EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Proposal for communicating on measures to prevent medication errors

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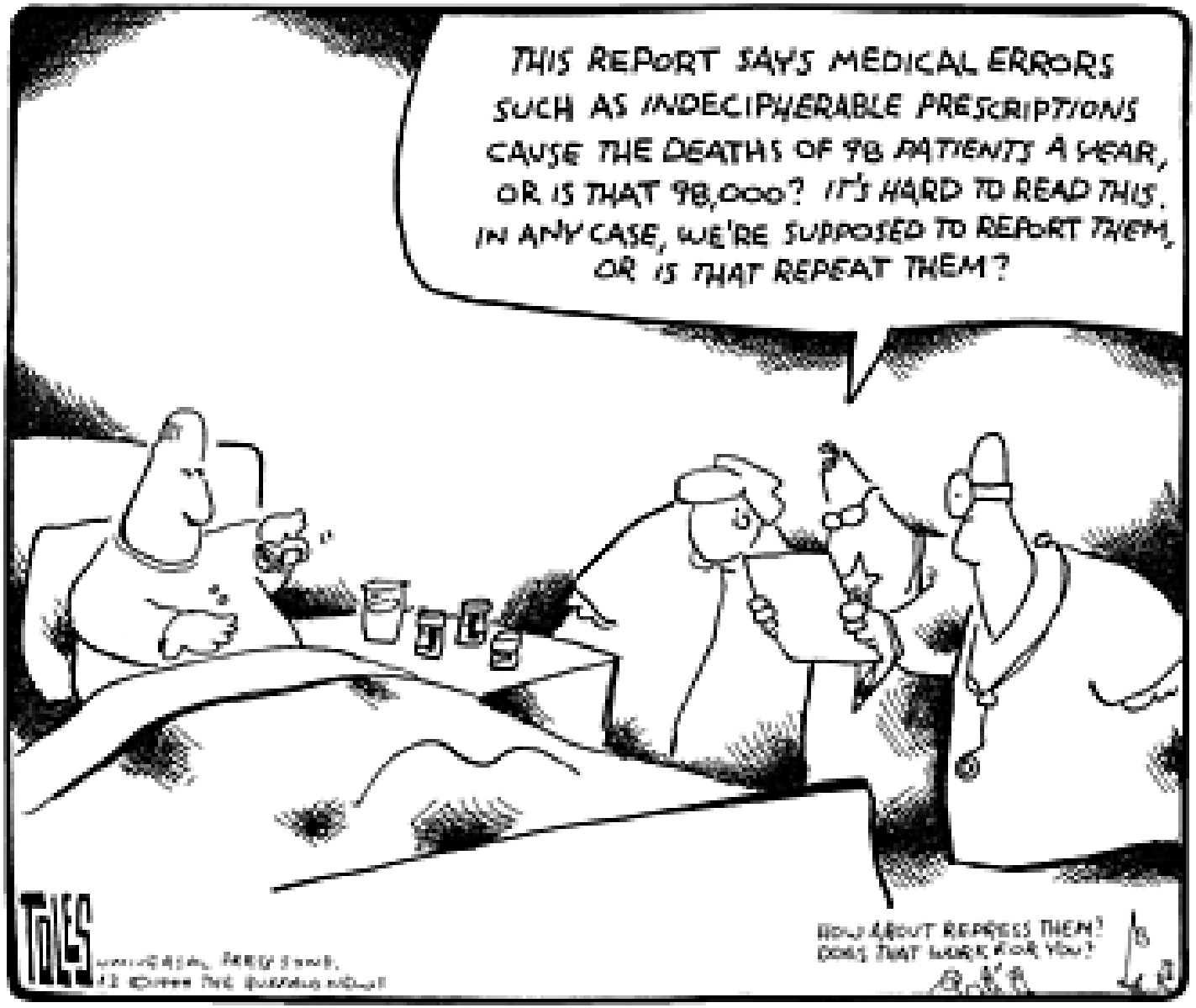
What is a medication error – examples

- 3 patients died due to the cancer medicine Velcade accidentally being given intrathecally instead of by the intended intravenous route.
- Reconstitution errors with the cancer medicine Jevtana have led to overdoses that were 15 % to 20% higher than the prescribed dose.



What is a medication error

- "any unintended error in the prescribing, dispensing or administration of a medicinal product while in the control of the healthcare professional or patient."
- 4 categories: wrong medication, wrong dose (including strength, formulation, amount), wrong route of administration, wrong patient
- Can lead to adverse drug reactions with negative outcomes for patients and significant financial cost implications to healthcare systems.

The impact of medication errors

- Medication-error rates in EU:
  - **Ambulatory care**: 7.5% at prescription, 0.08% at dispensing
  - **Hospital care**: 0.3–9.1% at prescription, 1.6–2.1% at dispensing
- Major public-health burden - estimated annual cost: 4.5 - 21.8 billion € (World Alliance for Patient Safety 2010)
- 18.7 - 56% of all adverse drug events among hospital patients result from medication errors that would be preventable

Medication errors are preventable

- All parts of healthcare system have important role to play in preventing medications errors.
- In EU, assessment of a medicine's potential to cause a medication errors is part of marketing authorisation evaluation
- This includes measures to reduce risk: routine or additional.

Routine risk minimisation

Routine risk minimisation involves the use of the following tools:

- the summary of product characteristics (SmPC)
- the package leaflet
- the labelling
- the pack size and design
- the legal (prescription) status of the product

Additional risk minimisation measures

- educational programme;
- controlled access programme;
- other risk minimisation measures such as patient alert cards; alerts on/in the packaging; pregnancy prevention programme and DHPCs.

Importance of reporting medication errors

- medication errors may still occur
- In order to further prevent them – reporting is essential
- Medication errors go often unreported especially if there is no harm associated.

Strengthened safety monitoring with pharmacovigilance legislation

- Medication errors now included in the definition of a reportable adverse drug reaction
- Now adverse drug reactions resulting from medication errors at EU level to be reported.
- Pharmacovigilance and Risk Assessment Committee (PRAC) - dedicated committee

Communication

- Key in tackling medication errors
- Increasing proactive and effective communication at EMA on medication errors is expected to:
  - increase public awareness and recognition of medication errors;
  - contribute to the safe use of medicines;
  - promote the reporting, discussion, understanding and prevention of medication errors ;

EMA communication practice

- Review of EMA communication practice on medication errors following recent cases, medication errors workshop and other initiatives around medication errors

Current communication practice

- No consistent communication on medication errors in the past
- Q&A in case of medication errors with Velcade
- No communication for Macugen

Rationale for communicating on medication errors

- Part of safety communication fulfilling the objectives of pharmacovigilance
- EMA communication is additional source of information and complementary to other communication tools (DHPCs)
- Considering patients' role in preventing MEs there is an argument for increasing public awareness
- Requested by HCPs in this field

Proposal

- Routinely communicate when:
  - ➢ additional risk minimisation measures are recommended by EMA to reduce risk of medication error; or
  - ➢ a DHPC has been agreed at EU level
- Communication in format of existing safety communication

Examples for communication

- Included in pack
- Format similar to other safety communication:

➢ General description of error and measures to prevent future errors

➢ Dedicated section with recommendations to patients and HCPs

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Medication error prevention

Risk of dosing error with new high strength Humalog (insulin lispro) 200 units/ml

Humalog 200 units/ml should only be given in the prefilled pen (KwikPen)

Humalog, a diabetes medicine containing insulin lispro, will now be available in a strength (200 units/ml) that is higher than the already existing strength of 100 units/ml. To reduce the risk of overdose which could result from incorrect use the EMA is alerting patients and healthcare professionals of the strength and the risk minimisation measures in place.

For most insulins the highest strength is 100 units/ml. The higher strength formulation meets a medical need for patients requiring higher dose insulin, such as overweight patients. As there is a ri of overdose which could result from incorrect use, the EMA recommended that educational material be distributed to healthcare professionals expected to treat or dispense medicines to patients with diabetes, aimed at raising awareness about the higher strength of Humalog and providing informati on the safe use of Humalog. In addition, the Agency recommended that patients receive training through their doctors as well as suitable information on how to use Humalog correctly.

Information to patients and carers

- Humalog is already available as 100 units/ml (as a solution for injection in pre-filled pen, vials a cartridges) and will now be available as a solution for injection in a pre-filled pen in a higher strength of 200 units/ml. Humalog 100 units/ml labels and packaging are white, while the Huma 200 units/ml pen label and packaging are dark grey. The Humalog 200 units/ml pen label and packaging display the strength in yellow to clearly highlight the higher strength.
- Humalog 200 units/ml should only be administered using the Humalog 200 units/ml pre-filled pe (KwikPen).
- Insulin must never be transferred from the Humalog 200 units/ml KwikPen to a syringe or insulin pump for administration. Doing so can result in severe overdose.
- The pen device can be set to deliver a selected dose, and has a dose-counter window that shows the exact dose in units that will be delivered. Please make sure that the dose displayed matches the dose prescribed. It is not recommended to count audible clicks to determine the dose to be injected.
- You will be provided with information on the safe use of Humalog and your doctor or nurse will train you on how to use Humalog correctly.
- Always check the packaging and dispensing label before every injection to ensure you have the correct insulin.
- Should you have any questions, speak to your doctor or pharmacist.

Information to healthcare professionals

- Healthcare professionals must be aware that Humalog is now available in a higher strength of 200 units/ml. It should only be administered using the Humalog 200 units/ml pre-filled pen (KwikPen). Humalog 100 units/ml labels and packaging are white, while the Humalog 200 units/ml pen label and packaging are dark grey. The Humalog 200 units/ml pen label and packaging display the strength in yellow to clearly highlight the higher strength.
- Humalog 200 units/ml should only be administered using the Humalog 200 units/ml pre-filled pen (KwikPen).
- Insulin must never be transferred from the Humalog 200 units/ml KwikPen to a syringe or insulin pump for administration. Doing so can result in severe overdose.
- When prescribing Humalog, the strength should always be included on the prescription.
- The pen device has a dose-counter window that shows the exact dose dialled in units. Dose conversion is not required when transferring patients from one strength of Humalog to another.

More about the medicine

Humalog contains insulin lispro which is a fast-acting insulin solution for the treatment of diabetes in adults. Humalog 100 units/ml has been authorised in the EU since 30 April 1996.

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Medication error prevention

Risk of dosing error with Macugen pre-filled syringe

Excess volume must be expelled before administering the medicine

Following dosing errors with Macugen, the European Medicines Agency is reminding healthcare professionals of the steps that need to be taken when preparing Macugen for intravitreal injection (injection into the eye).

Macugen (pegaptanib), used to treat wet age-related macular degeneration, is supplied in a pre-filled syringe. Before Macugen is administered as an intravitreal injection, the excess volume of the medicine must be expelled from the syringe, according to the preparation instructions contained in the Summary of Product Characteristics (SmPC). Two cases have been reported (in a clinical trial and in clinical practice) where an excess volume was injected, resulting in elevated intra-ocular pressure (increased pressure inside the eye) that required treatment (anterior chamber paracentesis).

The SmPC, patient leaflet and packaging have been updated to ensure that the instructions are fully clear.

Information to healthcare professionals

- To ensure the safe intravitreal injection of Macugen, the excess product volume must be expelled from the pre-filled syringe in advance of administration. This is part of the preparation procedure described in the SmPC.
- The SmPC contains illustrated instructions on how to expel the excess product volume. This preparation procedure should always be followed before administering Macugen.
- The correct dose of Macugen to be injected is 90 microlitres.
- A letter will be sent out to healthcare professionals informing them of the importance of expelling excess product volume before administration. The SmPC, patient leaflet and packaging have been updated to ensure the instructions are fully clear.

Information to patients

- Before you receive Macugen, your doctor will prepare the injection by removing some of the medicine from the syringe before giving it to you, to ensure the right amount is injected.
- In case you experience a sensation of raised pressure in the eye or any other adverse reaction after receiving a Macugen injection, contact your doctor.

More about the medicine

Macugen is a medicine used to treat wet age-related macular degeneration. It contains the active substance pegaptanib, and is available in a pre-filled syringe. Macugen has been authorised in the European Union since January 2006.

Preparation & Publication

- To be implemented shortly; currently working on mock-up communication and webpage
- Preparation with involvement of scientific committees, healthcare professional and patient organisations (HCPs/PCOs)
- Dissemination to HCPs and PCOs directly and/or through newsletter
- Public health communication linked to the EPAR page
- Dedicated webpage with listing of communications as well as general information on Agency's activities regarding prevention of medication errors

Conclusion

- New legal provisions and strengthened European safety monitoring system medication errors to reduce the risk of medication errors
- In addition, streamlining communication at EMA on measures agreed to prevent medication errors:

➢ As part of routine safety communication

➢ Expected to contribute to the safe use of medicines by increasing awareness