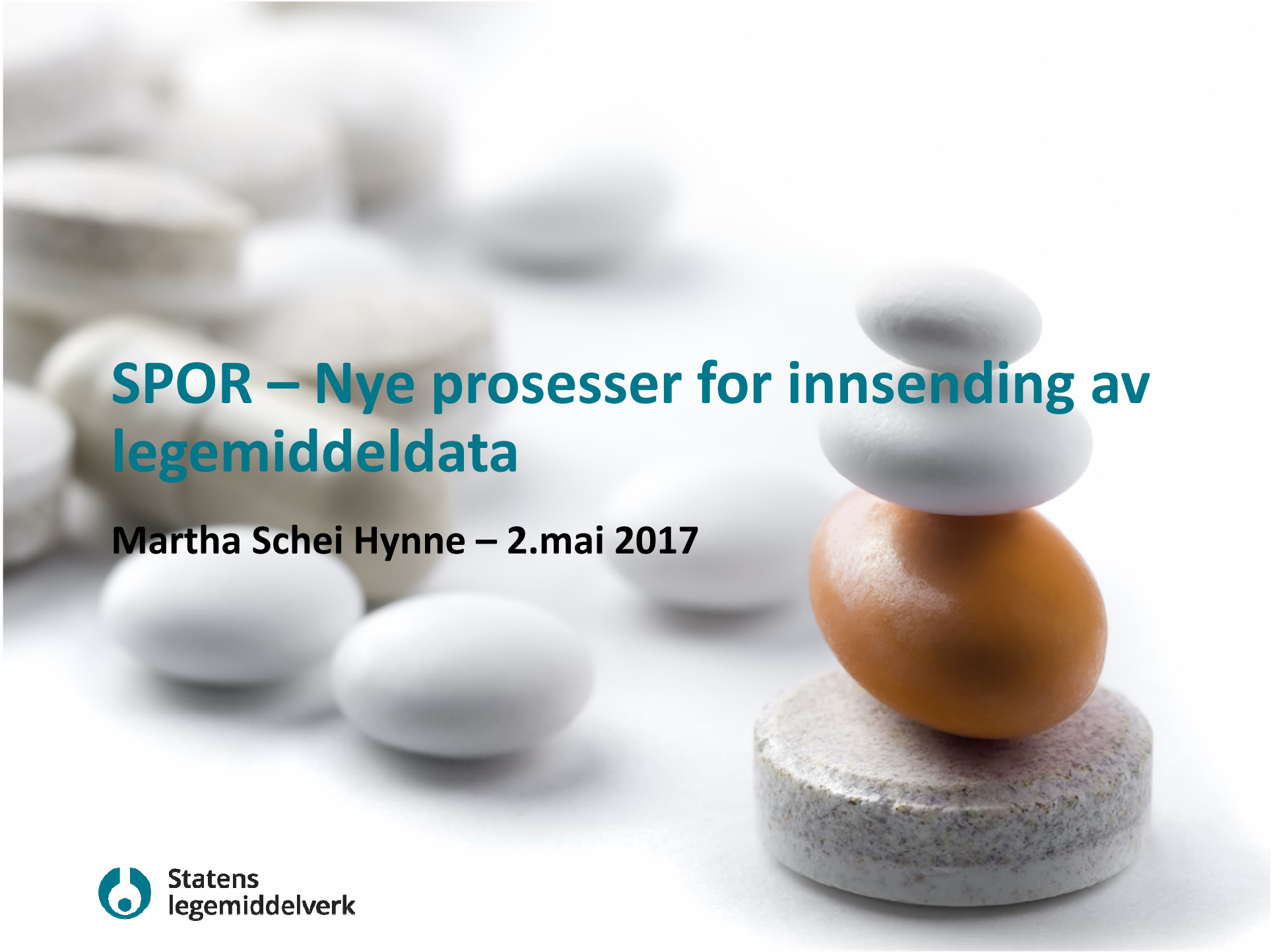


SPOR – Nye prosesser for innsending av legemiddeldata

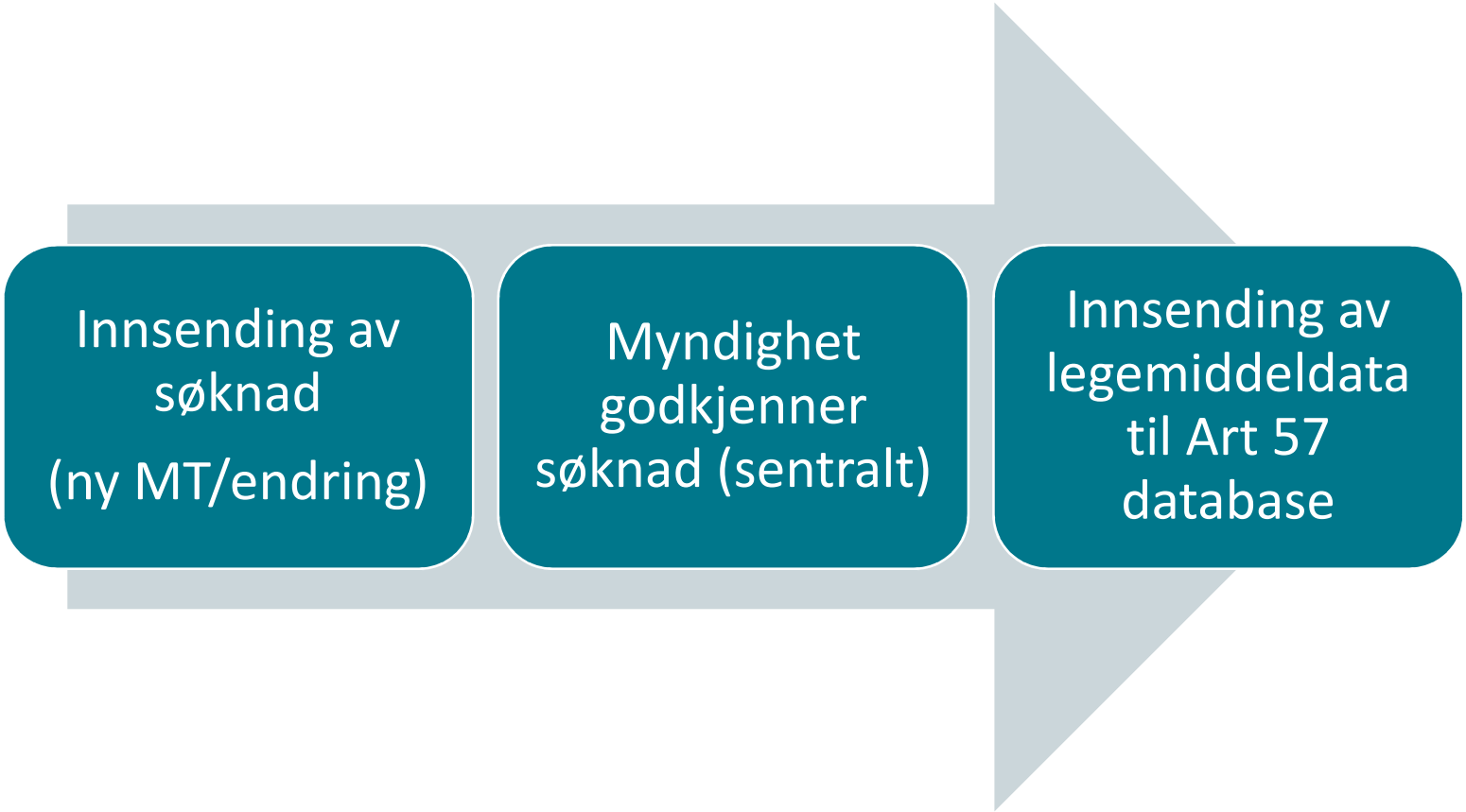
Martha Schei Hynne – 2.mai 2017

Statens legemiddelverk

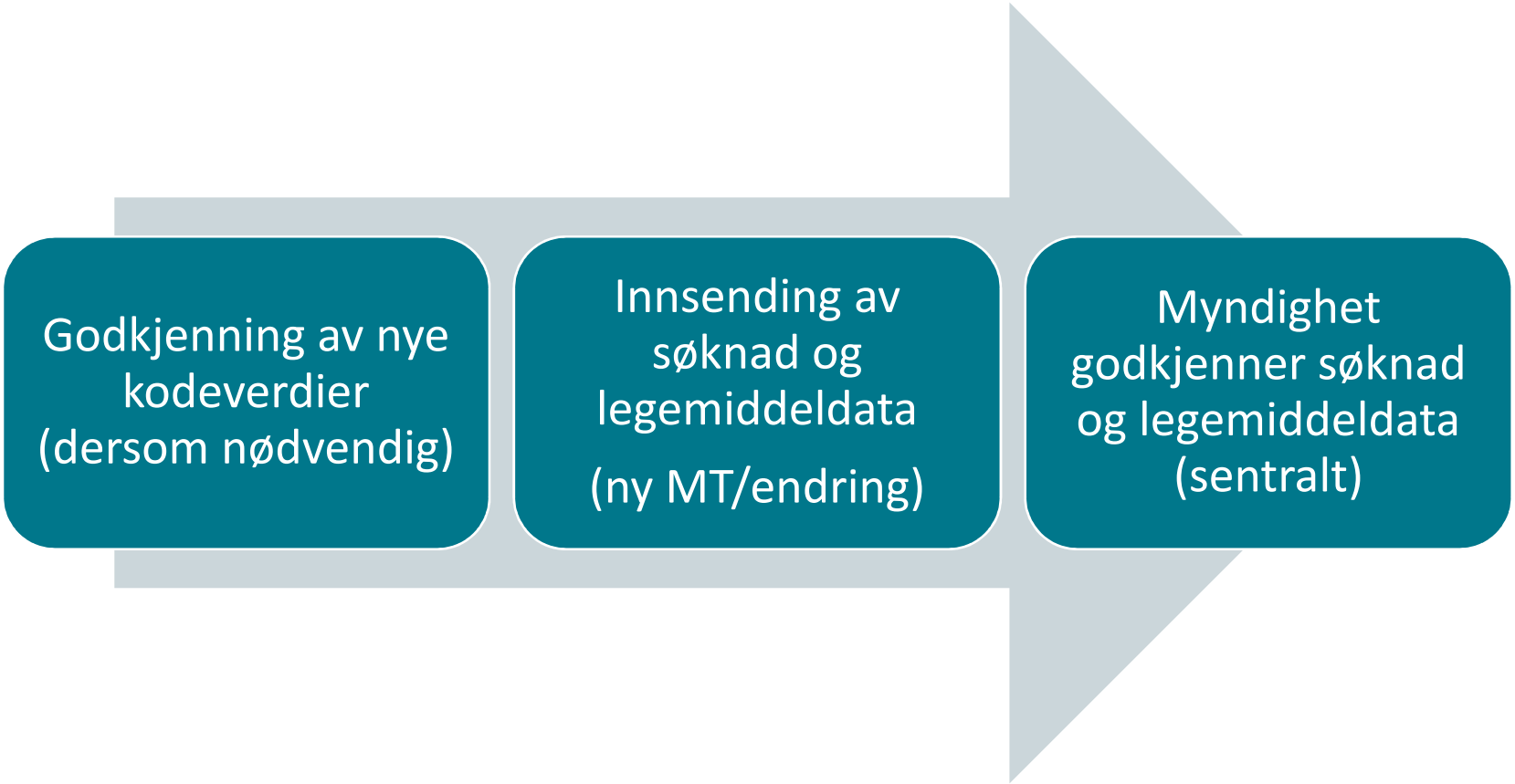
Hva er SPOR?

- Prosjektprogram i EMA/HMA 2016-2019
- Skal lage «Data management services» for «masterdata» → **Legemiddeldata**

Dagens prosess



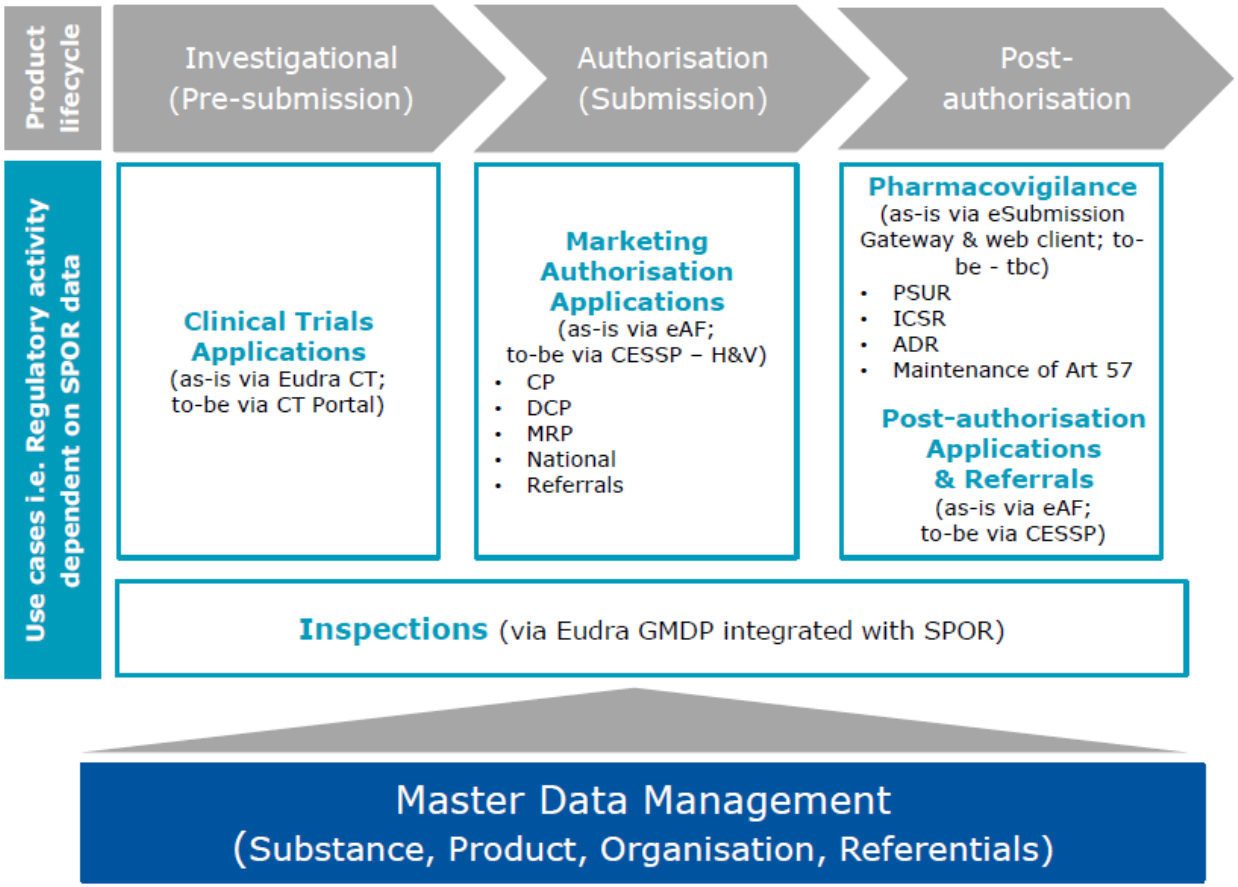
Ny prosess


Godkjenning av nye kodeverdier (dersom nødvendig)
Innsending av søknad og legemiddeldata
(ny MT/endring)
Myndighet godkjenner søknad og legemiddeldata (sentralt)

Legemiddeldata (P i SPOR)

Medicinal Product	Marketing Authorisation	Organisation (e.g. MAH, QPPV, PSMFL)	Packaged Medicinal Product	Pharmaceutical Product	Ingredient	Indication
MPID	Marketing Authorisation Number	Identifier	PCID	Administrable Dose Form	Ingredient Role	Indication Text
Combined Pharmaceutical Dose Form	(Marketing Authorisation) Country	Role	Package Description	Unit of Presentation	Substance	Indication as "Disease/ Symptom/ Procedure"
(I)MPID Cross-Reference	Legal Status of Supply	Location Address	Package Item (Container) Type	Route of Administration	Strength Range (for Substances)	
Reference Product Type	Authorisation Status	Location Role	Package Item (Container) Quantity	PhPID Identifier Sets	Specified Substance	
Additional Monitoring Indicator	Authorisation Status Date	Entity Identifier (according to Role e.g. PSMF ID)	Material	Device Type	Strength Range (for Specified Substances)	
Paediatric Use Indicator	Date of First Authorisation	Manufacturer/Establishment	Component Type	Device Trade Name	Confidentiality Indicator	
Orphan Designation Status	International Birth Date	Operation Type	Component Material		Reference Substance	
Full Name	(Jurisdictional Marketing Authorisation) Country	Manufacturing Authorisation Reference Number	Manufactured Dose Form		Reference Specified Substance	
(Medicinal Product Name) Country	(Jurisdictional Marketing Authorisation) Marketing Authorisation Number	Effective Date	Unit of Presentation		Reference Strength Range	
(Medicinal Product Name) Language	Procedure Identifier/Number	Confidentiality Indicator	Manufactured Item Quantity			
ATC Code	Procedure Type		Device Type			
Legal Basis of Approval	(Marketing Status) Country		Device Trade Name			
Medicinal Product Type	Marketing Status		(Data Carrier Identifier) Code System			
Falsified Medicines Code	Marketing Start Date		(Data Carrier Identifier) Value			
Authorised Dosage Form	Marketing Stop Date					
EURD Identifier	Risk of shortage supply					
	Risk of shortage supply comment					

Bruk av SPOR i regulatoriske aktiviteter



Hva vil endres?

- Legemiddeldata skal godkjennes/valideres av medlemsland/NCA
  - Dokumenter (SmPC, PIL, Mock-up) + Legemiddeldata
- Legemiddeldata skal holdes oppdatert ett sentralt sted
  - SPOR
  - Nasjonale systemer er synkronisert med SPOR
- Legemiddeldata skal kunne gjenbrukes
  - Pharmacovigilance
  - Klinisk utprøvning
  - Cross-border e-resept

Spørsmål?

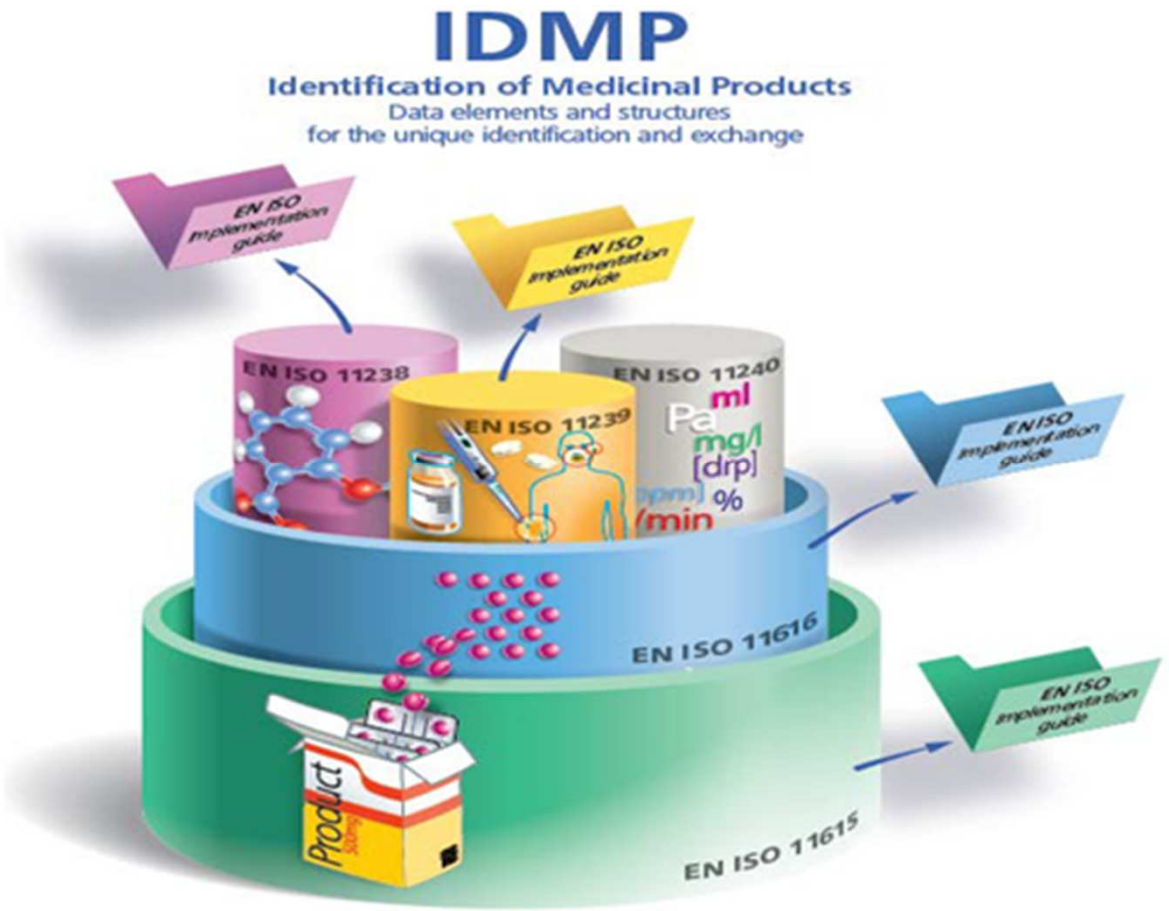
Følg oss

@legemiddelinfo

legemiddelverket

legemiddelverket.no

Statens legemiddelverk



Medicinal product

- Medisinen i pakningen
- Avhengig av merkevare

Pharmaceutical product

- Medisinen når den skal gis til pasienten
- Uavhengig av merkevare

Hva er ISO IDMP?

- Identification of medicinal product
- Internasjonale standarder (rammeverk)

Hva gjøres nå

- Kartlegging av hvordan SPOR «treffer oss»
  - Systemer
  - Prosesser
- Kartlegging av gevinster
- Mapping av kodeverksverdier (referentials)