

Approaches for Handling Special Situations using MedDRA

Manoj Kumar

Manager Pharmacovigilance and Sr. Safety Scientist

Disclaimer

- The views expressed in this presentation are my personal views and do not represent any official Regulator or any Company position (including my employer).
- The workshop is wholly fictional and is not based on any real-life clinical study or drug development activities. The drug described is not representative of any specific drug in development or on the market.
- The purpose of the exercise/ workshop is for discussion only.

Acknowledgements

- MedDRA MSSO
- ICH

Outline / Agenda of the session

- Identifying a 'Special Situation'
- How to apply MTS:PTC, in order to handle 'Special Situations'
- Workshop covering examples of several 'Special Situation' types

What is a Special Situation?

Special Situations are non-standard medical conditions that provide valuable information (e.g. clinical, safety) about a medicinal product, even when they don't occur in association with an adverse event or medical condition; therefore should be recorded/ reported/ monitored for:

- complying with regulatory guidelines (e.g. ICH, FDA, EMA)
- Meeting protocol specific requirements
- the continuous benefit-risk assessment of medicines



Special Situations

- Exhaustive list:
 - Overdose
 - Drug Abuse
 - Misuse
 - Off Label Use
 - Occupational Exposure
 - Lack of Therapeutic Efficacy
 - Medication Error



Regulatory background

GVP Module VI section **VI.B.6 Special Situations** includes guidance on the following scenarios:

- Use of a medicinal product during pregnancy or breastfeeding.
- Use of a medicinal product in a paediatric or elderly population.
- Reports of overdose, abuse, off label use, misuse, medication error or occupational exposure.
- Lack of therapeutic efficacy.

MedDRA Concepts

Concept	Intentional?	By Whom?	Therapeutic Use?	Additional Sections in MTS:PTC 4.16
Misuse	Yes	Patient/consumer	Yes*	3.16.1
Abuse	Yes	Patient/consumer	No	3.16.2
Addiction	Yes	Patient/consumer	No	3.16.3
Medication error	No	Patient/consumer or healthcare professional	Yes	3.15
Off label use	Yes	Healthcare professional	Yes	3.27

* Definitions of misuse may not always include the concept of therapeutic use; misuse may be similar to the concept of abuse in some regions.

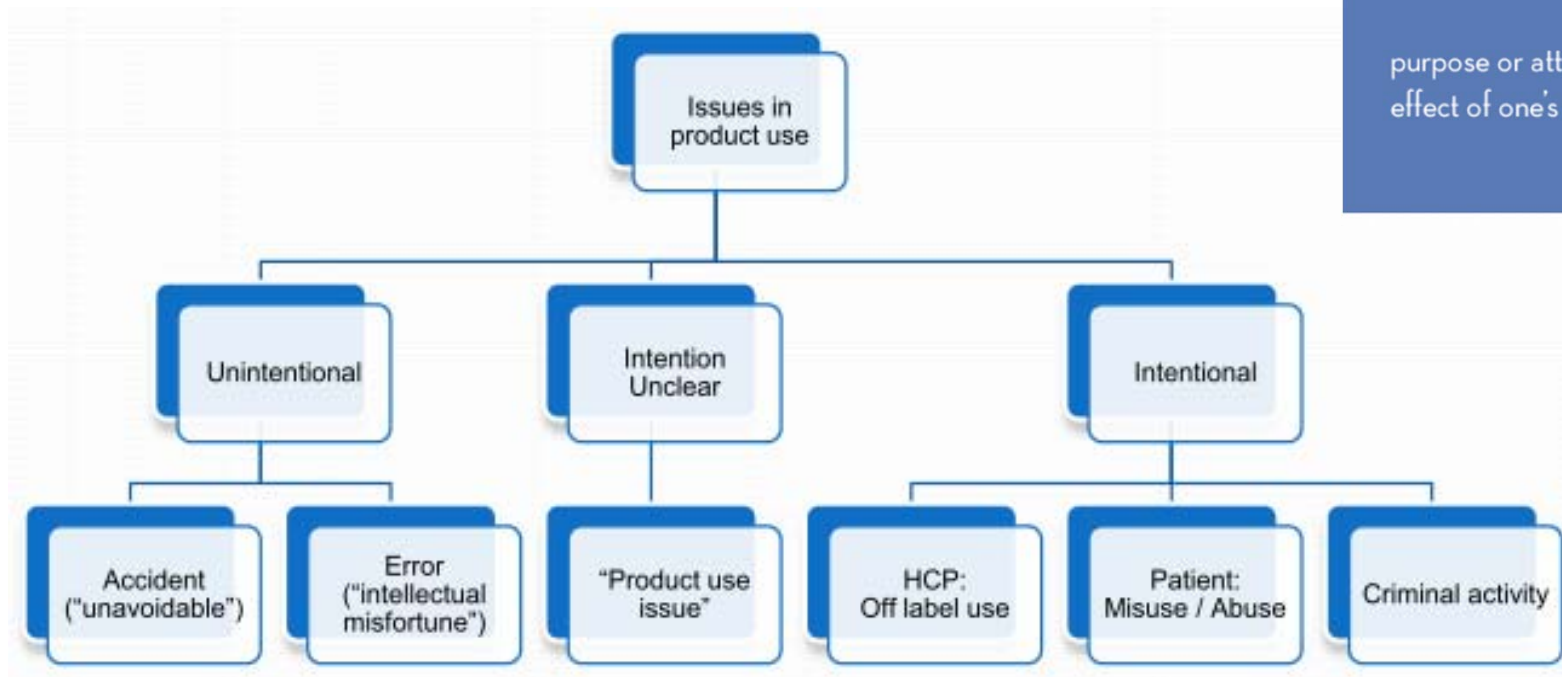
Key to some concepts

in·ten·tion

[in-ten-shuhn]

-noun

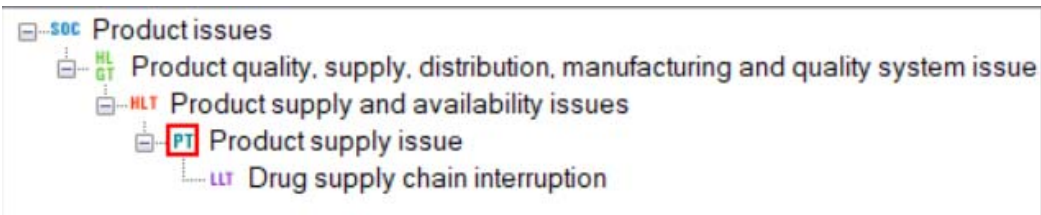
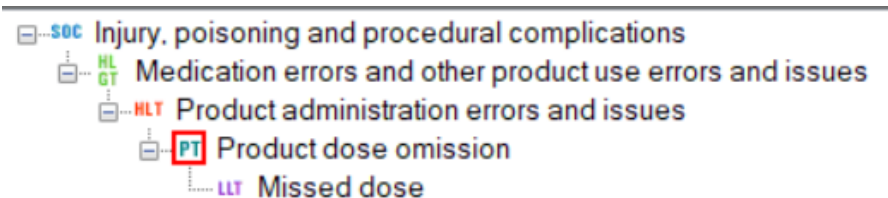
purpose or attitude toward the effect of one's actions or conduct





Product Availability

- “My husband missed a dose as the pharmacy was out of stock”
- “Patient missed doses as the delivery got lost and re-ordering took several days”



Patient Compliance

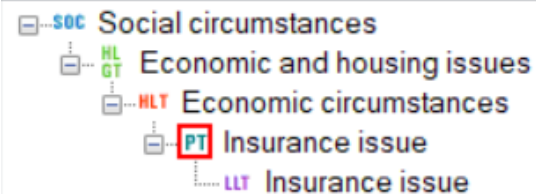
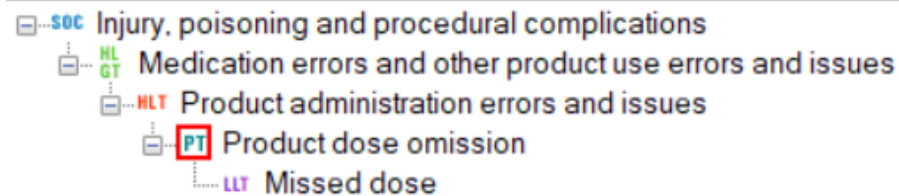
“Patient missed doses as he wanted to go on vacation and **didn’t want to carry** the home-infusion kit in the luggage. He was aware that he was **not following doctor’s instructions.**”

- ☐--SOC Injury, poisoning and procedural complications
 - ☐--HL
GT Off label uses and intentional product misuses/use issues
 - ☐--HLT Intentional product use issues
 - ☐--PT Intentional dose omission
 - LLT Intentionally missed dose

- ☐--SOC General disorders and administration site conditions
 - ☐--HL
GT Therapeutic and nontherapeutic effects (excl toxicity)
 - ☐--HLT Therapeutic and nontherapeutic responses
 - ☐--PT Treatment noncompliance
 - LLT Treatment noncompliance

Healthcare System Issues

“Patient could not receive the treatment due insurance issues”.



Off label use - Indication

- If a medical condition/indication is reported along with “off label use”, the preferred option is to select **terms for the medical condition/ indication and off label use**.
- Alternatively, select a term for the medical condition/ indication **alone**. Select LLT *Off label use* alone **only** if it is the only information available.

MTS:PTC (v4.16)

Off label use - Indication

“Drug indicated for use in adults used off label to treat a 6 year old child”

☐--SOC Injury, poisoning and procedural complications
 ☐--HL
 ☐--GT Off label uses and intentional product misuses/use issues
 ☐--HLT Off label uses
 ☐--PT Off label use
 LLT Off label use

☐--SOC Injury, poisoning and procedural complications
 ☐--HL
 ☐--GT Medication errors and other product use errors and issues
 ☐--HLT Product administration errors and issues
 ☐--PT Product administered to patient of inappropriate age
 LLT Adult product administered to child

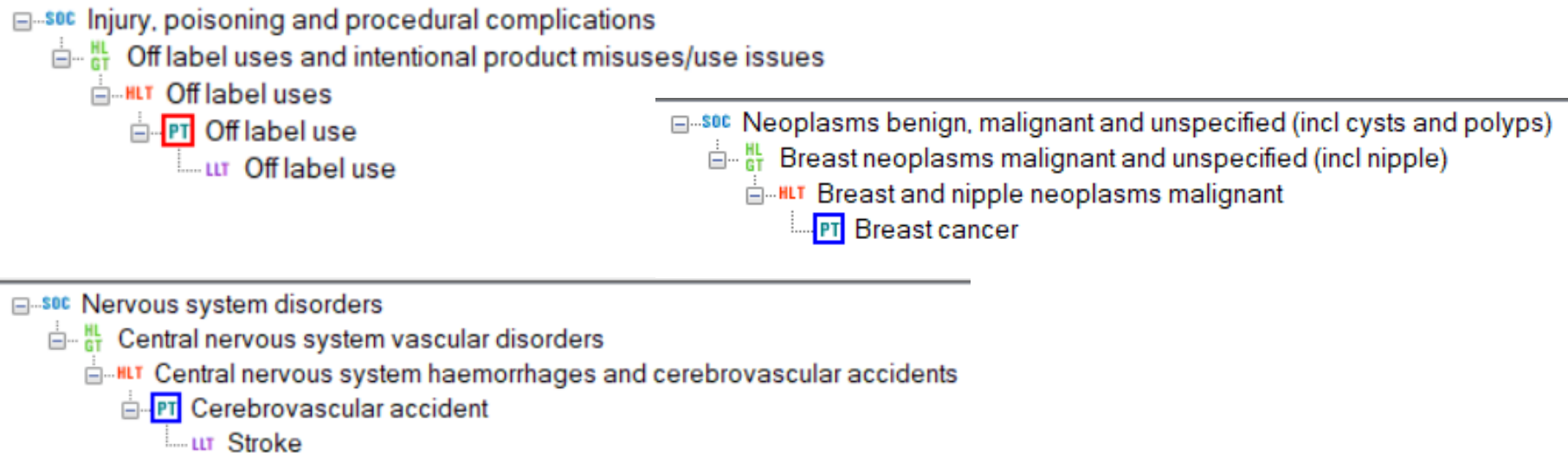
Off label use – Indication (when reported with an AR/AE)

- If an AR/AE occurs in the setting of off label use for an medical condition/ indication, the preferred option is to select a term for off label use, **and** a term for the medical condition/indication in addition to a term for the AR/AE.
- Alternatively, select a term for the medical condition/ indication and a term for the AR/AE.

MTS:PTC (v4.16)

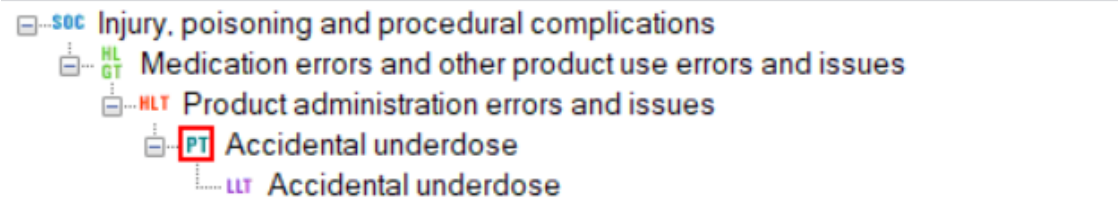
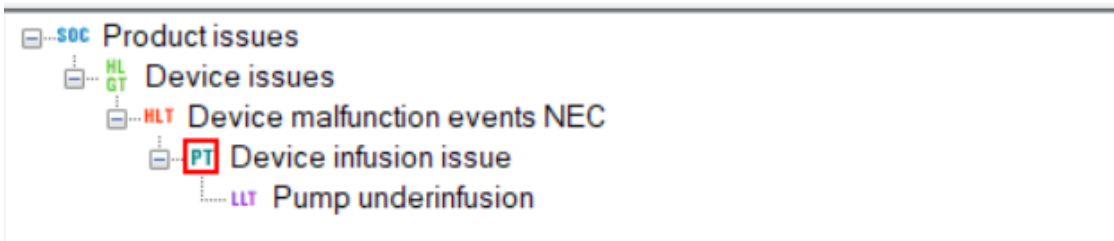
Off label use – Indication (when reported with an AR/AE)

“Patient received drug X for breast cancer and experienced a stroke”



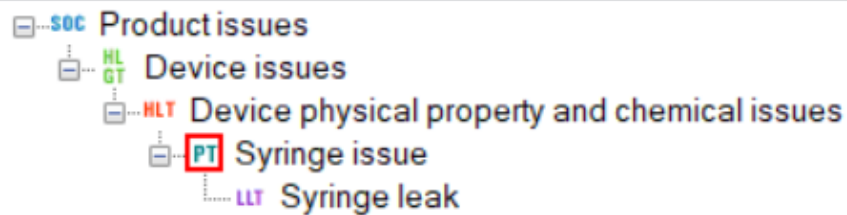
Quality Issue

“Patient received less than the prescribed dose as the pump had a defect”



Quality Issue..

“The vaccine was leaking through the barrel of the plunger”



Occupational exposure & Error

“Nurse got solvent in the eye as she had difficulties using the reconstitution kit”

☐--SOC Injury, poisoning and procedural complications
☐--HL
☐--GT Exposures, chemical injuries and poisoning
☐--HLT Occupational exposures
☐--PT Occupational exposure to product
☐--LUT Occupational exposure to product via eye

☐--SOC Injury, poisoning and procedural complications
☐--HL
☐--GT Medication errors and other product use errors and issues
☐--HLT Medication errors, product use errors and issues NEC
☐--PT Device difficult to use
☐--LUT Device difficult to handle

Identifying Multiple Errors

“My physician always prescribes drug A for me as I am allergic to drug B, which is much cheaper. The holiday fill-in didn’t check my files and wrote drug B down, which I and the pharmacist didn’t recognize. Nearly died from an anaphylactic shock when I took it.”

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[-] soc Injury, poisoning and procedural complications
  [-] hl gt Medication errors and other product use errors and issues
    [-] hlt Product monitoring errors and issues
      [-] pt Documented hypersensitivity to administered product
        [-] llt Documented allergy to administered drug
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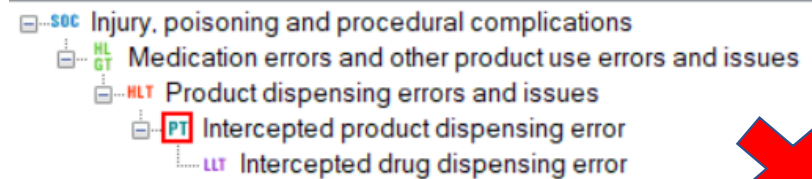
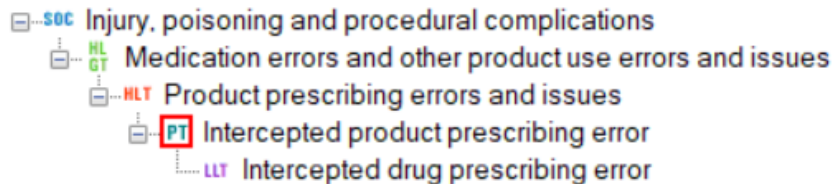
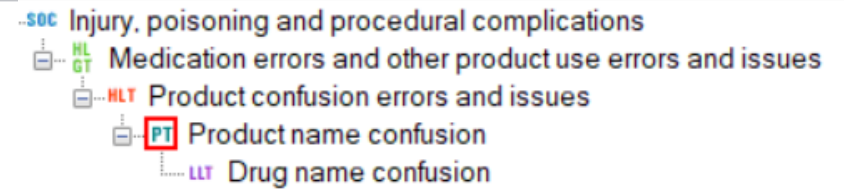
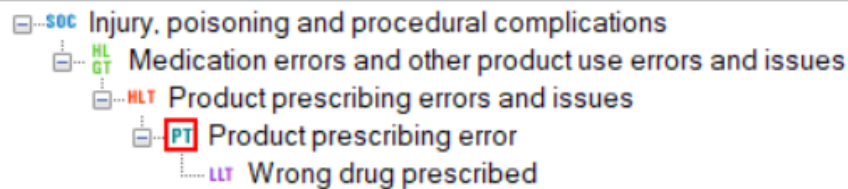
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[-] soc Injury, poisoning and procedural complications
  [-] hl gt Medication errors and other product use errors and issues
    [-] hlt Product dispensing errors and issues
      [-] pt Product dispensing error
        [-] llt Drug dispensing error
```

```
[-] soc Injury, poisoning and procedural complications
  [-] hl gt Medication errors and other product use errors and issues
    [-] hlt Product prescribing errors and issues
      [-] pt Contraindicated product prescribed
        [-] llt Contraindicated drug prescribed
```

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[-] soc Immune system disorders
  [-] hl gt Allergic conditions
    [-] hlt Anaphylactic and anaphylactoid responses
      [-] pt Anaphylactic shock
        [-] llt Anaphylactic shock
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Identifying Multiple Errors

“A patient was accidentally prescribed drug X. Because the names of drug X and drug Y were similar, the pharmacist thought there might have been an error. Prior to dispensing, the pharmacist rang the physician, who confirmed the error, which was intercepted. The patient then received the correct drug.”



Ambiguous Verbatim

- “Difficulty with needle insertion”
- LLTs
 - Needle issue?
 - Device difficult to use?
 - Wrong injection technique?
 - Poor venous access?
 - Infusion site induration?
 - ...
 - **Unevaluable event?**

Any questions?





Acknowledgements

- MedDRA MSSO
- ICH
- PAREXEL

