

## DENMARK

### Recent and planned developments in pharmaceutical policies 2019

#### Special topic: patient-based reimbursement decisions

##### CHANGES IN PRICING

- Price changes: The Danish association of the Pharmaceutical Industry has signed a voluntary price cap agreement regarding reductions of list prices. List prices will be reduced with 12,5% from 2019-2023, annualized 2,5 % each year.
- ERP system is in scope for being effective from January 2020 for hospital medicine and June 2020 for out-patient incl. generics, biosimilars, parallel imported drugs to reduce list prices for drugs not covered by the voluntary price-cap agreement

##### CHANGES IN REIMBURSEMENT

- The Ministry of Health initiated a pilot scheme where The Danish Medicines Agency have to include two products in a risksharing model running from 2019-2021. We are in the process of finding the two products and estimating the patient population for the products to be included in the model.

##### OTHERS CHANGES

- An Intentions Agreement between Denmark and Norway regarding joint negotiations on selected medicines. Signed in September 2018. Iceland joined the agreement 1 April.
- Joint Procurement procedure between Denmark, Norway and Iceland have been announced and with submission deadline by 21<sup>st</sup> May 2019 for suppliers to bid in.
- All Danish pharmacies are required to verify authenticity of medicine, as EU serialization directive started implementation Feb 9<sup>th</sup> 2019

##### SPECIAL TOPIC: patient-based reimbursement decisions

###### Out - patient

- If a pharmaceutical product is not eligible for general reimbursement the doctor can apply for single reimbursement for a specific patient. In 2018 we received 75.000 applications.
- The Danish Medicines Agency evaluates and decide whether or not a single reimbursement can be granted.
- The criteria's for single reimbursement are:
  - whether the drug has a therapeutic significance for the patient, which is proportionate to the drug's price including whether it has shown effect on the patient, or the expected effect must be considered predominantly likely, and
  - whether other rational treatment methods in the particular case have been found to be inadequate, not tolerated or inappropriate.
- The duration of the decisions vary from pharmaceutical to pharmaceutical.
- The procedure applies both to drugs with and without a MA in Denmark.
- If the drug are conditional reimbursed and the patient do not meets the conditions the doctor has to apply as well.