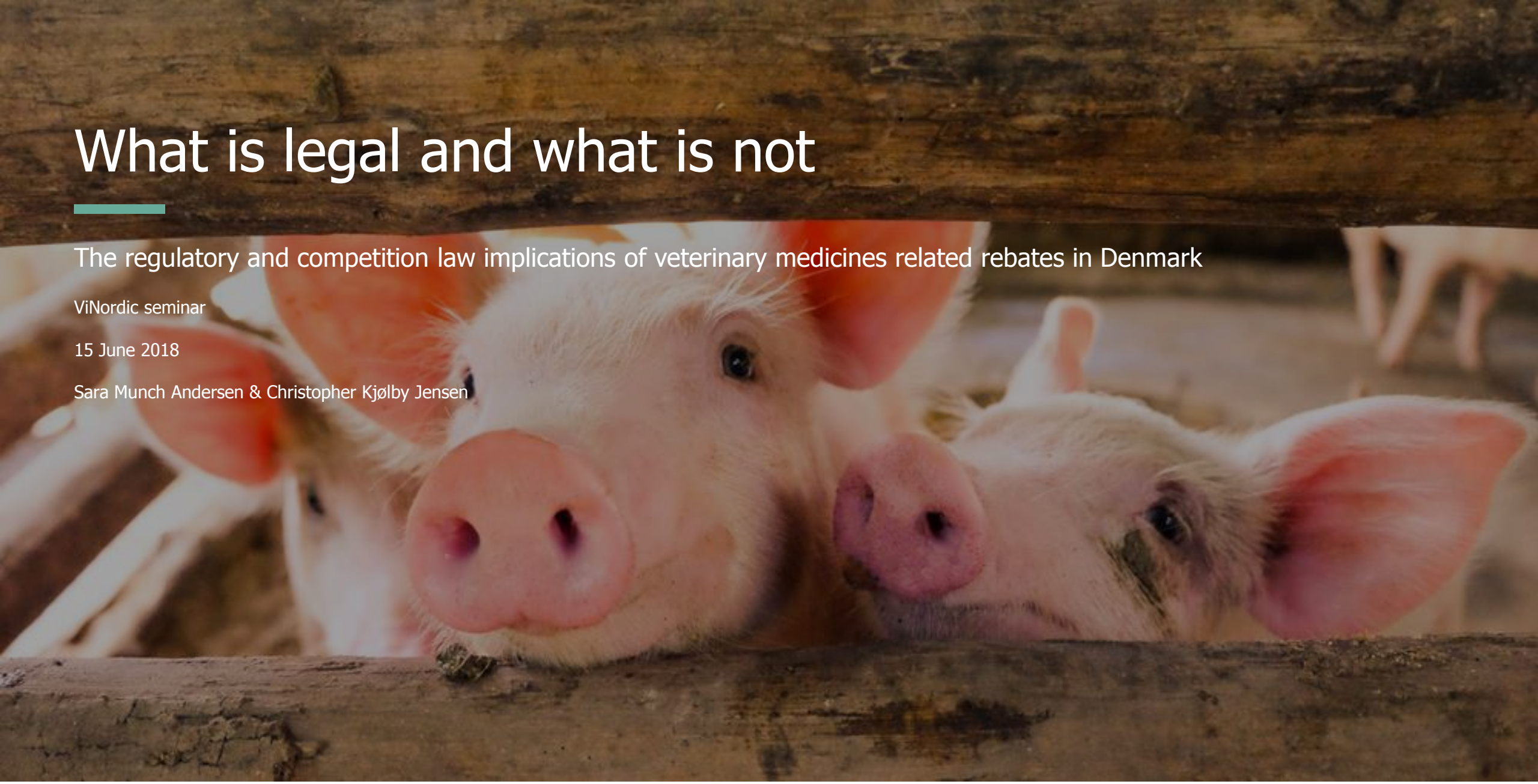

# What is legal and what is not

## The regulatory and competition law implications of veterinary medicines related rebates in Denmark

ViNordic seminar

15 June 2018

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PLESNER

# Agenda

1. Regulatory issues
2. Competition law aspects
3. Case studies
4. Key takeaways

# Regulatory

1. Background
2. Specifically concerning livestock
3. Overview of legislation
4. Sales to pharmacists – only cost-induced discounts
5. What about medicines to livestock?
6. Sale from producer to wholesaler/supplier
7. Sale to users
8. Control measures

# Background

**Introduction to pricing for pharmacy-restricted medicines**

- Principle: Same price for pharmacy-restricted medicines all over the country
- A registered product price for the pharmacies' purchased products ("AIP")
- A registered price for the pharmacies' sales price to customers ("AUP")
- The final price to customers will include a margin for the expedition and handling of prescriptions
- See Danish Medicines Act section 77

**Introduction to definitions**

- Medicinal products to livestock ("produktionsdyr"): That is medicinal products intended for use in animal species used for commercial purposes of producing meat, milk, egg, honey, wool or fur (see Executive Order on distribution of Medicines to livestock outside pharmacies, section 3(4)). This comprises e.g. cows, pigs, sheep, goats, horses, poultry, aquaculture and rabbits.
- Companion animals ("familiedyr"): all other animals than livestock
- See Directive 2001/82/EC of 6 November 2001 with subsequent amendments on the Community Code relating to veterinary medicinal products (NB: does not comprise medicated feedingstuffs). Implemented in Denmark by the Danish Medicines Act that comprises medicines to both animals and humans.

# Liberalization/deregulation

**Liberalization/deregulation of rules concerning livestock**

In 2007 sales of veterinary medicines to livestock were liberalized – medicinal products for livestock are no longer restricted to pharmacies but other retailers with a permit can sell directly to the user, Danish Act on Medicines section 60 (3).

At the same time the obligation to report a fixed price - ie. the pharmacies' purchased products price ("AIP") was repealed, see Executive Order on Medicinal Prices and Conditions for Delivery etc. ("Bekendtgørelse om medicinpriser og leveringsforhold m.v. nr. 1286 af 2017").

# More on livestock medicines

**Livestock:**

- Veterinary medicines to livestock (medicines marked in the price register as "AP", "BP", "HP", "APK", "BPK" and "HPK"): Generally, not restricted to pharmacies.
- Exemption 1: Extemperaneous medicines ("magistrelle lægemidler") to all animals are restricted to sales from pharmacies.

# Overview of legislation concerning sales

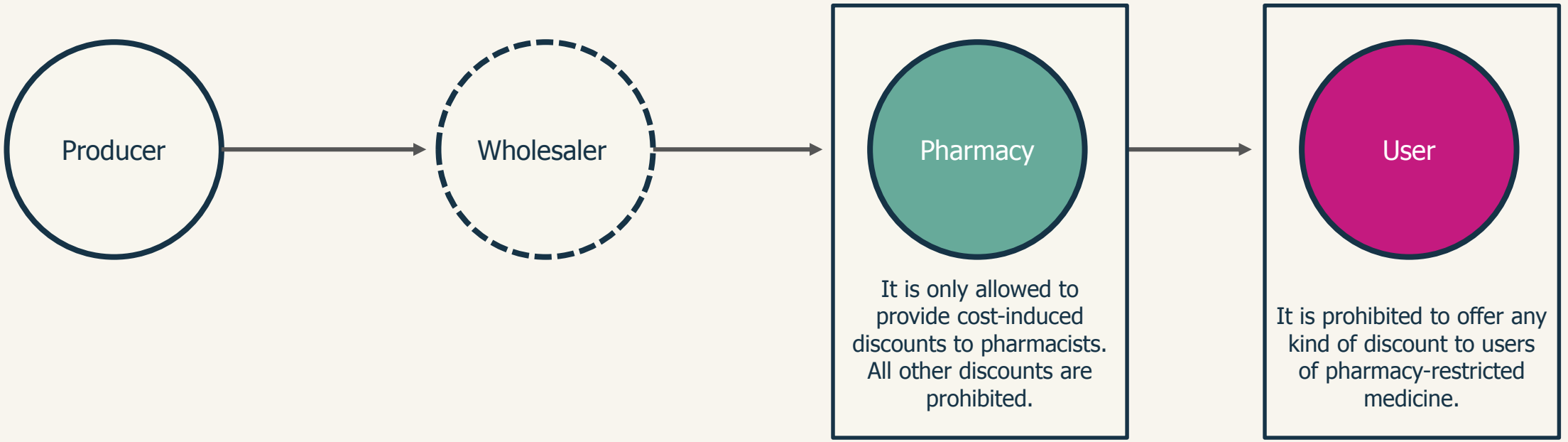
**Specific legislation in relation to pharmacy-restricted medicines:**

- Danish Act on Medicines section 71b
- Executive Order on Advertisement etc. for Medicines ("Bekendtgørelse om reklame mv. for lægemidler nr. 1153 af 22. oktober 2014")
- Guidance on Advertisement etc. for Medicines ("Vejledning om reklame for lægemidler nr. 10356 af 29. december 2014")

**Note the specific legislation in relation to medicines to livestock:**

- Danish Act on Medicines section 60(3)
- Executive Order on distribution of medicines to livestock outside pharmacies ("Bekendtgørelse om forhandling af lægemidler til produktionsdyr uden for apotek nr. 93 af 25. januar 2007")
- Executive Order on distribution of certain iron and vitamin preparations and certain antiparasitic medicines to animals outside pharmacies ("Bekendtgørelse om forhandling af visse jern- og vitaminpræparater samt visse antiparasitære lægemidler til dyr udenfor apotek nr. 1345 af 28. November 2017")

# Sales structure – generally pharmacy-restricted medicines



# Danish Medicines Act's Regulation of discounts

71 b.- (1) In connection with the **sale of a pharmacy-only medicinal product**, cf. section 60(1), **to a pharmacis**t, the holder of an authorisation under section 39(1) (the discount provider) **may grant discounts provided only they reflect cost savings for the discount provider.** Such discounts shall be commensurate with the cost savings and must be in the form of a price reduction.

(2) The discount provider **shall prepare and publish information** about the access to obtaining the discounts mentioned in subsection (1) which the discount provider offers as part of the sale of pharmacy-only medicinal products (duty to display information).

(3) The Minister for the Interior and Health shall lay down specific rules on the provision of the discounts mentioned in subsection (1) and the duty to display information mentioned in subsection (2) and on accounting related matters, management statement and auditing of discounts granted.

(4) Pharmacists are not permitted as part of the sale of medicinal products mentioned in subsection (1) to request or receive discounts that are not compliant with the information that the discount provider has prepared and published pursuant to his duty to display information.

(5) Discount providers and pharmacists shall, for a period of three years, keep documentary evidence of any discounts mentioned in subsection (1) granted or earned as part of the sale of pharmacy-only medicinal products. The Minister for the Interior and Health may lay down rules detailing what documentary evidence must be kept.

(6) The Danish Medicines Agency may order discount providers and pharmacies to hand over all information necessary to check whether discounts have been granted and received in compliance with subsections (1) and (4) and rules issued in pursuance of subsection (3).

# Why do we have rules concerning discounts?

**Concerns:**

- Fixed price on pharmacy-restricted medicines - medicines have the same price all over the country. Rebates can undermine the fixed prices
- HCP's are not allowed to received economic benefits

**Cost-induced discounts are believed to contribute to a rational distribution by making it possible to reap of benefits of efficiency - which ultimately benefits pharmacists, consumers and the national healthcare**

# General prohibition of economic advantages to HCPs

**Executive Order on Advertisement etc. for Medicines Chapter 9**

***Gifts***

**Section 22. Economic advantages must not be offered or given to health professionals for advertising purposes or otherwise to promote the sale of a medicinal product, cf. however subsection (2) and Sections 24, 26, 29, 31, 36 and 37.**

***Subsection (2)*. The prohibition in Section 22(1) does not extend to gifts of insignificant value when the gift can be used in the recipient's business.**

# Detailed regulation - Only cost-induced discounts

***Requirements for discounts***

**Section 36:**

Irrespective of the provision of Section 22(1), **it is allowed to offer discounts on medicinal products if the discount is based on cost savings** on the part of the supplier and **if the discount is a direct consequence of the recipient's purchasing behaviour which deviates from the supplier's standard terms (cost-based discounts)**.

(2) **The discount should be proportional to the cost saving.** A supplier must apply the same principles to calculate discounts for recipients that show the same purchasing behaviour.

(3) It is not allowed to offer discounts which

1) are calculated on the basis of the supplier's purchase price or which are calculated using the supplier's purchase price as part of the calculation,

2) are based on cost savings that are a result of internal rationalisations within the supplier, or

3) are based on discounts offered by others to the supplier.

(4) Irrespective of the provision of Subsection (3)(iii), the supplier may offer cost-based discounts based on cost savings in the form of discounts offered to the supplier by a service provider that assists the supplier with the distribution of medicinal products (e.g., a carrier). The discount from the service provider must be based on a cost saving obtained by the service provider as a result of the recipient's purchasing behaviour, and the discount must be reasonably proportional to the cost relief.

## *The settlement of discounts*

**Section 37. Cost-induced discounts may only be offered in the form of a reduction of the retailer's purchase price. The discount must reach no one else than the direct buyer of the medicinal product, and it must be clearly linked to the delivery of the specific medicinal products or the specific consignment of medicinal products.**

# What does this mean?

**It is only allowed to provide cost-induced discounts to pharmacists/companies with permit to distribute medicines**
**All other discounts are prohibited.**

- The discount has to be equal to the deduction of costs and be a reduction of the price on the products in question. Furthermore, it has to be given directly to the pharmacist see section 37.
- What are cost-induced discounts? This will only be rebates that are the result of the pharmacist's reduction of the supplier's costs. For example - an agreement on fewer weekly deliveries.
- It can only be the pharmacist's (or group of pharmacists') behavior that can justify a discount.
- It cannot be the wholesaler's/supplier's behavior that can provide grounds for the discount.

- The same principles for discount shall apply to the pharmacists showing the same kind of "purchase behavior".
- It is not allowed to provide different discounts to the same conditions ie. if a discount is offered on a specific item number under certain conditions, it will be expected to be offered under the same conditions to another item number.
- But it is allowed to offer a different discount on products that are different and there are different requirements to the supply, e.g. specific conditions for storage.
- No discounts can be offered that are obtained in other intermediaries ("handelsled").
- Pharmacists are not allowed to give discounts to others.

# Pharmacists not allowed to request discounts

- For pharmacy-restricted medicines: It is prohibited that the pharmacist requests or receives discounts that are not in accordance with the seller's published discounts, see Danish Medicines Act section 71 b(4)

# Accessory rules for pharmacy-restricted medicines

**For pharmacy-restricted medicines there are a number of accessory obligations to the discount rules, for example:**

- Supplier's duty to publish discounts ("skiltepligt"), see section 38 of the Executive Order
- Suppliers and pharmacists have a duty to keep documentation for three years, see section 39-40 of the Executive Order
- Book keeping, management declarations, auditing, etc., see section 41-44 of the Executive Order

**Note the accessory rules only apply to pharmacy-restricted medicines.**

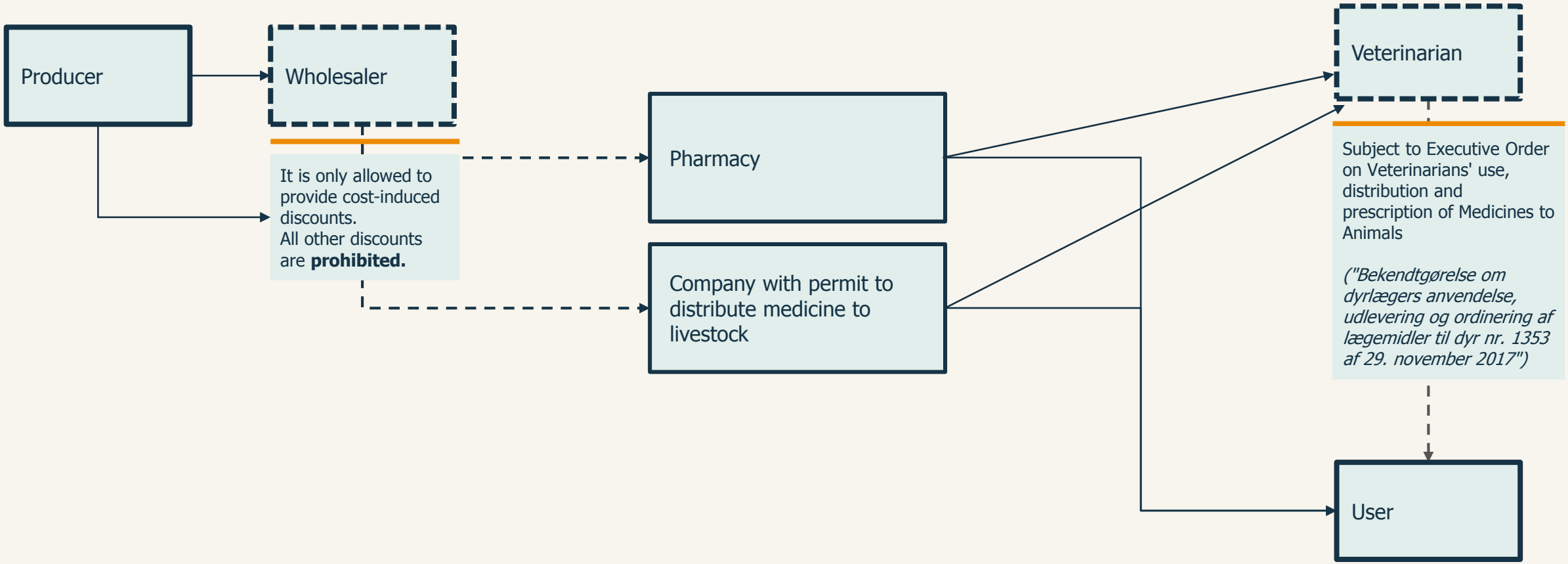
**The DMA may inspect the pharmacies and suppliers to verify the companies' compliance with the rules.**

# Prohibition to offer bonuses/economic advantage to users of pharmacy-restricted medicines

**Section 71 a: Bonuses or other economic advantage may not** be paid or offered **to users** of medicinal products in connection with the sale of a **pharmacy-only medicinal product**, see Section 60(1). However, bonuses may be paid to hospital owners in connection with the sale of pharmacy-only medicinal products to hospitals.

This applies to all – producers, wholesalers, pharmacists etc.

# Sales structure – medicine to livestock



# What about medicines to livestock?

**The pricing of medicines to livestock are liberalised – but what about the discount rules?**

In connection with the liberalisation of medicines and the issuance of the discount rules, the following was stated in the preparatory works:

"The proposed Section 71 a, first sentence, establishes that bonuses or other economic advantage may not be paid, including cost-induced discounts, in connection with the sale of a pharmacy-only medicinal product to the user.

With the proposed inclusion of a new subsection 3 in Section 60 (Section 1, no. 6, of the draft bill) - meaning the repeal of the pharmacy-only stipulation for medicinal products for production animals - this prohibition will in general in future only apply to the sale of medicinal products for humans and medicinal products for pets."

**But: The Ministry of Health has used the discretionary powers in the Danish Act on Medicines Section 70(1) to issue other rules on advertisements, discounts and other services.**

# What about medicines to livestock?

**Therefore – in the Executive Order on Advertisement etc. for Medicines ("Bekendtgørelse om reklame mv. for lægemidler nr. 1153 af 22. oktober 2014"):**

**Section 34.** Advertising to owners of or managerial staff in shops authorized to sell non-pharmacy OTC medicinal products or medicinal products for production animals, see Section 39(1) and Section 60(2) and (3) of the Medicines Act, is covered by the provisions in Sections 11-13, 22-30, 36 and 37, when the advertisement or economic advantage concerns such medicinal products.

**This means that the limitation to cost-induced discounts also applies to medicines to livestock – but not the accessory duties.**

The DMA has informed that the rules in section 36-37, applies to all medicines:

- pharmacy-restricted medicines,
- non-pharmacy-restricted OTC medicines and
- non-pharmacy-restricted medicines to livestock

# What about discounts from producer to wholesaler/supplier?

- The discount rules only directly apply to sales **to** pharmacists/companies with permit
- **BUT:** It should be noted that any discounts given by the producer to the wholesaler/supplier cannot be given to the pharmacist/company with permit.
  - For example any discount given to the wholesaler for cost reducing use of storage facilities with the wholesaler will not justify a discount to the pharmacist/company with permit.

**Remember - general competition rules apply - we will get back to this point.**

# Pharmacies/companies with permit sales to users

**Legislation:** Executive Order on calculation of consumer prices etc. on medicines ("Bekendtgørelse om beregning af forbrugerpriser m.v. på lægemidler nr. 283 af 12. April 2018")

**Chapter 1: Pharmacy-restricted medicines:** regulation of AIP and AUP (see intro)

**Chapter 2: Non-pharmacy restricted OTC medicines:** The pharmacist/ company with permit can set the sales price

**Chapter 3: Medicines to livestock:** pharmacist/company with permit can set the sales price

**Chapter 4: Extemperaneous medicines ("magistrelle lægemidler"):** generally pharmacist can set the price on the basis of costs of production and reasonable margin of profit

# Vet's sale to users

**Legislation:** Danish Executive Order on Veterinarians' use, distribution and prescription of Medicines to Animals (in Danish "Bekendtgørelse om dyrlægers anvendelse, udlevering og ordinering af lægemidler til dyr nr. 1353 af 29. november 2017"):

**Section 45 (1) Companion animals/all other animals than livestock**

The vet shall set the consumer price in accordance with section 1 in Executive Order on calculation of consumer prices etc. on medicines ("Bekendtgørelse om beregning af forbrugerpriser m.v. på lægemidler nr. 283 af 12. April 2018")

**Section 45 (2) Livestock**

Here the consumer price is calculated as the same as the vet's purchase price from the pharmacists or company with permit to distribute such medicines.

**Section 46 Extemperaneous medicines ("magistrelle lægemidler")**

The vet shall set the consumer price in accordance with section 8 in Executive Order on calculation of consumer prices etc. on medicines ("Bekendtgørelse om beregning af forbrugerpriser m.v. på lægemidler nr. 283 af 12. April 2018")

**Section 47: General requirement**

The Vet is only allowed to add 5 % fee to the consumer price.

**See also section 45(3)-(4) that contains rules on the calculation of consumer prices for multipacks and partial use and section 48 on the invoicing principles.**

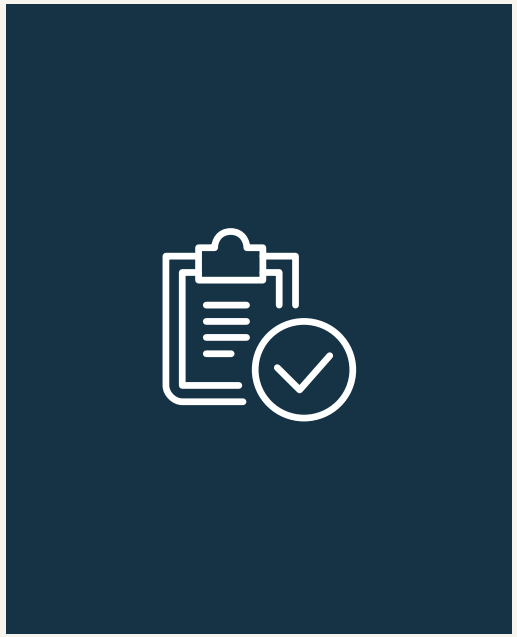
# Control measures

**The DMA may take various measures to control compliance with the discount rules:**

- Inspection
- Orders of disclosure of all information necessary for the DMA's control of compliance

# Competition law

# Agenda



1. Background and overview of applicable rules
2. Market definition & dominance
3. Competition law and rebates
4. Potential risks

# The two basic sets of competition rules

**Section 6 DCA and Article 101 TFEU**

Anti-competitive agreements

**Section 11 DCA and Article 102 TFEU**

Abuse of a dominant position

# Market definition – General considerations

**01.**

There is a tendency towards very narrow market definitions within the life science sector – also in relation to veterinary medicines/animal health products

**02.**

According to case law the relevant *product market* can (and often is) defined narrowly as individual products or even active ingredients

**03.**

The relevant *geographic market* is typically defined as national due to specific national sector regulations and market conditions

**04.**

The risk of being found to be dominant is therefore relatively high in relation to veterinary medicines/animal health products

# Market definition is complex

**European case law has divided animal health products into three main overall categories on national markets:**

- Biologicals (vaccines)
- Pharmaceuticals
- Medicinals Feed Additives

**Each of these categories are further segmented based on the following criteria:**

- Animal Species
- Active Substance/Ingredient
- Target Pathology/Scope of effectiveness
- Route/mode of administration
- Duration of Efficacy
- Duration of Withdrawal Periods

**Furthermore in relation to Pharmaceuticals the following sub-segments have been identified to be assessed under each criteria:**

- Parasiticides
- Antimicrobials
- Endocrine Treatments
- Anti-inflammatory treatments
- Analgesics

# Dominance

*A position of economic strength which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers*

**Market share guidance**

- Dominance very likely/presumed at 50 % or more over time
- Dominance likely at 40-50 % – especially if competitors are much smaller
- Dominance under 40 % is possible, but below 25 % unlikely
- There are no "block exemptions" for abuse of dominance

# Abuse

## The concept of abuse

Dominant undertakings have a special responsibility not to restrict competition in the market

An objective concept, i.e. the subjective intention of the dominant undertaking is generally not decisive

Enough that behaviour is capable of harming competition – no need to show actual harm in the market

"Normal" business behaviour may be problematic for dominant companies, e.g. discounts/rebates

# Examples of abusive behaviour

## Exclusionary abuses (i.e. behaviour that harms actual/potential competitors)

- Exclusionary rebates/discounts
- Predatory pricing
- Tying og bundling
- Exclusivity

## Exploitative abuses (i.e. behaviour that harms customers/trading partners)

- Excessive pricing
- Unfair trading conditions
- Discrimination

# Rebates - Introduction

Granting of rebates or discounts is **generally** allowed and considered a normal part of business

Pure price reductions not related to specific levels of sales are only problematic if they result in prices below LRAIC/ATC (predatory pricing)

- If price is below LRAIC/ATC, an individual assessment is required to assess legality of price reduction

However, **certain types of rebates/discounts** may create risk under the competition rules, e.g. if they are *exclusionary*:

- Require the customer not to buy, sell or distribute competitors' products
- Require the customer to buy more than 80% of its needs of a given product from dominant company
- Are based on aggressive, individual purchase targets, for example "if you buy 10 % more than last year, you get X % in discount"

# Rebates – Analytical framework

Main theory of harm: as efficient competitors (AECs) of the dominant company are excluded/foreclosed from the market because they cannot match the rebates offered

A three-step (semi-economic) analysis is applied

I. Is the company in a dominant position?
II. Is the rebate scheme capable of foreclosing AECs?
    - Rebates can for analytical purposes be divided into three overall categories:
        - **Quantity/volume rebates**
        - **Exclusivity/quasi exclusivity (loyalty) rebates**
        - **Other rebates**
III. Is the rebate scheme objectively justified, e.g. due to efficiencies?
    - It is not relevant for this assessment that the customer has asked for the rebate
    - "Meeting the competition"-arguments are rarely accepted

# Quantity and exclusivity rebates – The two extremes

**Quantity rebates**

- Standardised and cost related rebates (reflecting cost savings) linked to the volume purchased *in a single order*
- Presumably legal and therefore limited risk from a competition law perspective, provided that price is not predatory

**Exclusivity/quasi exclusivity rebates**

- Rebates conditioned upon the customer buying all/most if its needs of a given product from the dominant undertaking
- Generally *presumed* to be problematic as they are deemed to have similar effects to contractual exclusivity clauses
- Possible to present evidence against exclusionary effects in line with "other rebates"-category - requires rather complex economic analysis

# Other rebates

**Other rebates**

- Rebates not directly linked to exclusivity/quasi-exclusivity but which may potentially have a fidelity-building effect, e.g. incremental rebates and retroactive rebate schemes
- Need for case-by-case risk assessment of all relevant factual circumstances related to the rebate in order to assess whether rebate is capable of foreclosing AECs, e.g.:
  - Degree of dominance
  - Barriers to entry
  - Market coverage of rebate scheme
  - Conditions for granting of rebate and size and duration of rebate
  - Exclusionary strategy
  - Etc.
- The relevance and relative importance of the various elements depends on the specific facts in question
- A standardised, incremental rebate scheme which does not lead to predatory prices for each product at the margin is generally associated with a low degree of risk

# Other rebates – Risk factors

The following elements are typically an indication of a potential competition law risk:

- **High degree of dominance**
- **High share of market covered by rebate scheme**
- **Retroactivity**, i.e. rebate is calculated over all of the customer's purchases, not just additional incremental purchases. Retroactive rebates that tie in a customer over a long period are high risk. A simple example of a retroactive rebate scheme could be:
  - If the customer’s total purchase reaches 100 units = 5 % rebate
  - If the customer’s total purchase reaches 200 units = 10 % rebate on all 200 units, not just the incremental units between 100 and 200 units
  - If the customer’s total purchase reaches 500 units = 15 % on all 500 units, not just the incremental units between 200 and 500 units
  - Etc.

# Other rebates – Risk factors (continued)

- Rebates granted/calculated based on the purchases made over a **long reference period**
- **Customised rebates for each customer's individual basis** (vs. a standardised rebate scheme equally applicable to all customers)
- Rebates structured with large tiers/large increment between tiers. Rebates which include numerous small incremental tiers are generally less restrictive than rebate schemes with, for example, only one or two large tiers
- **Non-linear rebates**, i.e. there is not a direct proportion between the calculation of the rebate and the volumes purchased
- **Rebates conditional on the customer purchasing more than in the preceding reference period**
- **Lack of transparency** for the customer
- Rebates applied **across multiple products** (bundling)

# What are the risks ?

## Companies

- Reputational harm
- Fines of up to 10% of total annual world-wide revenue for each violation
- Damage claims from third parties having suffered a loss
- Exclusion from public tenders

## Individuals

- Personal fines
- Personal reputation can suffer
- Potential employment-related consequences

**Risks for breach of the regulatory discount rules**
DMA has the right to issue administrative fines, see Executive Order on Advertisement etc. for Medicines section 45.

# Case study

**Case no. 1**

The Pharmaceutical Company X produces generic medicines to cats. Company X has a market share of 25% and there are 5 other generics on the market providing the same medicine.

The pharmaceutical company directly supplies to the pharmacists. The chain of pharmacists have offered to receive deliveries only once per week instead of the two deliveries per week that were entailed in the published offer (compliance with the skiltepligt).

**What should Company X consider?**

# Case study

**Case no. 1**

**Company X should consider:**

1. Sale to a pharmacy of medicines = discount rules do apply
   - Is it a cost-induced discounts that the pharmacy is requesting?
2. Company X is unlikely to be dominant given the relatively low market share and the presence of 5 other generics on the market. Therefore, the competition rules will not likely apply.

# Case study

**Case no. 2**

The Pharmaceutical Company Y produces medicines to pigs.
The medicine is protected by a product-patent but there are other products available on the market to treat the disease.

The pharmaceutical company sells to a wholesaler.

Company Y wishes to offer the wholesaler rebates of increasing size based on the wholesaler's annual purchasing volumes from Company Y and other suppliers.

**What should Company Y consider?**

# Case study

**Case no. 2**

**Company Y should consider**

1. Sale to a wholesaler = discount rules do not apply.
2. The competition rules may apply:
   i. Is Company Y dominant?
   ii. Is the rebate scheme tied to exclusivity/quasi exclusivity?
   iii. Is the rebate scheme retroactive/incremental?
   iv. Will the rebate scheme likely be capable of excluding AECs?
   v. Etc.

# Key takeaways

- **Regulatory:**
  i. In relation to sales to pharmacies/businesses with permit: Be aware of the restriction to cost-induced discounts and prohibition of all other discounts/economic advantages
  ii. In relation to sales to wholesaler: Be aware that the discounts given cannot be passed on to the pharmacies/businesses with permit
- **Competition law:**
  i. Relatively high risk of dominance in the life science sector, including in the veterinary medicines/animal health products segment
  ii. Rebates schemes implemented by dominant companies need to be drafted carefully in light of the specific market conditions
  iii. The competition authorities have traditionally had high focus on rebates and unlawful rebate schemes can have serious financial and reputational implications

# Making our clients SUCCESSFUL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