Danish co-legislation model for disclosure

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Full disclosure takes shape in Denmark

W.G.

- The Danish Minister of Health and Prevention Astrid Kragh established a working group in beginning of 2012 on the future regulation and disclosure of the relations between industry and HCPs
- Recommendations for new legislation presented by the working in June 2013

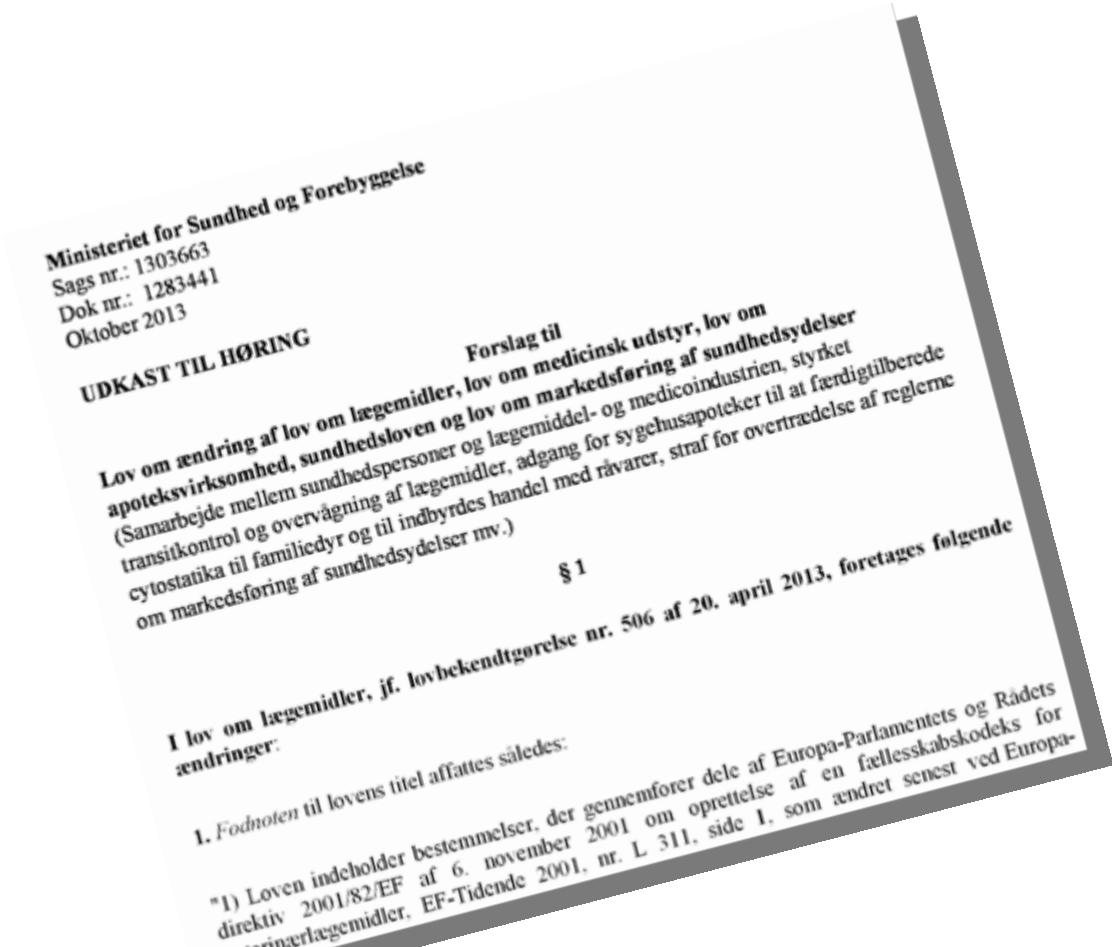
Who?

- PAYERS: The Danish national authorities and the Danish Regions
- INDUSTRY: Lif and the MedTech industry
- HCPs: Medical societies, the Danish Medical Association and the Danish Pharmaceutical Association
- POs: Patient and consumer organisations

What?

- Rules of financial advantages and competence
- Inclusion of the MedTech Industry
- Authority-based approval scheme/system
- **Disclosure – common platform**

Reform of legislation complies with the working group's recommendations



Ministeriet for Sundhed og Forebyggelse
Sags nr.: 1303663
Dok nr.: 1283441
Oktober 2013

UDKAST TIL HØRING

Forslag til

Lov om ændring af lov om lægemidler, lov om medicinsk udstyr, lov om apoteksvirksomhed, sundhedsloven og lov om markedsføring af sundhedsydelser
(Samarbejde mellem sundhedspersoner og lægemiddel- og medicoindustrien, styrket transitkontrol og overvågning af lægemidler, adgang for sygehusapoteker til at færdigtilberede cytostatika til familiedyr og til indbyrdes handel med råvarer, straf for overtrædelse af reglerne om markedsføring af sundhedsydelser mv.)

§ 1

I lov om lægemidler, jf. lovbekendtgørelse nr. 506 af 20. april 2013, foretages følgende ændringer:

1. *Fodnoten* til lovens titel affattes således:

"1) Loven indeholder bestemmelser, der gennemfører dele af Europa-Parlamentets og Rådets direktiv 2001/82/EF af 6. november 2001 om oprettelse af en fællesskabskodeks for veterinærlægemidler, EF-Tidende 2001, nr. L 311, side 1, som ændret senest ved Europa-

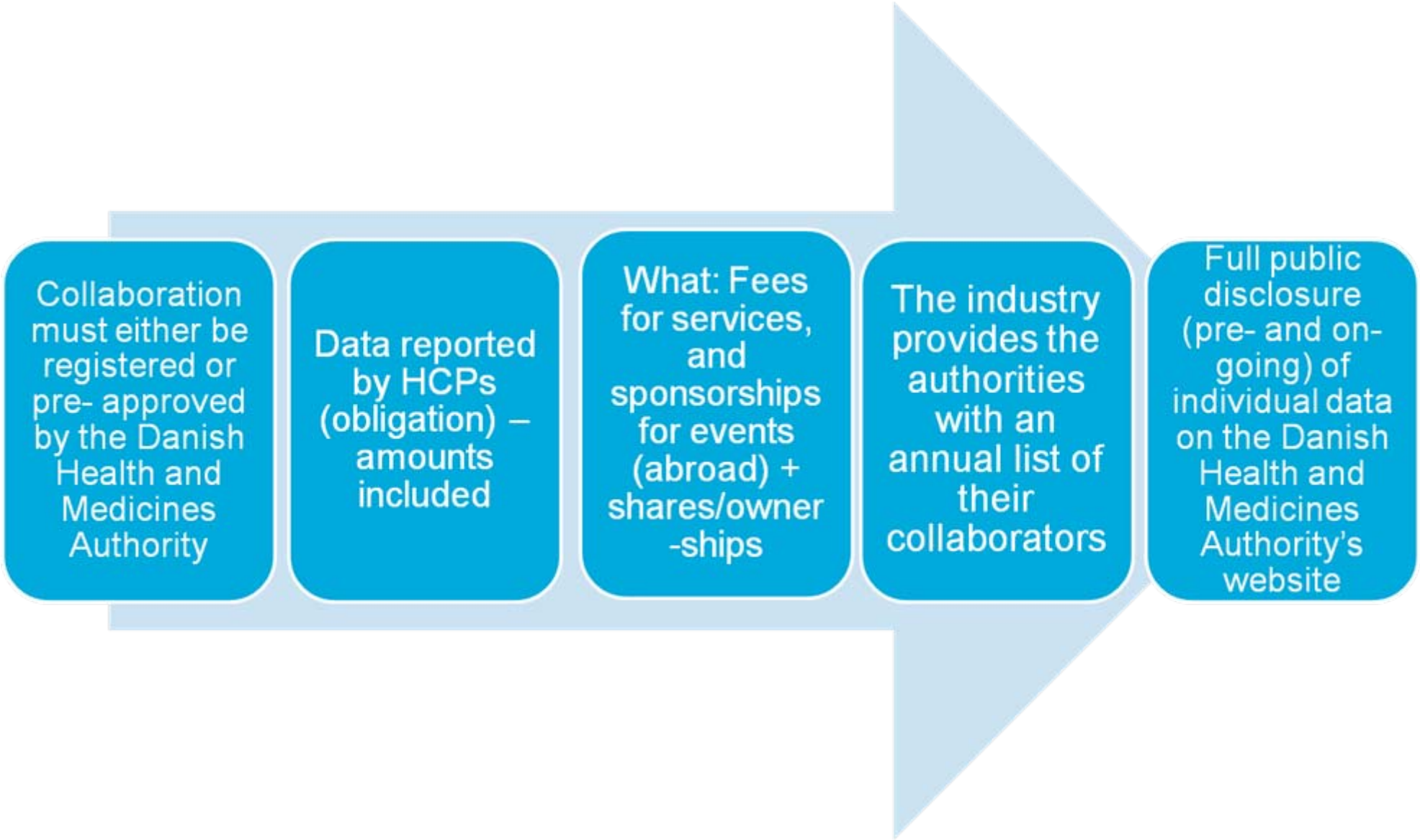
Value of co-legislation model and platform

- Establish common platform for disclosure
- Reach out to our stakeholders – credible partners
- Common commitment for transparency
- Common commitment to ”stand up for the value of collaboration”

Key advantages of the Danish model

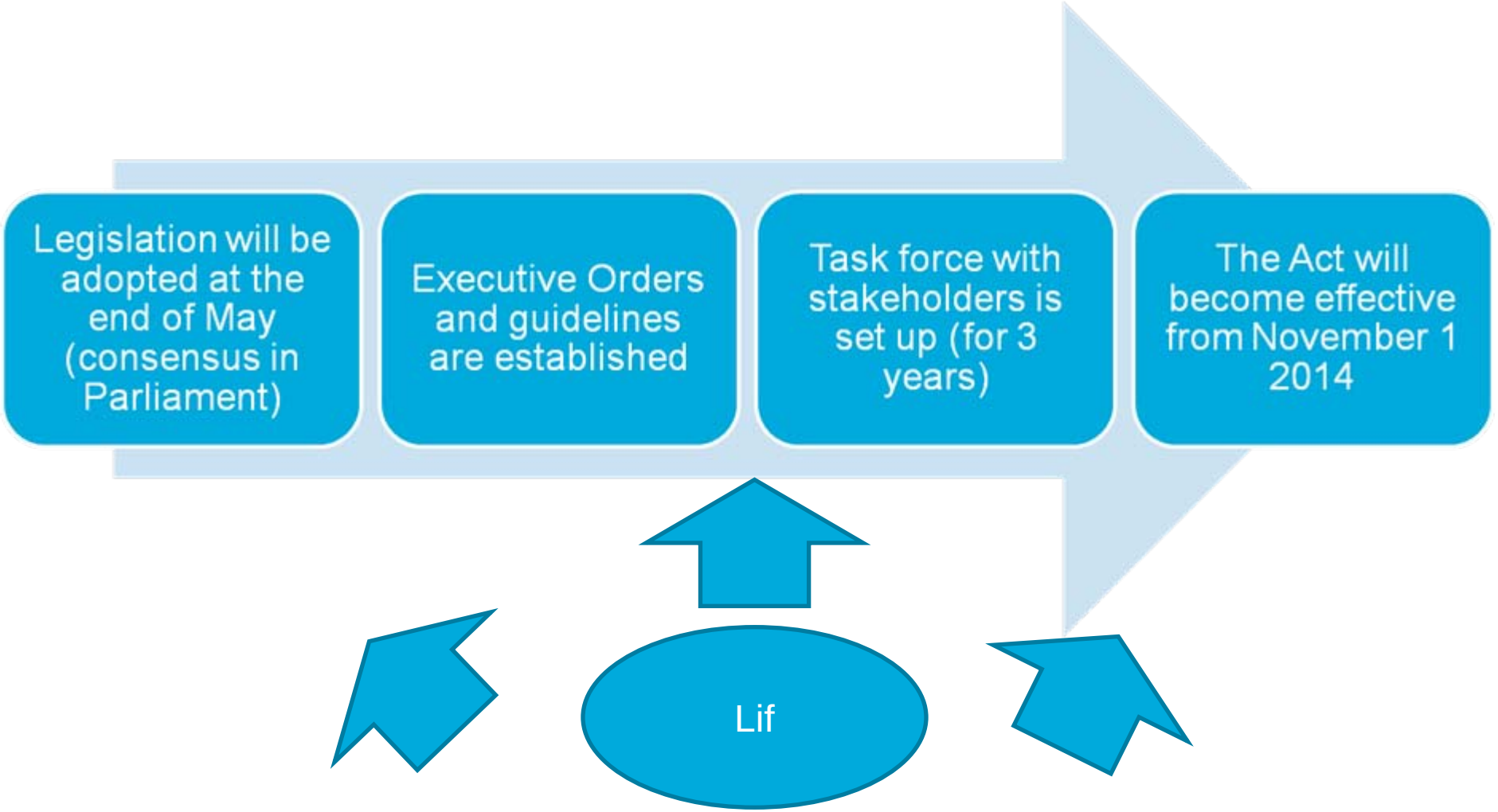
- Key reporting obligation imposed on HCP
- Limited administrative burdens imposed on industry
- No data privacy issue – no need for consent – all data de-facto individual disclosed
- Inclusion of MedTech industry under same regulation
- Inclusion of EFPIA's decision on disclosure
- Avoid two parallel systems and unnecessary bureaucracy which create no add-on value

Common Danish platform for disclosure



What	How
Fees for research (e.g. clinical research)	Registration & disclosure of individual data
Fees for education/speakers	Registration & disclosure of individual data
Fees for consultancy (e.g. advisory boards)	Pre-approval & disclosure of individual data
Fees for market research	Pre-approval & disclosure of individual data
Events – Sponsorships and companies	Registration of events held abroad. Individual disclosure (no amounts so far for events)
Donations and grants to hospitals	Lif has a disclosure code
Shares	Registration & disclosure of individual data Pre-approval if amount exceeds EUR 30,000
Ownership/Board of Directors	Pre-approval & disclosure

Status and timeline



Collaboration continues with our stakeholders

- Common information leaflet
- Joint public debate meetings
- Who: Lif, the MedTech industry, the Danish Generic Medicines Industry Association, the Danish Medical Association, the Medical Societies, the Danish Pharmaceutical Association, the Dentists Association and the Danish Nurses' Organisation.