmaceutical-Forum (NLF); constituting of Norway, Sweden, Finland, Denmark and Iceland, and the Beneluxa Initiative; constituting of Belgium, the Netherlands, Austria, Ireland and Luxembourg. Concrete outcomes of these platforms include the organisation of the international horizon scanning initiative (IHSI) as well as an increased interaction between these platforms. A number of strategic meetings have taken place where other international payers also joined these discussions.
- Recently, the European Commission has launched a new Pharmaceutical Strategy for Europe highlighting similar issues with regards to ensuring access to affordable medicines. The Strategy specifically refers to the strengthening of existing and potential new cross-country collaborations.
- Our joint efforts have focused on a number of issues related to the pricing and reimbursement of medicines. The Beneluxa Initiative and the Nordic Pharmaceutical Forum will initially aim to examine the following matters together:

1) The importance of cost effectiveness in the assessment of value of medicines.

- The appropriate use of cost effectiveness offers a framework, which allows decision makers to maximise health gain within a limited budget. It also allows decision makers to estimate the price which is likely to achieve value. Therefore, the certainty of cost-effectiveness should be considered in any negotiations. i.e. the (un)certainly about the effectiveness of the medicine balanced with the high monetary risk.

1) Availability of robust clinical evidence for decision makers in a timely manner.

- The Beneluxa Initiative and Nordic Pharmaceutical Forum agree that timely access to effective medicines for patients is important. However, a number of recent developments within the process of market authorisation have been designed to facilitate earlier access to medicines. With this, the challenge arises that there may be a lack of data demonstrating clear benefit at earlier time-points. This makes value assessments increasingly difficult. Therefore, the availability of clinical evidence (including studies where the endpoints are not met) is of vital importance to allow decision makers to adequately assess benefit and value.
- We aim to mainly examine the following: 1) the timing of the (cost) effectiveness assessment, and 2) the value-framework for assessing medicines in general, with a focus on those medicines for which there is limited or no data to support a decision based on the (cost) effectiveness.
- The need to collaborate on the challenges facing decision makers in relation to achieving value from medicines is abundantly clear. We will address some of these issues together through continuous dialogue and an intensification of the collaboration between countries aiming to achieve more alignment in our value assessments.