



# **Substitution of biosimilars in Norway**

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# 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, with effect as of 1st of July 2021
- 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

- Insulin glargin:
  - First price cut of 16 % planned 1st of March 2022
  - Second price cut: to be decided
  - MA-holders:
    - Sanofi (ref.product) and Eli Lilly (biosimilar) - substitutable
    - Viatris (biosimilar) - substitutable as of May??
  - Biosimilar 12 % of packages sold in January 2022, 7 % pre-substitution
- Teriparatid
  - Price cut to be decided
  - MA-holders:
    - Eli Lilly (ref.product), Gedeon, Stada, (Theramex) - substitutable
  - Biosimilar 46 % of packages sold in January 2022, ca 1/3 pre-substitution

# 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](mailto: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 %