



Substitution in pharmacies and biosimilars - Norway

2022 European Commission Biosimilar Public Event

13th of December 2022

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I will talk about biosimilars and

- Events leading to the «legalisation» of substitution in Norwegian pharmacies
- Sales of insulin glargine and teriparatide after substitutability is introduced

Events 2001 - 2020

- Generic substitution in pharmacies allowed 2001
- Generic substitution an established measure:
 - Substantial savings for the national insurance scheme and patients
 - Accepted by most parties/people
 - In average: Prescribers reserve 5 - 7 % of packages against substitution, patients 10 %*
- 2020: Generics 75 % of packages on the substitutable segment*

Events 2013 - 2016

- NoMA suggests to change legislation to allow substitution of biological medicines in pharmacy
- Industry:
 - Suspected trouble with immunogenicity
 - Doctor only should switch patients
- Ministry funded «NorSwitch»-study: Remicade/biosimilar
- Hospitals: Tendering - Biosimilars gain market share and provide substantial savings
- Out-patient sector: Nothing happens....

Events 2017 - 2020

- 2017: Article «Interchangeability of Biosimilars: A European Perspective»*:
 - Sum up of available information
 - «Switching patients from the original to a biosimilar medicine or vice versa can be considered safe»
- Improved pharmaco-vigilance:
 - Batch-number – from pharmacy to prescriber/electronic patient record
- 2020: Ministry sends proposal to allow substitution in pharmacies on hearing
 - Many positive responses
 - Negative response from industry

*<https://pubmed.ncbi.nlm.nih.gov/28120313/>

Events 2021

- Norwegian Parliament votes change of law, unanimously
- NoMA:
 - June – August: Hearing of proposal to include 4 biological substances in substitution list:
 - Is substitution in pharmacy safe? E.g. is device «similar», patient group, therapeutic window
 - November: Substitution of insulin glargin and teriparatid in pharmacies possible

Events 2022

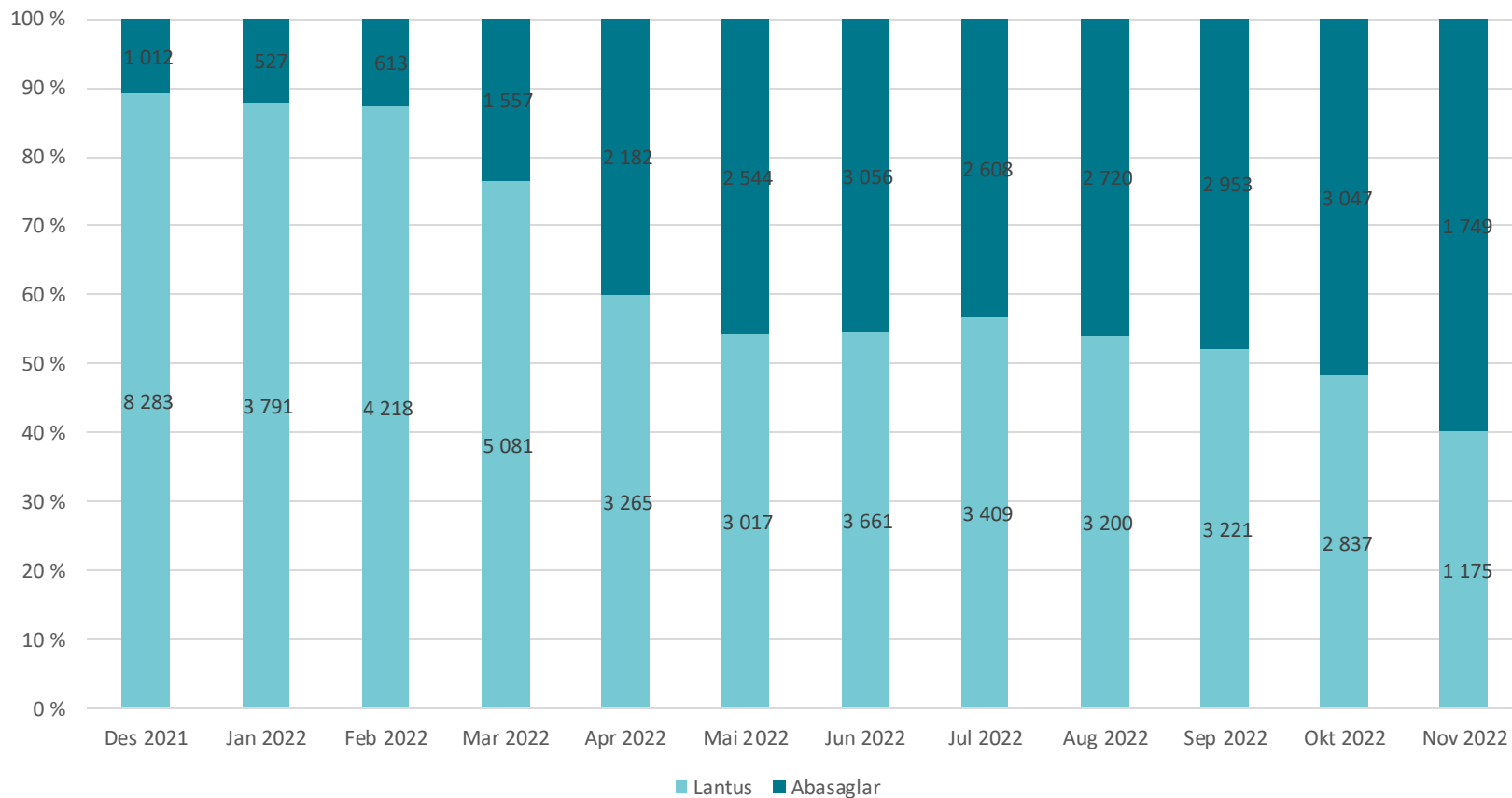
- EMA statement on interchangeability (September)
- November: insulin lispro and teriparatide substitutable in pharmacies

Insulin glargin (diabetes I)

- Insulin glargin:
 - Substitutable in pharmacies 1st of November 2021
 - Price reduction of 16 % 1st of March 2022
 - Second price cut: to be decided
- MA-holders:
 - Sanofi (ref.product) and Eli Lilly (biosimilar) – substitutable, marketed
 - Viatrix (biosimilar) – substitutable, so far not marketed in Norway
- Biosimilar 60 % of packages sold in November 2022, 7 % pre-substitution

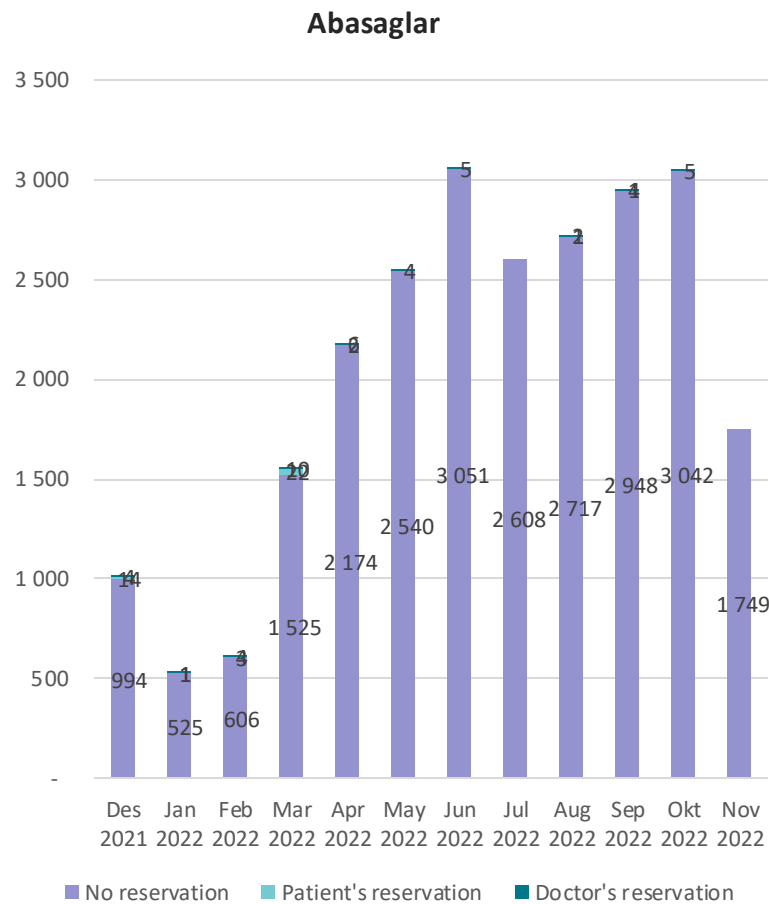
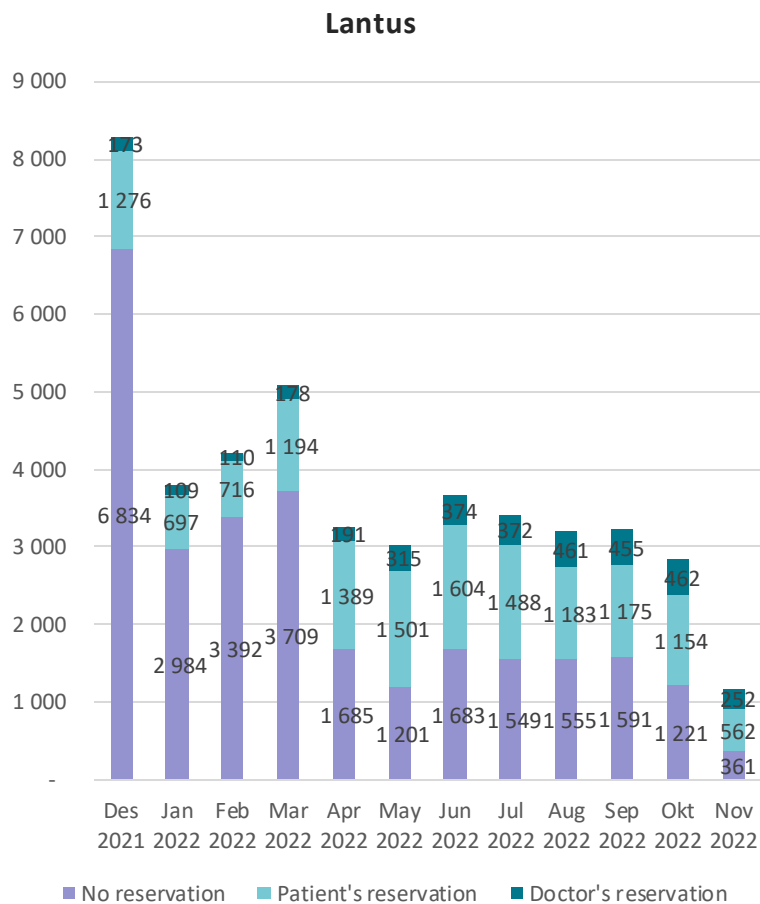
Insulin glargin – Volumes

Share of total packages sold per month



Source: VareWeb's statistics (of 17.11.2022)

Insulin glargin – Reservations per month



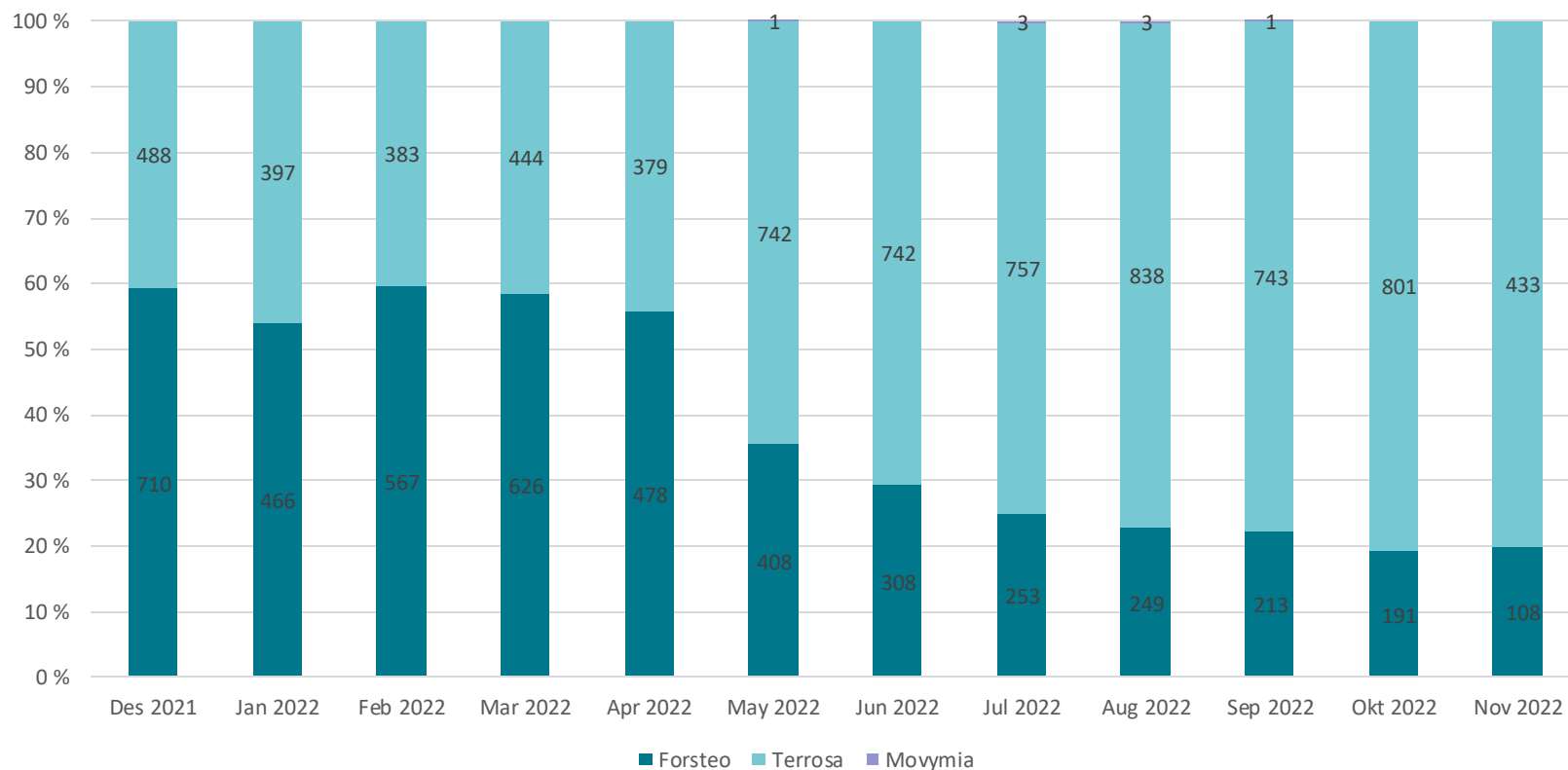
Source: VareWeb's statistics (of 17.11.2022)

Teriparatide (osteoporosis)

- Teriparatide
 - Price reduction 22 %
 - MA-holders:
 - Eli Lilly (ref.product), Gedeon, Stada, (Theramex) - substitutable
 - Biosimilar 80 % of packages sold in November 2022, ca 1/3 pre-substitution

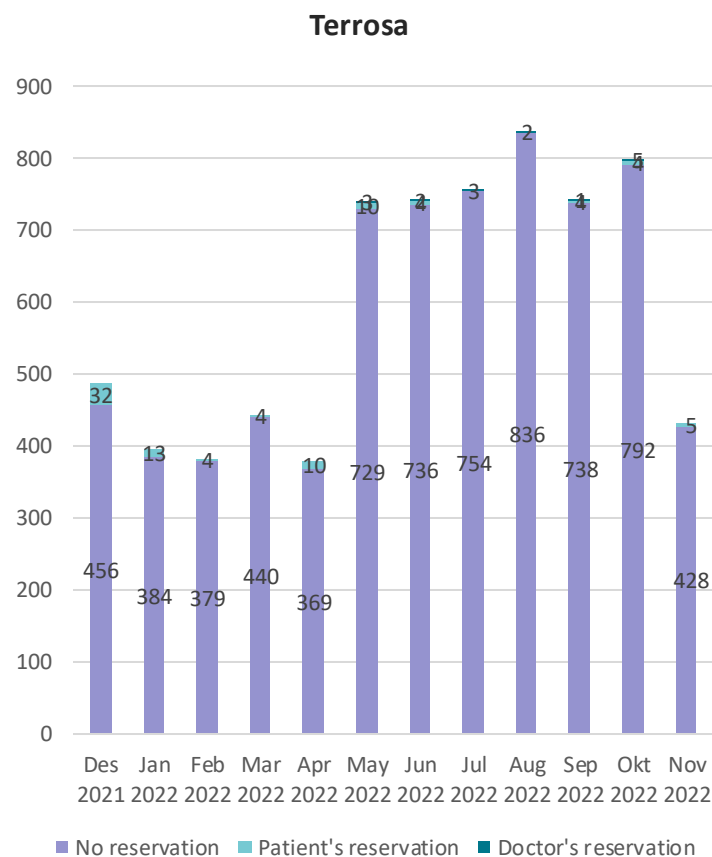
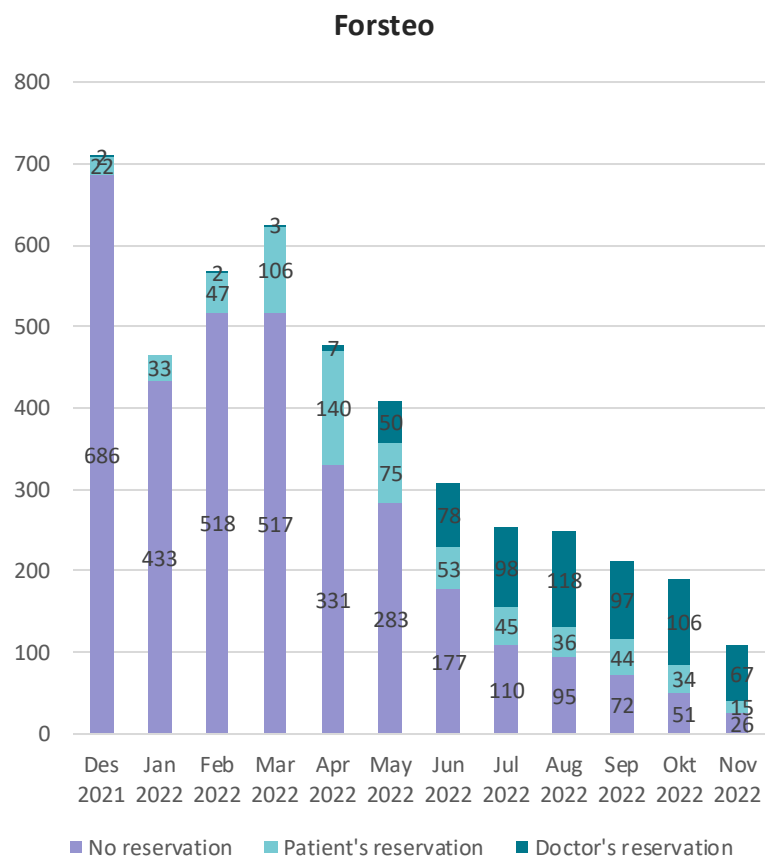
Teriparatid – Volumes

Share of total packages sold per month



Source: VareWeb's statistics (of 17.11.2022)

Teriparatid – Reservations per month



Source: VareWeb's statistics (of 17.11.2022)

Savings?

- Takes time before companies that compete on price will engage
- Norway early mover, small market
- Early days.....

- Questions?
 - May be mailed to: helga.festoy@noma.no

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Extra slide: Stepped price model - biologicals

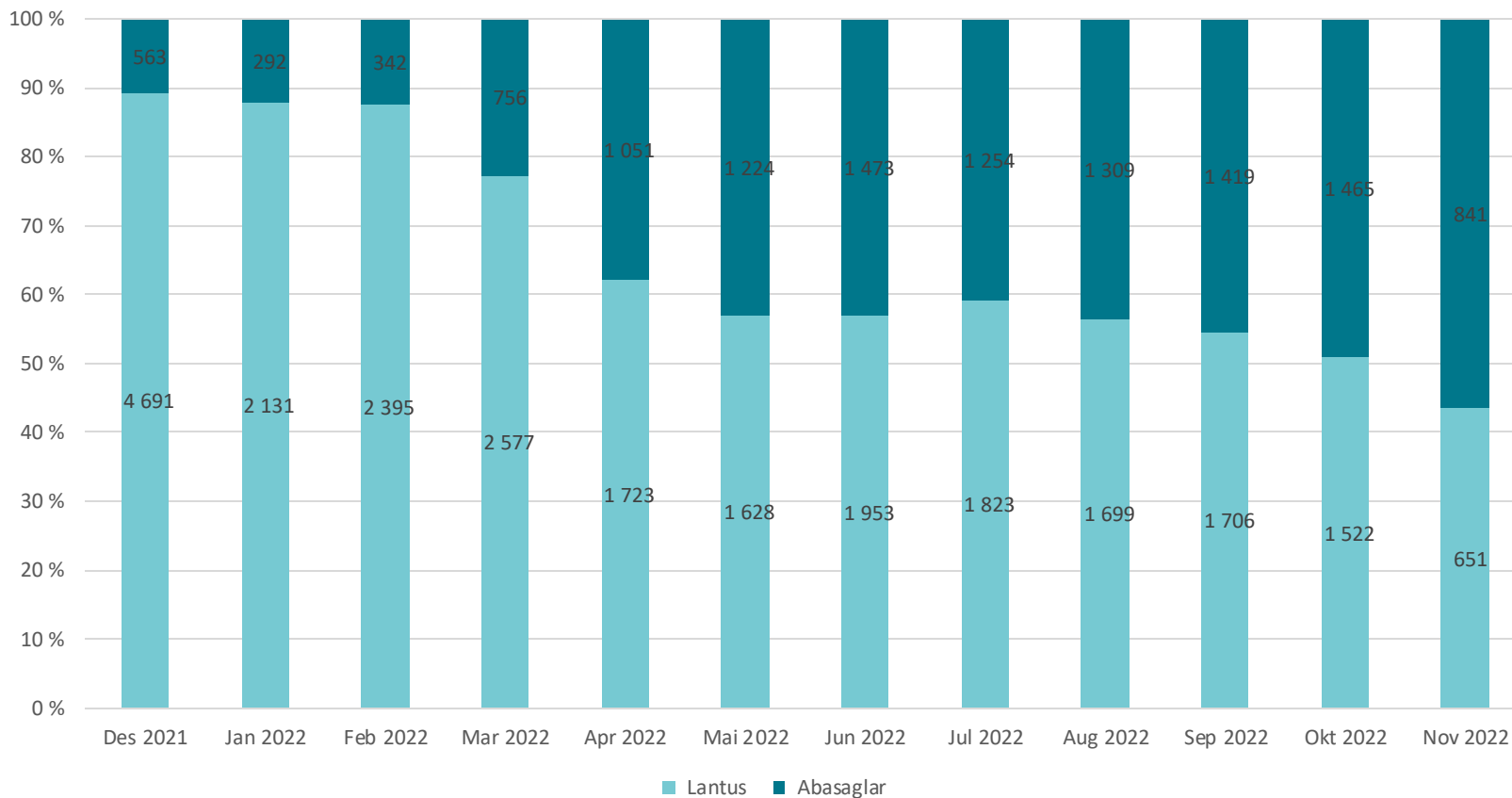
Turn-over pre competition	1. Price cut	2. Price cut (+ 6 mnths)	3. Price cut (> 18 mnths)	
< 100 mill. NOK	25 %	50 %	Turn over > 15 mill. NOK:	60 %
> 100 mill. NOK	25 %	70 %	Turn over > 30 mill. NOK:	75 %
			Turn over > 100 mill. NOK:	80 %

The model states maximum price cuts.

The NoMA may decide lower cuts, on a discretionary basis.

Insulin glargin – Sales revenue

Share of total sales revenue* (in 1000 NOK) sold per month

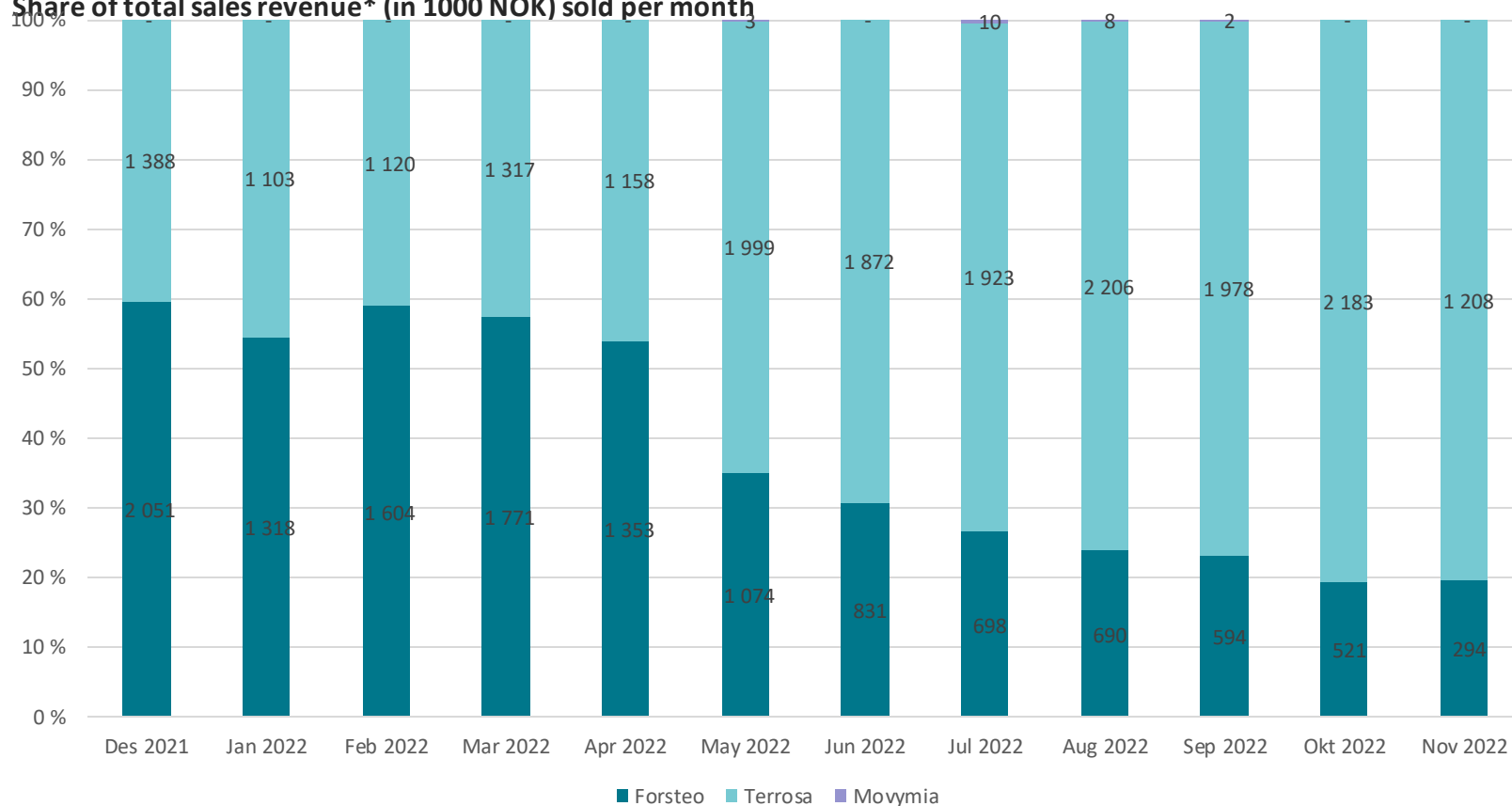


Source: VareWeb's statistics (of 17.11.2022)

* PRP sales revenue including VAT

Teriparatid – Sales revenue

Share of total sales revenue* (in 1000 NOK) sold per month



Source: VareWeb's statistics (of 17.11.2022)

* PRP sales revenue including VAT