

Product Quality & Medication Error Terms – Identify Issues for PtC MedDRA Term Selection

EU Informal MedDRA User Group
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Topic Objectives

- Experience and practice sharing
 - Medication Error (ME)
 - Product Quality Issues (PQI)
 - Challenges encountered with product complaints and use of ME & PQI terms
- Identify practical commonalities
- Seek help from ICH PtC MedDRA Term Selection EWG for future updates/guidance

Medication Error vs. Product Quality Issues

Medication Error

- Expanded since MedDRA version 8.0
- *MedDRA Introductory Guide*
 - “Injury, poisoning and procedural complications” SOC
 - Definition in Appendix B, MedDRA Concept Description since version 9.0 – **rich in explanations of the interpretations & uses**
- *PtCs MedDRA Term Selection*
 - Section 3.15 – **elaborate with explanations and helpful examples**

Product Quality Issues

- Introduced into MedDRA version 12.0
- FDA proposed terms (see next slide)
- *MedDRA Introductory Guide*
 - “General disorders and administration site conditions” SOC
 - Definition in Appendix B, MedDRA Concept Description – **need more definitions**
- *PtCs MedDRA Term Selection*
 - Planned (Oct 2010?) - **need explanations with examples**

FDA intentions for Product Quality Terms

- One terminology for food & medical product quality
 - e.g. contamination, mislabelling & other quality issues
 - product quality reports: lay & medical sources
- Identify real time health hazards
- Detect quality problems and post marketing trends
- May lead to recalls or manufacturing process changes

Use of ME & PQI @ Lundbeck ?

- New and complex areas
- Intended use of Medication error term as flagging for RMP potential updates

Puzzles: ME or PQI ?
Internal decision for
case entry to safety vs.
QA databases

Challenging distinction
between Product Quality
Issues & Medication Error
terms, e.g. PTs: “**Drug
Label Confusion**” (ME term)
vs. “**Product Label
Confusion**” (PQI term)

Challenging distinction within
Product Quality Issues terms,
e.g.

HLTs: “**Product physical
issues**” vs.

“**Product quality issues NEC**”
– easily misinterpreted



Use of ME & PQI @ Lundbeck (cont)

- “Train the Trainer” Practice
 - Safety Advisors & Safety Data Managers
 - Quality Assurance, incl. Qualified QA Specialist
- References used i.e.
 1. *Introductory Guide*
 2. *PtC MedDRA Term Selection*
 3. Old webinar training material with updates basing on latest version of MedDRA



The Use of Medication Error Concepts in MedDRA

2006
MSSO

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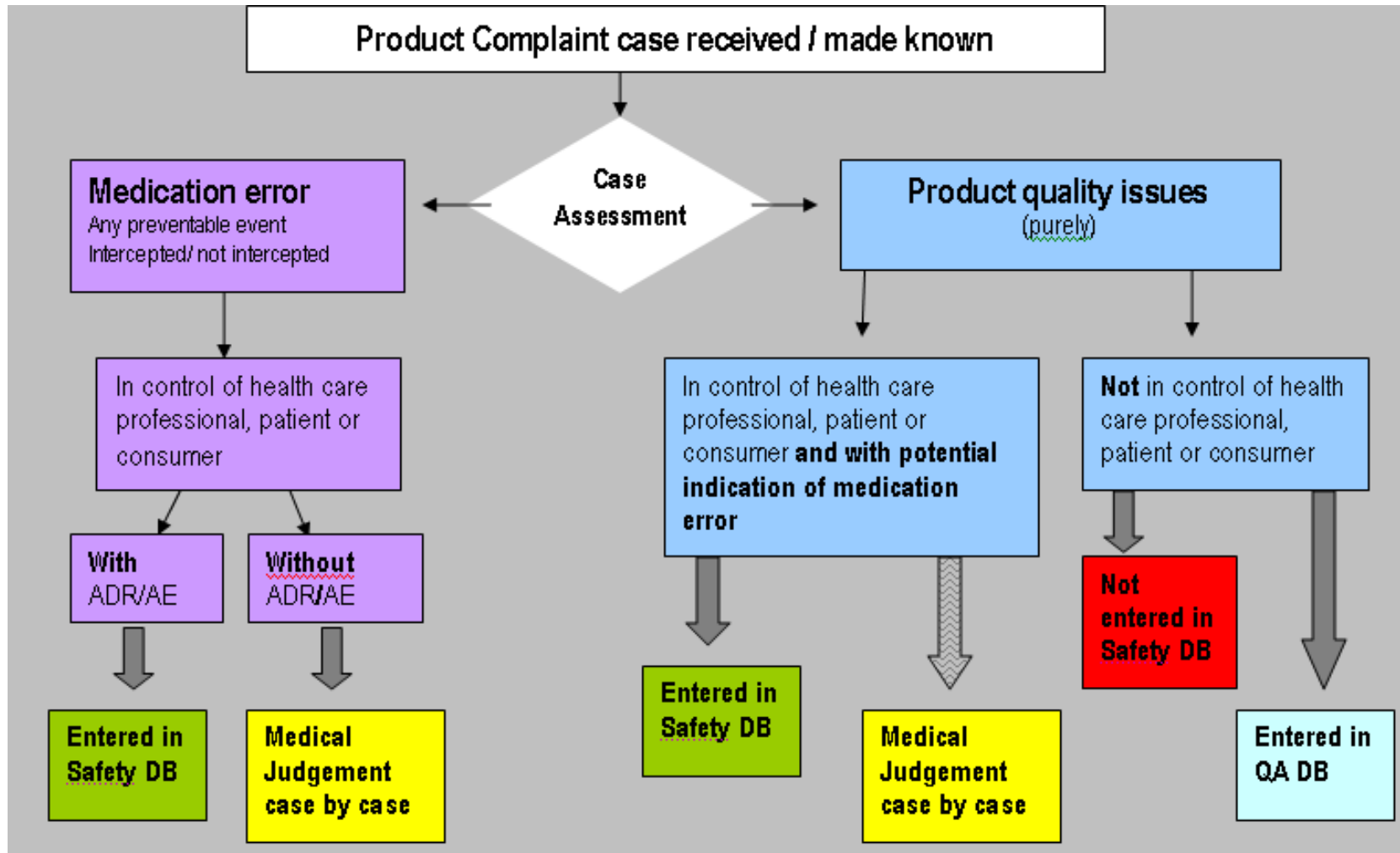


Judy McMeekin, Pharm.D.

Use of ME & PQI @ Lundbeck (Cont)

- Seek guidance from
 - Experienced peer
 - MSSO Help Desk (MSSO physicians very helpful)
- Weekly Safety Advisor meeting – review all cases, especially cases coded with “Medication Error” terms
- Monthly review of product complaint cases by the QPPV Manager – discussion with Qualified person from QA – PQI can lead to “Potential ME”
- Submission of CR, definitions and questions for future help from PtCs MedDRA Term Selection document

Lundbeck **Debated** Flow Chart for Complaint Cases Assessment in Global PV Centres



GSK Practice & Use of ME vs. PQI Terms

- To date no issues with coding
- Coding as reported, assisted by extensive synonym list and autoencoder
- Medical advice available as required
- Safety reviews are irrespective of whether AE is classified as medication error or product quality.
 - Reviews by product specialist
 - Twice weekly targeted review (alerts specific for product)
 - Monthly review – all PTs reported (includes med error and product quality/complaint)

GSK: Use of PQI PTs to date

(all products, incl consumer health)

- Failure of child resistant mechanism
 - Medication residue
 - Product colour issue
 - Product counterfeit
 - Product deposit
 - Product friable
 - Product label confusion
 - Product solubility abnormal
 - Product tampering
 - Product odour abnormal
 - Product taste abnormal
 - Medication residue
 - Product quality issue
- Verbatims include*
- *X gum stuck to teeth,*
 - *change in texture of inhaled Y,*
 - *tablet stuck to roof of mouth,*
 - *cream was liquid,*
 - *clothing stains from topical product,*
 - *product did not agree with body,*
 - *use of Z rearranged system*

GSK: use of “Product label” PTs

- Single report of “Product label confusion”. Consumer says shampoo label not clearly written.

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 - Linda Kim-Jung, Pharm.D.
 - Judy McMeeekin, Pharm.D.

- **Question & Answer**

Summary and User Recommendations

- Use
 - “*MedDRA Introductory Guide*” including “*Appendix B*”
 - “*ICH PtCs MedDRA Term Selection*”
- Study well descriptions related to these two areas
- Contact MSSO Helpdesk
 - Change request
 - Questions
 - Definitions to be added to “*Appendix B*”
 - Guidance with “**Preferred option**” (if relevant) for Product Quality Issues - update to “*ICH PtCs MedDRA Term Selection*” (expected October 2010)