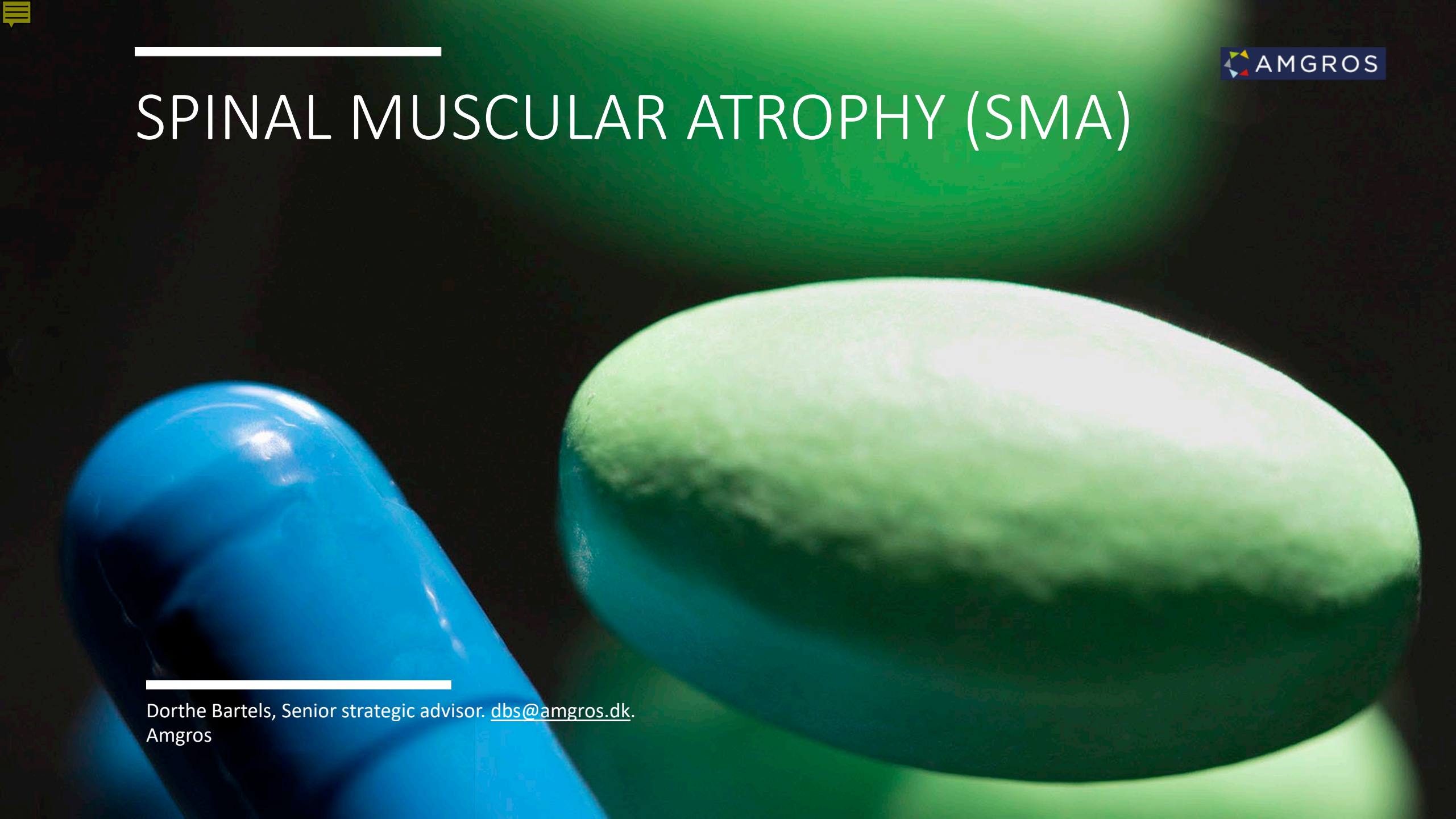




SPINAL MUSCULAR ATROPHY (SMA)

The background of the slide features large, out-of-focus, abstract shapes in vibrant blue and green, resembling smooth stones or bubbles, set against a dark background.

Dorthe Bartels, Senior strategic advisor. db@amgros.dk.
Amgros

DENMARK – A UNIQUE MARKET AND A UNIQUE SET-UP



- **Public hospitals set-up:**
 - Politically managed regions responsible for public healthcare and funded through national taxes
 - **No patient** co-payment for hospital services, including pharmaceuticals.
- **NATIONAL Guidelines and tenders (since 2010)**
 - Danish Medicines Council develops **national guidelines** for therapeutic areas
 - Amgros makes **national calls for tenders** (ATC-code 5 level), and the hospitals follow the tender and the decision.
 - Amgros makes **national contract-** for the hospitals in Denmark.
 - The 5 regions implement the guidelines and tender results at the hospitals

SMA - DENMARK

Spinraza - in Danish Medicine Councils (DMC):

- 4 refusal in DMC (not cost-effective)
- Limited Approval i DMC Oct. 2020.
 - used unmet need





Rare genetic disease

6 new cases annually

3 pharmaceuticals for treating the disease

Presymptomatisk SMA, SMA1,
SMA2, SMA3, SMA4

Screening from January 2023

Spinraza

Spinraza Evaluated by the Medicine Council since 2017

Intrathecal injection every 4 months
Recommended for: Presymptomatic SMA SMA1 SMA2 (age of onset max 24 months and max 4 years of disease duration)

Limited approval

Zolgensma

Evaluated by the Medicine Council in 2021

IV ONE-OFF treatment

Recommended for presymptomatic

Evrysdi

Evrysdi Evaluated by the Medicine Council in 2021

Daily oral treatment

Recommended for: SMA1
SMA2 and SMA3 (age < 6 years)

Effect and price

WHY IS THERE SO MUCH FOCUS ON THIS PARTICULAR DISEASE AREA ?



MUSKELSVINDFONDEN

Marcus må ikke få den medicin,
som er udviklet til ham

Stadig nej til medicin til børn
med SMA over seks år, men lidt
flere børn kan få

Ge
ske



Grøn
Koncert

Børn med mu-
a screening

M
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ba
ik

Medic
musk
perso

Både
strien
at der
ale

af personer med spinal
m står bag et lægemiddel til

MEDICINE COUNCIL HAS DEVELOPED A COMMON REGIONAL TREATMENT GUIDELINES - 2022

- Approved and published in December 2022
- All three drugs were equated for the patient populations where they overlap
- Expanding the patient population was now - a matter of price



FIRST RESULT ==> AND THEN A DIFFERENT APPROACHE

Jan – Feb. 2023

- Amgros publishes a tender with a deadline of February 15, 2023
- The tender is not like other tenders: it was divided into patient groups
- The Medicine Council continues to reject expanding the population - based on price

=> Encourages Amgros and companies to renegotiate

April – June 2023

- Amgros invites companies and the patient organization (Muscular Dystrophy Foundation) to joint **DIALOG** meetings about the disease and "ceasefire"
- Amgros renegotiates price and agreement types with companies
- D. 21 juni 2023 approved DMC treatment with Spinraza and Evrysdi - patient up to 25 years

CONTINUED WITH INVOLVMENT OF PATIENT ORGANISATION

June 2024

- **DIALOG** meeting with Patient Organisation and companies
- Negotiation - people over 25 years
- MEA – agreement with evrysdi
- Approval in june 2024

THANKS

