MEDICINES SHORTAGES – A REALITY CHECK?
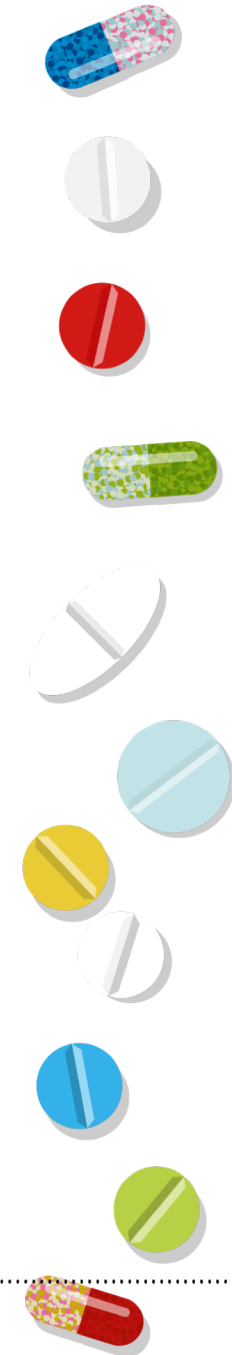
A Danish perspective

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AMGROS

DISCLOSURE

- Conflict of interest: Nothing to disclose

QUESTIONS

1. Are the pharmacy able to influence the number of back orders reaching the hospital?

2. Is it good practice to manage all drugs at the pharmacy in the same way?

3. Is it worth to share information with the suppliers regarding forecast, back orders, delivery performance a.m.?

AMGROS

AGENDA

- Supply of medicines to Danish Hospitals

- Brief introduction to Amgros and the Danish supply chain

- Amgros' tender business and drug shortages

- Amgros' logistic business and drug shortages

- Operational handling of back orders

- Tactical planning avoiding future back orders

- Strategic development

- Reporting

Nils Linde-Laursen, Logistic manager
Bachelor of Engineering, Bachelor in Supply Chain Management.
Working at Amgros since 2014
Experience: More than 20 years in European Pharmaceutical industry

Nils Linde-Laursen

AMGROS
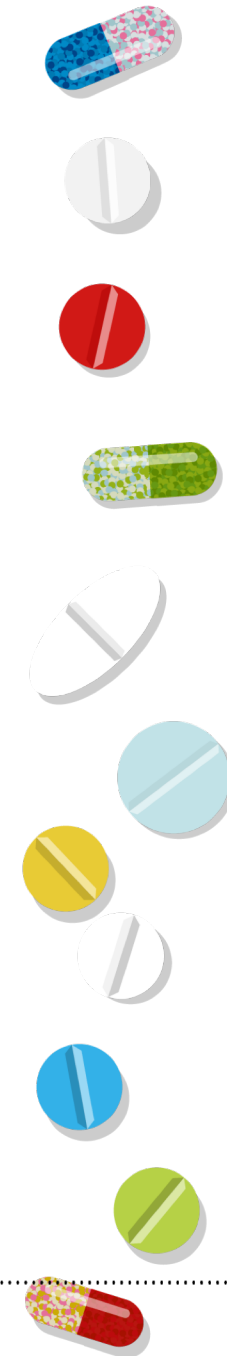
SUPPLY OF MEDICINES TO DANISH HOSPITALS

A BRIEF INTRODUCTION TO THE DANISH SETUP FOR SUPPLYING HOSPITAL MEDICINE - 1

- Equal and free access to health care for all citizens

- No patient co-payment for hospital services, including pharmaceuticals

- **National** tenders and guidelines

- Prescription for most of the "advanced" pharmaceuticals are restricted to hospitals

- *Retail pharmacies (primary care) are private businesses*
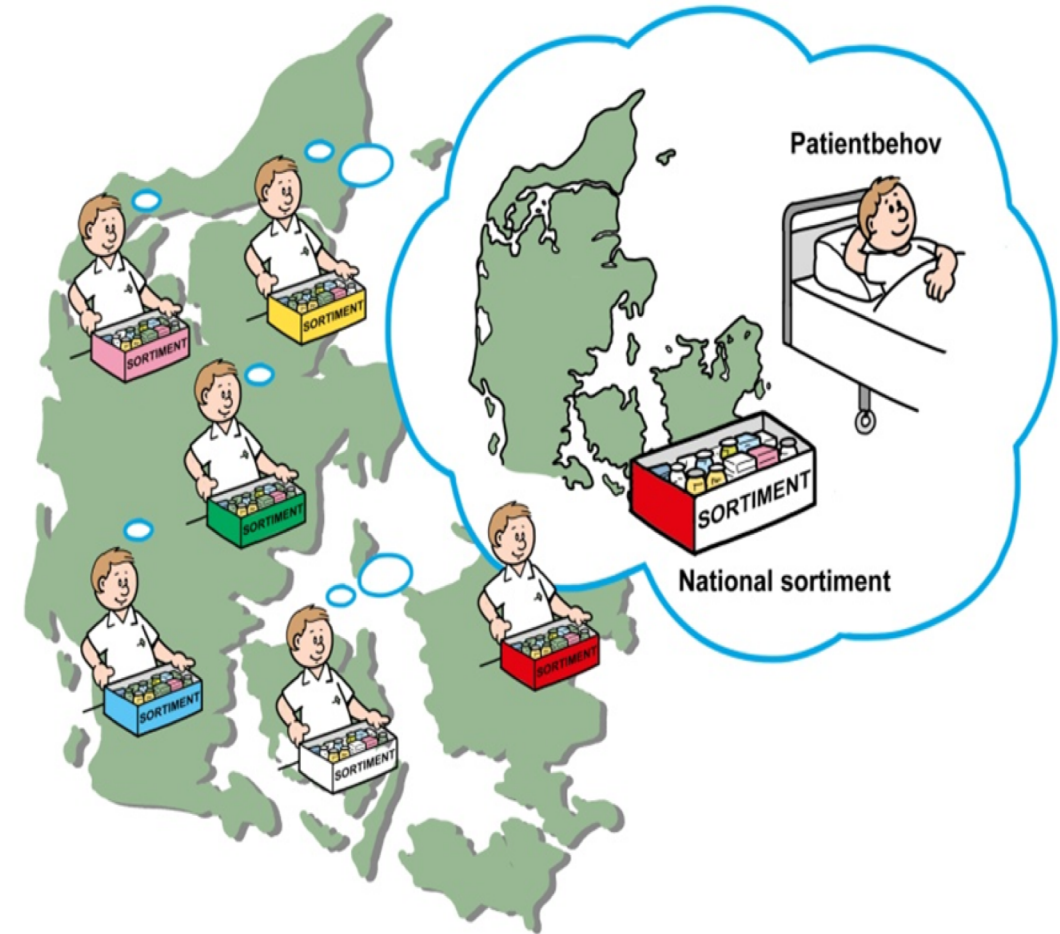
A BRIEF INTRODUCTION TO THE DANISH SETUP FOR SUPPLYING HOSPITAL MEDICINE - 2

- 5.7m inhabitants

- A public health care system owned by and managed individually by the 5 regions
  - Mainly financed through general taxes

- A few facts:
  - 50 hospitals
  - 8 hospital pharmacies
  - 1 national setup for procurement and supply
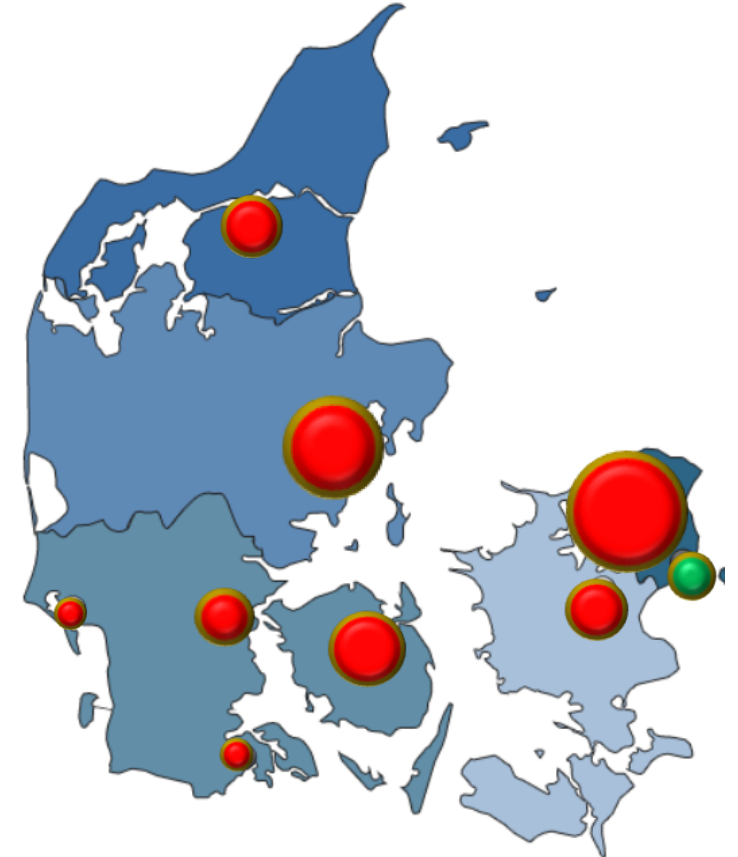
MARKET SHARE IN DENMARK

TOTAL MARKET (2017) – 2.6 BILLION EURO (PPP)
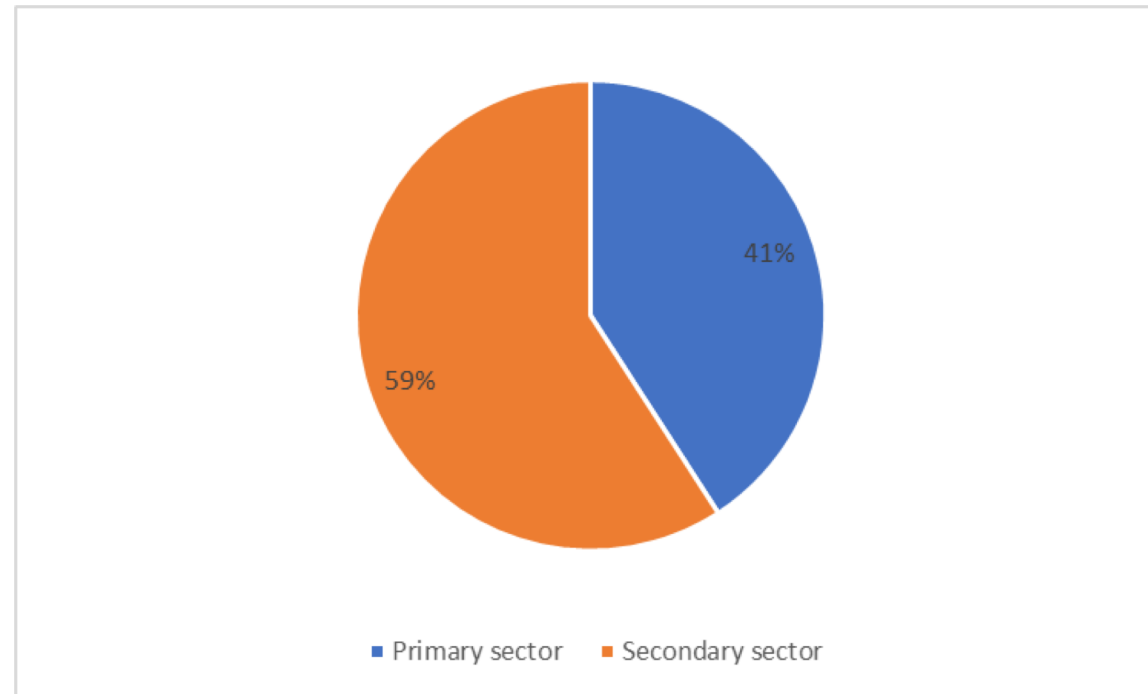
Hospital market share 59% (value)
Turnover 1.52 Billion EURO

Changes with annual EU tenders

8 hospital pharmacies + Greenland

Growth rate app. 5%

41%

59%

■ Primary sector ■ Secondary sector

Primary care market share 41% (value)
Turnover 1.05 Billion EURO

Generic substitution every 2nd week

App. 210 private pharmacies

Growth rate >1%

Source: DLI

BRIEF INTRODUCTION TO AMGROS AND THE DANISH SUPPLY CHAIN

VERY SHORT ON ONE OF AMGROS' BUSINESS AREAS

- Ensure that the right pharmaceuticals are bought at the right price for Danish hospitals

- Cut administration costs and achieve volume discounts by consolidating procurement of hospital medicine.

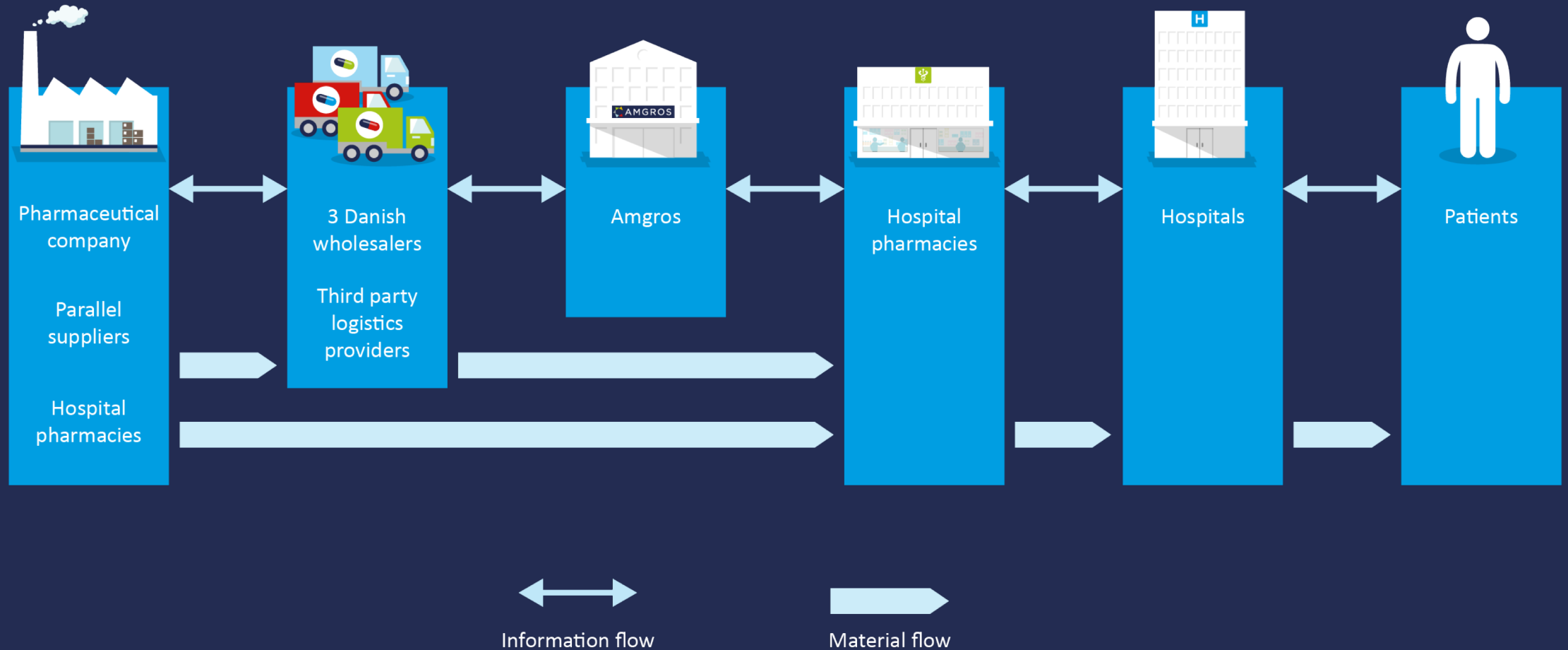| 3.171	340	27,28
MIO. IS HOW MUCH WE HAVE SAVED THE REGIONS OVER THE LAST 12 MONTHS	IS THE NUMBER OF EU TENDERS WE HAVE HELD OVER THE LAST 12 MONTHS	IS THE AVERAGE PCT. DISCOUNT WE HAVE ACHIEVED FROM SUPPLIERS OVER THE LAST 12 MONTHS

(426 million €)

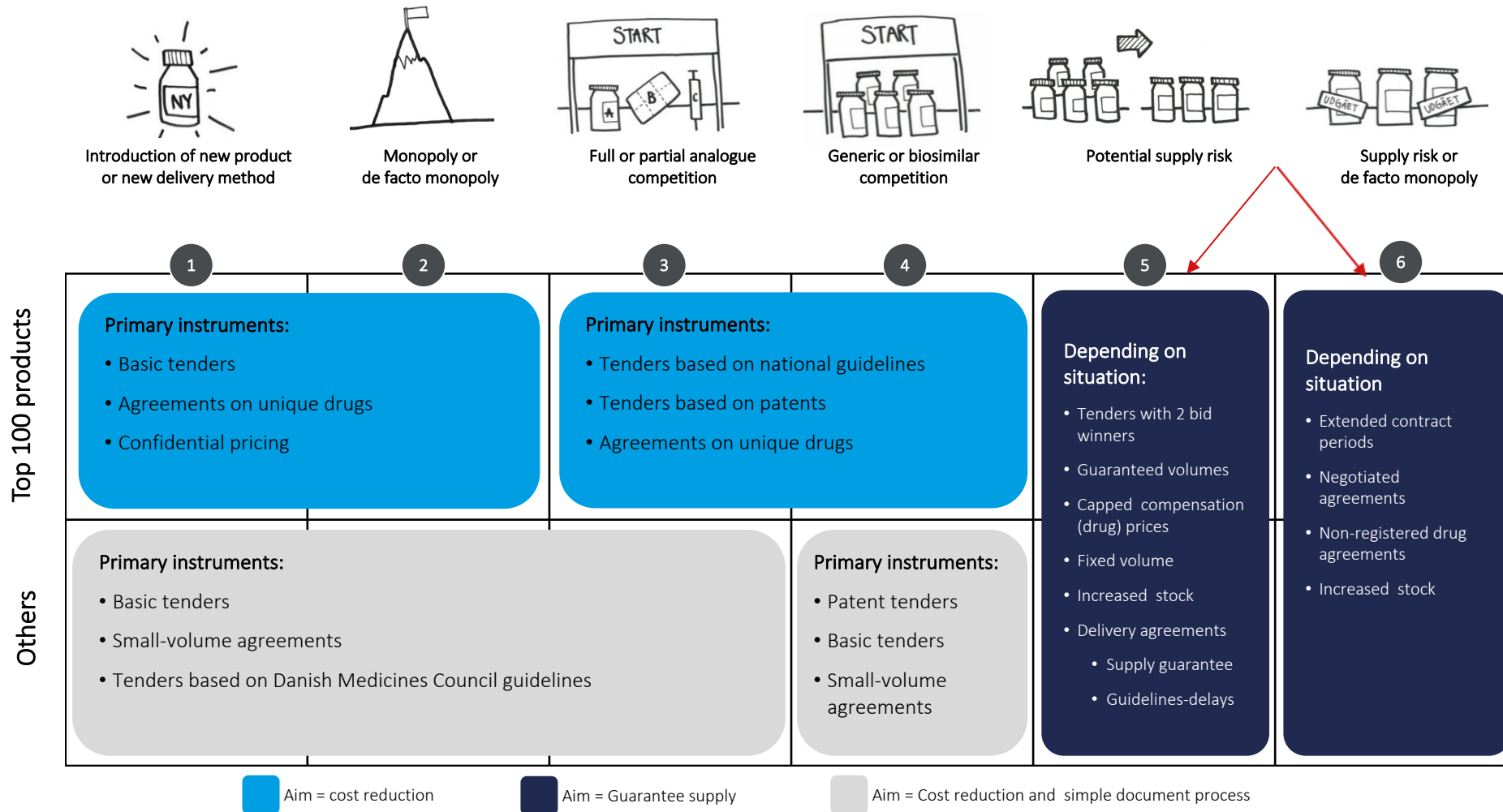- To learn more visit: http://www.amgros.dk/en

THE SUPPLY CHAIN FOR HOSPITALS

Pharmaceutical company	3 Danish wholesalers	Amgros	Hospital pharmacies	Hospitals	Patients
Parallel suppliers	Third party logistics providers				
Hospital pharmacies					

←→ Information flow

▷ Material flow

AMGROS

AMGROS' TENDER BUSINESS AND DRUG SHORTAGES

AMGROS' CATEGORY STRATEGY BASED ON THE LIFECYCLE MODEL COMBINED TENDER AND SUPPLY APPROACHES

	1 Introduction of new product or new delivery method	**2** Monopoly or de facto monopoly	**3** Full or partial analogue competition	**4** Generic or biosimilar competition	**5** Potential supply risk	**6** Supply risk or de facto monopoly

Top 100 products	**Primary instruments:**
	• Basic tenders
	• Agreements on unique drugs
	• Confidential pricing
			Primary instruments:
			• Tenders based on national guidelines
			• Tenders based on patents
			• Agreements on unique drugs
					Depending on situation:
					• Tenders with 2 bid winners
					• Guaranteed volumes
					• Capped compensation (drug) prices
					• Fixed volume
					• Increased stock
					• Delivery agreements
					    • Supply guarantee
					    • Guidelines-delays
						Depending on situation
						• Extended contract periods
						• Negotiated agreements
						• Non-registered drug agreements
						• Increased stock

Others	**Primary instruments:** • Basic tenders • Small-volume agreements • Tenders based on Danish Medicines Council guidelines			**Primary instruments:** • Patent tenders • Basic tenders • Small-volume agreements		

■ Aim = cost reduction   ■ Aim = Guarantee supply   ■ Aim = Cost reduction and simple document process

AMGROS

AMGROS' LOGISTIC BUSINESS AND DRUG SHORTAGES

SOME NUMBERS FOR AMGROS SUPPLY CHAIN

	2016	2017
Order lines		
Total for the year	309,395	312,300
Order lines delivered within 3 working days	299,450	302,537
Order lines delivered after 3rd working day	9,945	9,763
Delivery performance		
Share delivered within 3 working days	96.8%	96.9%
Share delivered within 10th working days	99.0%	98.9%
Back order periods		
Periods at least per year	1,394	1,323

AMGROS

ITEM NUMBERS IN BACKORDER AND BACK ORDER DAYS

(EU TENDER PRODUCTS)

Definition of drug shortage:

Amgros register a drug shortage if a drug is not received at the Hospital Pharmacy within 3 days after ordering at the supplier
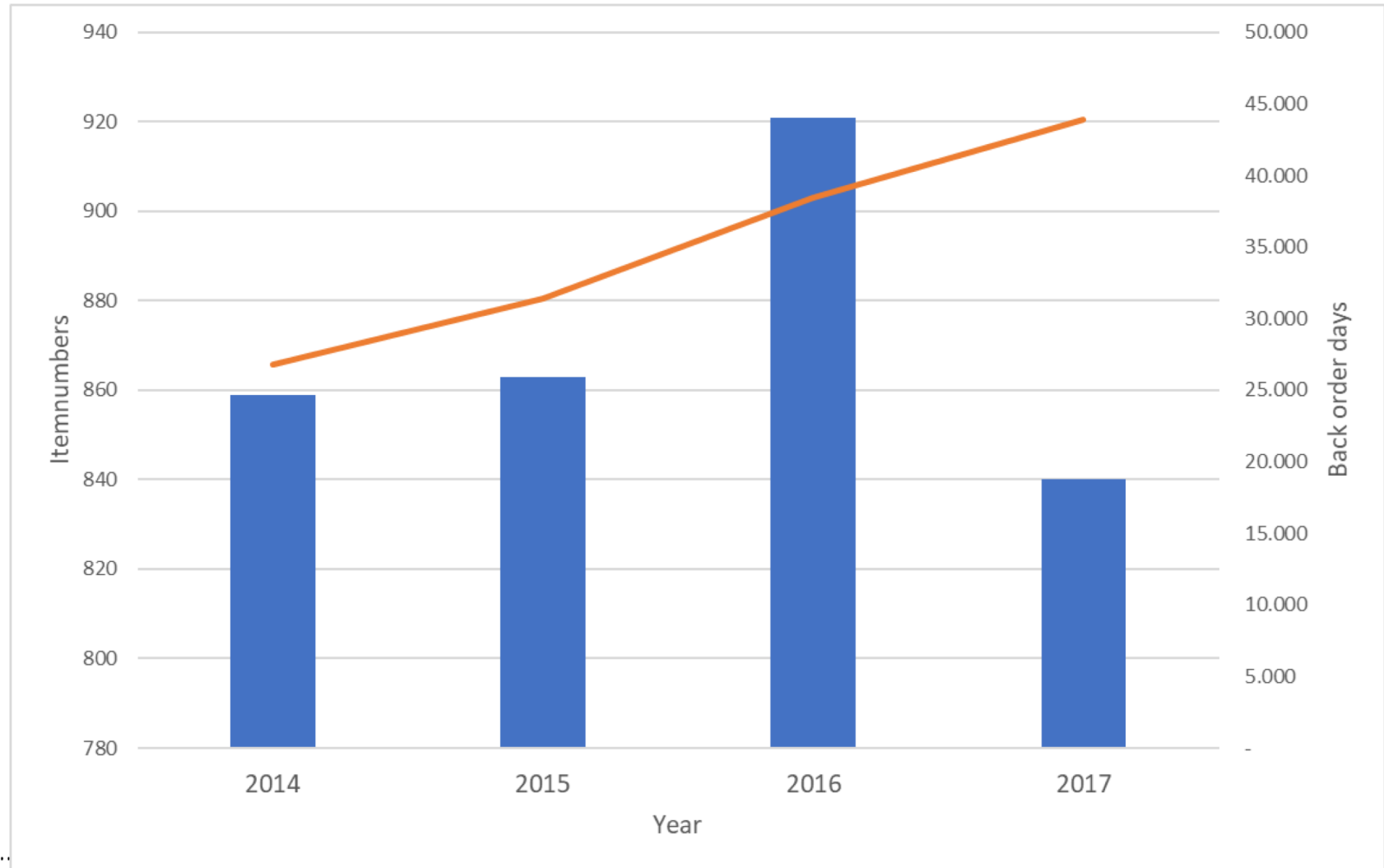
AMGROS

TOTAL NUMBER OF ITEMS, 2017

Itemnumbers bought through Amgros 2017

Chart showing item numbers: Total itemnumbers (~7.000), Itemnumbers without backorders (~7.000), Generic substitution (~1.150), Analog substitution (minimal), Substituted by specialities (minimal). Y-axis ranges from - to 8.000.
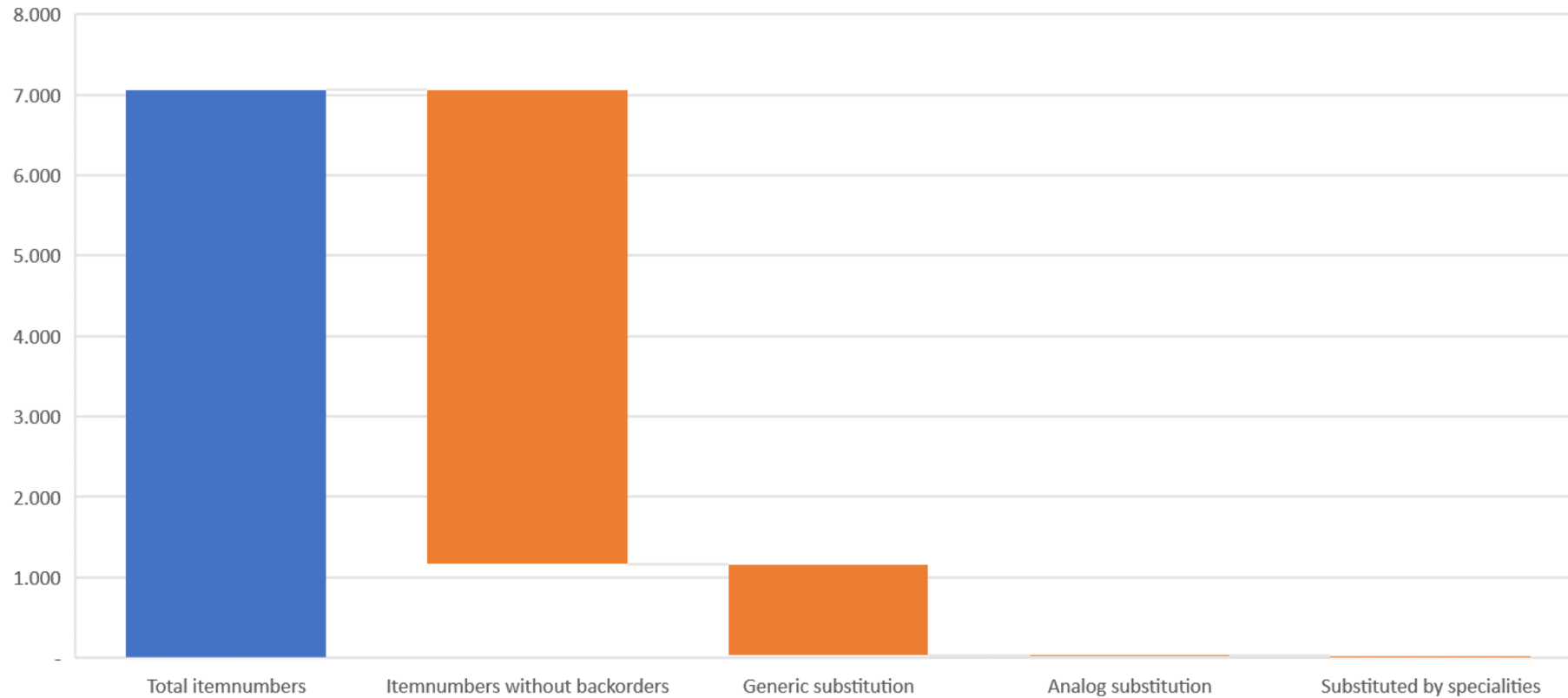
Back order solutions through Amgros:
Generic: 1,135 SKU
Analog: 5 API (9 SKU)
Specialties: 11 API (25 SKU)

Pharmacies do as well handle some situations on small volume products

AMGROS

OPERATIONAL HANDLING OF BACK ORDERS

AMGROS

AMGROS BACK ORDER SYSTEM (AMRO)

System in Amgros (AMRO)

Information on pharmacy portal

- Amgros register and update information for all backorders in AMRO

- AMRO is linked to our supplier portal

- Information updated on pharmacy portal, which can be accessed by all pharmacies

FOCUSED FOLLOW-UP WITHIN THE LOGISTIC DEPARTMENT

- Stand-up meetings every Tuesday at 10am

- Focusing on "the worst problems" such as critical drugs and supplier with most back orders

- "Top 6" suppliers. Who to meet next?

NOT REGISTERED SPECIALTIES

- Used as a solution for back order situations, where we cant find i registered drug
- National solutions handled by Amgros. Individual through local hospital pharmacy
- Resources from several parties involved
- Every clinic using the drug, need to get permission to use specialties, up to 2,000 clinics

HOW WE ESCALATE DRUG SHORTAGES
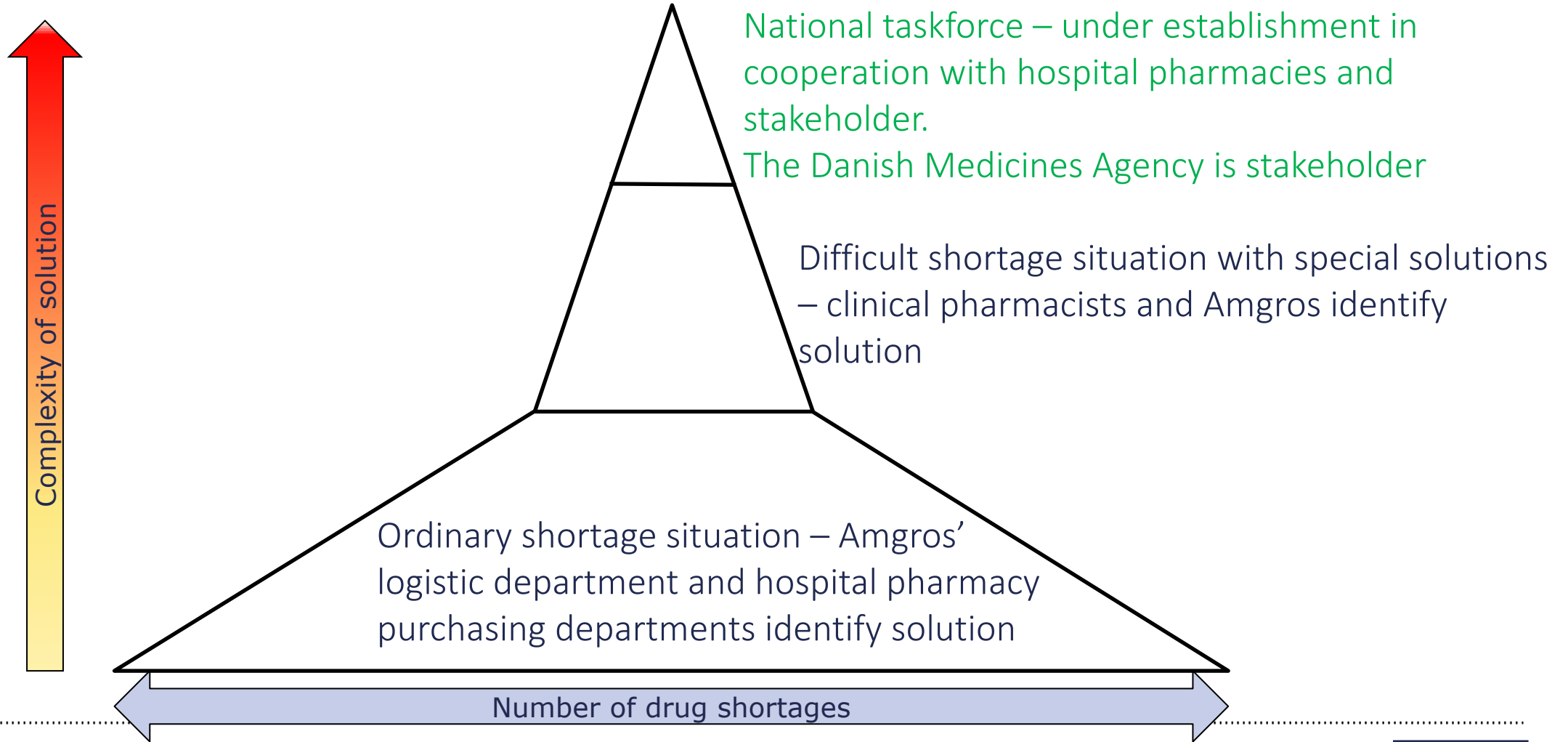
Complexity of solution

National taskforce – under establishment in cooperation with hospital pharmacies and stakeholder.
The Danish Medicines Agency is stakeholder

Difficult shortage situation with special solutions – clinical pharmacists and Amgros identify solution

Ordinary shortage situation – Amgros' logistic department and hospital pharmacy purchasing departments identify solution

Number of drug shortages

AMGROS

TACTICAL HANDLING OF BACK ORDERS

AMGROS

AN EXAMPLE OF A USEFUL TOOL:
SHARED LIST OF CRITICAL MEDICINES

- The list is developed in cooperation with clinicians and hospital pharmacist and is updated annually

- The list includes drugs which are difficult to substitute in case of drug shortages

- Some drugs are included based on experience of handling previous drug shortages or drug substitution

- Inventory increased at hospital pharmacy where possible

- The list is used for daily prioritizing

Liste over kritiske lægemidler pr. 20. juni 2017

Kritiske lægemidler valgt af FILU

Antibiotika	
J01CA01	Ampicillin pulver til inj.
J01CF01	Dicloxacillin pulver til inj.
J01DH02	Meropenem
J01CR05	Piperacillin /Tazobactam
J01CA11	Selexid *)
J01XA01	Vancomycin pulver til inj.
J05AB01	Aciclovir pulver til inj.

Anæstesimidler	
N01AX10	Propofol
N01AH06	Remifentani (Ultiva)
N01AB08	Sevofluran
Kritiske lokalanalgetika	
N01BB01	Bupivacain
N01BB09	Ropivacain

Cytostatika	
L01XA02	Carboplatin *)
L01XA01	Cisplatin konc. *)
L01AA01	Cyclophosphamid pulv.t.inj. *)
L01BC01	Cytarabin *)
L01CD02	Docetaxel *)
L01DB01	Doxorubicin inf.væske og pulver *)
L01DB03	Epirubicin inf. væske og pulver *)
L01CB01	Etoposid konc. *)
L01BB05	Fludarabin konc. og pulver *)
L01BC02	Fluorouracil *)
L01BC05	Gemcitabin konc. væske og pulver *)
L01AA06	Ifosfamid *)
L01XX19	Irinotecan *)
L01BA01	Methotrexat inj. og konc. *)
L01XA03	Oxaliplatin *)
L01CD01	Paclitaxel *)
L01XX17	Topotecan pulver *)
L01CA02	Vincristin *)
L01CA04	Vinorelbin konc. *)
V03AF03	Calciumfolinat

Pressorstoffer m.fl.	
C01CA24	Adrenalin
C01BD01	Amiodaron konc. og inj.
C01CA03	Noradrenalin

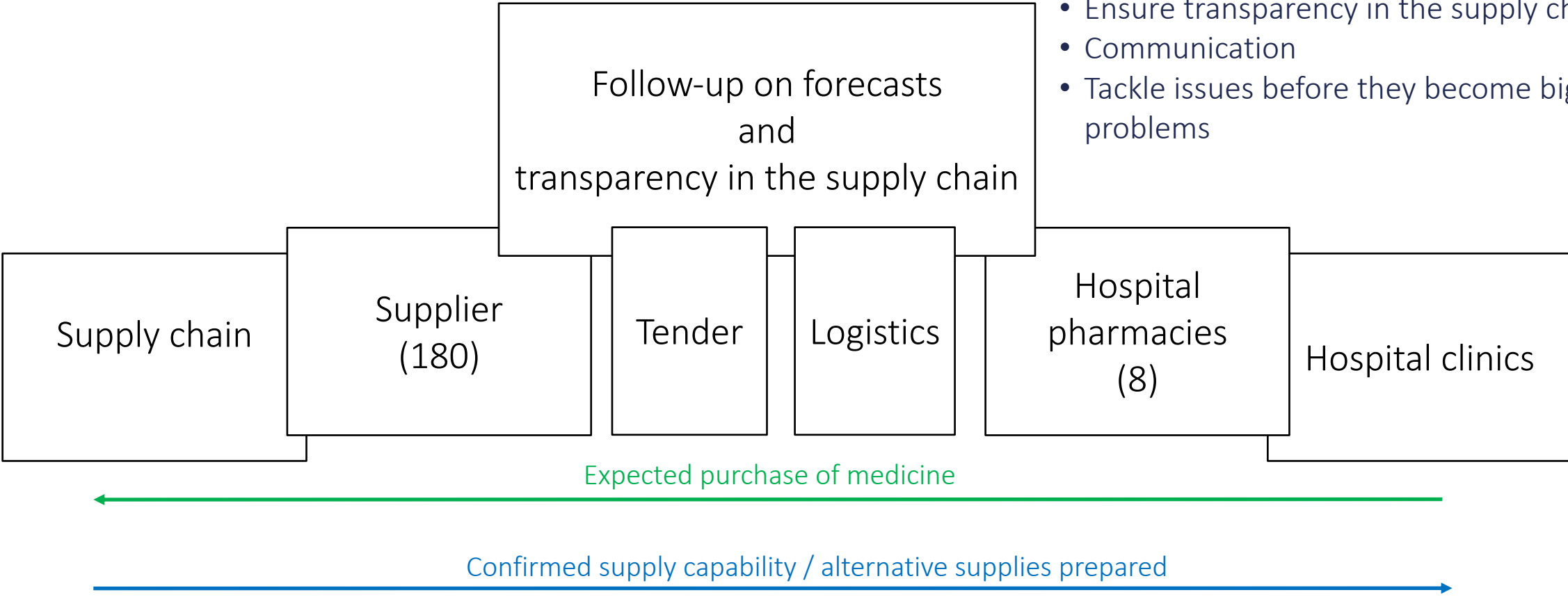*) Medtaget på listen baseret på restordrehistorik, forsyningssituation og besværlighed ved vareskift

AMGROS

MONTHLY PLANNING AND COMMUNICATION PROCESS
FOCUS ON EXPECTED PURCHASE VOLUME (PRODUCT NUMBER LEVEL)

Purpose:
Predict and solve supply disruptions by:
- Ensure transparency in the supply chain
- Communication
- Tackle issues before they become big problems

Follow-up on forecasts
and
transparency in the supply chain

| Supply chain | Supplier (180) | Tender | Logistics | Hospital pharmacies (8) | Hospital clinics |

Expected purchase of medicine

Confirmed supply capability / alternative supplies prepared

AMGROS

STRATEGIC DEVELOPMENT

STRATEGIC INITIATIVE IN AMGROS

A strategic goal in Amgros:

Optimize the on time and effective supply of drugs from supplier to hospital pharmacy

Initiatives under this strategic goal comprises among others :

- Establish a possibility to have a central inventory of critical drugs

- Establish monitoring system for potential critical back order situations, e.g. Pip Taz in 2017

- Develop our standard agreements with suppliers being more attractive to bid on contracts and supply according to these

- Participate in a Nordic group focusing on supply security (Nordisk Lægemiddel Forum, forsyningssikkerhed)

- National task force to manage critical back orders

AMGROS ACTIONS AND INITIATIVES

REPORTING

MONTHLY REPORT TO THE HOSPITAL PHARMACIES

- Monthly reporting on:
  - Delivery performance nationally and locally
  - Number of items in backorder
  - Ranking of suppliers with most backorders
  - Development in forecast accuracy
- Quarterly reporting on:
  - Delivery service for the 20 suppliers with most order lines
  - 20 best og worst performing suppliers with at least 100 order lines per month in the quarter

Logistikrapport, Sygehusapotekerne i Danmark

Gældende for: Februar 2018

Dato: 07. Marts 2018
Udarbejdet af: Lars Munck og Nils Linde, Amgros

AMGROS

AMGROS
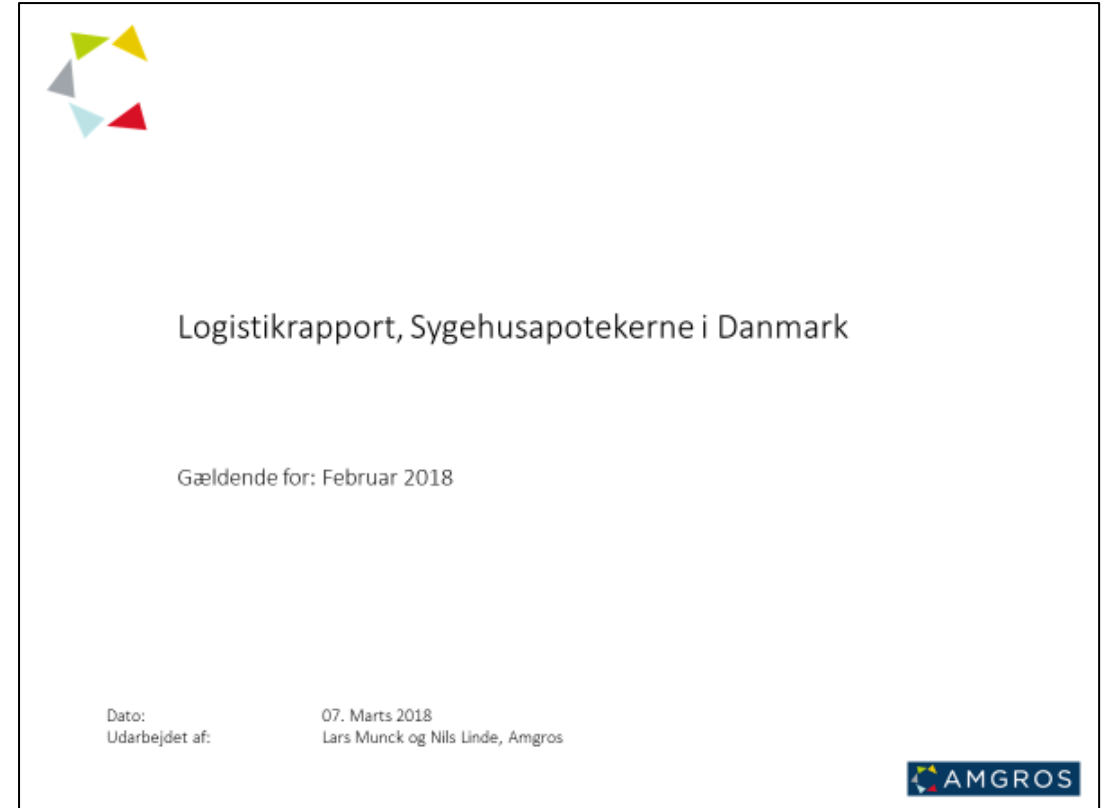
EXAMPLE OF DATA COLLECTION: INTERNAL REPORT ON DELIVERY PERFORMANCE

- Report is based on all suppliers delivering more than 1,000 order lines per year

- Suppliers are informed on their delivery service annually from 2016

- B and C suppliers are asked for improvements

- In 2016 received feedback from 26 out of 50 suppliers

- Monthly follow-up with one supplier

Leveringsservice for leverandører med mere end 1.000 ordrelinjer i 2017 *)

Måling: Opfølgning på opfyldelse af kontraktkrav om 3 dages leveringstid.

	Nr	2017	Q4-2017	Q3-2017	Q2-2017	Q1-2017
Total		96,7%	96,4%	96,8%	96,7%	97,0%
	1	99,9%	99,9%	100,0%	99,9%	100,0%
	2	99,9%	100,0%	99,6%	100,0%	100,0%
	3	99,7%	99,1%	100,0%	99,8%	100,0%
	4	99,6%	100,0%	99,1%	100,0%	99,4%
	5	99,6%	99,7%	99,8%	99,2%	99,6%
	6	99,5%	99,7%	98,8%	99,8%	99,6%
	7	99,4%	99,3%	99,4%	99,2%	99,9%
	8	99,4%	98,9%	99,8%	99,1%	100,0%
	9	99,4%	99,8%	99,5%	99,5%	98,7%
	10	99,4%	100,0%	99,7%	99,6%	98,1%
	11	99,4%	100,0%	98,0%	99,4%	100,0%
	12	99,3%	99,8%	98,3%	99,6%	99,7%
	13	99,1%	98,7%	99,9%	98,7%	99,1%
	14	99,1%	99,9%	99,1%	98,5%	99,0%
	15	99,1%	98,4%	99,3%	98,9%	100,0%
	16	99,1%	98,6%	98,3%	99,1%	99,3%
	17	99,0%	99,0%	100,0%	98,1%	99,4%
	18	99,0%	98,5%	98,2%	99,5%	99,7%
	19	98,9%	96,3%	100,0%	99,7%	100,0%
	20	98,9%	97,6%	99,5%	99,0%	100,0%
	21	98,8%	98,6%	100,0%	100,0%	99,4%
	22	98,6%	97,6%	99,8%	97,5%	99,6%
	23	98,4%	98,5%	99,8%	97,0%	99,4%
	24	98,2%	97,6%	98,4%	99,4%	99,6%
	25	98,1%	97,1%	98,0%	98,4%	99,2%
	26	97,7%	95,2%	100,0%	99,8%	95,9%
	27	97,5%	97,5%	95,1%	97,8%	99,6%
	28	97,3%	99,7%	99,6%	94,2%	96,2%
	29	97,3%	96,3%	99,1%	97,1%	96,9%
	30	97,3%	97,8%	97,1%	98,0%	96,0%
	31	97,1%	96,6%	97,5%	96,6%	97,6%
	32	97,0%	96,2%	96,9%	98,8%	96,2%
	33	96,9%	96,8%	98,9%	97,5%	94,4%
	34	96,8%	99,5%	96,3%	98,7%	90,9%
	35	95,9%	95,4%	99,3%	96,0%	93,5%
	36	95,6%	97,8%	96,3%	91,4%	98,0%
	37	95,2%	96,6%	93,0%	94,6%	97,0%
	38	95,2%	92,4%	95,3%	92,6%	99,7%
	39	95,1%	96,0%	97,1%	95,5%	91,9%
	40	94,9%	92,0%	98,6%	99,1%	90,3%
	41	94,5%	95,5%	94,4%	94,8%	93,3%
	42	94,2%	97,1%	89,8%	94,9%	94,1%
	43	93,6%	96,1%	90,1%	91,7%	96,9%
	44	92,8%	86,1%	96,6%	95,1%	94,1%
	45	92,5%	92,8%	96,2%	97,2%	83,9%
	46	92,0%	88,4%	91,5%	93,1%	100,0%
	47	91,8%	94,2%	95,4%	87,8%	89,8%
	48	91,3%	88,9%	88,9%	91,8%	95,3%
	49	90,9%	88,4%	95,6%	92,5%	92,3%
	50	88,7%	93,2%	88,4%	85,8%	100,0%

A-leverandører	>=98%
B-leverandører	>=95%, <98%
C-leverandører	<95%

QUESTIONS

1. Are the pharmacy able to influence the number of back orders reaching the hospital?   Yes

2. Is it good practice to manage all drugs at the pharmacy in the same way?   No

3. Is it worth to share information with the suppliers regarding forecast, back orders, delivery performance a.m.?   Yes

AMGROS

TAKE HOME MESSAGES

- Share information in the supply chain and give transparency to stakeholders

- Get insight into changes in the supply chain, react on changes

- Dedicated staff with a holistic approach to medicine shortage and education in supply chain management
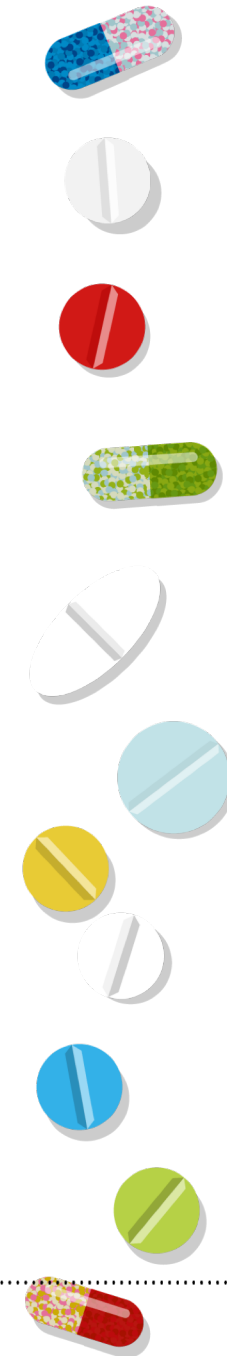
AMGROS

FURTHER QUESTIONS?

AMGROS

DIALOGUE WITH SUPPLIERS

Daily on line supplier portal:

- Daily follow up on backorder situation. Possibility to report supply changes

- Amgros inform about forecast for all drugs, including forecast changes

- Supplier confirmation of forecast changes and reporting any kind of supply issues

Weekly selection of "TOP6-backorder suppliers" in order to focus on response from suppliers with most issues and collecting satisfying information from them

Weekly e-mail with the message: *"You are among the suppliers with most critical backorders. Please, explain supply situation, within 24 hours".*

Face-to-face meetings each quarter with suppliers with poorest level of improvement.

AMGROS

DIFFERENCES BETWEEN HOSPITAL PHARMACIES AND PRIVATE PHARMACIES

	Private pharmacies/private market	Hospital pharmacies/hosp. market
Number	Approx 210	8
Owners	Privately owned	Five Regions
PPP turnover in 2015	Approx. EURO 1 billion	Approx. EURO 1.3 billion
Growth rate	> 1%	Around 5%
Type of procurement	Private purchase	Public procurement
Discount on drugs	Few possibilities	More possibilities
Substitution	Generic subst. every 2 wks.	Changes with annual EU tenders
Patients	Regular	Unusual/Special diseases
Can special requirements be made?	No	Yes, e.g. for patient safety

AMGROS

AMGROS' APPROACH TO PHARMACEUTICAL LIFECYCLE STAGES AND GENERALIZED PRICE DEVELOPMENT

PRICE

0 1 2 3 4 5 6

TIME

| Horizon scanning | Introduction of new product or new delivery method | Monopoly or de facto monopoly | Full or partial analogue competition | Generic or biosimilar competition | Potential supply risk | Supply risk or de facto monopoly |

AMGROS
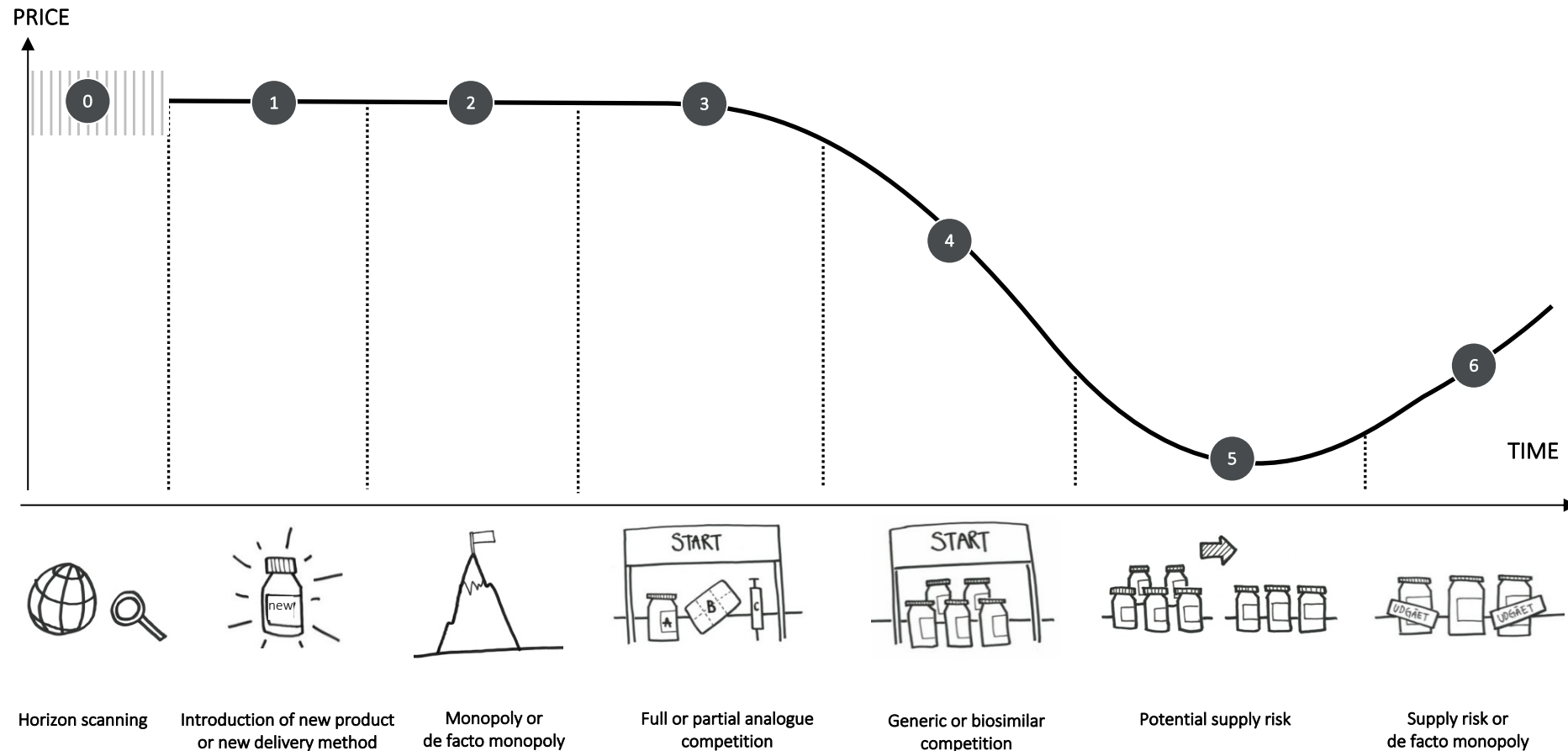
PHARMACEUTICAL LIFE CYCLE AND THE POSSIBILITY OF COMPETITION

Negotiation

Analogue
=> guidelines

Generic competition +
Supply issues

PRICE

2016
130m EUR kr.
Discount 6%

2016 (purchase SA)
480m EUR
Discount 22%

2016 (purchase SA)
430mEUR
Discount 35%

TIME

Horizon scanning

Introduction of new product
or new delivery method

Monopoly or
de facto monopoly

Full or partial analogue
competition

Generic or biosimilar
competition

Potential supply risk

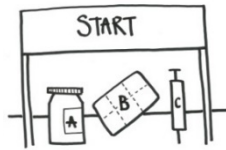Supply risk or
de facto monopoly

AMGROS

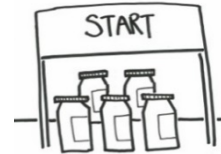# IDENTIFIED PRESENT AND FUTURE LIFECYCLE OPPORTUNITIES

	Introduction of new product or new delivery method	Monopoly or de facto monopoly	Full or partial analogue competition	Generic or biosimilar competition	Potential supply risk	Supply risk or de facto monopoly
	1	**2**	**3**	**4**	**5**	**6**
OPPORTUNITIES	• A strong negotiator • Volume discounts • Agreement on innovative drugs • Confidential pricing • Nordic tenders ? • Parallel suppliers	• Analogue competition? • Time span of lifecycle stage not completely dependent on patent alone • Volume discounts • Parallel suppliers (app. after 1 year) • Agreement on unique drugs • Confidential pricing	• Analogue competition with national guidelines • Therapeutic guidelines including analogue possibility • The following tenders results in competitive pricing • Parallel suppliers • Volume discounts • Confidential pricing	• The first patent expiration is used to drive prices in the analogue/generic market • Biosimilars may be able to affect the prices in the market	• Maintain a naturally balanced competitive situation • Improved terms for suppliers in delivery agreements • Analogue alternatives	• Tailored agreements to ensure supply guarantee • Extended contract periods • Optimized agreement terms • Analogue alternatives

AMGROS

TOP6-BACKORDER PROGRAM

How: What: KPI's:

Ownership and framework

180 suppliers
TOP6

Overview

- This week You have most backorders
- Confirm/update ETA
- Inform reasons

replies / week

Leading KPI's

Not satisfied -> Face-to-face meeting

REASONS?
ACTIONS TO IMPROVE!

Reporting and celebrating

Meetings/mth

Patience