

Prevention and mitigation measures in Norway

Multistakeholder workshop on GLP-1 analogues 01.07.2024
Guri Wilhelmsen, Senior Adviser, Norwegian Medical Products Agency

Background

- Medicines for patients with chronic diseases are generally reimbursed by the National Insurance Scheme (NIS)
- NoMA is responsible for health technology assessments (HTA) and reimbursement
- Frequent use of foreign packages (unauthorised) to solve shortage situations
 - NoMA grants permit to wholesalers/MAH
 - If critical indication
 - Patient group of substantial size
- All GLP-1 analogues fulfil these criteria

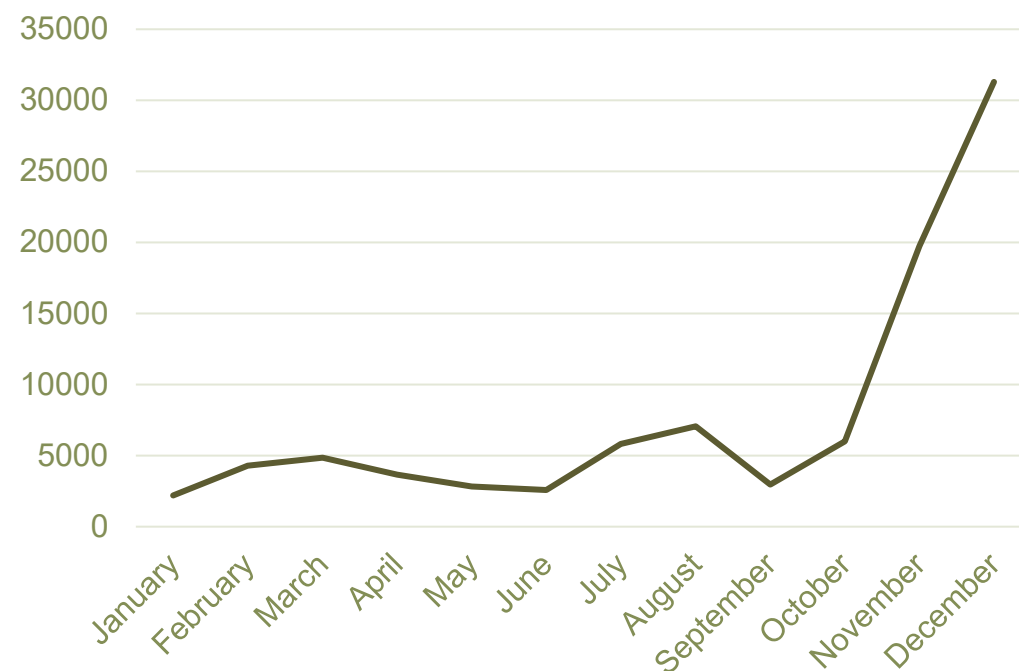
Risk assessment of notifications

- Shortage duration > 2 weeks
- No equal alternatives with Norwegian marketing authorisation.
- MAH or wholesalers have access to foreign packages.

Expensive shortage

- Foreign packages (unauthorised) usually financed and reimbursed by the National Insurance Scheme (NIS).
- The price of foreign packages of Ozempic has been up to seven times higher than the price of Norwegian packages.
- So far in 2024, additional expenses for the National Insurance Scheme had reached NOK 931 million (81 million EUR)
- Extraordinary situation for Ozempic:
 - Ongoing shortage for a long time
 - Price
 - Growing patient group

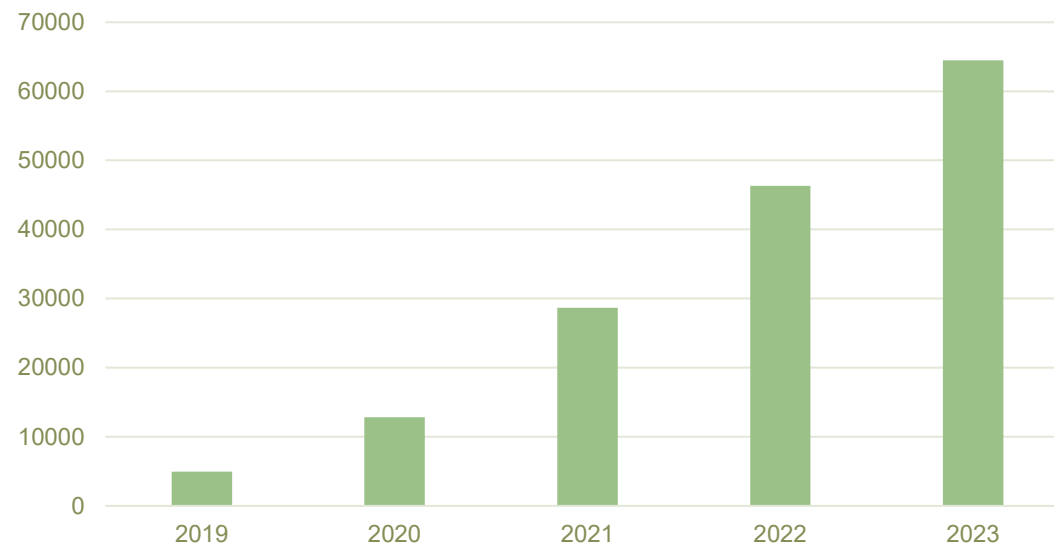
Number of foreign (unauthorised) packages in 2023



Prescriptions

- Number of patients increasing
- Ongoing partial shortage – deliveries not sufficient to meet demand
- Ozempic reimbursed to diabetes patients, but on certain conditions *
- More than 64.000 diabetes patients reimbursed in 2023
- About 16.000 diabetes patients received treatment at the expense of the National Insurance Scheme (NIS) outside the approved reimbursement criteria in 2023
- Off label prescribing not the main issue (not reimbursed)

Number of patients receiving reimbursement for Ozempic 2019-2023



Reimbursement of Ozempic accounted for almost 10% of NIS' total expenses on medicines in 2023

Measures effective from 01.07.2024

Introduced with the intention to secure access to medicines for diabetes patients and limit expenses

Improve access for patients in greatest need of treatment by control of reimbursed prescribing and dispensation in pharmacies

- Transition from pre-approved reimbursement to individual grants (application from doctor)
- Controlled distribution and rationing in pharmacies
 - Stop in dispensing of off-label prescriptions
 - Dispensing four weeks at a time to diabetes patients eligible for reimbursement
- Removal of reimbursement of foreign packages
 - To compensate for reduced number of packages, diabetes patients will also receive individual grants for treatment with semaglutide tablets

Revised National Budget:

Boosting access to diabetes medications and reducing national insurance user fees

News story | Date: 16/05/2024

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The government's revised national budget contains proposals for individual grants for the diabetes medication Rybelsus and the rationing of Ozempic in pharmacies.

Reimbursement costs for the diabetes medication Ozempic have risen significantly since 2019, and these costs now account for approximately ten per cent of total national insurance drug costs.

The medication is being used extensively for the treatment of obesity, which is not included in the approved uses for the blue prescription scheme. High levels of demand for Ozempic around the world have resulted in a global shortage of the drug.

