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## 9 Do Consumer Reports of Adverse Drug Reactions Add Value or Noise to Postmarketing Safety Surveillance?

*Ahmad S*,(1) *Westin L*,(2) *Aagaard L*,(3) *Moses G*(4)
(1)Food and Drug Administration (2)KILEN, Consumer Association for Medicines and Health (3)Danish Medicines Agency (4)Adverse Medicine Events Line, Mater Health Services

**Background:** Spontaneous adverse drug event reporting systems remain the cornerstone of drug safety surveillance. Traditionally most national regulatory agencies used to accept adverse drug reaction (ADR) reports from healthcare professionals only. Recently a number of countries have started accepting reports from patients and consumers as well. This session will address the advantages and limitations of consumer reports from the perspectives of two regulatory agencies and two consumer-group run systems that encourage and promote reporting by patients and consumers.
**Objectives:** To share the experience of consumer reporting from 4 countries in 3 continents

To describe the value and limitations of consumer reports

This session is likely to attract the attention of all those involved in collecting, and evaluating spontaneous reports of ADRs including government regulators, industry, and academia.
**Description:** Reports from consumers have the potential to identify new signals of possible ADRs sooner. There is data which suggest that there is substantial difference in reports submitted by consumers and healthcare professionals - report from the former were sometimes far richer especially when it came to description of behavioral effects. At the same time there is concern that reports from consumers takes longer to process because of difficulty in coding, are of inferior quality, and generate more noise. The session will include perspectives from the U.S. Food and Drug Administration, the Danish Medicines Agency, and two consumer-groups driven initiatives to stimulate consumer reporting in Sweden and Australia, on the value and limitations of consumer reports.
**Conflicts of interest:** None declared.