



Regulation of pharmaceutical markets: How to set prices?

Dag Morten Dalen
Finnish Health Economics Day
January 26, 2024



Plan of talk

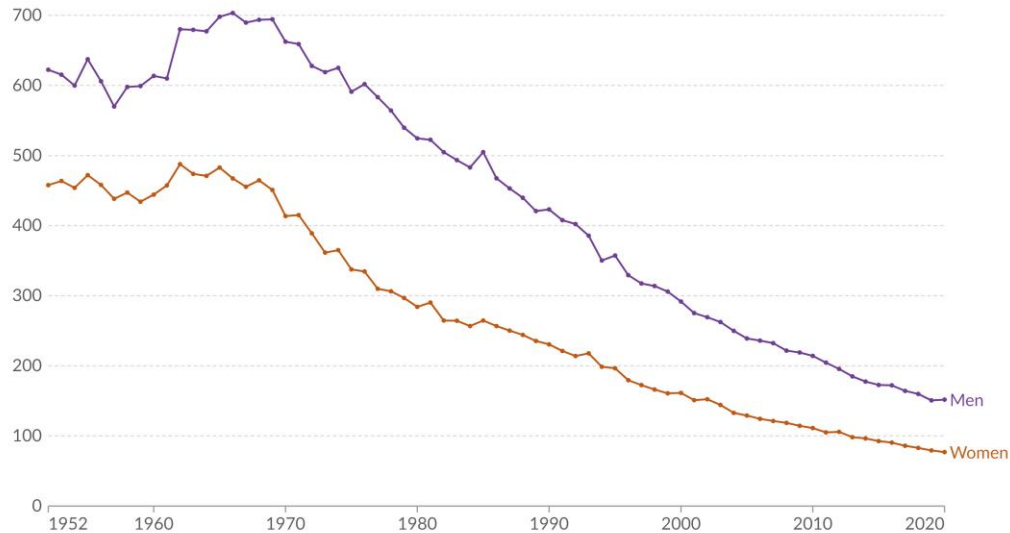
1. Pharmaceuticals in health care
2. Innovation, incentives and cost structure
3. Willingness to pay, need to pay and should pay
4. What we need to pay – different bargaining situations
 - Phase 1: Innovative drugs
 - Phases 2-3: Mature patented drugs
 - Phase 4: Generic competition
5. Summing up

Pharmaceuticals have been important for improvement in public health

Death rate from cardiovascular diseases by sex, Finland

Reported annual death rate from cardiovascular diseases¹ per 100,000 people in each group, based on the underlying cause² listed on death certificates.

Our World in Data



Data source: WHO Mortality Database (2022)

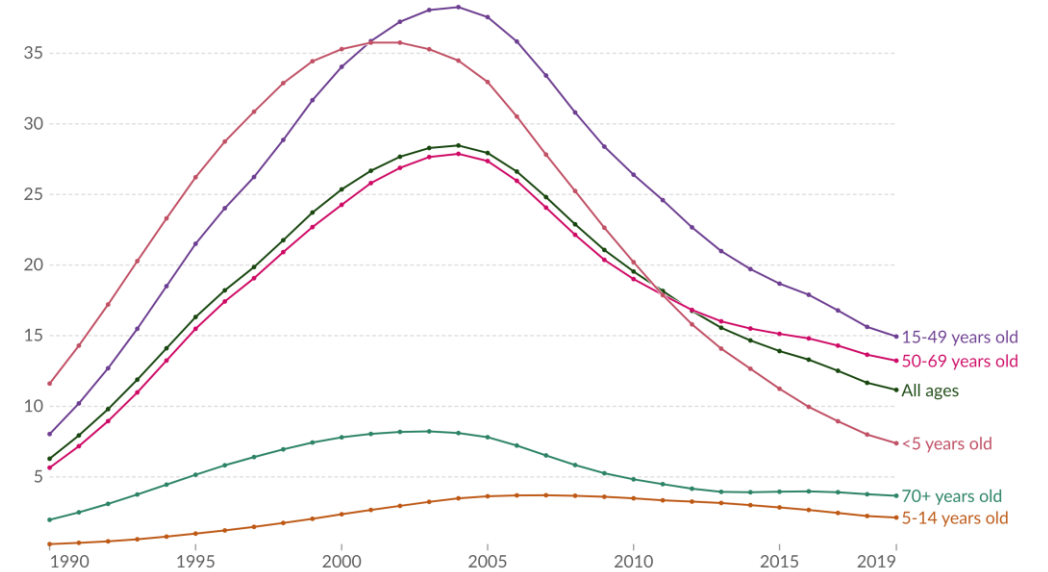
OurWorldInData.org/cardiovascular-diseases | CC BY

Note: To allow for comparisons between countries and over time, this metric is age-standardized³. All deaths in a country may not have been registered with a cause of death².

HIV/AIDS death rate by age, World, 1990 to 2019

Death rates from HIV/AIDS, measured as the number of deaths per 100,000 individuals across various age categories.

Our World in Data



Data source: IHME, Global Burden of Disease (2019)

OurWorldInData.org/hiv-aids | CC BY

Pharmaceutical innovations and longevity

- Drug innovation: **Mean vintage** (year of initial world launch) of the drugs for the treatment of a disease that have previously been launched in country
 - 6 months (66 %) of the 2006-218 increase in mean age at death of Americans was due to pharmaceutical innovations
 - 1.23 years (73%) of the 2006-2016 increase in mean age at death in 26 countries was due to pharmaceutical innovation.
- Between 1994 and 2008, the 5-year observed survival rate for all cancer sites combined increased from 52.1% to 61.2%.
 - 70% due to the increase in the novelty of medical ideas 12–24 years earlier.



The effect of pharmaceutical innovation on longevity: Evidence from the U.S. and 26 high-income countries

Frank R. Lichtenberg


Cain Brothers & Company Professor of Healthcare Management, Columbia University, Kravis Hall 522, 665 West 130th Street, New York, NY 10027, USA

ECONOMICS OF INNOVATION AND NEW TECHNOLOGY
2019, VOL. 28, NO. 7, 722–740
<https://doi.org/10.1080/10438599.2018.1557421>

 **Routledge**
Taylor & Francis Group

 Check for updates

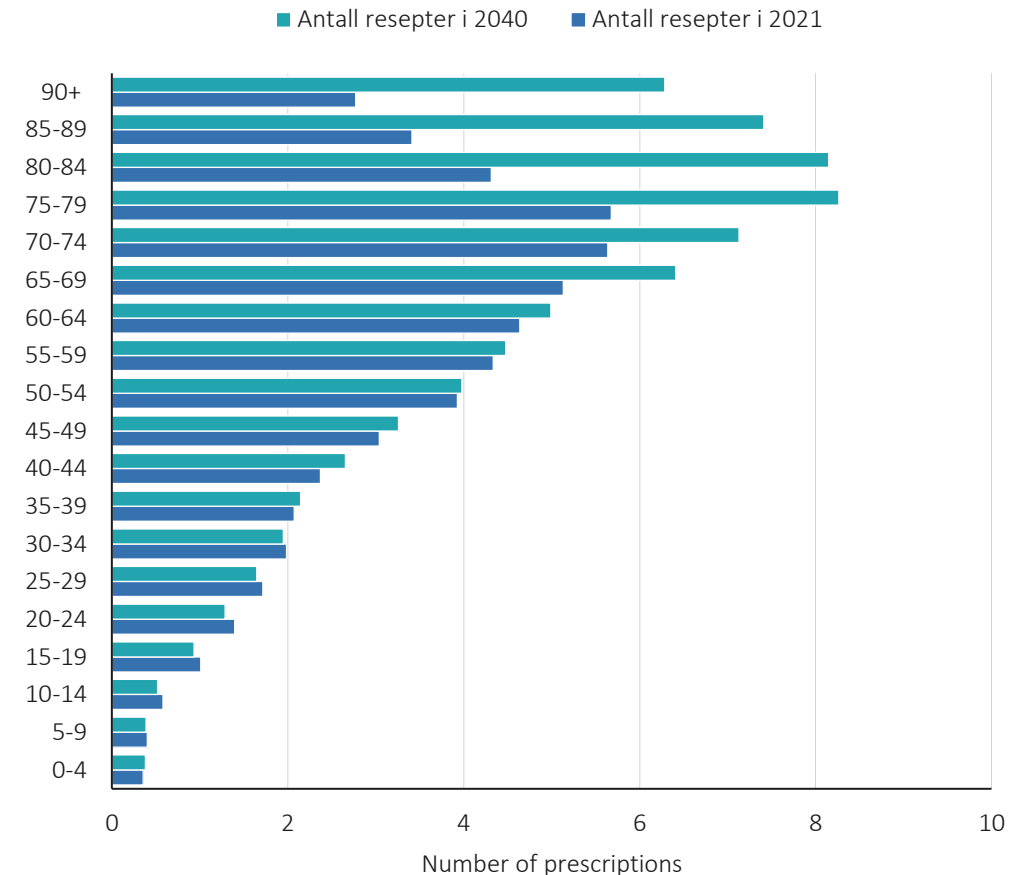
The long-run impact of new medical ideas on cancer survival and mortality

Frank R. Lichtenberg  a,b,c

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Pharmaceutical innovations will continue to improve health

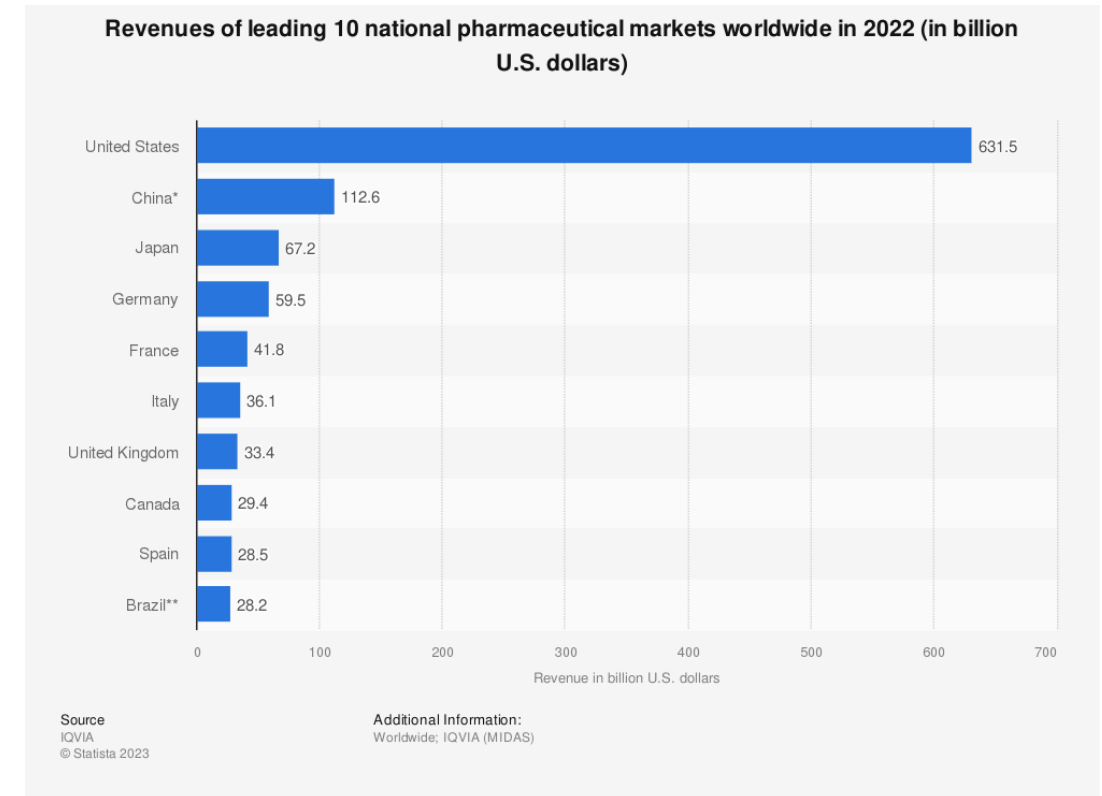
- More people will live long enough to get cancer and dementia, and we continue longer with prescription drugs (+)
 - Increased incentives to develop drugs
 - 2,5 billion USD of extra discounted life cycle to obtain a new drug (Dubois et al., 2015)
 - Implementation of Medicare Part D in 2006, increased the number of drugs entering preclinical testing by 58 % (Blume-Kohout and Sood, 2013)
- Prices in the US affect us all (-)
- Better diagnostics and reduced costs in drug discovery using AI. Gene therapies.



Source: Vista Analyse (2023)

Small vs. large countries

- Small Nordic countries – even combined – have no on impact on the pace and direction of drug innovation.
- We should not ask what should we pay for drugs to stimulate new drug discovery?
- Instead:
 1. What are we willing to pay, and what do we need to pay to get access to valuable drugs?
 2. How should we cooperate with other countries, support industry and universities to stimulate drug innovations?



Willingness to pay for new drugs

$$\frac{Price_{new} - Price_{current}}{QALY_{new} - QALY_{current}} \leq threshold$$

$$Price_{new} \leq Price_{current} + threshold \cdot \Delta QALY$$

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The price of cost-effectiveness thresholds under therapeutic competition in pharmaceutical markets[☆]

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- Sequential pricing: CE thresholds may have adverse effects for payers and patients
- How to set thresholds?
- If we expand treatment effects (e.g. productivity), thresholds could change as well
- Threshold \neq need to pay

The bargaining game

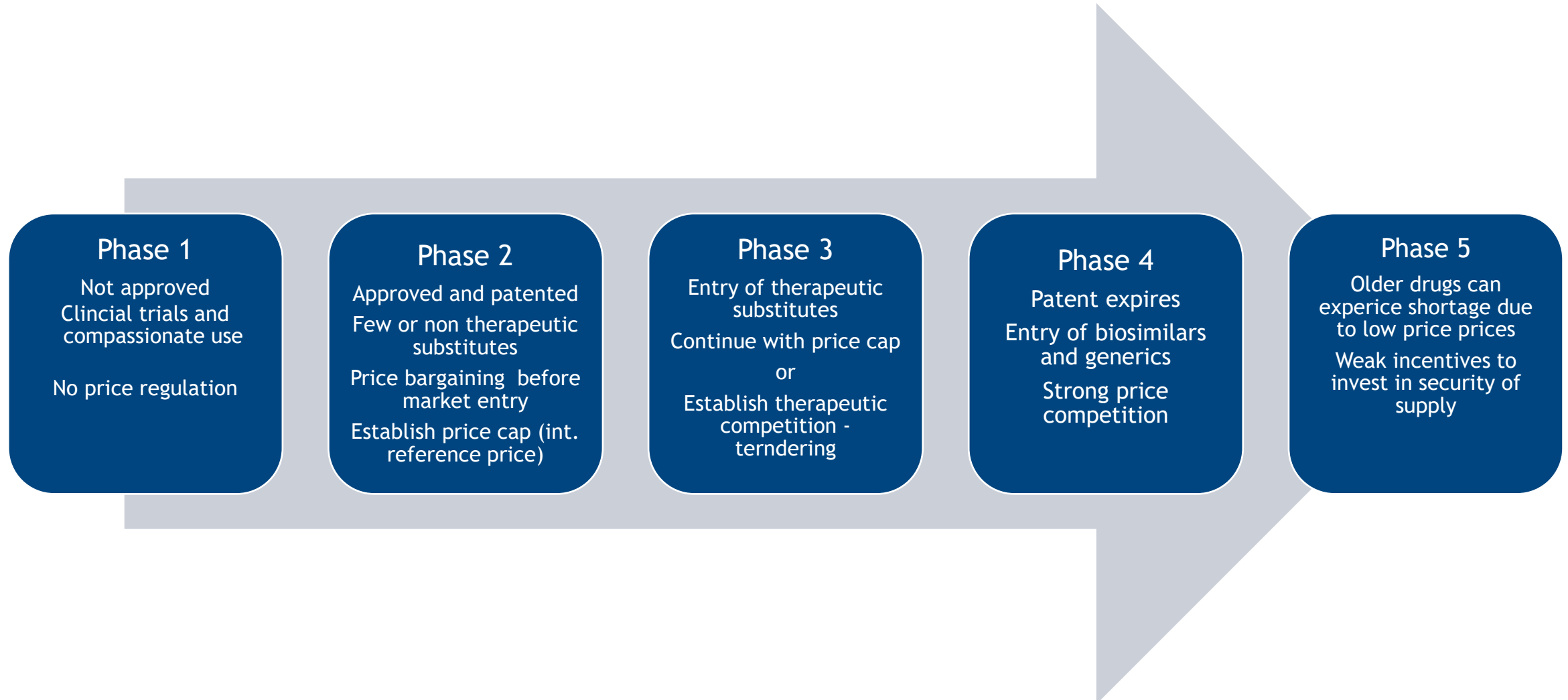


1. Value of an agreement – for both
2. Outside option – for both
3. Ability to say no
4. Patience on behalf of patients, who are told to be patient
5. It's the patients who pay the concentrated price of disagreements

In 2018 spinal muscular atrophy (SMA) patients hand over a protest to the Minister of Health, after the hospitals' said «no» to Spinraza for age 18+ patients (but said “yes” to children under 18.

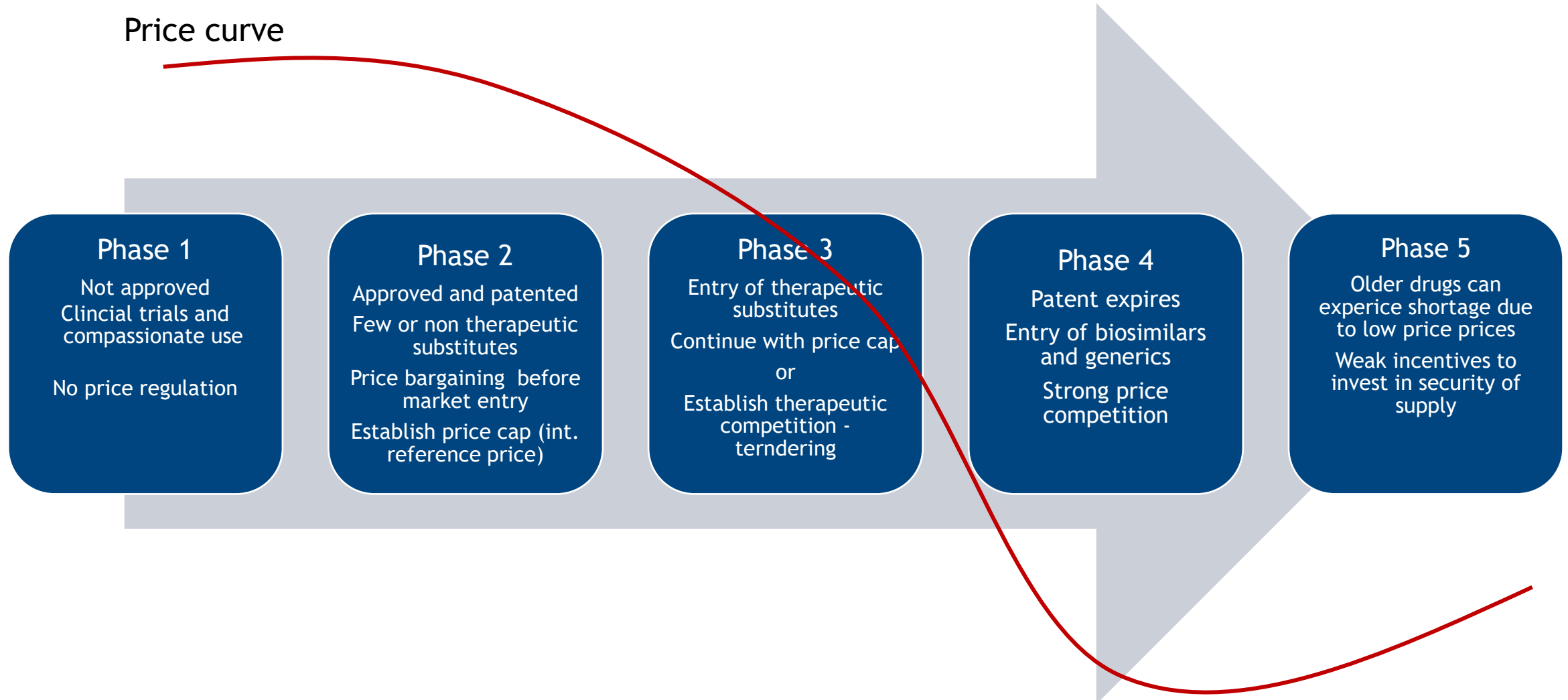
Source of picture: Stavanger Aftenblad, 11. juni 2018

Different bargaining positions



Different bargaining positions – different ways of paying for drugs

Price curve



Phase 1: Innovative drugs



Potential significant improvement compared with existing drugs, but uncertainty can be large. Patients are risk-seekers - not risk-averse



We need to accept high profit and prices close to maximum willingness to pay. Not for 10 years - but until outside options improves. Pricing schemes that reflects uncertainty



Patience is costly, and early access is valuable. The costs patience are covered by the patients - not tax-payers or future patients



High level of conflict - means ongoing bargaining. Commitment to thresholds are important

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Minutes from Decision forum (Oct. 2017):

“The price offer for the medicine [Spinraza] is clearly unacceptable and is perceived as unethical. This applies both when assessed against the effect and the supplier's need for earnings and profit margin”

After four rounds and many months, the price came down from 1 mill. NOK to 0,6 mill. NOK per dosage (according to a newspaper's sources) and introduced to children in 2018.

In April 2023, Spinraza was introduced to 18 +.

Phase 2 and 3: Currently funded patented drugs

- International reference pricing
- Novel, innovative drugs often attract therapeutic substitutes, and enable competition.
- Small-country argument: Reduce prices since bargaining power of buyer increases (“outside option” improves!)
- Large-country argument: Mitigate overinvestment due to profit-shifting.
- **Not always desirable:**
 - Value of multiple drugs - combination therapies and personalized medicine.
 - Weak substitutability

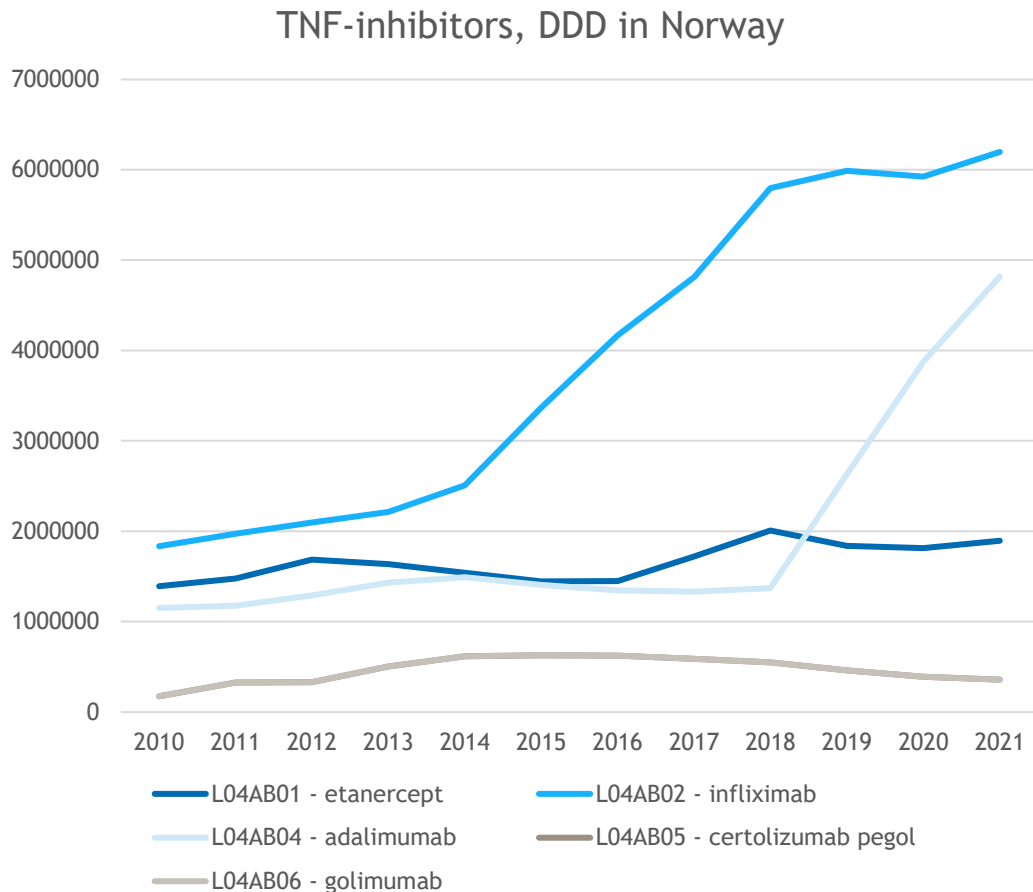
Novo Nordisk and Eli Lilly set to face new challenger in weight-loss race

Danish biotech group Zealand Pharma is developing an alternative obesity treatment to compete with big rivals



FT, January 23 2024

Phase 2 and 3: Norwegian experience - tendering of hospital drugs



Source: Sykehusinnkjøp and own calculations

- Hospital procurement – owned by the four regional health authorities (that run the hospitals)
- Specialist groups, with clinical expertise:
 1. Advise on tender documents
 2. Provide recommendation to physicians.
 3. Support implementation of procurements
- Tenders has reduced prices significantly, increased demand.
- It is not winner-takes-it-all
 - Regional markets and doctors' discretion

Phase 2 and 3: Norwegian experience - tendering of prescription drugs

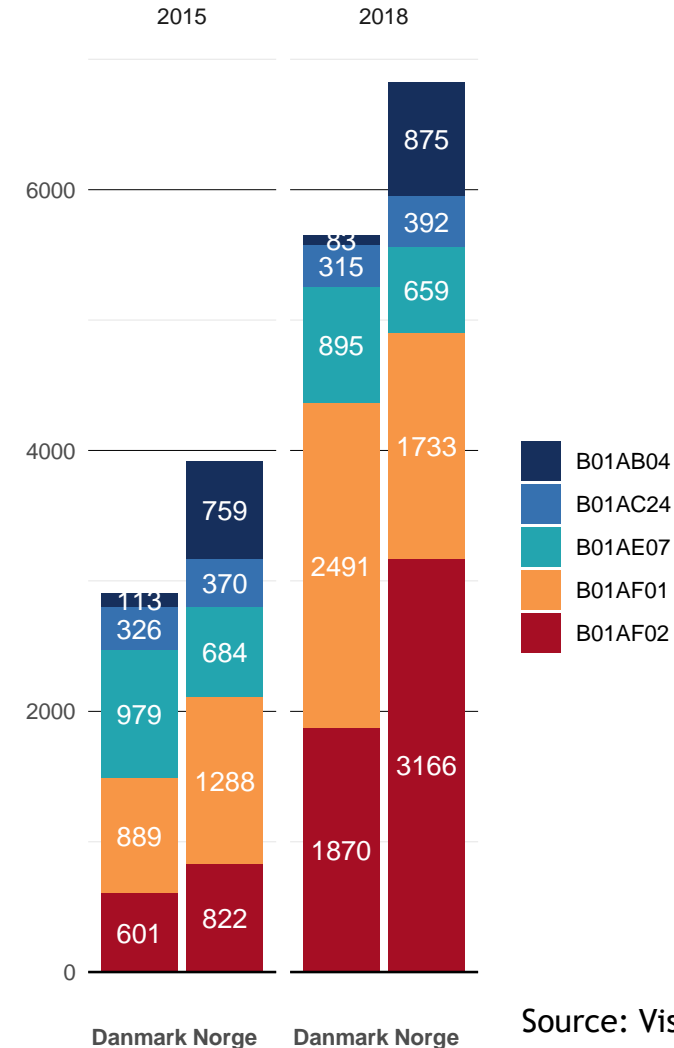
First pilot for tendering for drugs prescribed outside hospitals:

- PCSK9 inhibitors - a new class of drugs that lower low-density lipoprotein (LDL), or “bad” cholesterol.

Possible candidates:

- DOAC – Direct oral anticoagulants.
- CGRP-inhibitor for migraine.
- SGLT2-inhibitors for diabetes and heart failure.

Are they substitutes?



Xarelto vs. Eliquis

Source: Vista Analyse (2021)

Phase 4: Generics and biosimilars

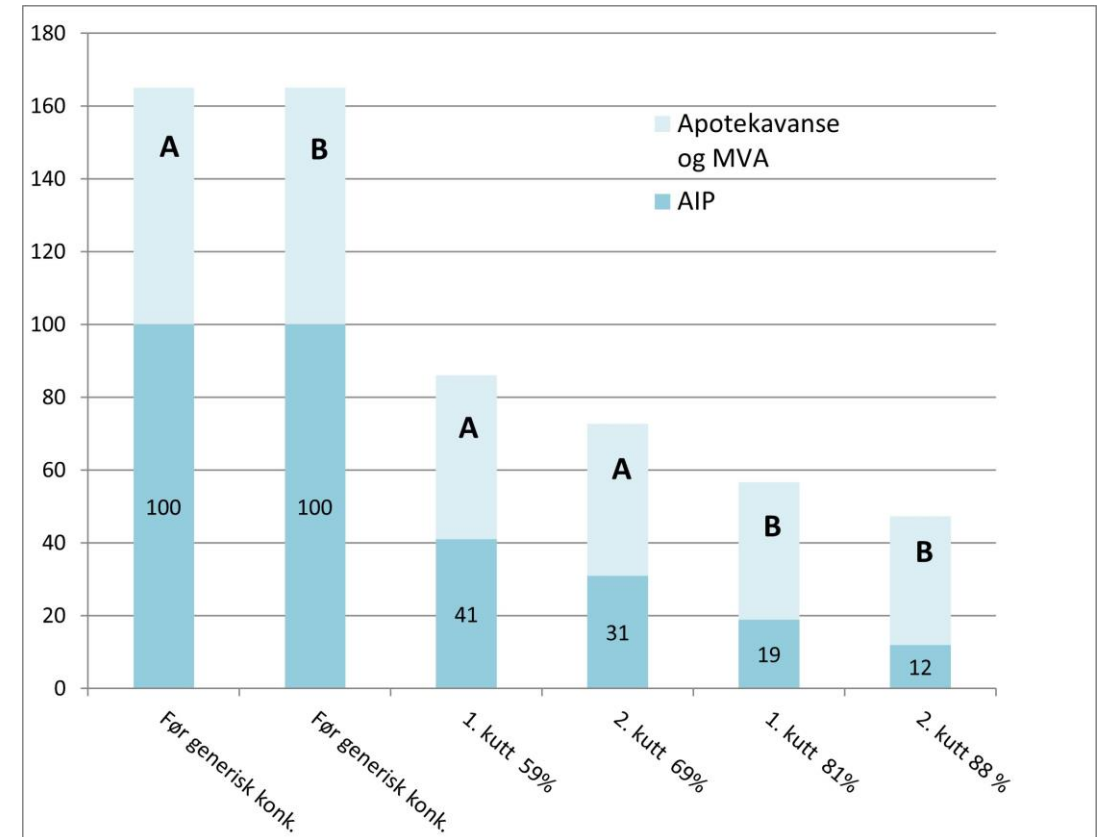
Huge potential for saving costs – that Nordic countries have succeed with (more or less)?

Decentralized competition – and dramatic shift in bargaining power

Norway struggled until 2004. Why?

- Vertical integration and price cap regulation of pharmacies input price.
- Wholesalers could collect huge rebates, but avoid transferring this to retail prices

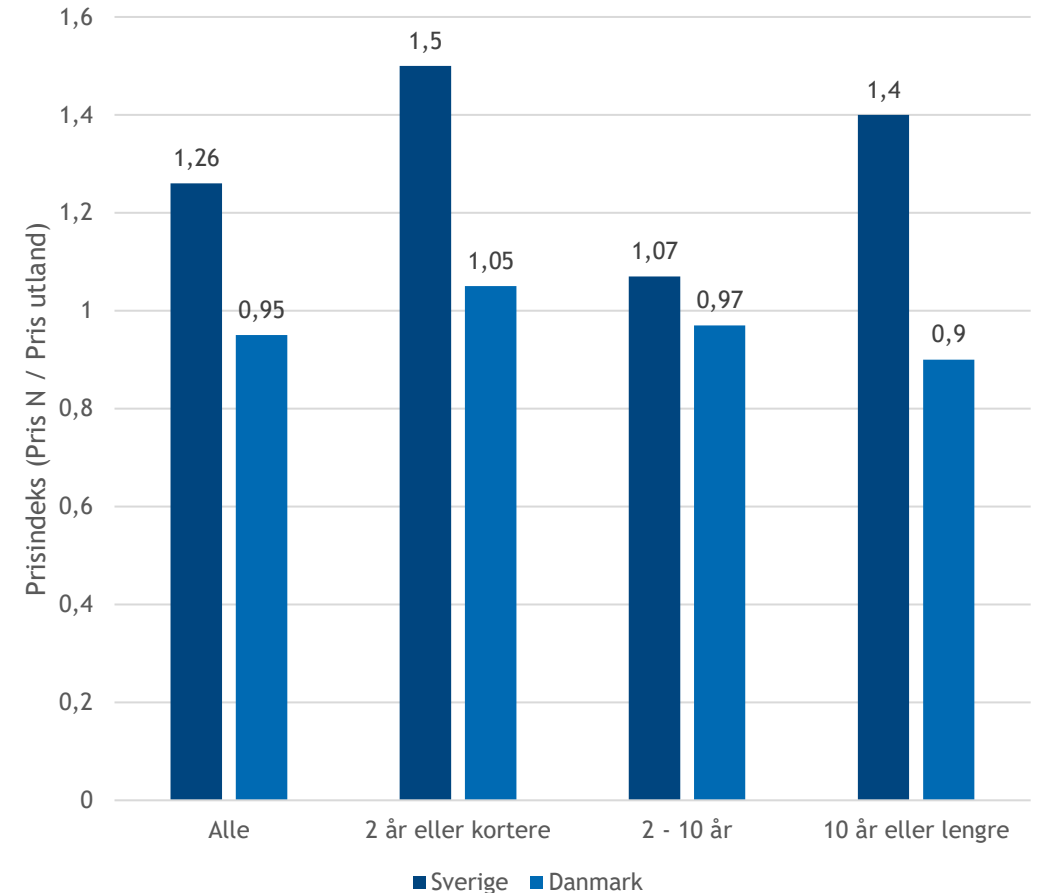
From 2004: Step price model introduced in Norway – proposed by one of the pharmacy chains



Source: Norwegian Medical Products Agency (NOMA)

Step price vs two market-based models

- Denmark and Sweden both have a market-based model for generics.
 - “The product of the month”
 - “The product of the period (2 weeks)”
- 2019 exchange rates, not purchasing power parities
- So, these prices should not be equal
- Hard to recommend a step-price model, but no rush to replace it.
 - We can benchmark against the market
 - Low administrative costs
 - Ad-hoc adjustments if needed



Source: Vista Analyse (2021)

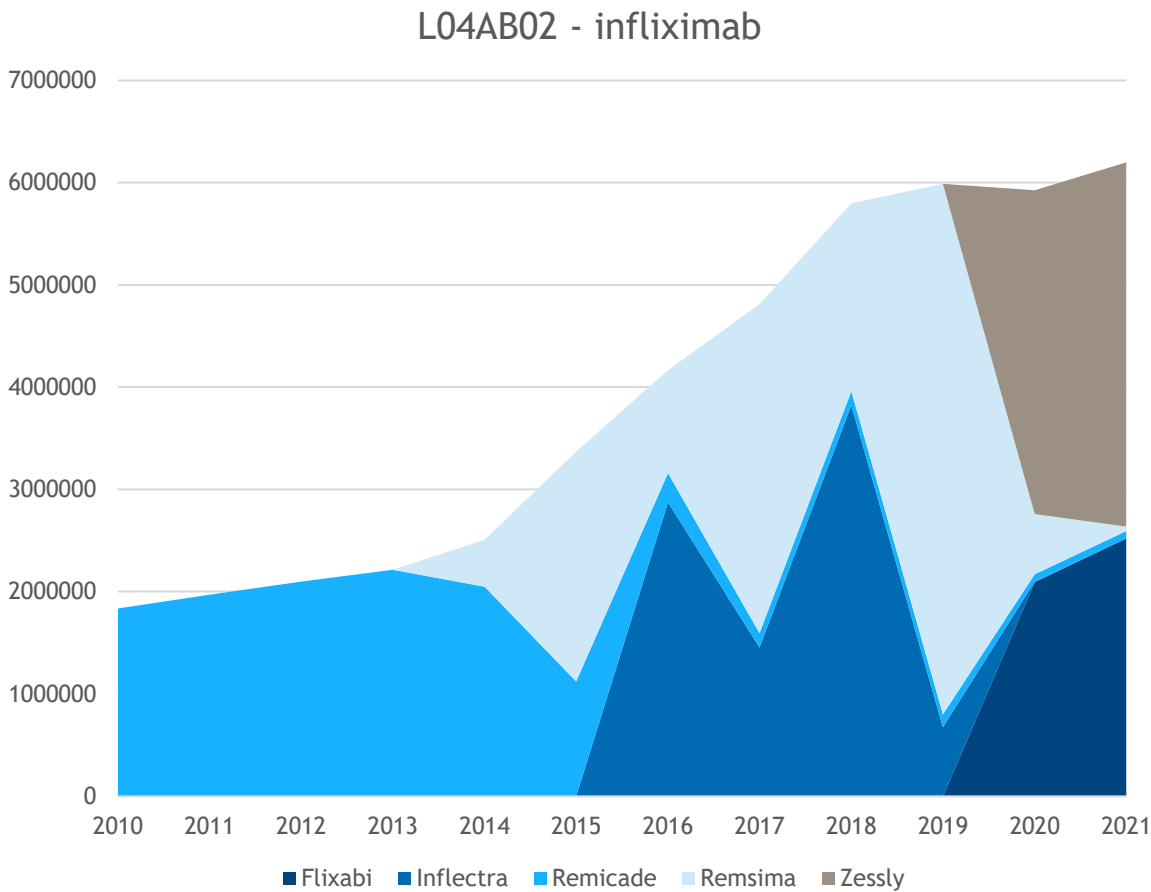
The brand name drug still asked for

- When they do, the government pays the price premium.
- In 2019, this added approx. 200 mill. NOK in costs.
- Controls reveals errors
 - Technical
 - Wrongly referring to patients' preferences
- Controversial topic, and hard to regulate

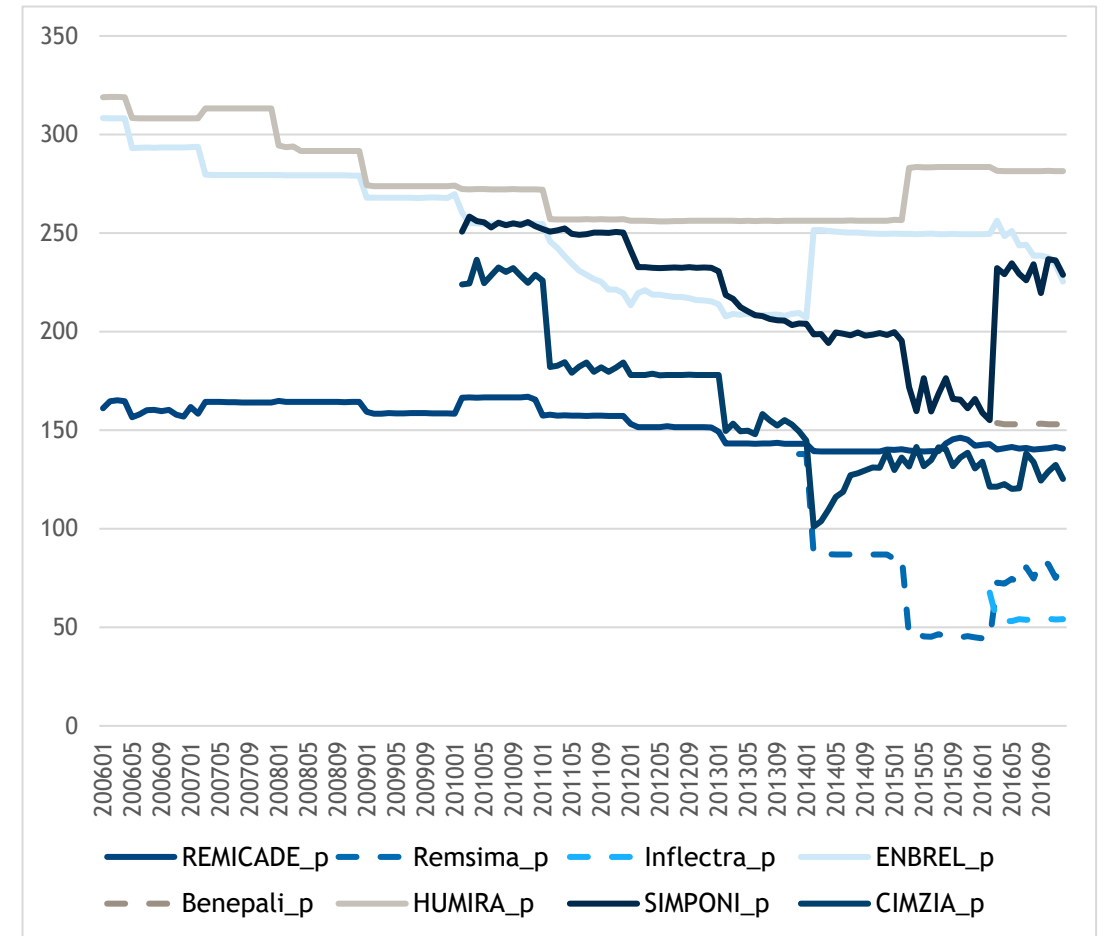
ATC-kode	Refusjonsbeløp 2019	Antall pakninger 2019	Andel legereservasjon av antall pk	Merkostnad legereservasjon	Preparatet med høyest merkostnad innen atc-koden
A02BC05	86 627 055	517 491	24 %	26 840 737	Nexium
C10AA05	116 475 853	1 073 875	9 %	20 392 290	Lipitor
R06AE07	46 399 920	567 405	9 %	13 494 036	Zyrtec
C09DA06	29 025 065	198 233	12 %	10 332 246	Atacand Plus
C09CA06	46 307 224	495 553	8 %	8 864 891	Atacand
C07AB02	119 518 178	1 612 982	9 %	8 025 256	Selo-zok
C10AX09	40 646 014	141 772	9 %	7 479 216	Ezetrol
N02CC01	80 859 096	267 318	10 %	7 330 703	Imigran
A02BC01	27 343 977	105 596	22 %	6 698 875	Losec MUPS

Source: Vista Analyse (2021)

Biosimilar markets are competitive



Source: Sykehusinnkjøp and own calculation



Source: Farmastat and own calculations

Summing up

1. Pharmaceuticals will continue to be important for health care. We live longer and the population is aging. Scientific development will create new drugs – if profitable.
2. Small Nordic countries should take the role as procurer – in a responsible way. Not bring innovation as a separate concern – best stimulated a national R&D-pharma policy.
3. Is all about bargaining, and there are three main bargaining positions
4. Innovative drugs can have high (potential) therapeutic value, with large uncertainty. Conflict area, with need to find better models - both for pricing and evaluating efficiency and uncertainty.
5. Use therapeutic competition (tendering) for patented drugs. When savings potential and the demand effect is large.
6. Generic competition is (often) efficient and gives huge cost savings. Maintaining security of supply of older drugs needs attention.

