



Guiding Principles and Policy Options

Alberta Biosimilars Forum
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Chief Negotiator
Pharmaceuticals



HINAS

Norwegian Health Procurement

Drug Procurement Cooperation (LIS)

LIS prepare the basis and specifications
for purchase and delivery
agreements of pharmaceuticals in
cooperation with the state owned
hospitals

Europe

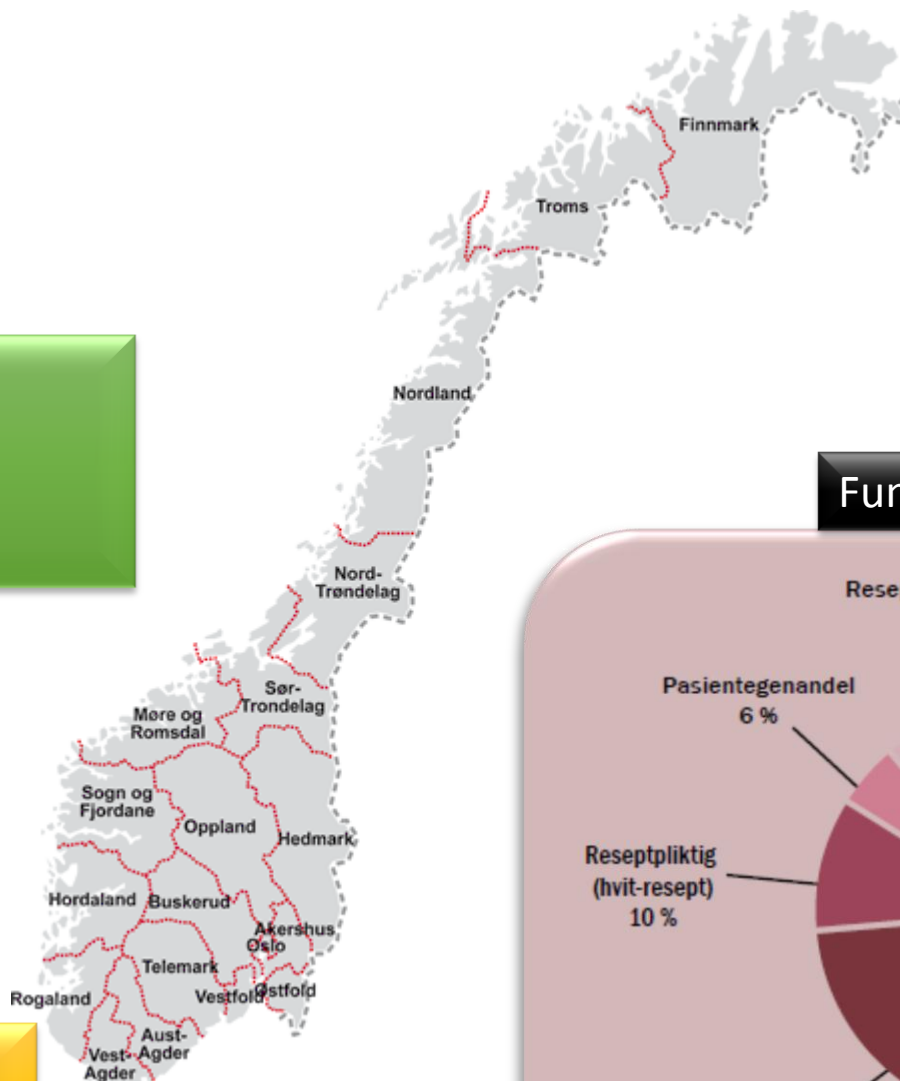




5,2 million
inhabitants

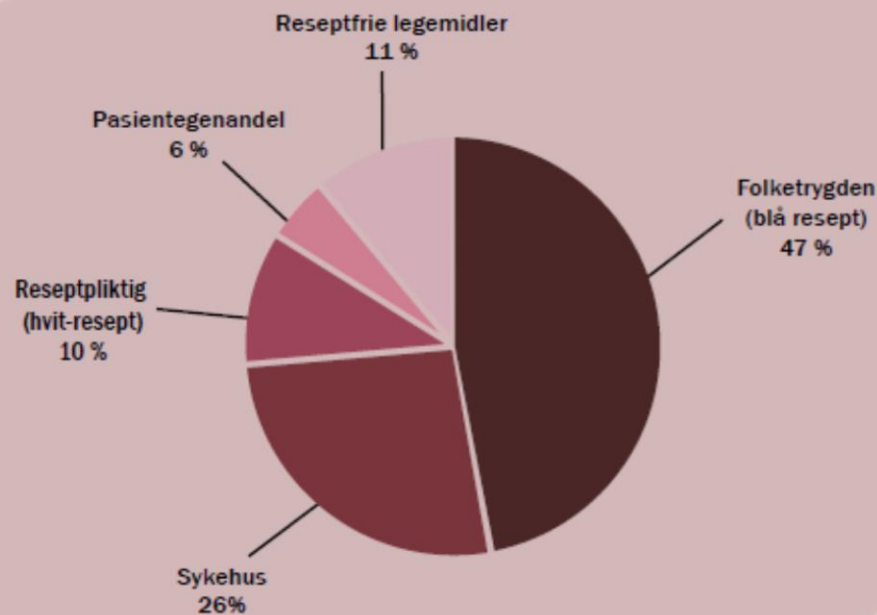
Publicly financed
system providing
universal health
coverage

Not an EU member,
but does follow EU
regulations

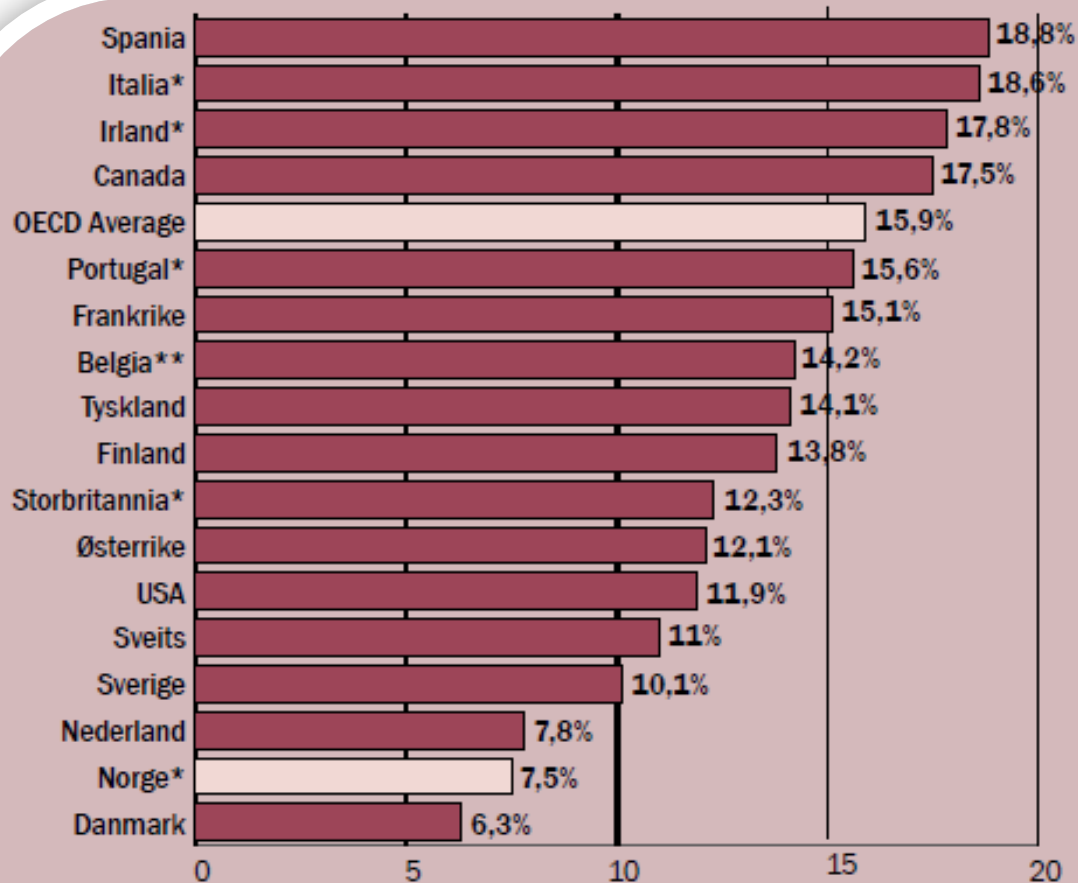


Drug sales 2015:
NOK 23,4 billion (PP)
NOK 15,2 billion (PPP)

Funding of drugs 2014



Drug costs as share of health expenditure



* Omfatter også offentlige utgifter til reseptfrie legemidler

** Kun reseptbelagte legemidler

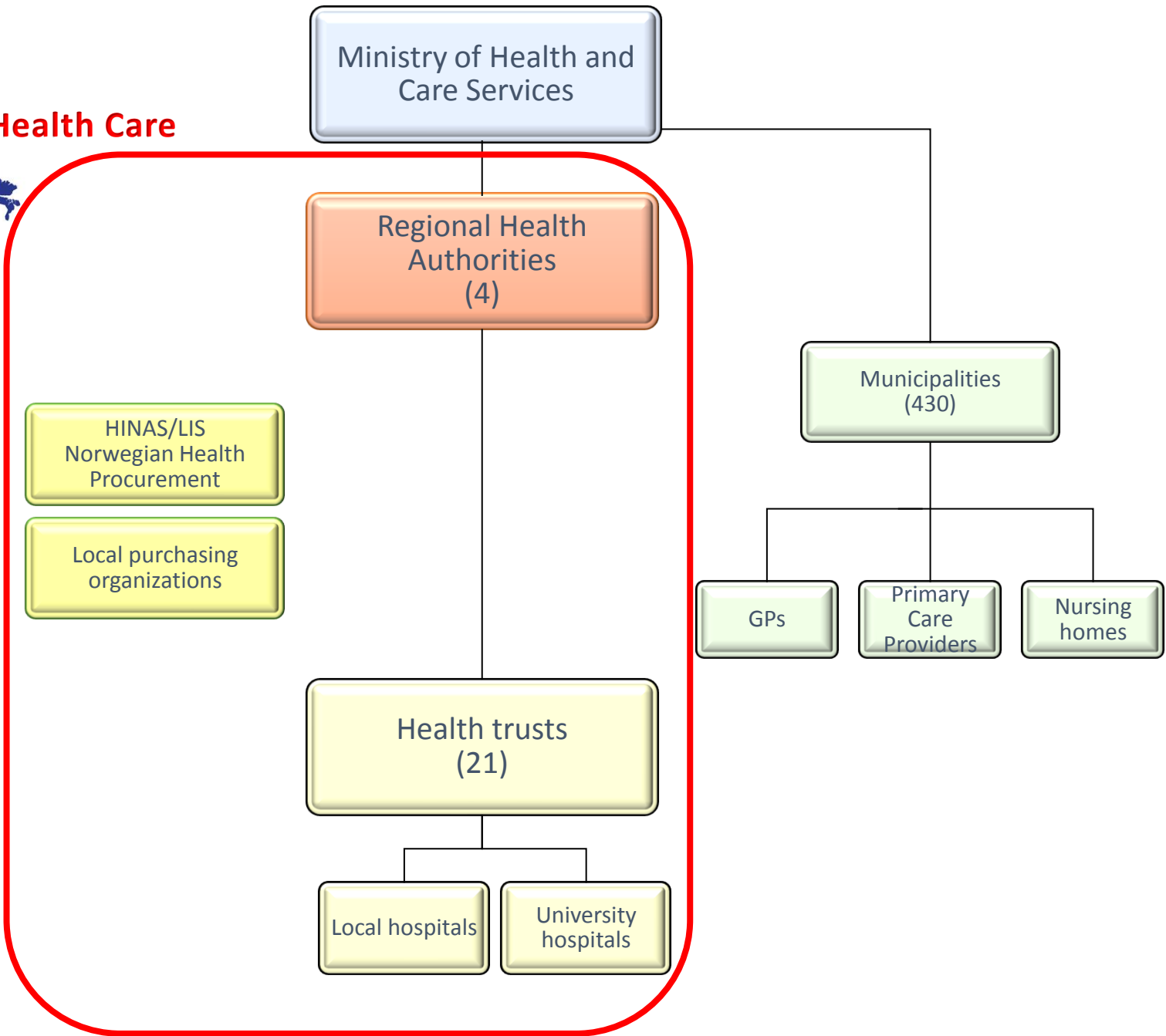
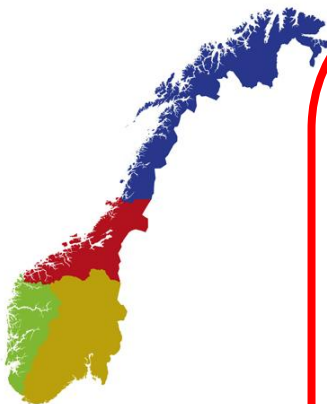
Data fra 2015

Kilde: OECD Health 2015

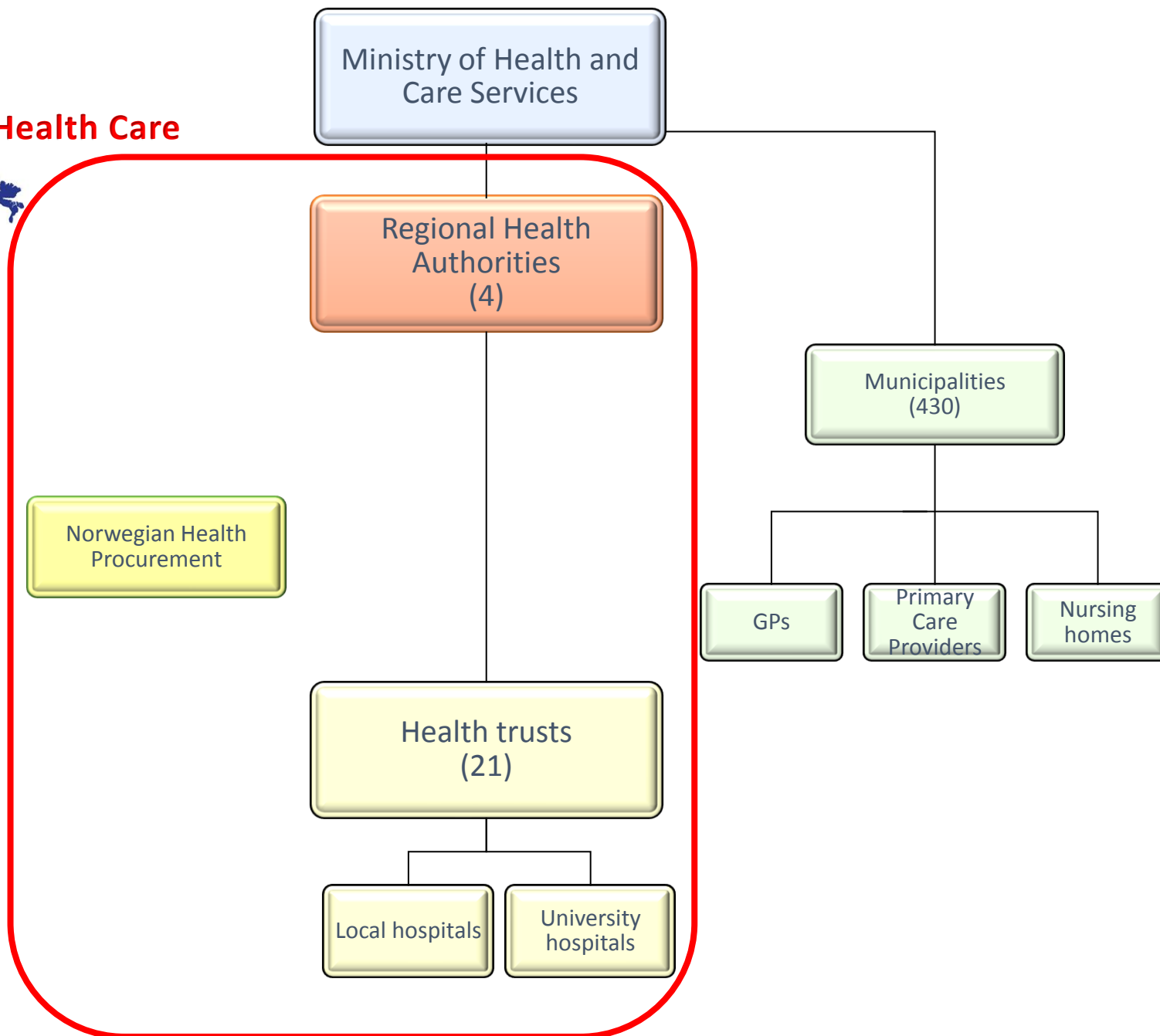
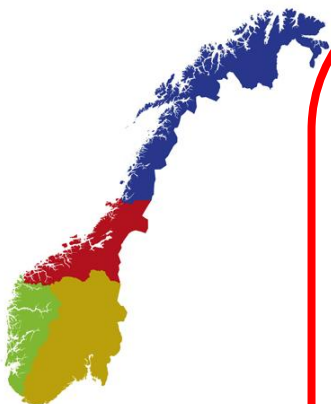


After June 2015

Specialty Health Care

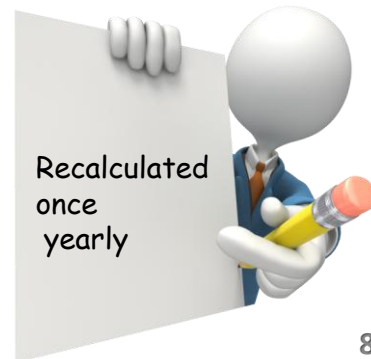
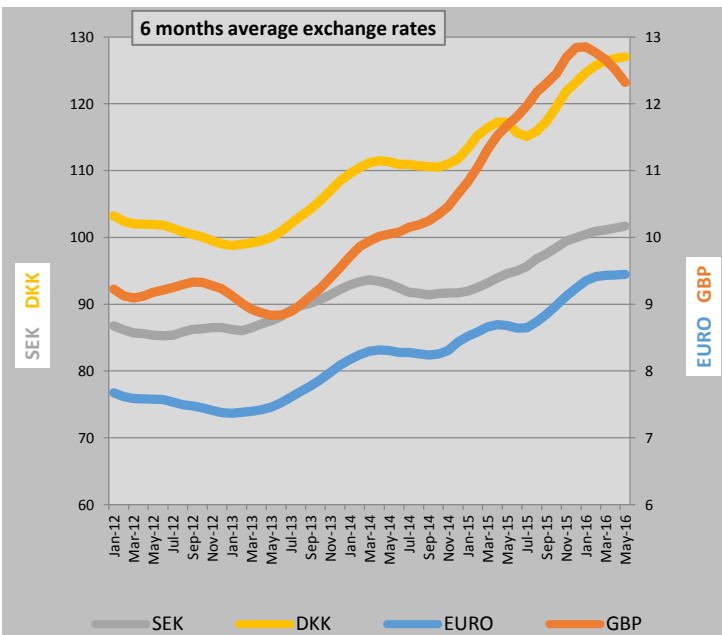
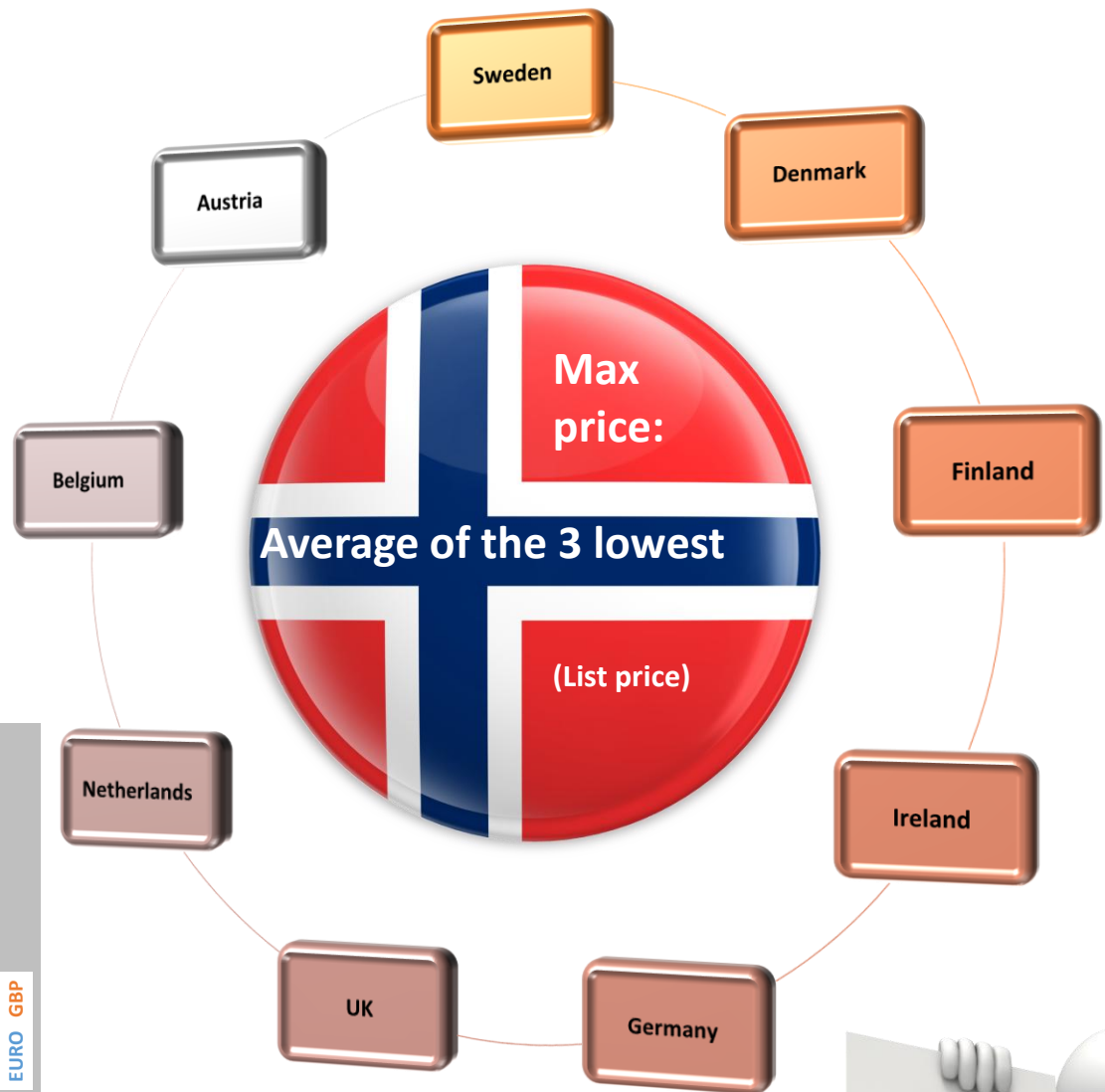


Specialty Health Care

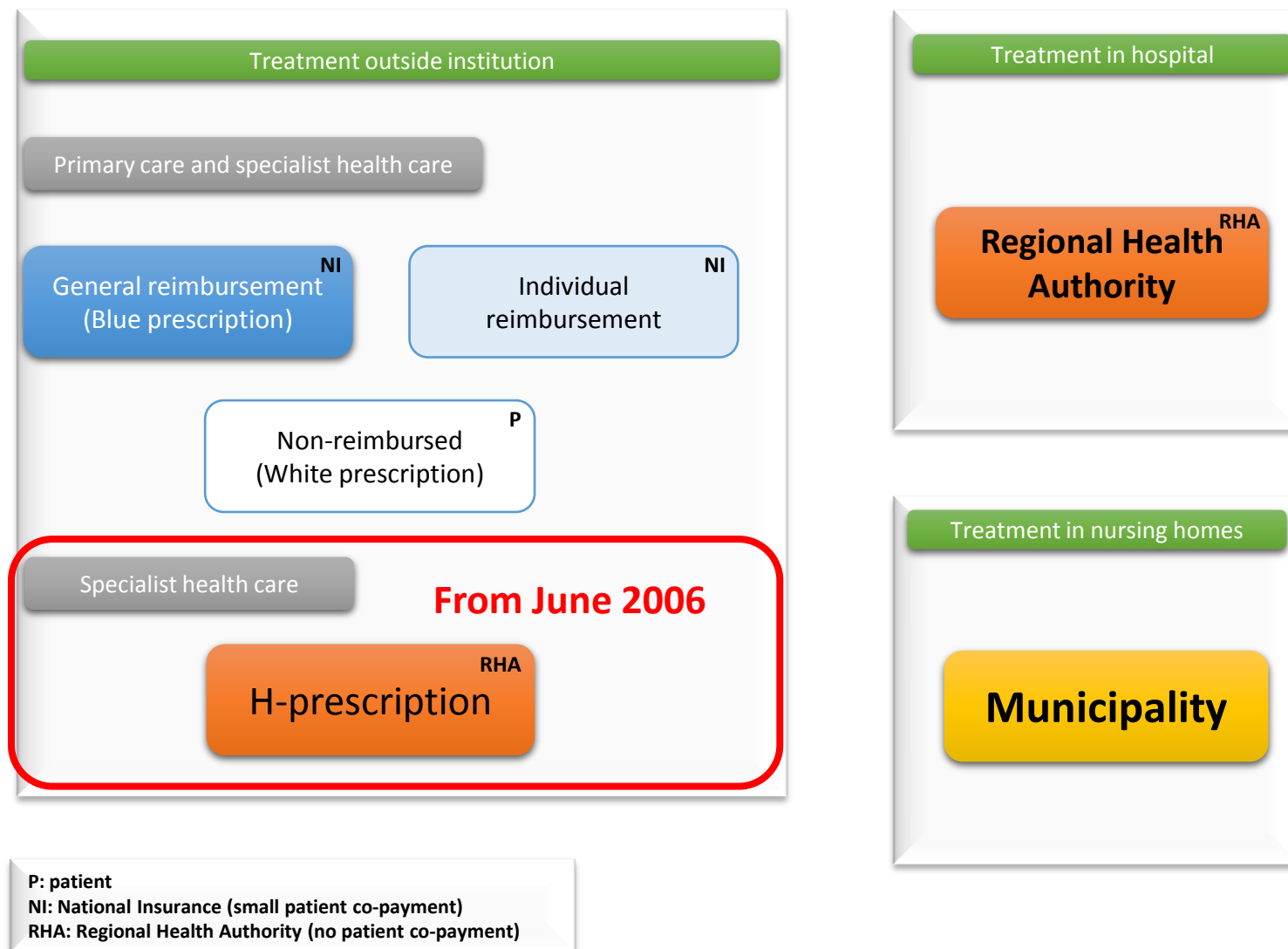


Pricing

Price is based on
basket countries and
exchange rates



Purchase drugs in Norway, who pays?



Guiding principles – biosimilar access policy

- Passive attitude – choose to do nothing
 - Let biosimilars promote themselves
 - Price difference is the primary cause for success
 - Biosimilar supplier needs to do active marketing
- but does this work?
 - Are doctors innovative enough to do this?
 - How big price difference is needed to start using biosimilars?
- We tried this in Norway



- No guiding principles
- No information from the authorities
- Much negative information from industry 2010 – 2013 (to doctors, politicians, patient organizations)
- Low impact on prices
- Low impact on biosimilar market share
- Some discount for inpatient use in hospital (filgrastim, epoetin)



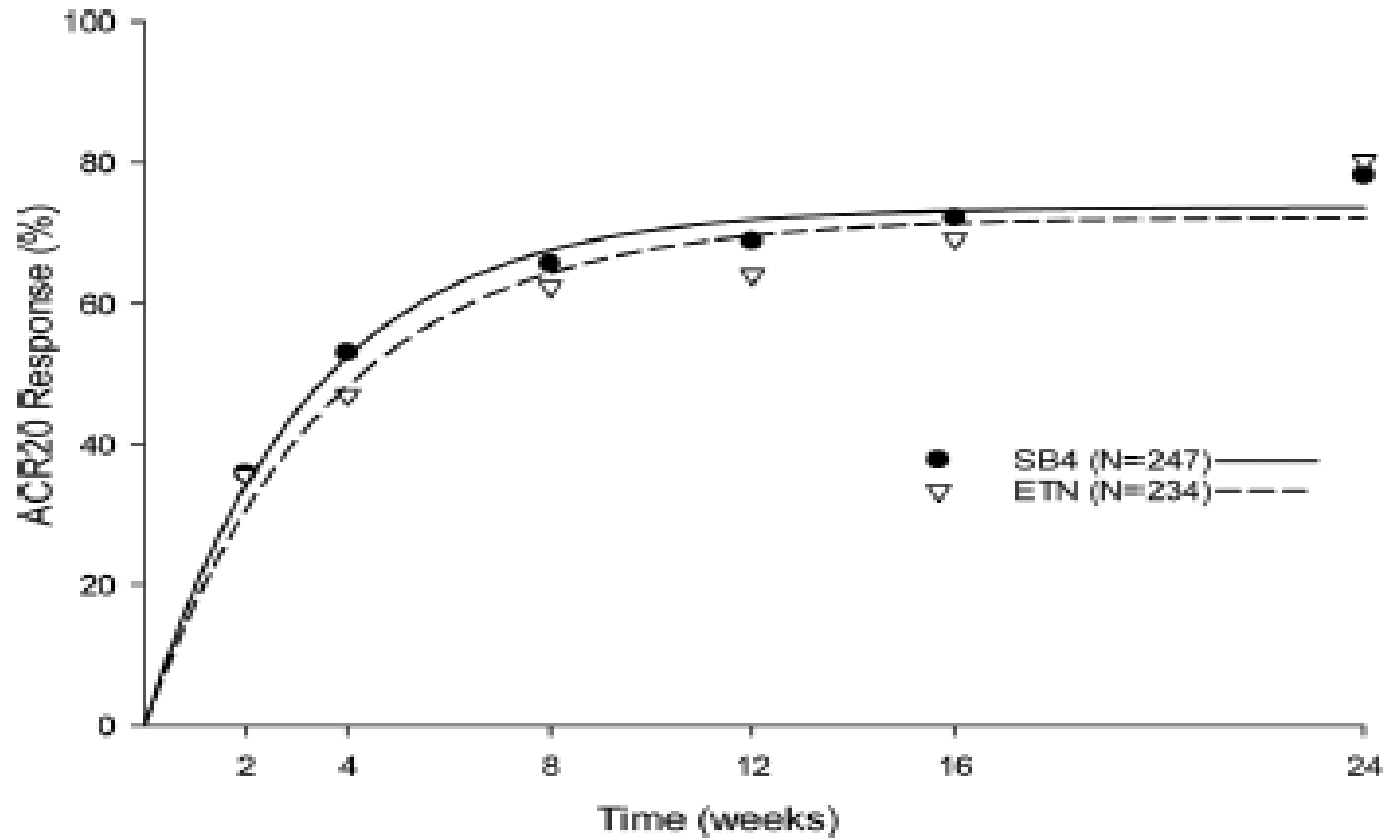
- 2010 authorities tried to include filgrastim for automatic switch in pharmacies (like generics)
- Lost against industry in court case
- 2013 Norwegian Medicines Agency on their webpage asks doctors to use the cheapest somatropin (Omnitrope)
- Low impact

Guiding principles – biosimilar access policy

- Passive attitude did not work
- Industry's campaign against biosimilars focusing mainly on safety did work well.
- To make biosimilars a success, patients, health personnel and payers need to feel that it is safe to use
- Several meetings and a lot of focus in media have shown what is most important

- Important principles for biosimilar access
 - Document the effect of biosimilars
 - Document the safety of biosimilars
 - Immunogenicity is important
 - Good communication with the patient
 - Explain why extrapolation is safe
 - Doctors treating the patients need support from their superiors
 - Education of health personnel and patient organizations

Clinical effect

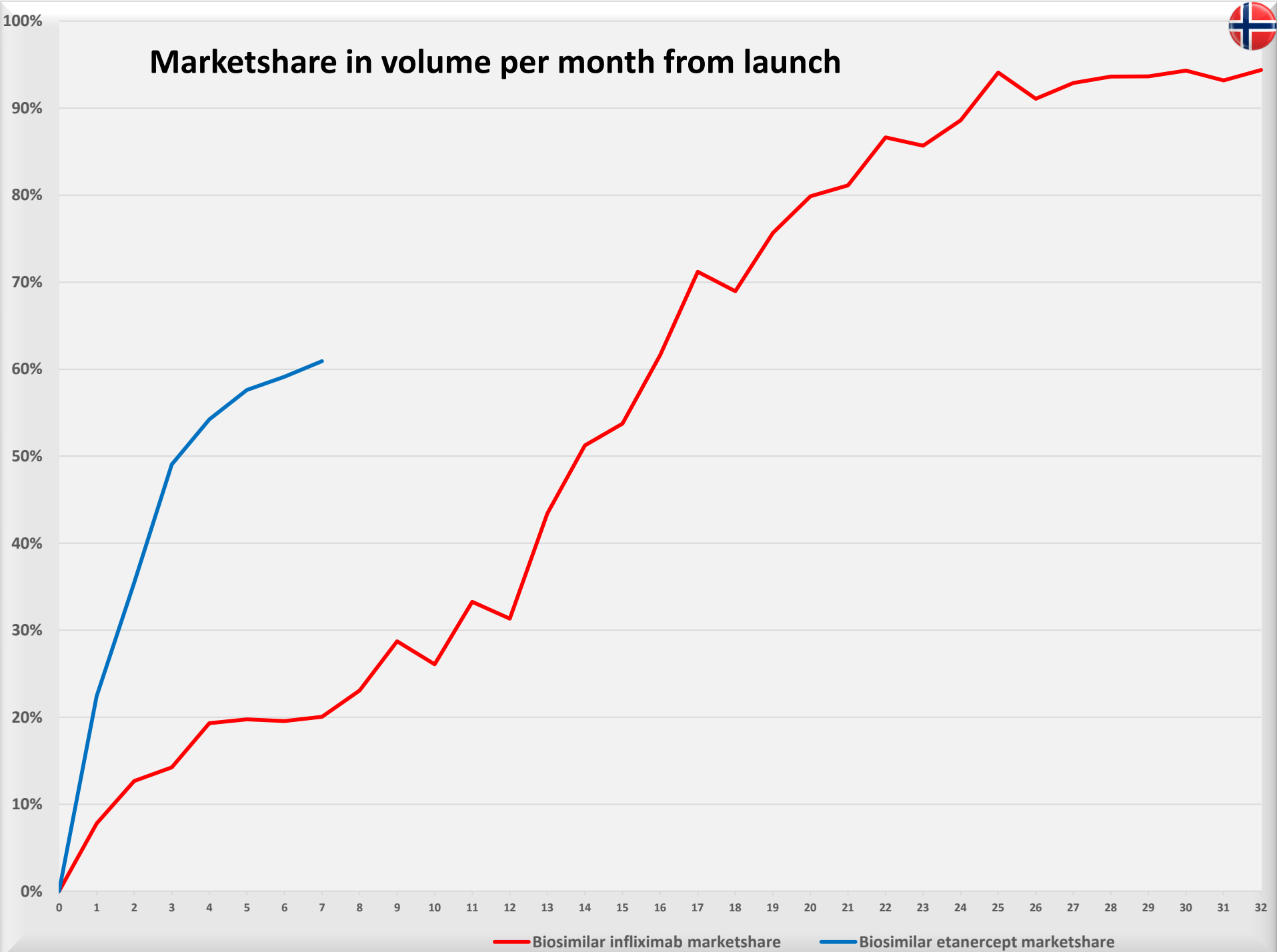




- With biosimilar infliximab came a possibility to include a biosimilar in an existing national tender for both inpatient and outpatient use
 - Tender lasts one year
 - Products are ranked per indication based on price
 - Not allowed to parallel export with tender prices
- Two years later biosimilar etanercept included in the same tender
- This initiative was taken by LIS



Marketshare in volume per month from launch



Good effect of the TNF-tender

- The other product groups with existing biosimilars were transferred from National Insurance funding to Hospital funding from January 1st 2016 to use the advantage of using a tender.
- Discounts in these tenders from 50 to 76 %.

Outpatient medicines funded by the hospitals

Anti-TNFs



MS (multiple sclerosis)



Oncology (some indications)



HCV (hepatitis C)



Growth hormone



Colony stimulating factors



Coagulation factors



Anaemia



Biosimilars

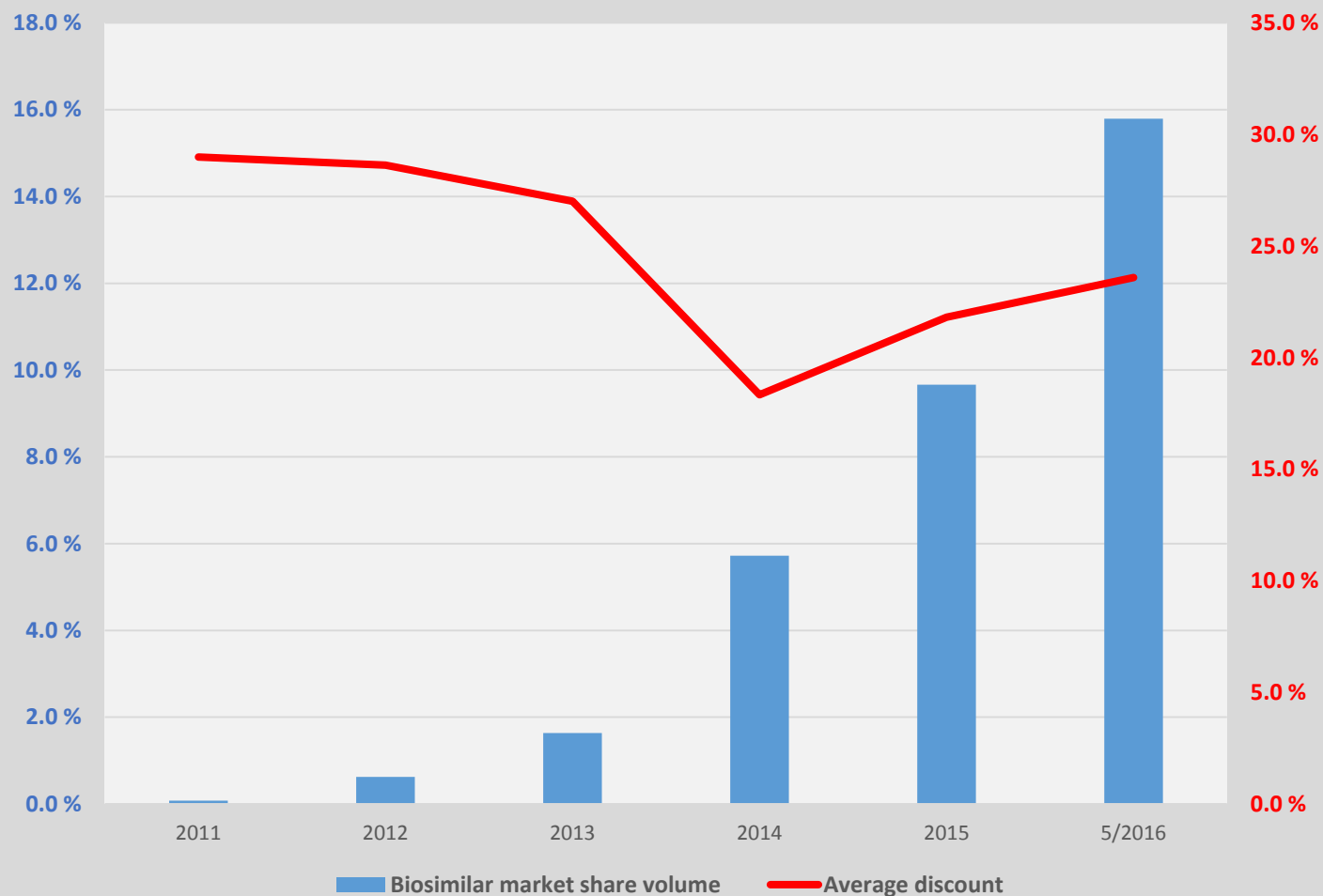
Biosimilars

Biosimilars

Biosimilars



Somatropin biosimilar impact



76 %

Originator

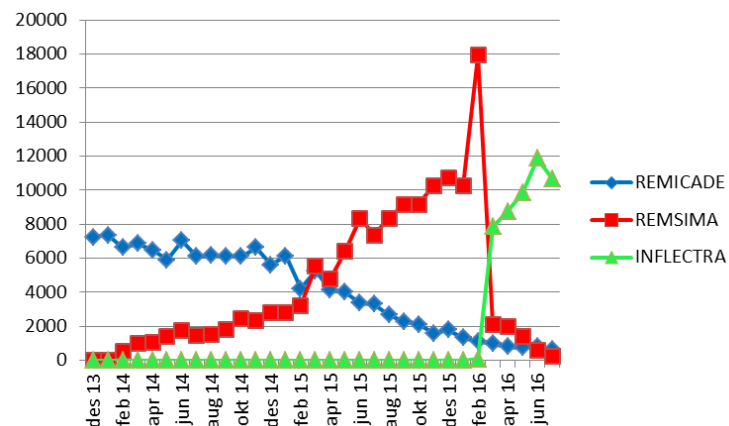
30 %

Biosimilar

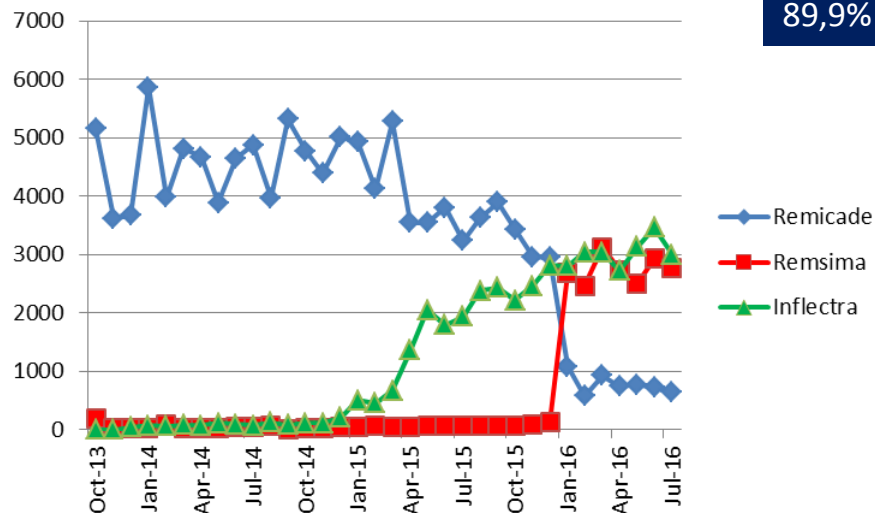
Tender from
1st June 2016

Not included in a tender

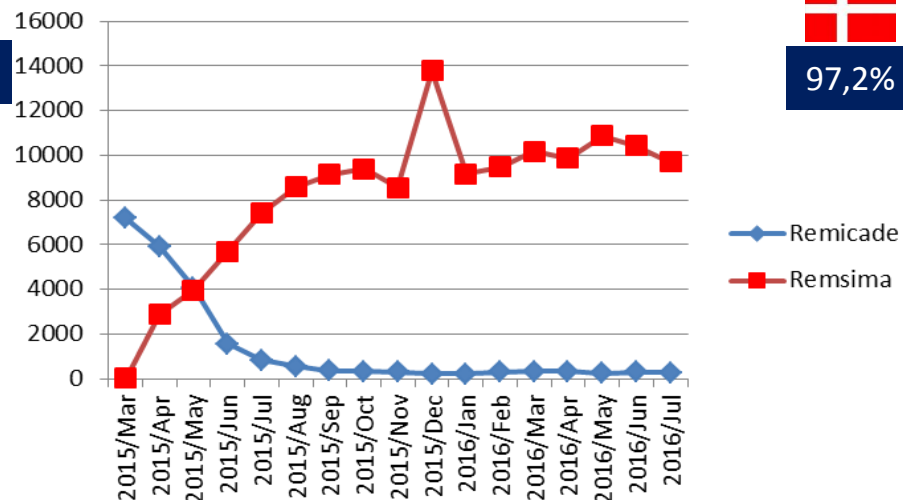
Infliksimag



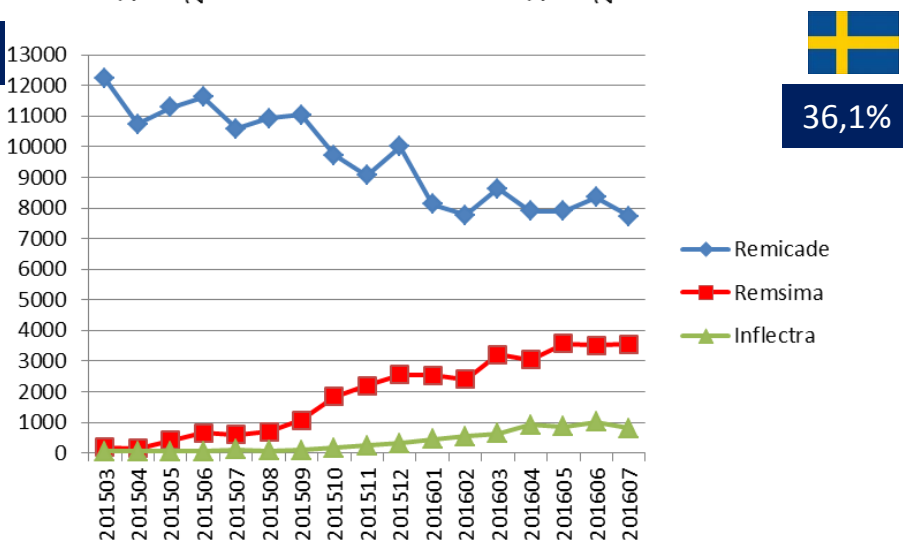
94,3%



89,9%



97,2%

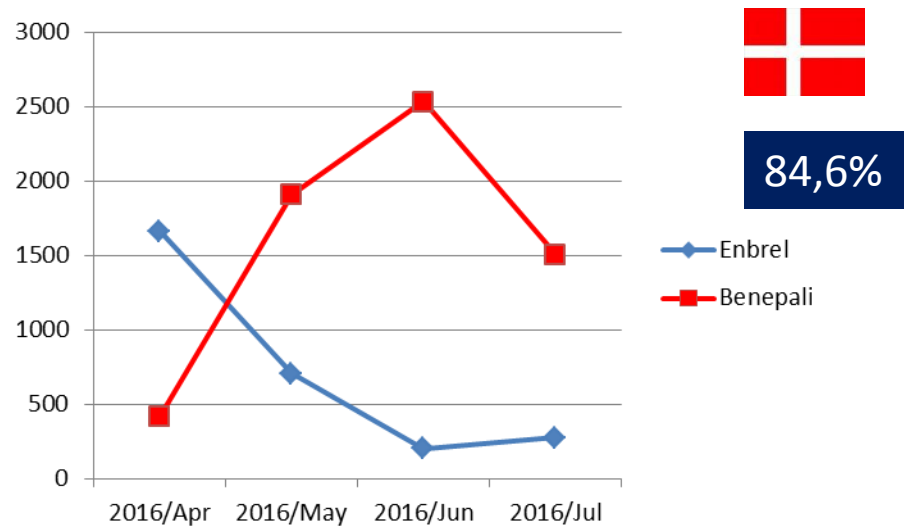
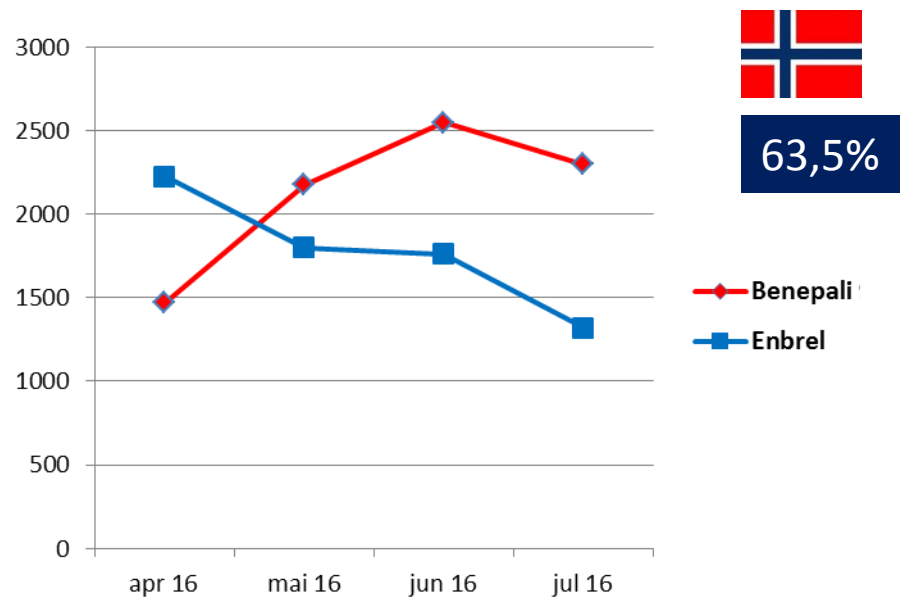


36,1%

References:

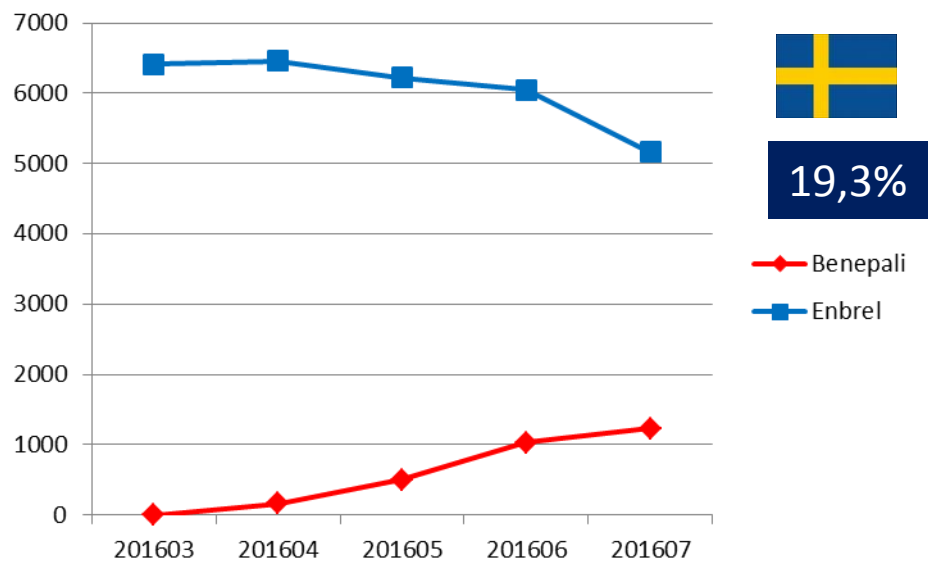
The development of the infliximab market is based from sales data from respective Nordic country. Norway: Farmastat AS <https://farmastat.no/>; Denmark: DLIMI AS <https://www.dli-mi.dk/Pages/default.aspx>; Finland: IMS Health OY <http://www.sld.fi/>; Sweden: Reveal AB <http://www.reveal.se/lakemedelsstatistik/>

Etanercept 50mg



+

0%



References:
The development of the etanercept market is based from sales data from respective Nordic country. Norway: Farmastat AS <https://farmastat.no/> ; Denmark: DLIMI AS <https://www.dli-mi.dk/Pages/default.aspx> ; Finland: IMS Health OY <http://www.sld.fi/> ; Sweden: Reveal AB <http://www.reveal.se/lakemedelsstatistik/>

Prices and savings with biosimilar infliximab in Norway

| Patient | Year | Remicade | Remsima | Inflectra | Saving per patient | Discount |
|---------------------------------------|------|--|--|---|--------------------------------------|----------|
| Rheumatoid arthritis, 75 kg, one year | 2014 | 84 000 NOK 10 500 EUR 14 000 USD | 51 000 NOK 6 400 EUR 8 500 USD | (60 000 NOK) (7 500 EUR) (10 000 USD) | 33 000 NOK 4 100 EUR 5 500 USD | 39% |
| | 2015 | 83 400 NOK 9 700 EUR 11 000 USD | 26 000 NOK 3 000 EUR 3 400 USD | (51 000 NOK) (5 900 EUR) (6 700 USD) | 57 400 NOK 6 700 EUR 7 600 USD | 69% |
| | 2016 | 83 000 NOK 8 700 EUR 9 800 USD | (40 400 NOK) (4 300 EUR) (4 800 USD) | 32 400 NOK 3 400 EUR 3 800 USD | 50 600 NOK 5 300 EUR 6 000 USD | 61% |

Policy options

- Decide for switch in pharmacy (same as for generics)
 - MoH (Ministry of Health) lost court case in 2011
 - MoH gave NoMA (Norwegian Medicines Agency) an assignment in 2012 to look upon price regulation and exchange list option for biosimilars
 - Nothing has happened so far
 - Biologics are injectables. Can be difficult to switch.
- Access to marketing authorization can be simplified
- Access to reimbursement can be simplified
- Decide to use the cheapest drug for all, not only new patients



A RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP STUDY TO EVALUATE THE SAFETY AND EFFICACY OF SWITCHING FROM INNOVATOR INFLIXIMAB TO BIOSIMILAR INFLIXIMAB COMPARED WITH CONTINUED TREATMENT WITH INNOVATOR INFLIXIMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS, SPONDYLOARTHRITIS, PSORIATIC ARTHRITIS, ULCERATIVE COLITIS, CROHN'S DISEASE AND CHRONIC PLAQUE PSORIASIS

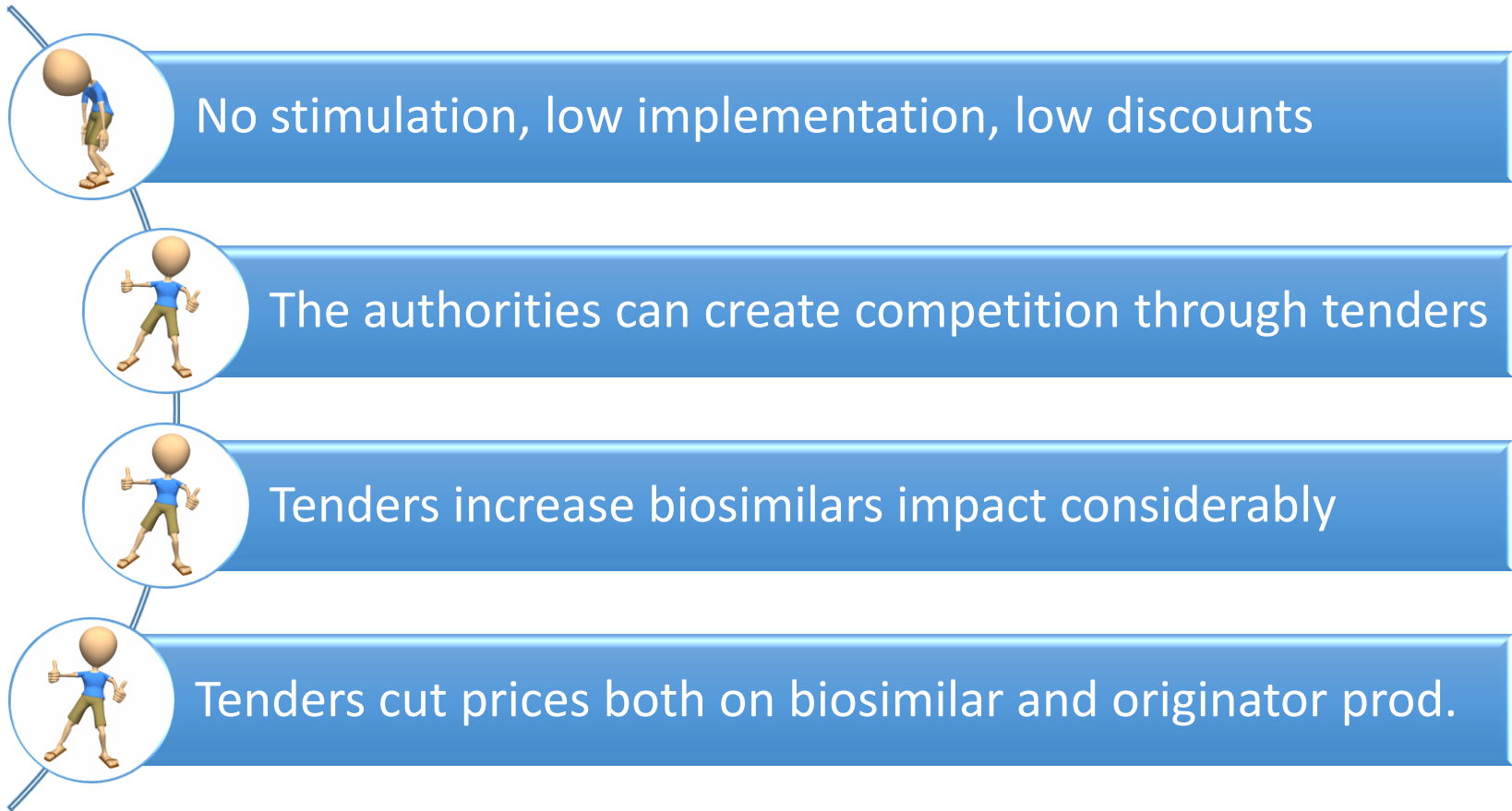
The Nor Switch study

EudraCT Number: 2014-002056-40

Policy options

- Use tender to control use of originator and biosimilar.
- LIS is handling biosimilars by including biosimilars in tenders.
 - All products compete on price.
 - LIS makes treatment guidelines with ranking based on price
 - Our ranking is supported by the managing directors in the regional health authorities.
 - Tenders first ranked for new patients. Now also a lot of switching is taking place

What works?



Drug purchasing based on LIS agreements

LIS total 2014 and 2015

| | Max price | LIS price | Discount NOK | Discount % |
|-------------|------------------|------------------|------------------|---------------|
| NOK 1000 | | | | |
| 2014 | 5 579 353 | 4 016 655 | 1 562 698 | 28,0 |
| 2015 | 7 135 659 | 4 989 011 | 2 146 648 | 30,1 |