

Ting i tiden tapas

Regulatorisk høstmøte 23. november 2017, Audun Hågå

BREXIT

And the winner is....



Amsterdam!



United Kingdom

**Danmark
Denmark**

**Nederland
Netherlands**

**Deutschland
Germany**

**België
Belgique
Belgium**

SCOTLAND

NORTHERN IRELAND

Isle of Man

**Ireland
Éire**

ENGLAND

WALES

Antwerpen

Lille

Luxembourg

Inverness

Aberdeen

Dundee

Edinburgh

Glasgow

Dublin

Liverpool

Manchester

Leeds

Cambridge

Oxford

Bristol

Cardiff

Southampton

Brighton

Plymouth

Guernsey

Haugesund

Stavanger

Kristiansand

Oslo

Drammen

Fredrikstad

Karlstad

Örebro

Göteborg

Jönköping

Vendsyssel

Aalborg

Aarhus

København

Malmö

Sjælland

Kiel

Lübeck

Hamburg

Rostock

Bremen

Hannover

Wolfsburg

Braunschweig

Magdeburg

Berlin

Den Haag

Gent

Essen

Köln

Frankfurt am Main

Mannheim

Nürnberg

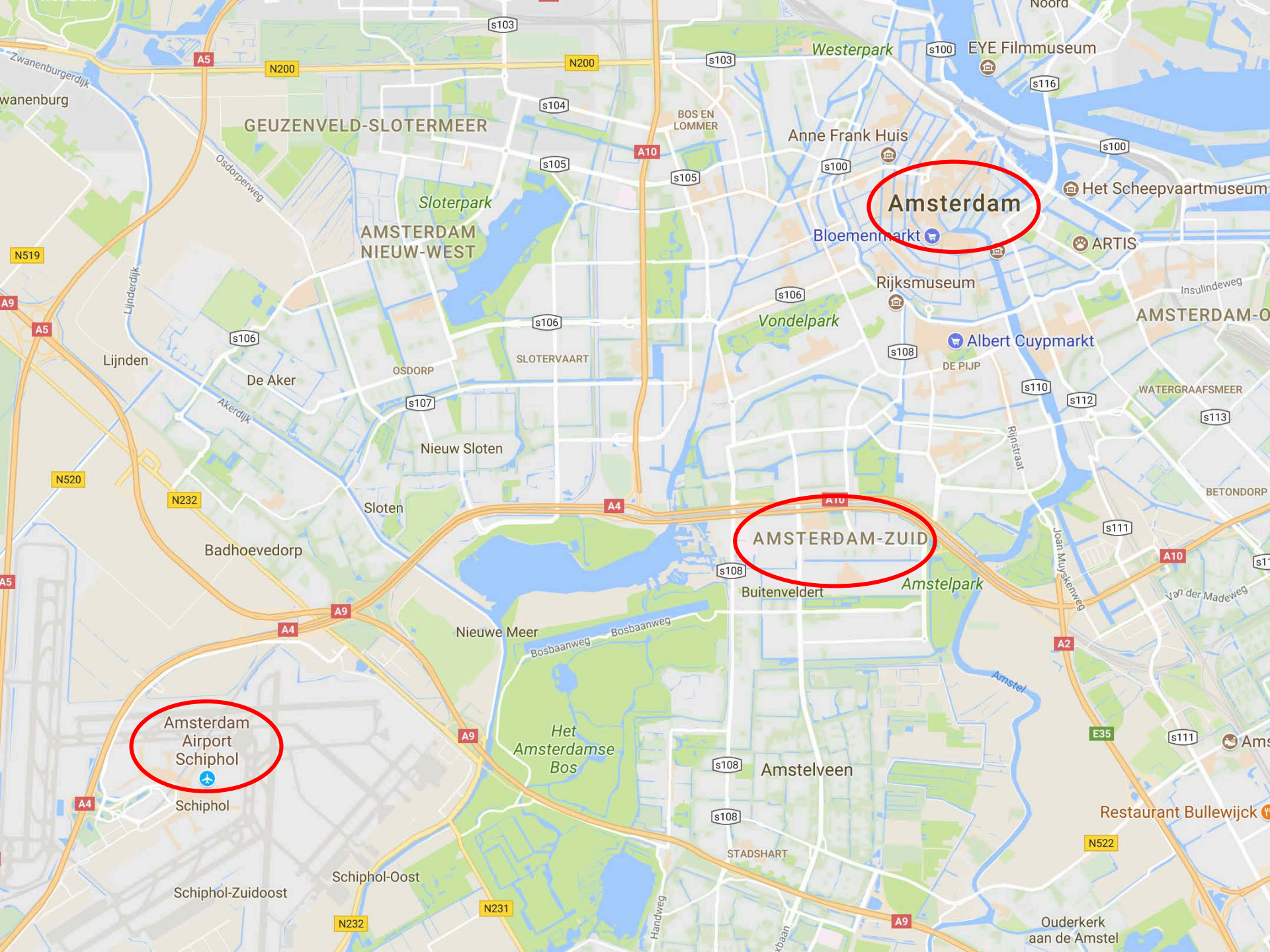
Dresden

Praha

**Česko
Czech**

North Sea

English Channel



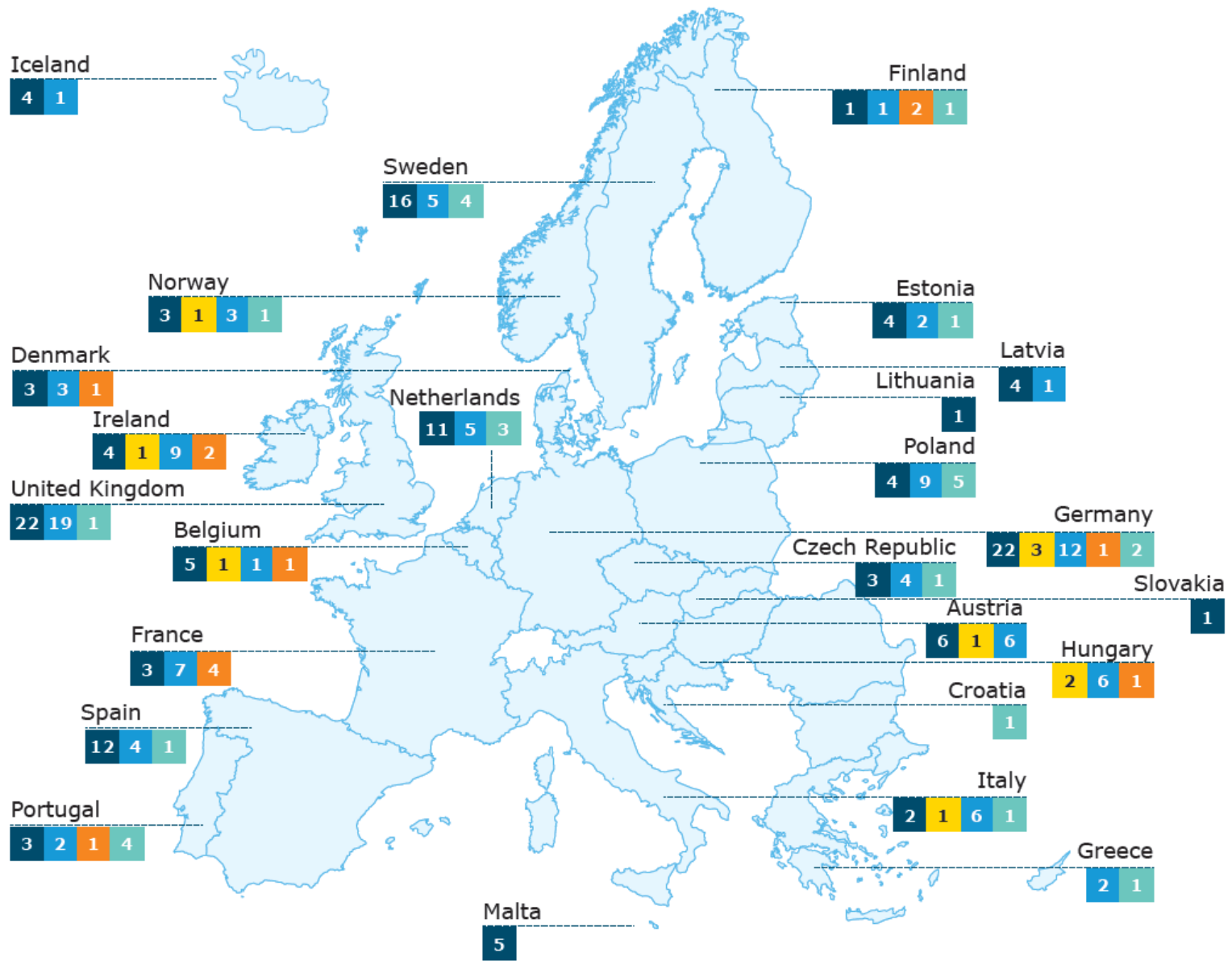
Amsterdam

AMSTERDAM-ZUID

Amsterdam
Airport
Schiphol

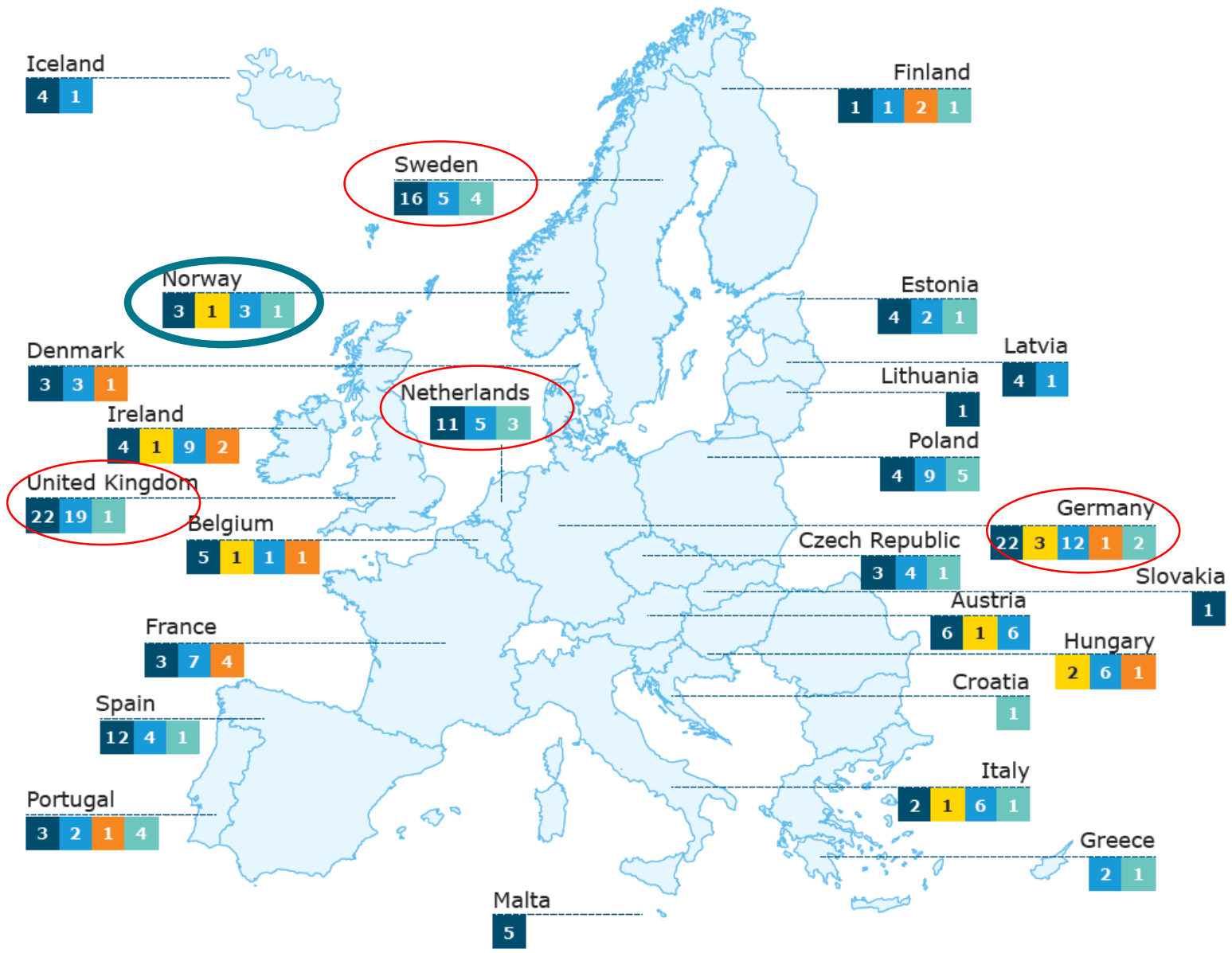
Brexit konsekvenser

- UK har stått for stor del av jobben i nettverket
 - Scientific advice
 - Utredninger for markedsføringstillatelse
 - Oppfølging (Pharm. vigilance, PSUR, PRAC)
 - Veterinærområdet
 - Inspeksjoner (GMP, GCP, GVP)
 - Ledere og nestledere i arbeidsgrupper og komitéer
- Vi andre må overta!



Rapporteur regular
 Co-rapporteur regular
 Assessor part of MNT

Rapporteur MNT
 Co-rapporteur MNT



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 Co-rapporteur regular
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 Rapporteur MNT
 Co-rapporteur MNT

Konsekvenser

- Overta legemidler der UK er rapp og co-rapp, reference MS
- Øke kapasiteten i nettverket – utfasing av UK

Vi satser også!

- Besluttet å ansette 6 nye medarbeidere
- Satsningsområder i EU-arbeidet (Hum og Vet)
 - Fiskehelse
 - Antibiotika
 - Nevrologi
 - Onkologi
 - Vaksiner

Vi satser også!

- Type legemidler
 - Biologiske inklusive biotilsvarende
 - Legemidler med immunologiske effekter
 - ATMP (celler og vev, genterapi)
- Prioriterte prosedyrer
 - Sentral prosedyre (CP)
 - Sentral scientific advice – parallell scientific advice

Digitalisering

Carl von Linné
1707-1778



łosoś (PL)

Lašiša (LT)

Saumon (FR)

Zalm (NL)



Lax (SE)

Salmon (UK)

Lachs (DE)

Lohi (SF)



Salmo salar

Comprimido revestido por película (PT)

Comprimé pelliculé (FR)

Filmoverttrukket tablet (DK)

Filmomhulde tablet (NL)



Filmtablette (DE)

Tabletter, filmdrasjerte (NO)

Film-coated tablet (UK)

Compressa rivestita con film (IT)

ISO IDMP

ISO Identification of Medicinal Products



100000073665 (ID)

Hvorfor er dette viktig?

Utvexsle elektronisk informasjon





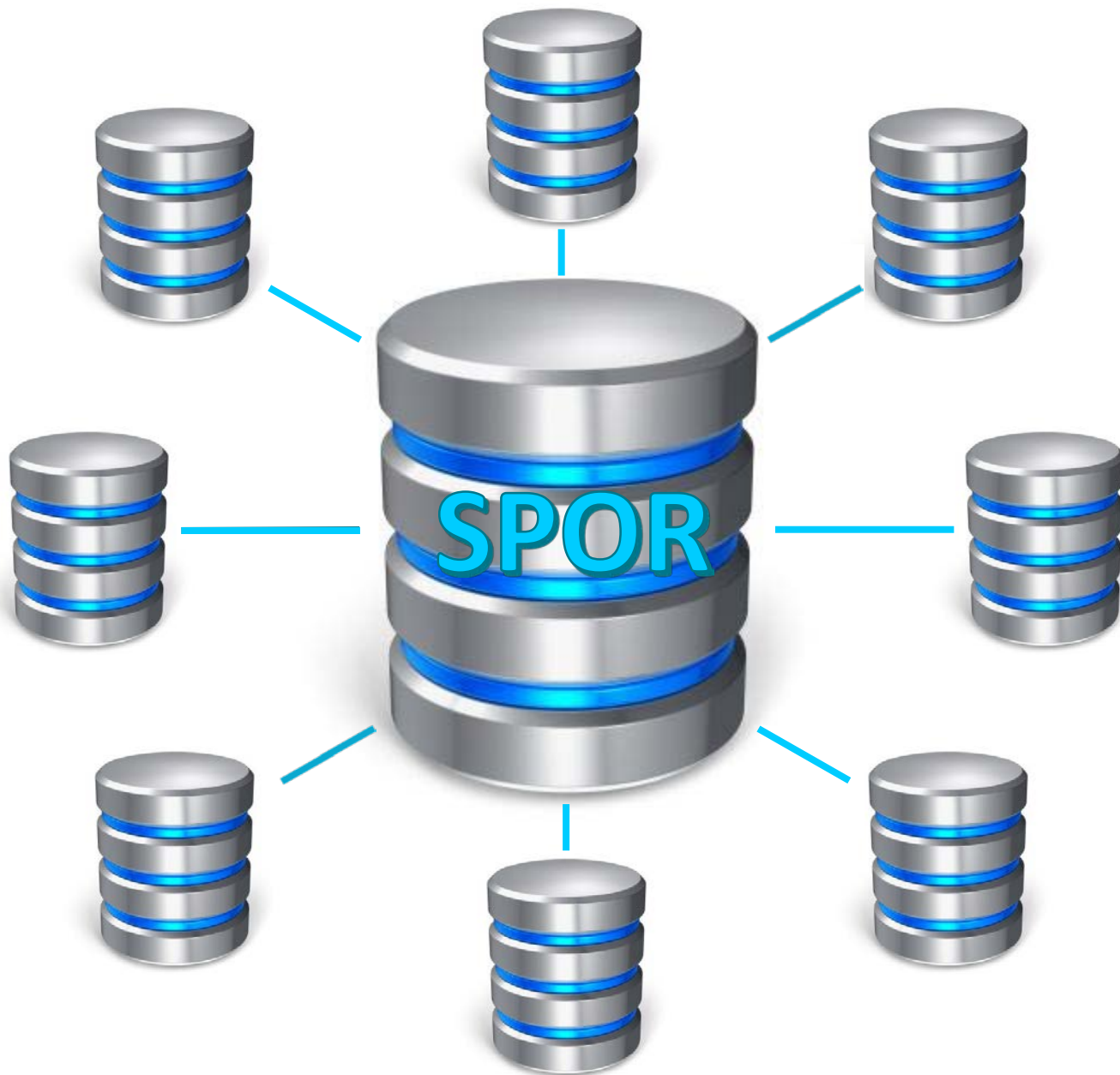
SPOR

Substances

Products

Organisations

Referentials



What's in it for industry?

- Reduced number of submissions of same data
 - E.g. MA, Art57, FMD, supply chain
- If used in eHealth
 - Investigating and monitoring effect and adverse events in more automated ways

What's in it for regulators?

- Reduced need for data entry in local NCA-systems
- Reduced need to store data locally
- SPOR data to be used in e.g.
 - MA / Variations
 - Pharmcovigilance
 - Rapid alerts and recalls
 - Shortages and inspections
- Facilitate cooperation and work sharing between NCAs

What's in it for patients and prescribers?

- Patient safety: Enable faster responses to safety issues
- Enable standardized and global decision support
- Enable cross border eHealth

What's in it for all of us?

- Potentially less mistakes and misunderstandings in datahandling
- New great ways of using the data to be discovered!

Følg oss



@legemiddelinfo



legemiddelverket

legemiddelverket.no



Statens
legemiddelverk