LÆGEMIDDEL STYRELSEN

DANISH MEDICINES AGENCY

EU Experiences with Patient Reporting

Second Stakeholders Forum on the Implementation of the New Pharmacovigilance Legislation, London 17 June 2011

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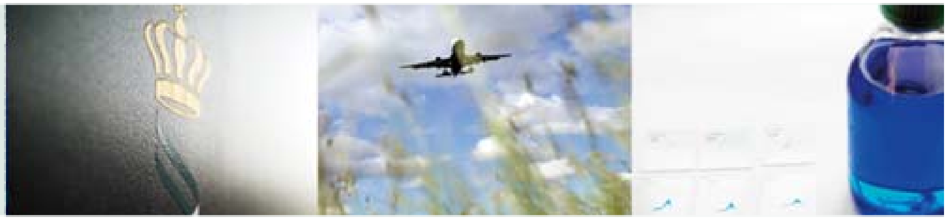
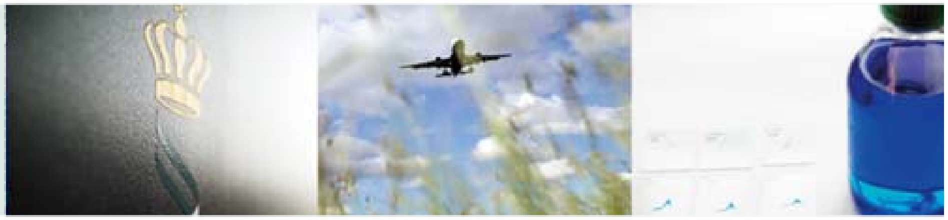


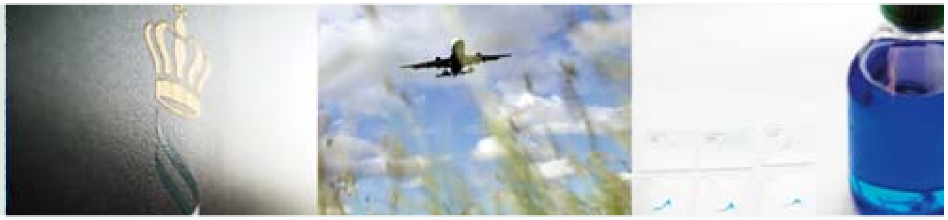
Overview

- The legal basis for patient reporting
- Experiences with patient reporting in some EU member states



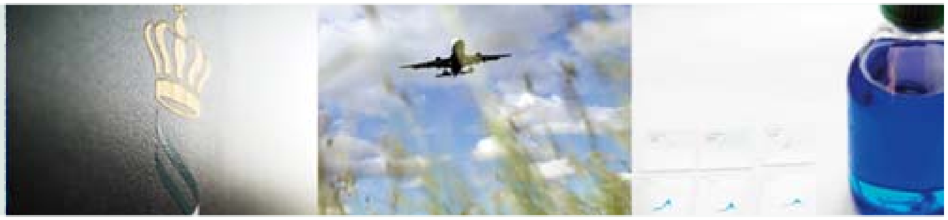
Legal basis for patient reporting

- Directive 2010/84/EU of 15 Dec 2010
    - Amends, as regards pharmacovigilance, directive 2001/83/EC relating to medicinal products for human use
    - Recital 21
    - Art. 102
    - Art. 106 (e)
    - Art. 107 (a)



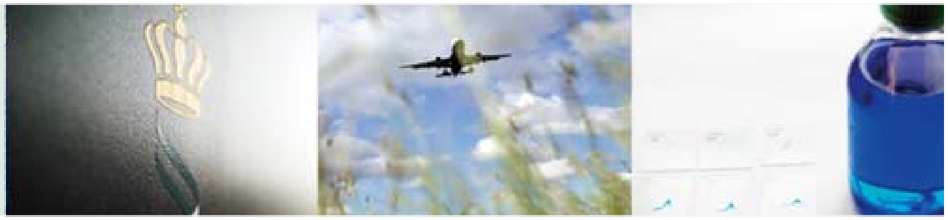
Legal basis for patient reporting (2)

- Directive, recital 21
  - *Union rules in relation to pharmacovigilance should continue to rely on the crucial role of healthcare professionals in monitoring the safety of medicinal products, and should take account of the fact that patients are also well placed to report suspected adverse reactions to medicinal products. It is therefore appropriate to facilitate the reporting of suspected adverse reactions to medicinal products by both healthcare professionals and patients, and to make methods for such reporting available to them*



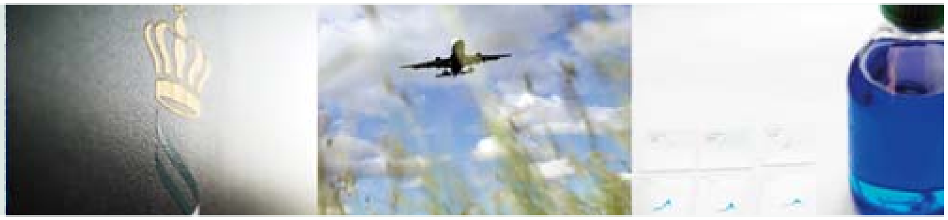
Legal basis for patient reporting (3)

- Directive, art. 102
  - *The member states shall:*
    - *(a) take all appropriate measures to encourage patients, doctors, pharmacists and other health care professionals to report suspected adverse reactions to the national competent authority; for these tasks, organisations representing consumers, patients and healthcare professionals may be involved as appropriate;*
    - *(b) facilitate patient reporting through the provision of alternative reporting reporting formats in addition to the web-based formats*



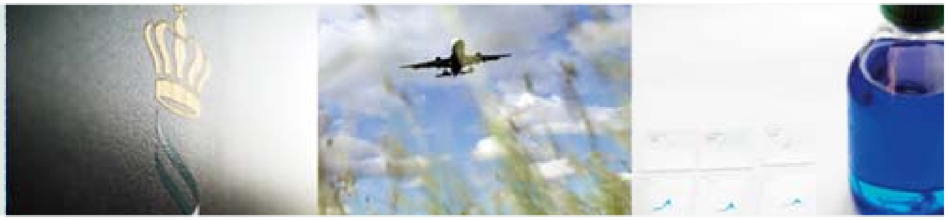
Legal basis for patient reporting (4)

- Directive, art. 106 – concerning information to be provided on the national web portals
- ....*By means of the national medicines web-portals the member states shall make publicly available at least the following:*
  - *(e) information on the different ways of reporting suspected adverse reactions to medicinal products to national competent authorities by healthcare professionals and patients, ...*



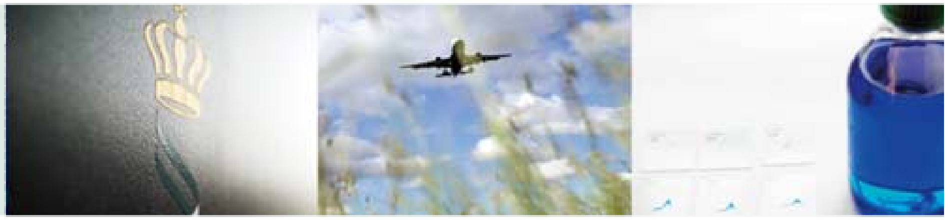
Legal basis for patient reporting (5)

- Directive, art. 107a – concerning recording and reporting of suspected adverse reactions
  - 1. *Each member state shall record all suspected adverse reactions that occur in its territory which are brought to its attention from healthcare professionals and patients. Member states shall involve patients and healthcare professionals, as appropriate, in the follow-up of any reports they receive….(in order to comply with article 102(c) and (e))*



Danish experience with patient reporting

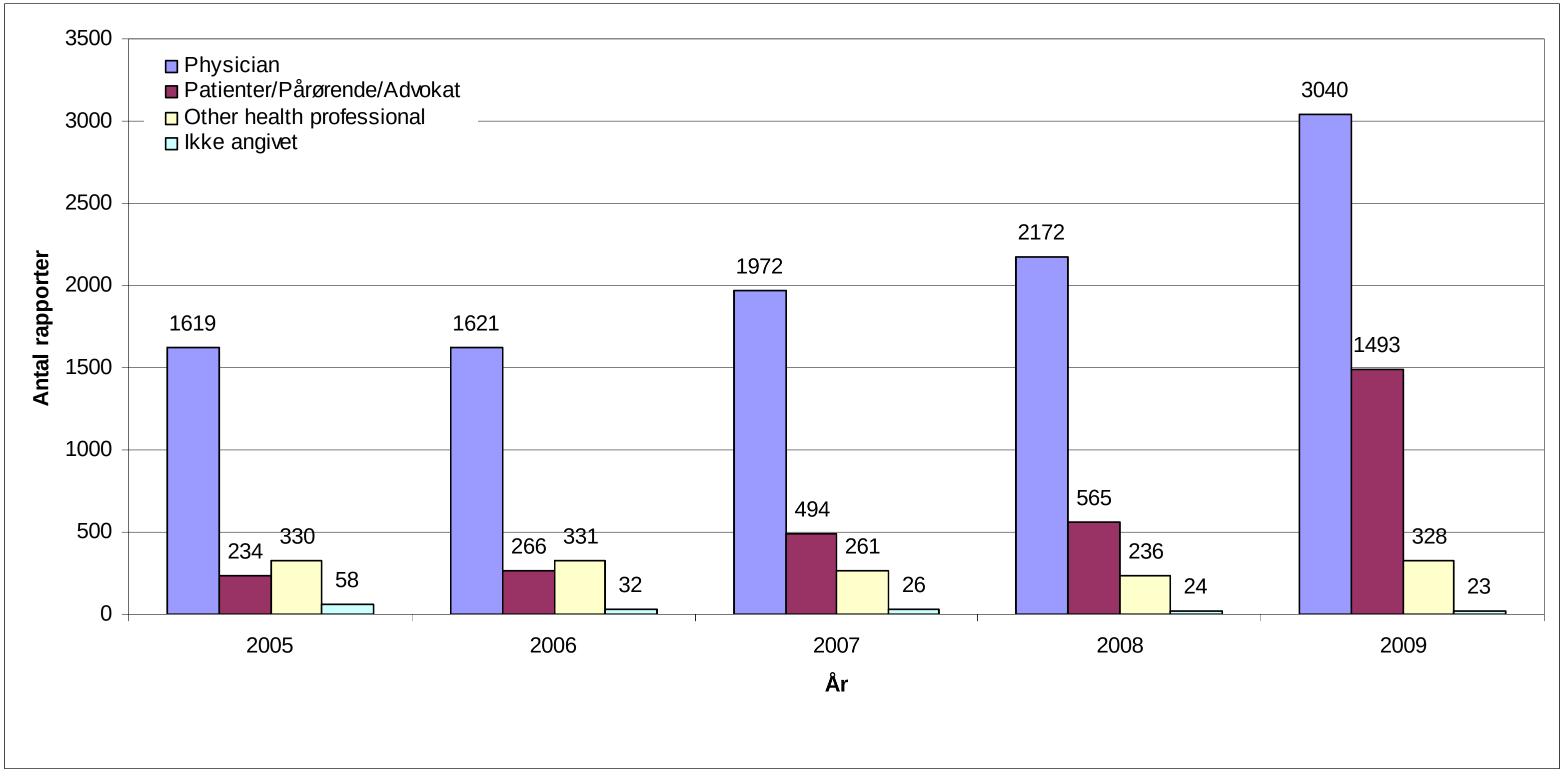
- Implemented in national legislation in 2003, promoted by leaflet and later (in 2010) by a campaign in pharmacies and collaboration with patient organisations
- Main reason was underreporting of ADRs by HCPs and a strong request from consumers to become involved
- Initially same reporting scheme as for HCPs, but today separate forms; electronic reporting
- The vast majority (>2/3) of cases report ADRs which are already mentioned in the SmPC and are non-serious
- Male : female ratio 1:2

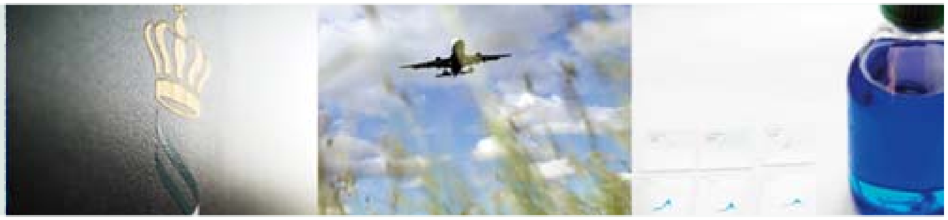


Danish experience with patient reporting (2)

- Media attention elicit stimulated reporting
- Social media are used to disseminate information
- Consumer reports are handled as HCP reports; quality issues; lay language require interpretation
- Medical confirmation is requested if the patient has provided permission
- Analysis of ADRs reports (total 6319 reports / 15.531 ADRs) received during 2004-2006
    - Reporter source, seriousness, SOC and suspected drug
    - Consumers reported 11%; 45% serious (as for HCPs); only ADRs within the neurology SOC differed significantly

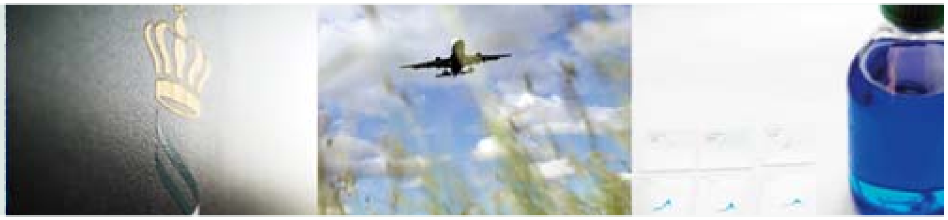
Danish experience with patient reporting (3)
Who submits ADR reports?





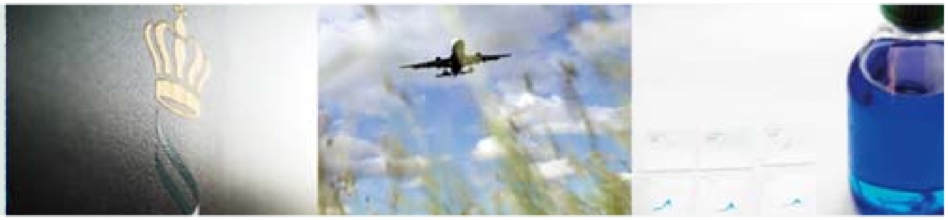
Survey report on patient reporting – a Monitoring Medicines FP7 project (EC)

- Review of direct patient reporting of adverse drug reactions in 11 EU (DK, NL, NO, SE, UK) and non-EU (e.g. AUS, NZ, US and CAN) countries
- Authors: Florence van Hunsel, Linda Härmark and Kees van Grootheest, from Netherlands Pharmacovigilance Centre Lareb and University of Groningen



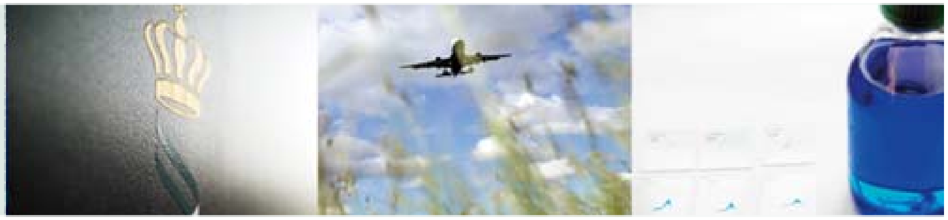
Survey report on patient reporting – a Monitoring Medicines FP7 project (EC)

- Objective → harmonised global consumer reporting
  - *“Strengthen consumer reporting of ADRs through*
    - *review of existing consumer reporting methods*
    - *identification of optimal methods for consumer reporting*
    - *and training in best practice in consumer reporting of medication-related problems”*



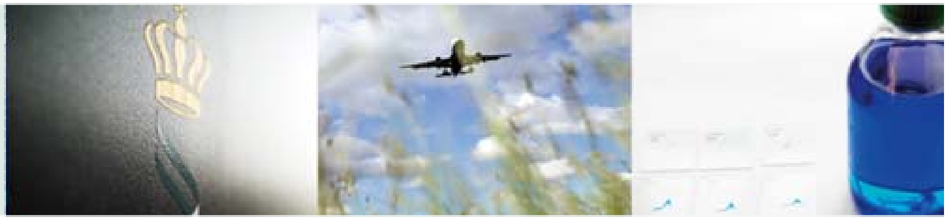
EU experiences according to the survey (DK, NL, NO, SE, UK)

- Governmental organisation in 4 MSs, independent foundation in 1 MS (NL)
- Organisations collect both HCP reports (in 2 MSs via regional centres) and consumer reports
- Motives for introducing patient reporting
  - Empowerment of the patient-trend, underreporting, EU-initiative underway
- Launch in 2003 (DK, NL), 2005 (UK), 2008 (SE) and 2010 (NO), in some MSs following pilot projects
- Electronic (DK, NL, NO), + paper (SE), + telephone (UK); free text + mandatory, E2B



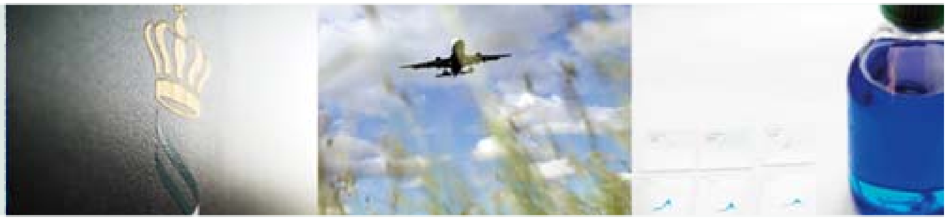
EU experiences according to the survey (DK, NL, NO, SE, UK) (2)

- ADRs coded in MedDRA terminology
- Automated or manual check for duplicates
- Personalized feedback in 1 MS (NL)
- Follow-up information can be requested in 4 MSs (DK, NL, SE, UK)
- Permission to contact the HCP can be obtained in 4 MSs (DK, NL, SE, UK)
- Causality assesement of all ICSRs in 1 MS (NL); classification according to serious / non-serious in all MSs



Recommendations originating from the survey

- Create awareness – reach the public by better marketing
- Offer electronic reporting according to international (E2B) standards and use universal designs of forms
- Perform field testing of reporting forms to ensure they are comprehensible to the public
- Prepare for the handling of consumer reports



EU experiences with patient reporting Conclusions

- Prior to the legal basis for patient reporting - as of July 2012 - several EU MSs have launched patient reporting schemes
- The contribution from patients are gradually increasing, but awareness of the opportunity to report is low
- Differences in how patient reports are handled; electronic reporting preferred option; in majority of MSs patient reports are used for signal detection
- Need for further evaluation of patient reporting to get more insight into which kind of information is provided