



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Session 2

Data analysis based on overview of EudraVigilance data

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Medication-errors workshop
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Acknowledgement

Steven Le Meur (EMA)



Analysis of EudraVigilance

- Spontaneous cases from 01/01/2001-01/01/2016 *
- Cases retrieved using Standardised MedDRA Query (SMQ) *'Medication errors'*
- Broad and Narrow search terms used

*(message type ICSR, Backlog, Master, (excluding PSUR) based on gateway date, serious and non-serious)



Number of Medication Error cases in EudraVigilance

SMQ	Global	EEA
Broad	147,800	41,300
Narrow	88,300	24,300

Total cases 3,830,000

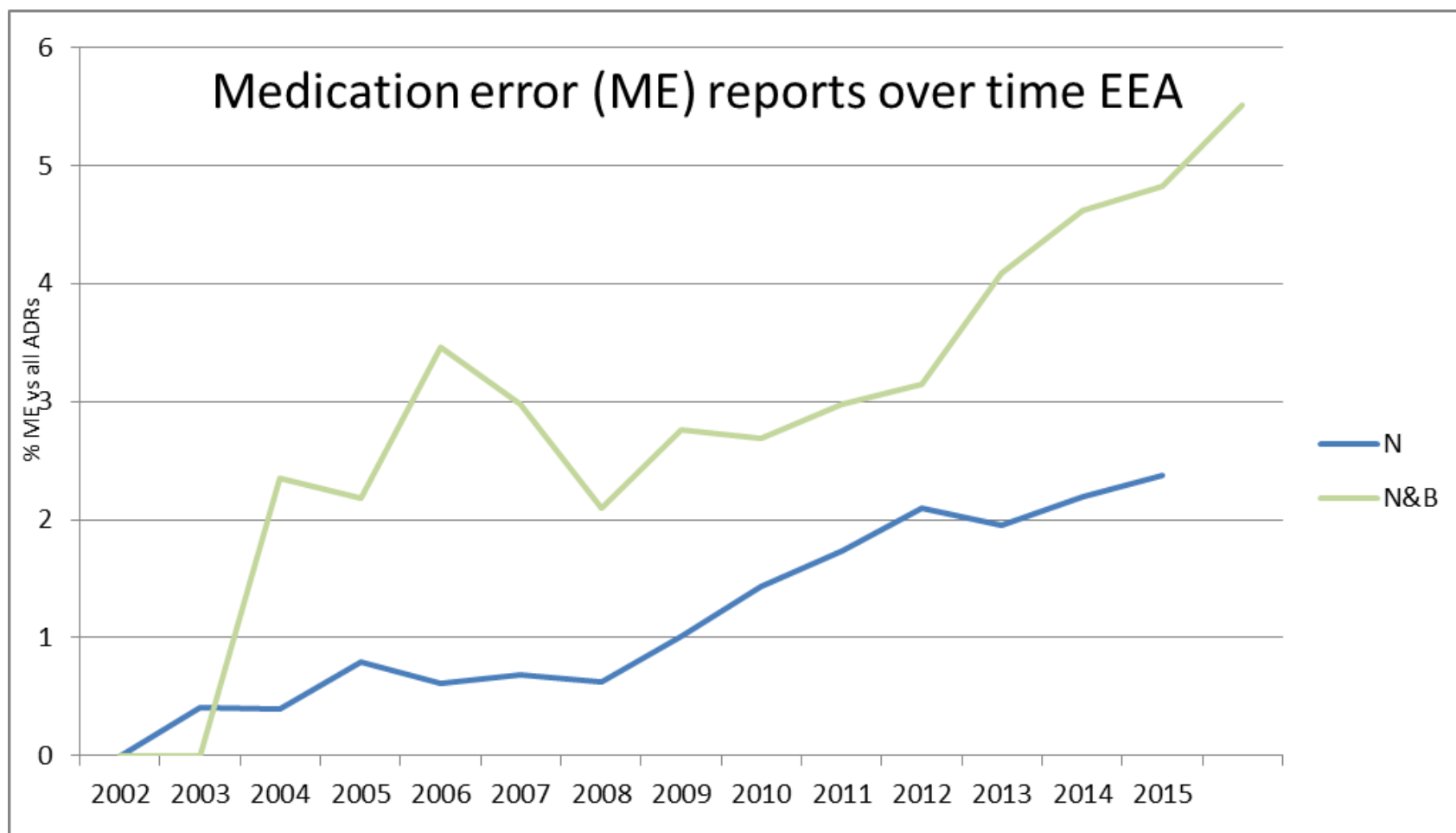


Source of reports (Narrow SMQ)

Primary source	% of cases EEA	% cases Non-EEA
Only HCP	77.9	41.9
Only Patient	13.3	38.0
Patient + Others (HCP / Legal)	7.8	18.1
Others (Legal / Not reported)	0.9	1.8

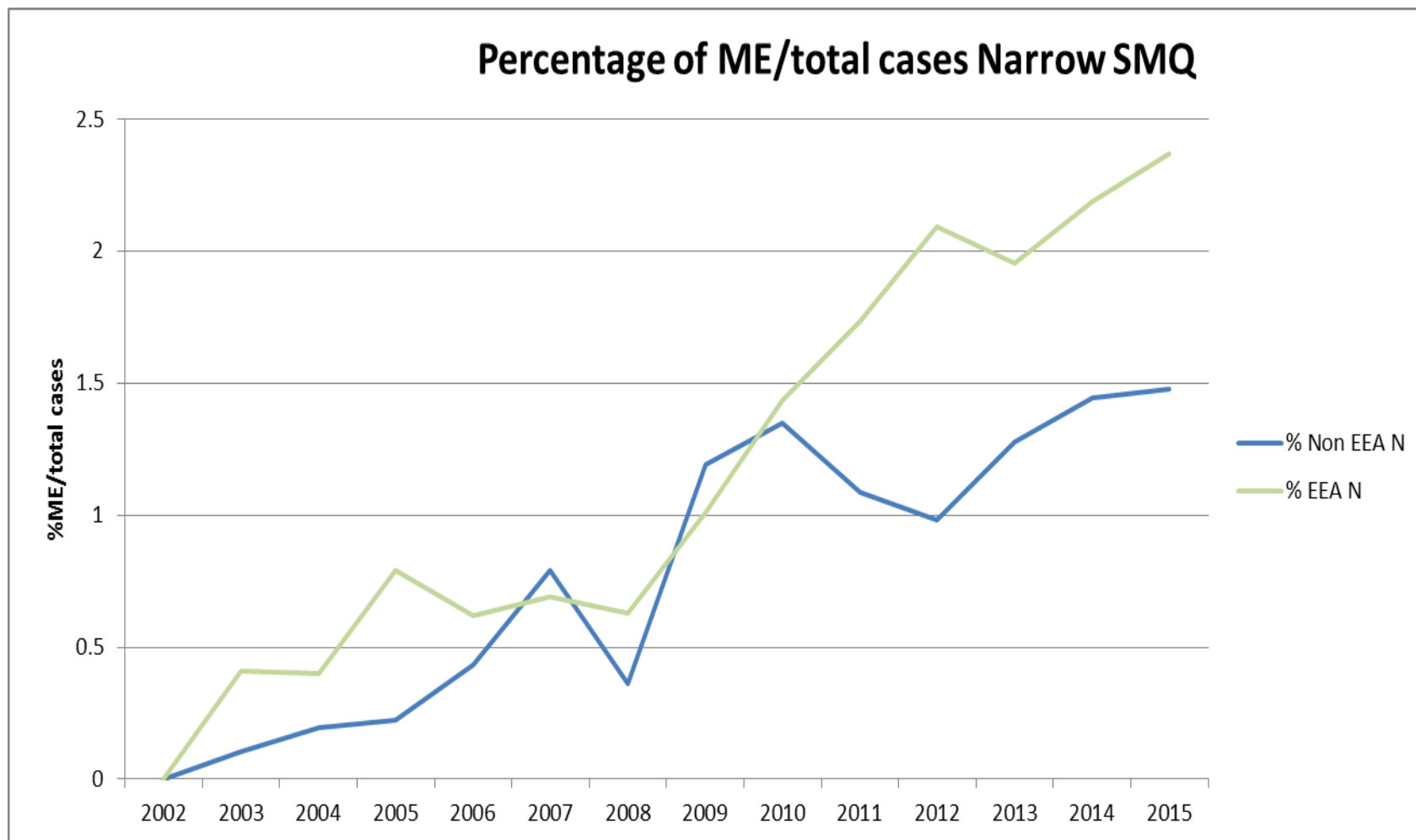


Percentage of medication error reports/total cases over time in the EEA



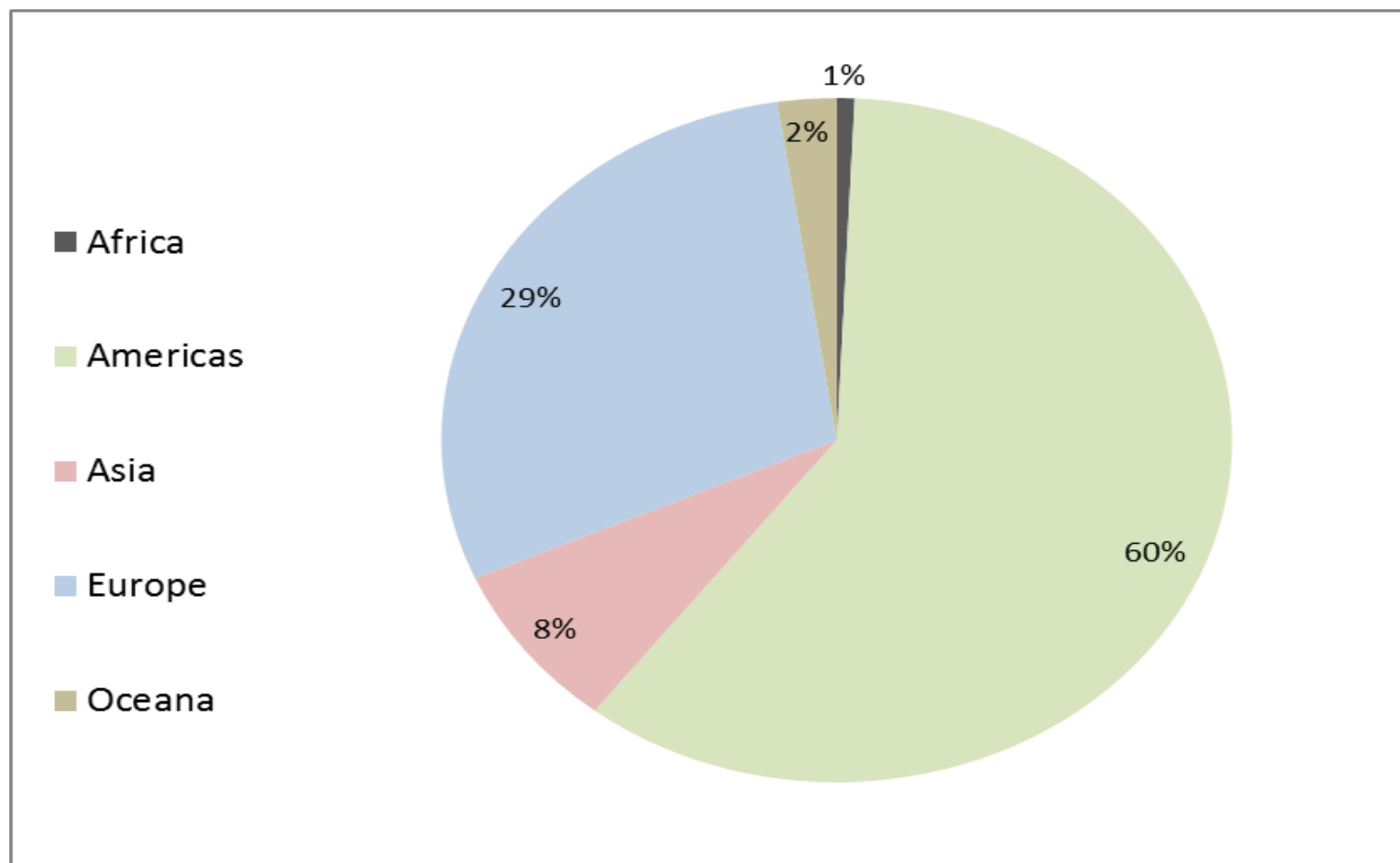


Narrow SMQ- percentage of ME vs total cases in EEA and non-EEA



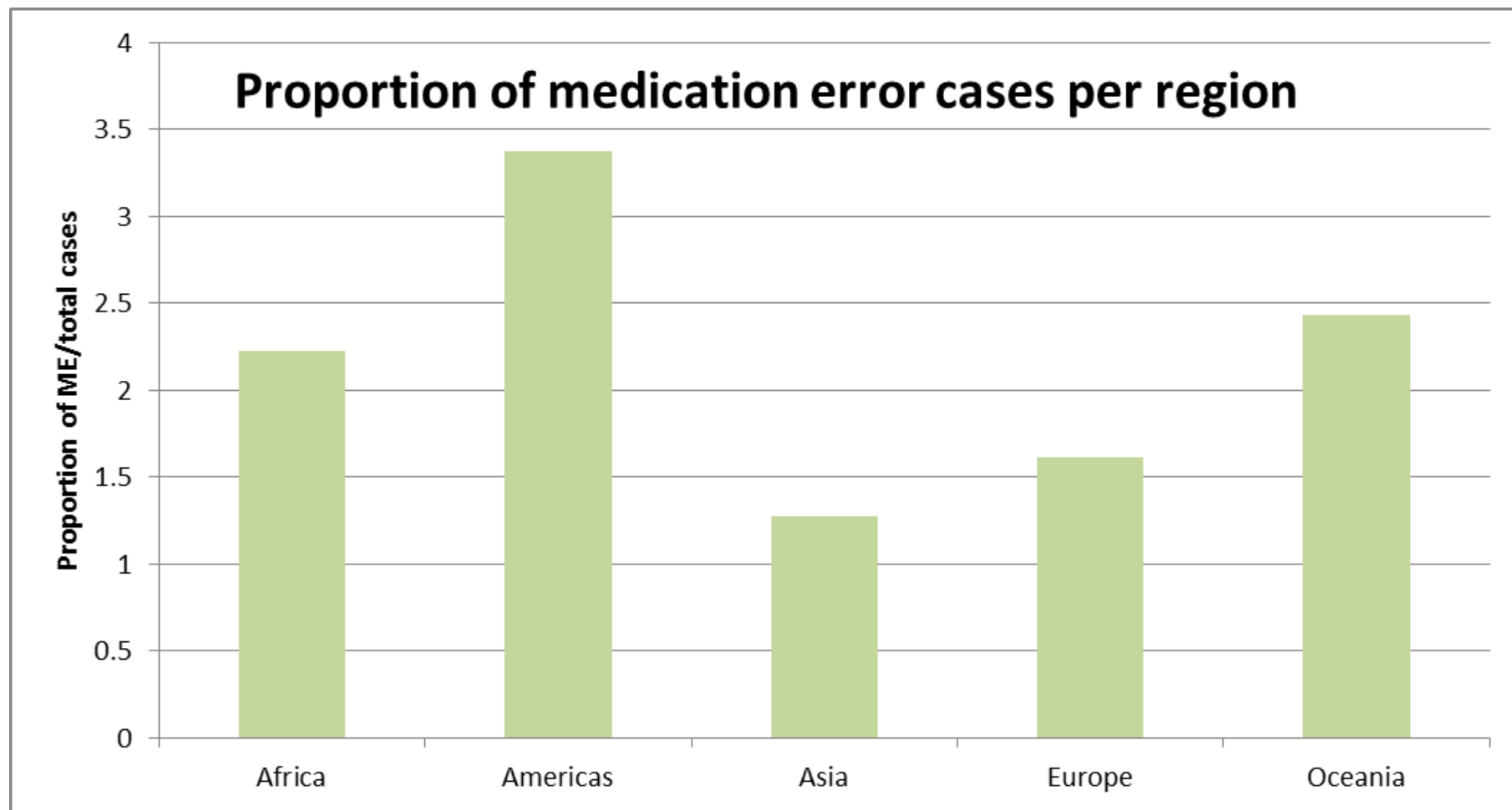


Medication errors (Narrow SMQ) by region



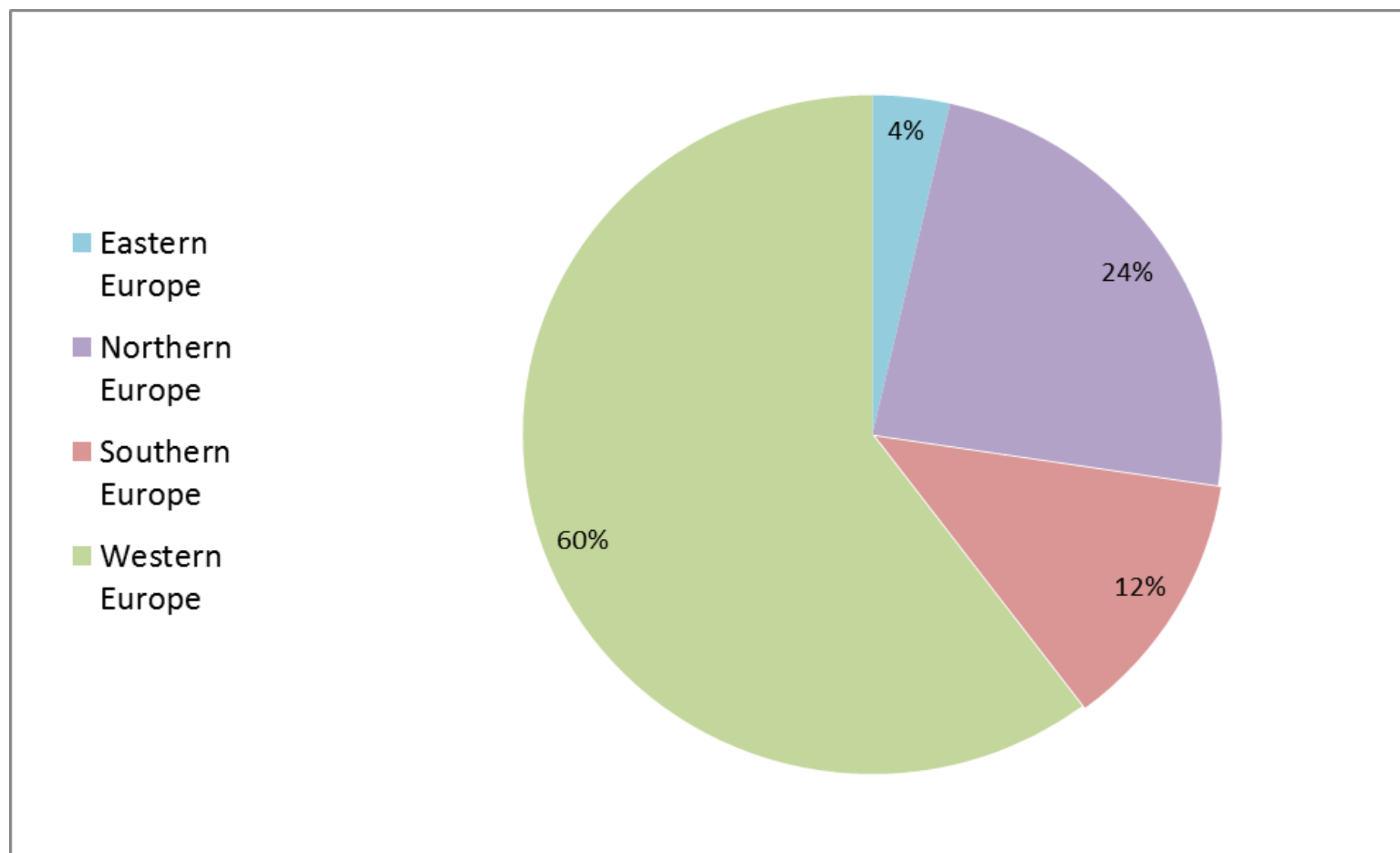


Narrow SMQ medication errors



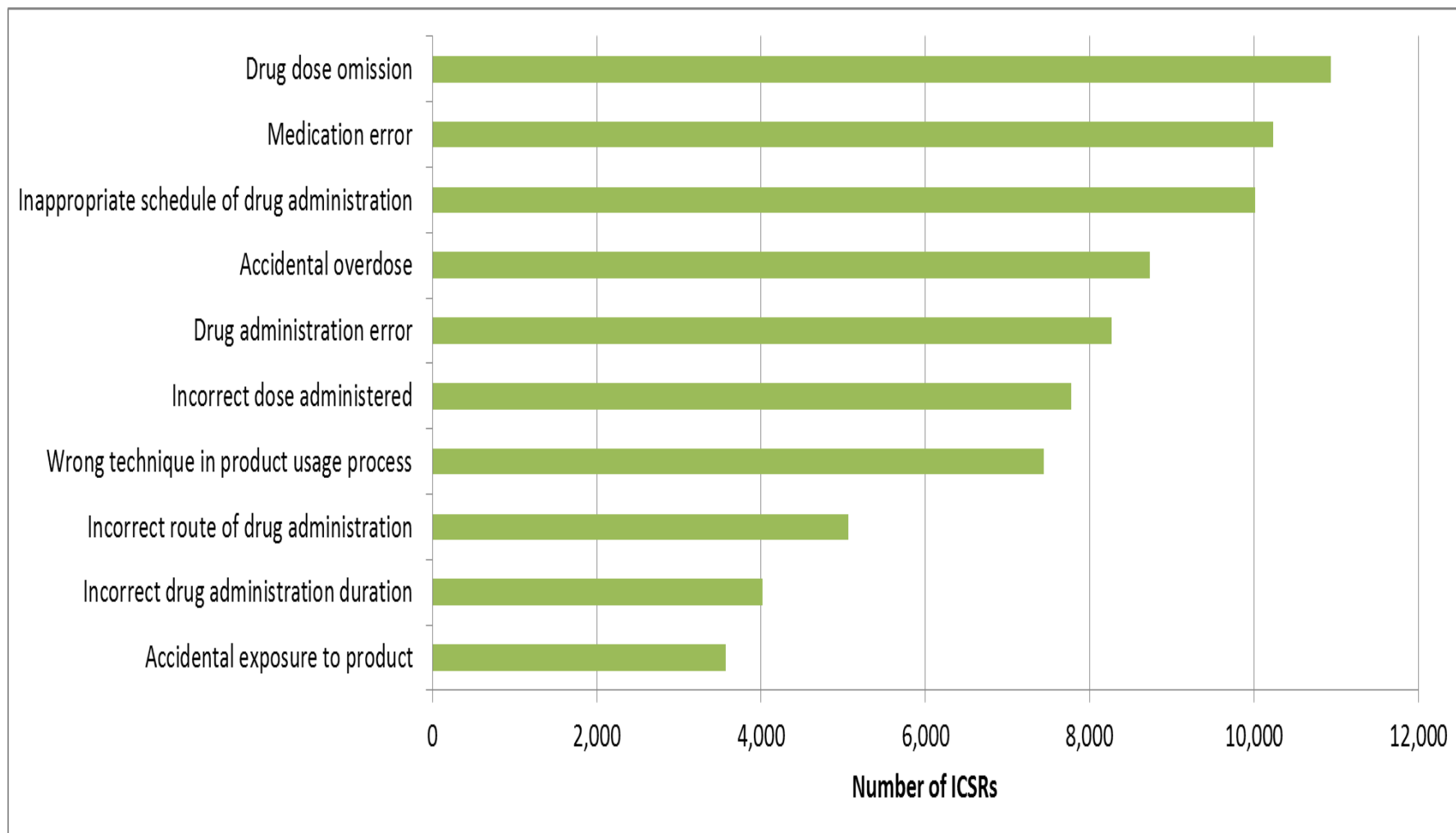


Medication errors (Narrow SMQ) by region of EU



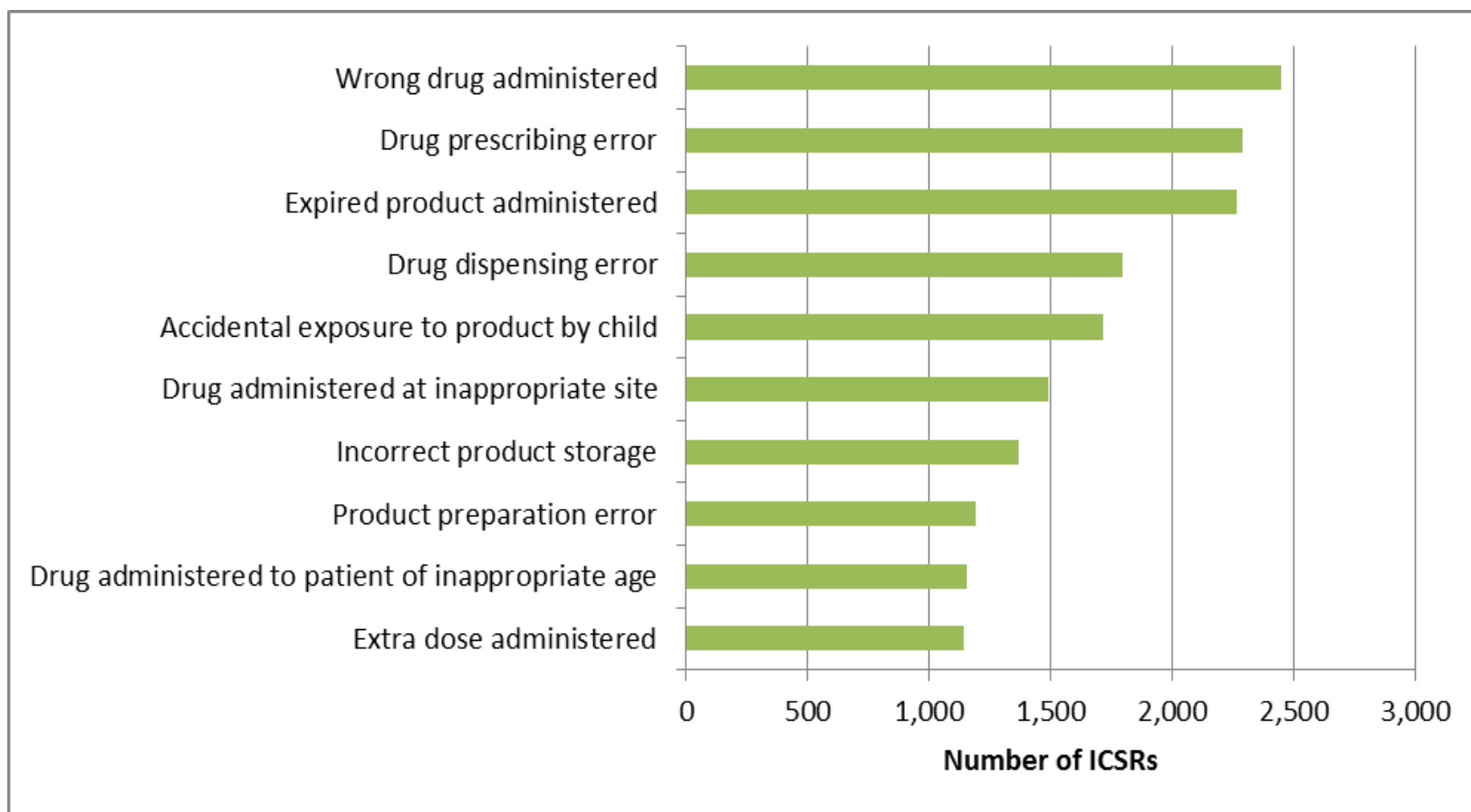


Global top 10 PTS (from N SMQ list)



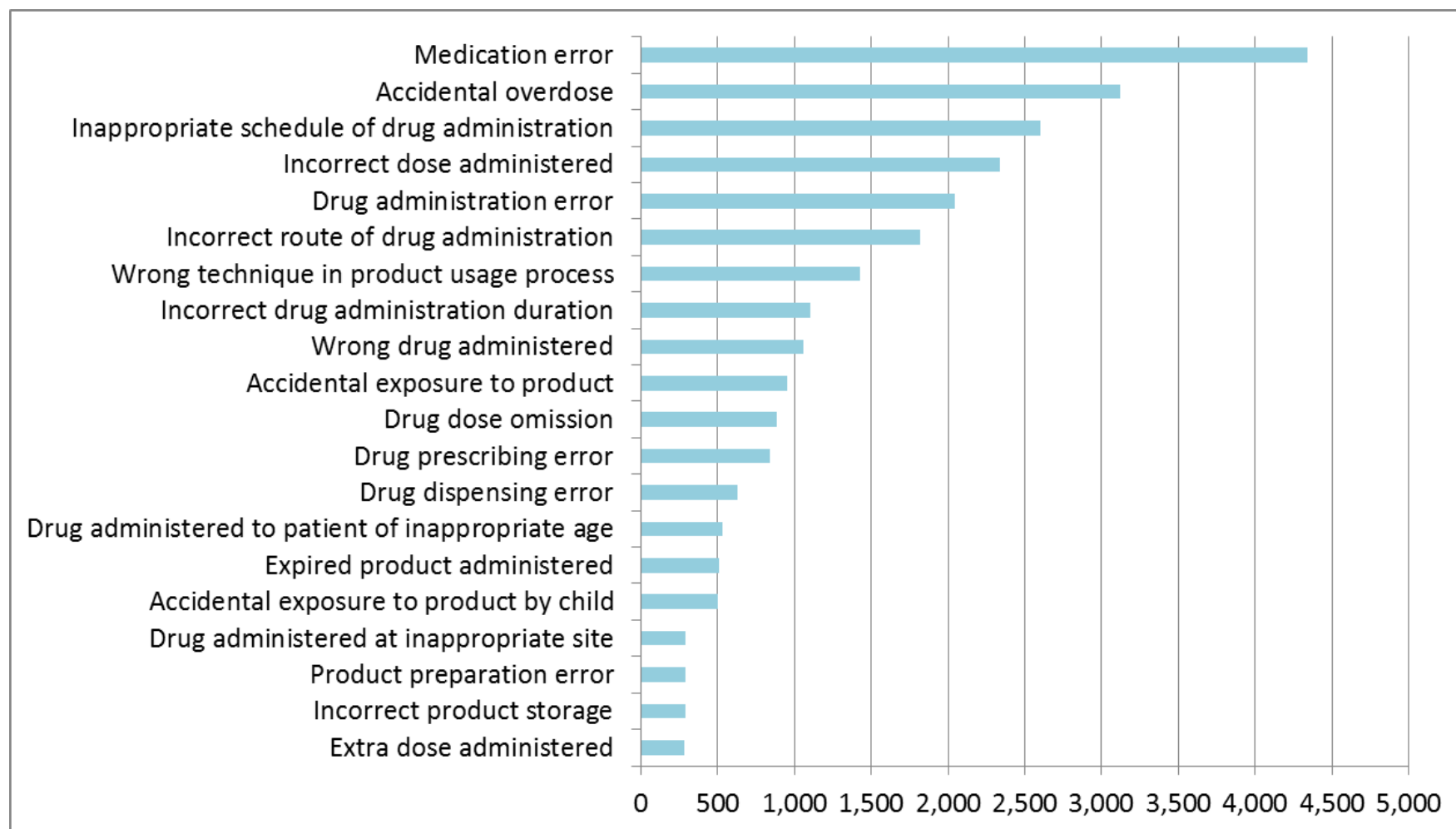


Global top 10-20 PTS (from N SMQ list)



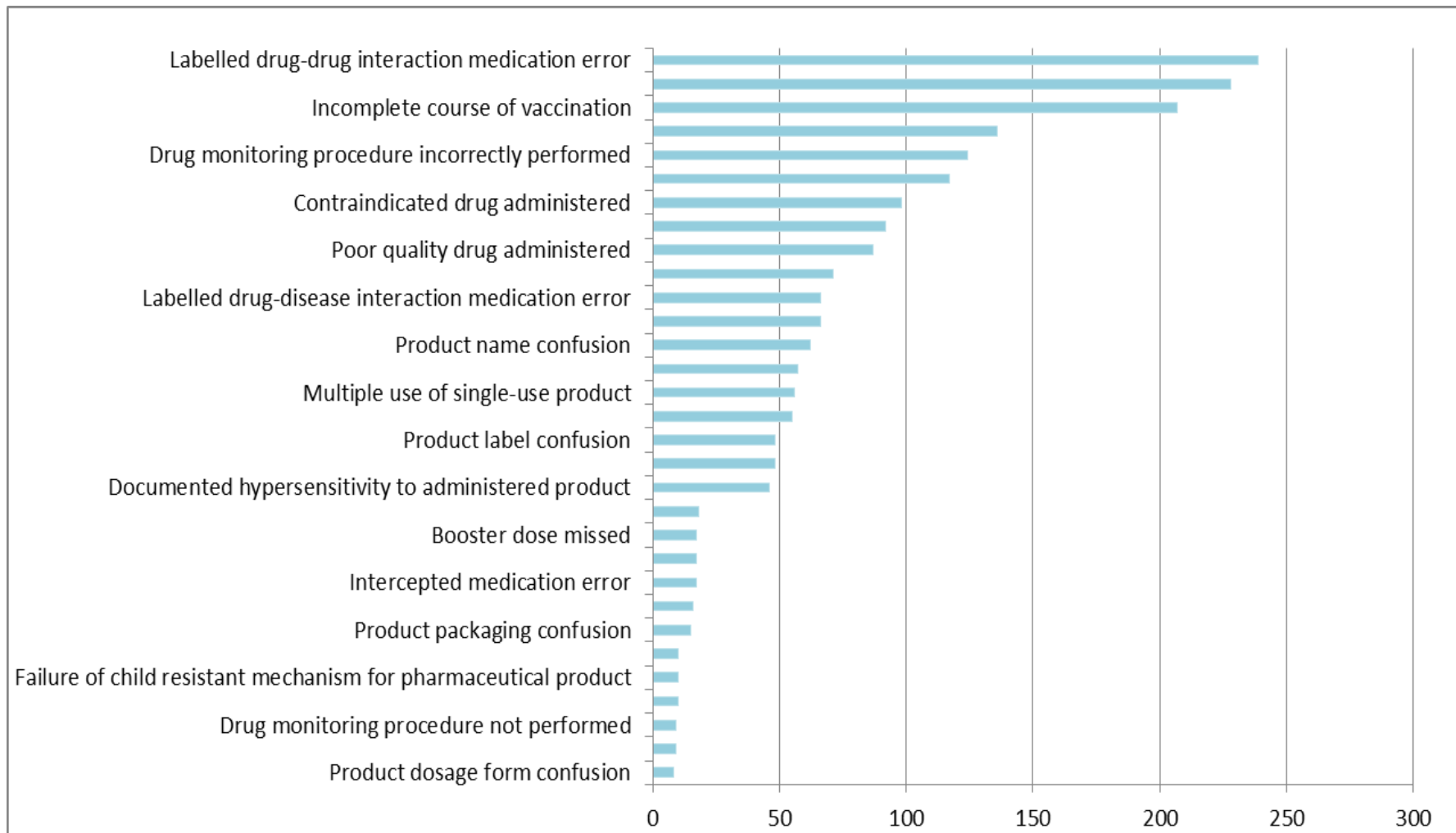


EU top 20 from N SMQ





EU ME cont.....



Ranking of Anatomical Therapeutic Chemical (ATC) reported most frequently with cases of ME (Narrow SMQ)



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Ranking	EEA	Non EEA
1	J07 (Vaccines)	N02 (Analgesics)
2	N05 (Psycholeptics)	N05 (Psycholeptics)
3	N02 (Analgesics)	A10 (Diabetes)
4	B01 (Antithrombotics)	B01 (Antithrombotics)
5	G03 (Sex hormones)	L04 (Immunosuppressants)
6	N06 (Psychoanaleptics)	R03 (Obstructive airways disease)
7	A10 (Drugs used in diabetes)	N06 (Psychoanaleptics)
8	N03 (Antiepileptics)	G03 (Sex hormones)
9	L01 (Antineoplastic)	N03 (Antiepileptics)
10	J01 (Antibacterials for systemic use)	N07 (Other nervous system drugs)
11	L04 (Immunosuppressants)	A02 (Drugs for acid disorders)
12	N01 (Anaesthetics)	J07 (Vaccines)
13	C01 (Cardiac therapy)	M01 (Anti-inflammatory and antirheumatic products)
14	N07 (Other nervous system drugs)	L01 (Antineoplastic)
15	G02 (Genitourinary system and sex hormones)	C09 (Renin angiotensin)

ATC code for suspect drug based on XEVMPD



Drugs associated with top 5 errors (Global)

- Accidental overdose: Paracetamol, Oxycodone, Morphine, Fentanyl, Alprazolam
- Drug administration error: Cisapride, Insulin, Fluticasone/Salmeterol, Fentanyl, Salbutamol
- Incorrect dose administered- Rivaroxaban, Insulin, Mifepristone, Mifoprostol, Paracetamol
- Wrong technique in drug usage process: Fentanyl (misuse), Diclofenac, Valsartan, Etanercept, Aripiprazole
- Incorrect route of administration- Tiotropium, Fentanyl, Varicella vaccine, Baclofen, Bupivacaine



Prescribing

Circumstance or information capable of leading to device use error
Circumstance or information capable of leading to medication error
Documented hypersensitivity to administered product
Drug prescribing error
Intercepted drug prescribing error
Intercepted medication error
Intercepted wrong patient selected
Medication error
Product dosage form confusion
Product name confusion

Dispensing

Circumstance or information capable of leading to device use error
Circumstance or information capable of leading to medication error
Documented hypersensitivity to administered product
Drug dispensed to wrong patient
Drug dispensing error
Incorrect product storage
Intercepted drug dispensing error
Intercepted medication error
Intercepted product selection error
Intercepted wrong patient selected
Medication error
Product dosage form confusion
Product label confusion
Product name confusion
Product packaging confusion
Product selection error
Transcription medication error
Wrong device dispensed
Wrong patient received medication

Preparation

Accidental exposure to product
Accidental exposure to product by child
Accidental use of placebo
Circumstance or information capable of leading to device use error
Circumstance or information capable of leading to medication error
Device use error
Expired device used
Exposure via direct contact
Inadequate aseptic technique in use of product
Incorrect product storage
Intercepted medication error
Medication error
Product dosage form confusion
Product label confusion
Product name confusion
Product packaging confusion
Product preparation error
Product selection error
Transcription medication error
Vaccination error
Wrong device used
Wrong technique in product usage process

Administration

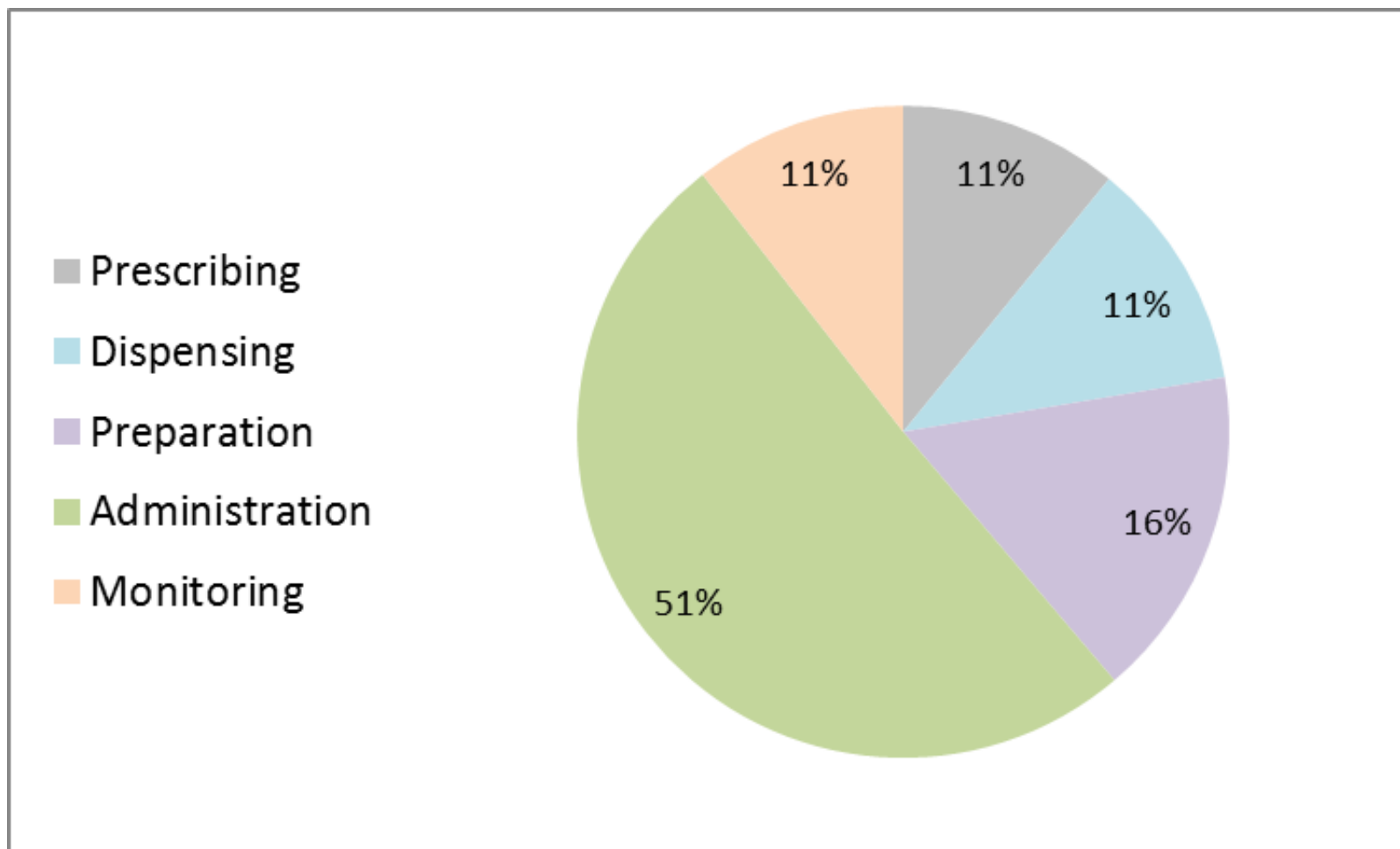
Accidental device ingestion
Accidental device ingestion by a child
Accidental exposure to product
Accidental exposure to product by child
Accidental overdose
Accidental poisoning
Accidental underdose
Accidental use of placebo
Booster dose missed
Circumstance or information capable of leading to device use error
Circumstance or information capable of leading to medication error
Contraindicated drug administered
Device use error
Documented hypersensitivity to administered product
Drug administered at inappropriate site
Drug administered in wrong device
Drug administered to patient of inappropriate age
Drug administration error
Drug dose omission
Drug dose titration not performed
Drug titration error
Expired device used
Expired product administered
Exposure via direct contact
Extra dose administered
Failure of child resistant mechanism for pharmaceutical product
Inadequate aseptic technique in use of product
Inappropriate schedule of drug administration
Incomplete course of vaccination
Incorrect dosage administered
Incorrect dose administered
Incorrect dose administered by device
Incorrect drug administration duration
Incorrect drug administration rate
Incorrect drug dosage form administered
Incorrect product formulation administered
Incorrect route of drug administration
Intercepted drug administration error
Intercepted medication error
Intercepted wrong patient selected
Lack of application site rotation
Lack of infusion site rotation
Lack of injection site rotation
Medication error
Multiple use of single-use product
Paravenous drug administration
Poor quality drug administered
Product dosage form confusion
Product label confusion
Product name confusion
Product packaging confusion
Vaccination error
Wrong device used
Wrong drug administered
Wrong patient received medication
Wrong technique in product usage process

Monitoring

Accidental use of placebo
Booster dose missed
Circumstance or information capable of leading to device use error
Circumstance or information capable of leading to medication error
Device use error
Documented hypersensitivity to administered product
Drug monitoring procedure incorrectly performed
Drug monitoring procedure not performed
Expired device used
Incomplete course of vaccination
Intercepted medication error
Labelled drug-disease interaction medication error
Labelled drug-drug interaction medication error
Labelled drug-food interaction medication error
Medication error
Medication monitoring error
Therapeutic drug monitoring analysis not performed
Wrong device used

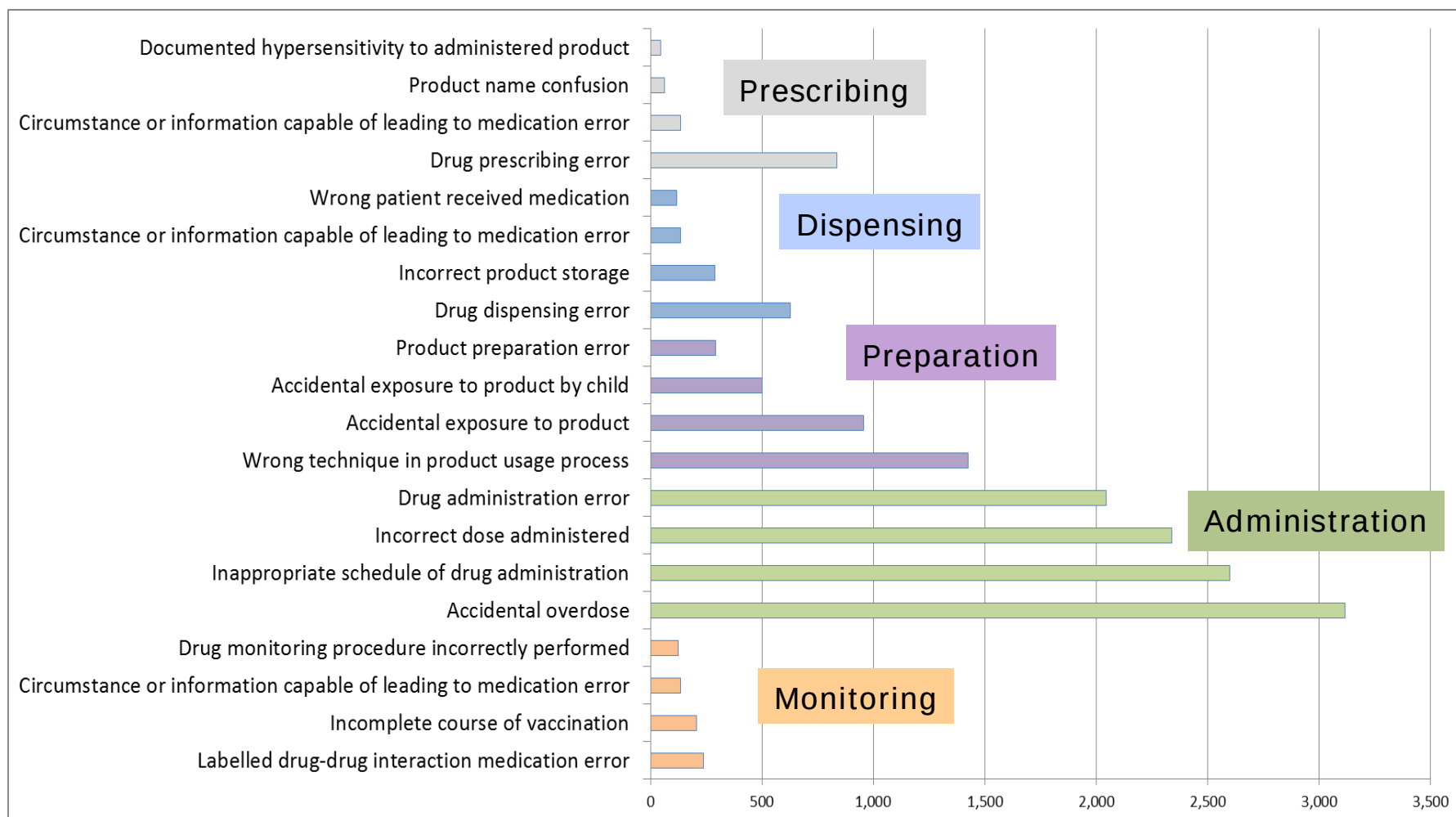


Stages of error based on EMA categorisation





Top 4 medication errors for 5 stages



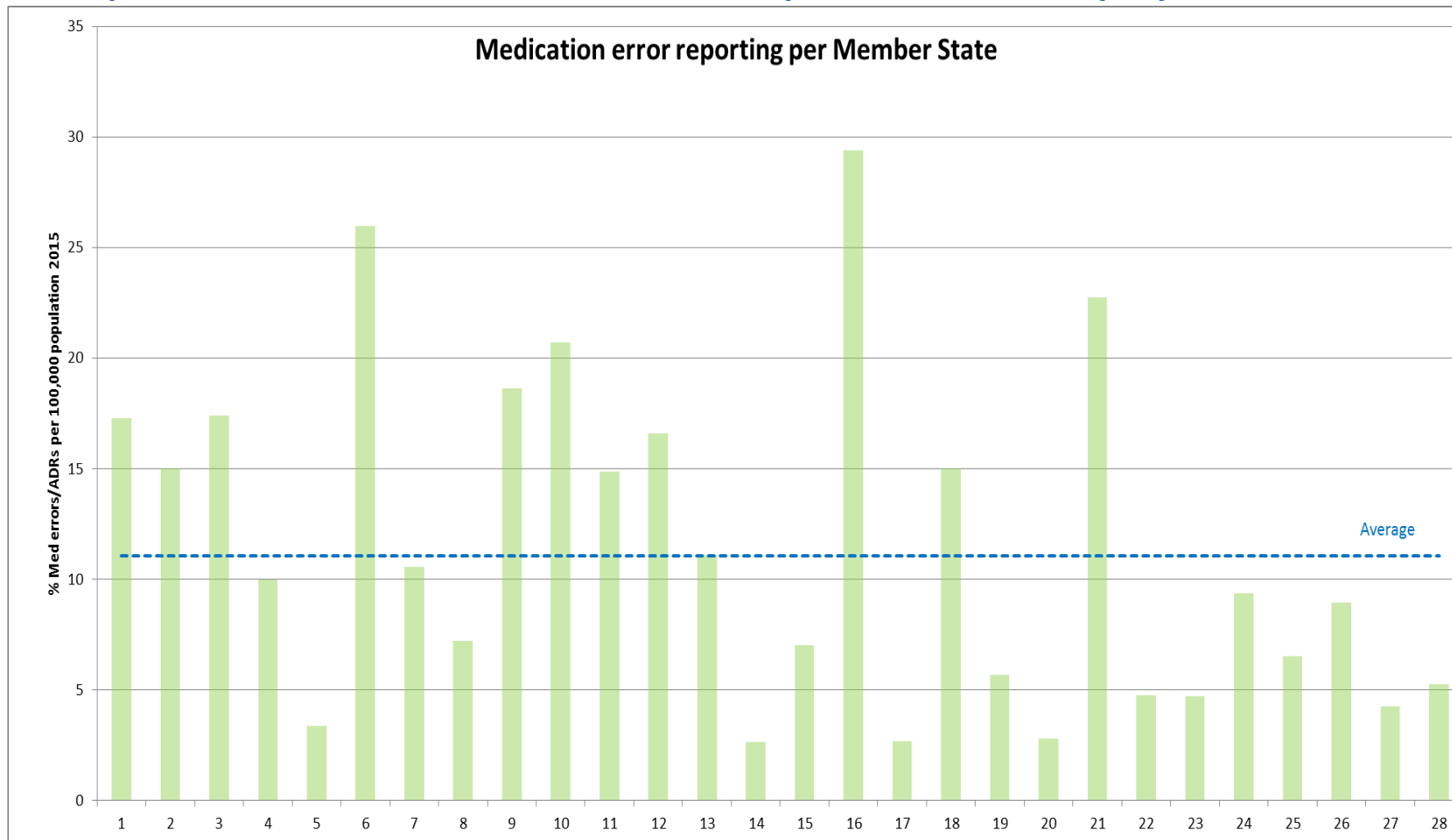


Age for cases from Narrow SMQ

	Total	EEA	NON-EEA
Age Group	Number of Cases	Number of Cases	Number of Cases
0-1 Month	500	195	305
2 months-2 Years	4,100	1,400	2,700
3-11 Years	3,400	1,100	2,200
12-17 Years	1,700	684	1,100
18-64 Years	27,400	7,100	20,200
65-85 Years	14,200	3,500	10,700
More than 85 Years	2,100	596	1,500
Not Specified	34,400	9,500	24,900



Proportion of errors v all ADRs per 100,000 population





Summary

- Numbers of reports coded with a term from the Narrow SMQ medication error have steadily increased since 2008 with a peak around 2012
- Impact of MedDRA? Term availability or coding guidance?
- Legislation and increased awareness?
- Potential further analysis:
 - Case review for data quality- are there gaps in coding guidance?
 - Case review for root cause analysis
 - Assess public health impact in order to identify any proposals for signal management prioritisation



Thank you for your attention.



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