EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA perspective on Medication Errors and MedDRA coding and reporting

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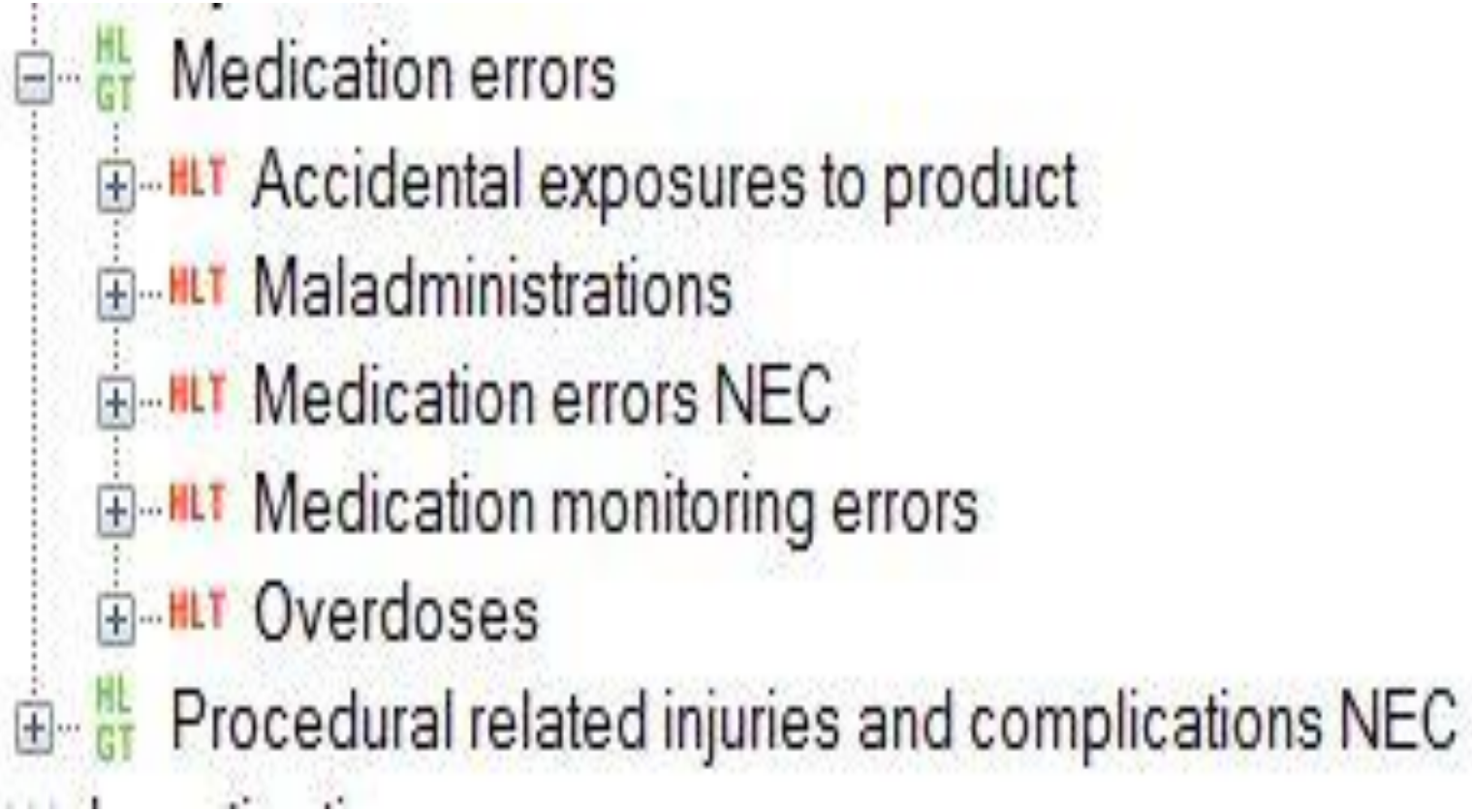
MedDRA v 16.1 HLGT



Intercepted errors

- Intercepted errors or near misses are not reportable as ICSRs but there is some misunderstanding for intercepted errors, where some coders use the intercepted term to signify that the medication error did not result in any permanent harm, or that the potential for a medication error had been noticed (but still occurred)

- Intercepted errors are those which do not reach the patient and should reflect the point of interception

Example of incorrect selection of intercepted term:

- '*Patient received oral vaccine intramuscularly due to confusion generated by the presentation of the product and suffered fever'*

  Coded as :

  – Intercepted wrong route of administration + Fever

  Should be:

  – 'Inappropriate route of vaccination' + Fever.

– A Term is also required for the confusion/ Product Quality issue:

  - Product packaging issue?
  - Circumstance or information capable of leading to medication error?
  - Or add term for confusion due to presentation?

Use of both intercepted and ME error term in same report

- '*Shift nurse noticed a smaller than expected volume of insulin remaining in the vial and was able to conclude that the patient had received a much larger dose than they should have*'

  Coded as:

  - 'Intercepted drug administration error' and 'Wrong dose administered'.
  - <u>Should Only</u> use intercepted or ME term

Product/drug name confusion

- *Patient received wrong drug with wrong route of administration due to name confusion*

– Use Drug name confusion rather than Product name confusion (MedDRA v 17.0 PT Product name confusion)

- However, it is recognised that not everyone understands when to use product and when drug, consider development of additional guidance

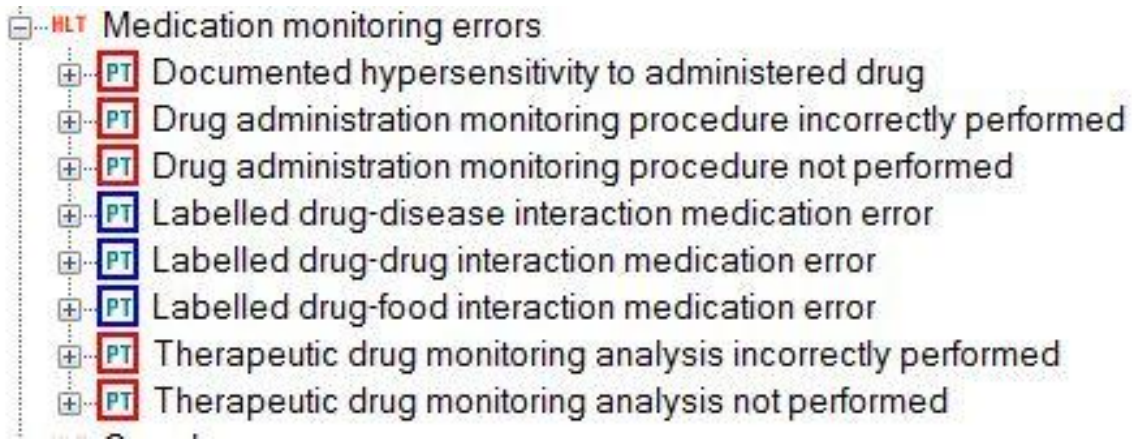
Medication error workshop February 2013

- Agency organised medication error (ME) workshop to raise awareness of the new legal provisions amongst the stakeholders involved in the reporting, evaluation and prevention of medication errors

- Six key recommendations, one related to MedDRA:
  - Harmonisation and further development of terminologies and definitions of medication errors at EU and international level

Monitoring errors

- ME workshop categorisation considers monitoring errors to be where clinical/lab data is required for use of medicine e.g blood counts for medicines with haematological effects, pregnancy tests for teratogenic drugs
- V 16.1 updates:



MedDRA Preferred Terms Grouped according to Draft WHO Medication Errors Classification

Prescribing

Circumstance or information cap
leading to medication erro
Documented hypersensitivit
administered drug
Drug administered to patien
inappropriate age
Drug name confusion
Drug prescribing error
Incomplete course of vaccina
Intercepted drug prescribing
Intercepted medication err
Labelled drug-disease interac
medication error
Labelled drug-drug interaction m
error
Labelled drug-food interaction m
error
Medication error
Product dosage form confus
Vaccination error
Product name confusion
Product substitution issue
Drug chemical incompatibil
Drug physiologic incompatib
Drug therapeutic incompatib
Contraindication to vaccin
Contraindication to medical tre

Dispensing

Circumstance or information cap
leading to medication erro
Documented hypersensitivity
administered drug
Drug administered to patien
inappropriate age
Drug dispensing error
Drug label confusion
Drug name confusion
Incorrect storage of drug
Intercepted drug dispensing
Intercepted medication err
Labelled drug-disease interac
medication error
Labelled drug-drug interaction m
error
Labelled drug-food interaction m
error
Medication error
Product dosage form confusi
Vaccination error
Product label confusion
Product name confusion
Product label on wrong product
Product substitution issue
Incorrect product storage
Drug chemical incompatibility
Drug physiologic incompatibility
Drug therapeutic incompatibility
Contraindication to vaccine
Contraindication to medical treatment

Preparation

Circumstance or information ca
leading to medication er
Drug label confusion
Drug name confusion
Expired drug administer
Incorrect drug dosage fo
administered
Incorrect storage of dru
Intercepted medication e
Medication error
Poor quality drug administ
Product dosage form conf
Vaccination error
Wrong technique in drug usag
Product label confusio
Product name confusio
Product label on wrong pr
Incorrect product storag
Drug chemical incompatib
Product expiration date is

Administration

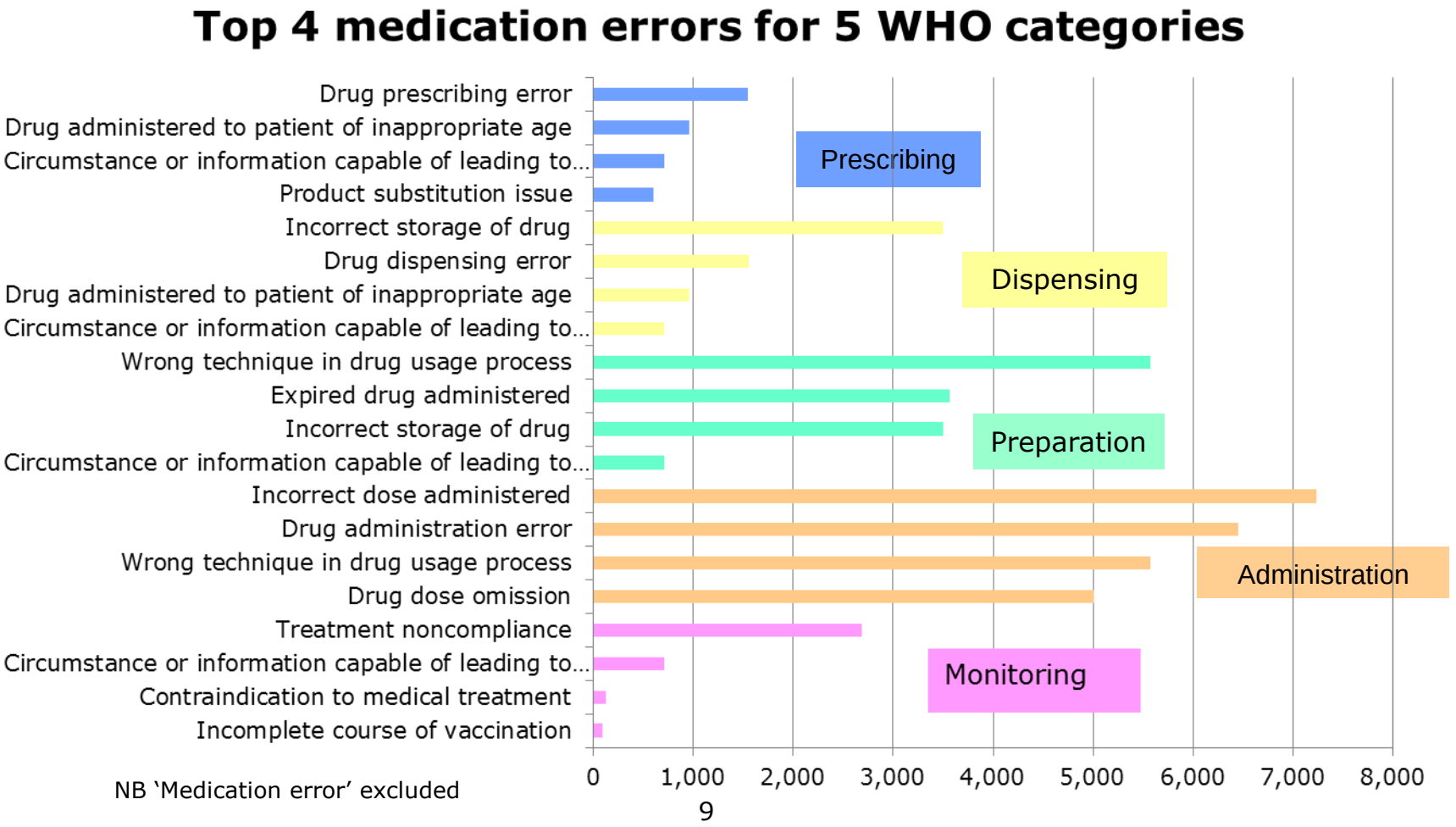
Circumstance or information capa
leading to medication error
Counterfeit drug administere
Drug administered at inappropriat
Drug administered in wrong dev
Drug administered to patient of inapp
age
Drug administration error
Drug dose omission
Drug label confusion
Drug name confusion
Expired drug administered
Inappropriate schedule of drug administration
Incomplete course of vaccination
Incorrect dose administered
Incorrect dose administered by device
Incorrect drug administration duration
Incorrect drug administration rate
Incorrect drug dosage form administered
Incorrect route of drug administration
Intercepted drug administration error
Intercepted medication error
Medication error
Multiple use of single-use product
Poor quality drug administered
Product dosage form confusion
Vaccination error
Wrong drug administered
Wrong technique in drug usage process
Product label confusion
Product name confusion
Treatment noncompliance

Monitoring

Circumstance or information capable of leading to medication error
Incomplete course of vaccination
Medication error
Treatment noncompliance
Contraindication to medical treatment

MedDRA (15.1) HLGT Medication Errors minus HLT Overdose
MedDRA (15.1) HLGT Product Quality Issues

Top 4 medication errors according to draft WHO medication errors classification



NB 'Medication error' excluded

Use of plain medication error term

- Overuse of LLT ‘Medication error’
- Underuse of more specific terms :
  - Vaccine specific term, many are actually vaccine errors
  - Many ‘Medication error’ are errors in dosing/administration/contraindication to medical treatment
  - It is not necessary to code LLT ‘Medication error’ in addition to the more specific terms

Examples of difficult reports to code

- Partial or unsuccessful injection often coded as LLT 'Accidental exposure while administering drug'. However, PT is Accidental exposure to product
  - Drug administration error? Term request for unsuccessful/incomplete injection?
- *Physician had prescribed X instead of Y but as the patient still had tablets of X , unfortunately she had taken both anticoagulant drugs at same time:*
  - Drug administration error?

Examples from NHS England (1)

- *Emergency admission of patient for lithium toxicity in a critical condition. Lithium levels were out of date, the last level was within therapeutic range hence lithium was re authorised. Out-patient appointments had been subject to cancellation hence Lithium not being regularly monitored. At the time of the report patient was being ventilated.*

  - Code: 'Lithium toxicity'
  - New term (v 16.1) for monitoring error : 'Therapeutic drug monitoring analysis incorrectly performed'

Examples from NHS England (2)

- *Patient known to have seizures well controlled on carbamazepine. Ran out of supplies and could not get a repeat prescription or emergency supply and was without medication for 3 days. Went into status and admitted to hospital*

  - Code: ‘Status epilepticus’
  - The supply issue not possible to code

Examples from NHS England (3)

- *91 year old with stage 4 chronic kidney disease on long term aspirin 75mg od. She was then prescribed Naproxen 500mg bd without gastro protection which led to gastric erosion which perforated.*

  - Code: ‘Gastric perforation’
  - Coding for the lack of gastro protection?
    - Condition of SPC to ensure that gastro protection is co-prescribed?
    - Prescribing error? /Dispensing error? Not possible to capture that error was with an omitted medicine not the suspect drugs

Missing concepts not within scope of MedDRA

- Wrong patient (Terms available only at LLT – Promote to PT?)
- Medication errors due to problems with supply/ordering/delivery
- Medication errors due to errors in healthcare system for example discharge medications not explained properly

Overdose/Underdose

- Overdose is considered to be a medication error in MedDRA hierarchy. EMA consider overdose as a separate issue & excluded HLT from the proposed list of medication error terms as presented at the medication error workshop. (include PT 'Accidental overdose'?)
- Prescribed overdose (LLT now promoted to PT)- overdose HLT in HLGT medication errors:
  - EMA would consider prescribed overdose to be off label use
  - Prescribed underdose (LLT now promoted to PT) - maladministration in hierarchy
  - EMA would also consider prescribed underdose to be off label
  - EMA would consider Intentional underdose to be misuse

Medication error or Quality issue

- Example: '*Patient taking warfarin had decreased INR because container contained 2 different medicines*'.
- Quality issue:

– 'Wrong product and correct product in same container'

  - Implies error at which stage? Manufacturing /distribution /pharmacy or patient/carer

- Also needs a corresponding medication error term:
  - 'Drug dose omission'
  - 'Insufficient dosage'

Off label vs medication error

- Example: Drug administered to patient of inappropriate age (medication error) vs Drug use in unapproved population (off label)

- Select LLT based on knowledge of setting of ADR (off label/medication error/misuse)

- **Key message** – follow up if possible when it is unclear if it is an off label use, product quality issue or medication error

Misuse for illegal purposes

- RMP now requires monitoring of potential for misuse for illegal purposes.
- Misuse for illegal purposes has the additional connotation of an intention of misusing the medicinal product to cause an effect in another person. This includes, amongst others: the sale, to other people, of medicines for recreational purposes and use of a medicinal product to facilitate assault.
- *Mother gave child her opiate medicine for pain*- should not be coded as ‘Drug diversion’ but as ‘Intentional drug misuse’
- *Patient swallowed transdermal opiate patch* – should not be ‘Drug diversion’ or ‘Incorrect route of drug administration’ (ME) but LLT ‘Intentional use by incorrect route’ (PT intentional drug misuse)

Drug diversion/Chemical submission

- Example: '*Took street diazepam*'
  - Code: Drug diversion

- Example: *'Female drugged, assaulted and suffered memory loss'*
  - Code : Chemical submission (+assault and memory loss)

- Chemical submission concept not included in the drug abuse SMQ as it is an illegal misuse but users may wish to add to internal search strategies

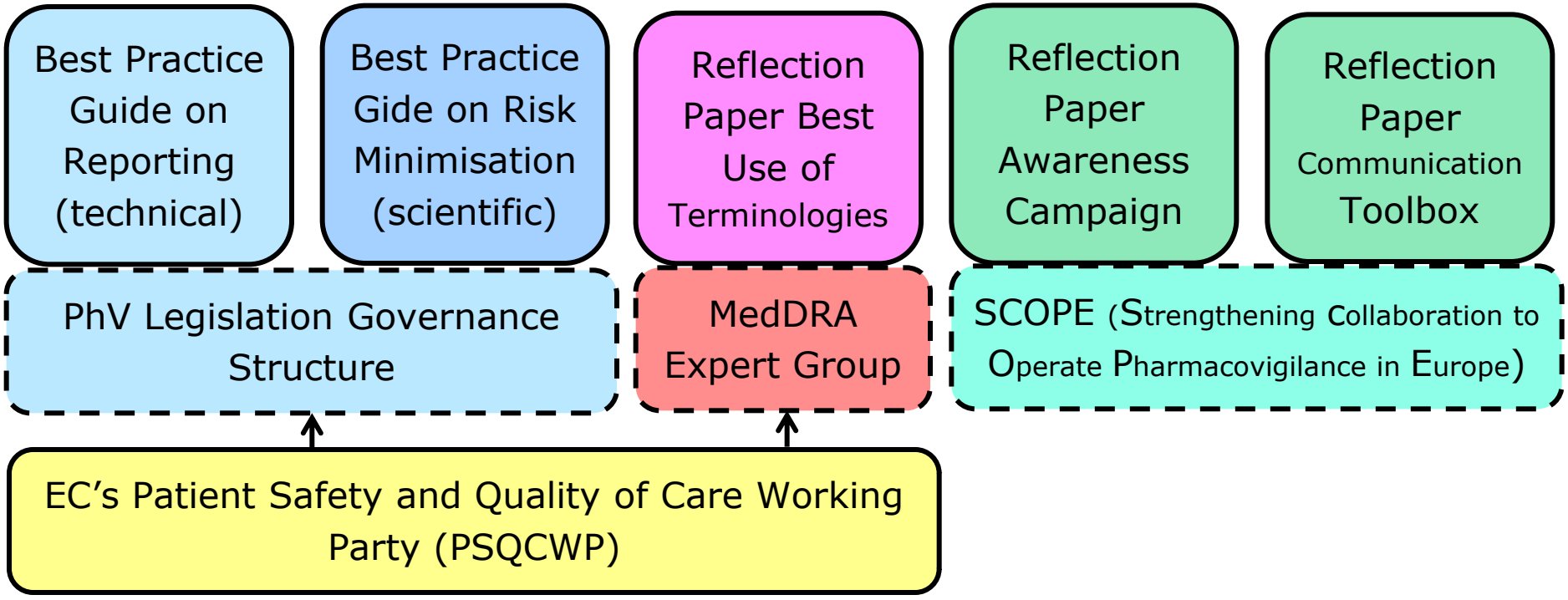
Occupational Exposures – PTC

Reported	LLT Selected	Comment
Physical therapist developed a photosensitivity rash on hands after exposure to an NSAID-containing pain relief cream that she applied to a patient	Occupational exposure to drug Exposure via skin contact Photosensitive rash	
Pathologist chronically exposed to formaldehyde developed nasopharyngeal carcinoma	Occupational exposure to toxic agent Nasopharyngeal carcinoma	Exposure to formaldehyde is a known risk factor for this type of malignancy
Nurse splashed injectable drug in her own eye resulting in excessive tearing	Inadvertent exposure to drug Excess tears	An additional term for occupational exposure – e.g., LLT *Occupational exposure to drug* – could also be selected, if applicable to regional requirements

**Occupational exposure may be chronic or an acute/accidental exposure such as the example of nurse splashing drug in her eye. The term 'Inadvertent exposure to drug' is a medication error- EMA perspective we would like also an occupational term in these types of report.

Proposed deliverables and frameworks for MEs

The proposed deliverables and frameworks are subject to further discussions with the EU regulatory network.



Next steps

- The Agency in collaboration with the European Commission and the EU regulatory network will further discuss the proposed deliverables;
- A prioritised implementation plan will be made public end 2013;
- Implementation of deliverables planned over 24 month (2014-2015)

Thank you

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