French National Agency for Medicines and Health Products Safety

MANAGEMENT OF MEDICATION ERRORS ASSOCIATED WITH THE USE OF DELIVERY DEVICES FOR ORALLY INGESTED LIQUID DRUGS – THE FRENCH DRUG AGENCY

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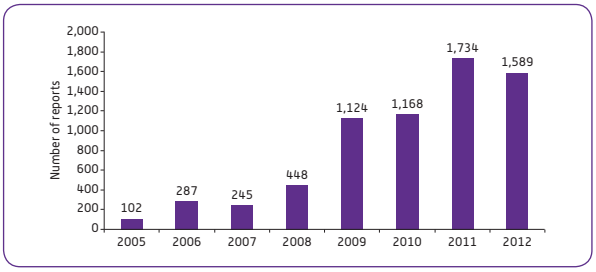
AIM

To quantify and analyse medication errors due to the use of Delivery Devices (DD) of orally ingested liquid drug products (not including homeopathic drugs) and establish recommendations to reduce this risk.

INTRODUCTION

Within the framework of the objectives set by the Public Health Law to reduce drug-related adverse events (adopted in 2004), the National Agency of Medicine and Health Product Safety (ANSM) has set up in 2005 a dedicated unit to collect and manage, in a single location, reports of medication errors (ME) or potential errors related to the packaging, labelling or names of medicinal products, and perform the follow up of those likely to present a risk to Public Health. The "Medication Errors Guichet" enables healthcare professionals to report directly to the Agency, medication errors without adverse reaction or near misses in addition of reports collected from the Pharmacovigilance System. In 2011 and 2012, respectively 1,734 and 1,589 medication errors have been collected.

Figure 1: number of reports of ME collected by the dedicated unit of the French Agency since 2005



Among medication errors reported, some were dosing errors related to the use of delivery devices of orally ingested liquid drug products.

METHODS

- Retrospective analysis of medication errors (risk, near misses and patent) reported in the ANSM medication error database for the period of May 2005 to February 2013.
- Analysis of liquid oral multidosis products authorised and available on the French Market.
- Current recommendations on this topic (Non Urgent Information – NUI to European member states, bibliography).
- French Agency medication errors working group (various experts).

RESULTS

1. MEDICATION REPORTS RECEIVED AT THE ANSM BETWEEN 2005 AND FEBRUARY 2013

Twenty six reports of risk of ME and 109 reports of proven errors resulting in patient administration associated with the use of DD for orally ingested liquid drug products have been identified.

Of the 109 errors, 46% were without an AE, 37% with AE (half serious), 17% with no available information (NAI). A high percentage of patients (94%) belong to the paediatric population, 4% were adults, age was unknown in 2%.

Figure 2: distribution of the places of occurrence for the 109 proven ME and of the persons who gave the medication

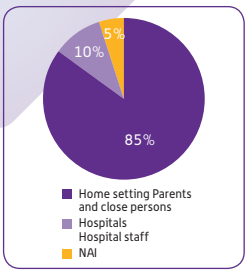
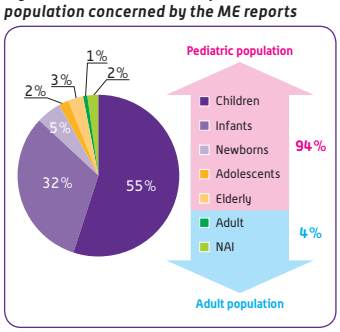


Figure 3: distribution of the patients's population concerned by the ME reports



Two major causes of errors were identified, 38 were directly attributable to DD and 92 attributable to human errors of utilization.

Some of these reports led in the past to corrective measures on a case by case basis at the request of ANSM, e.g. adding a DD when none was available, adding table of equivalence or warnings in the SPC, labelling and leaflet etc.

Figure 4: ME attributable to the delivery device : causes

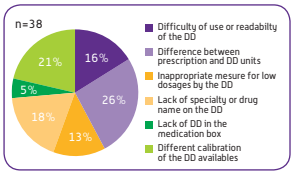
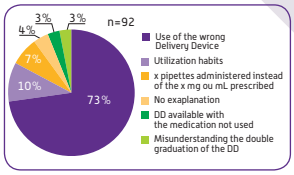
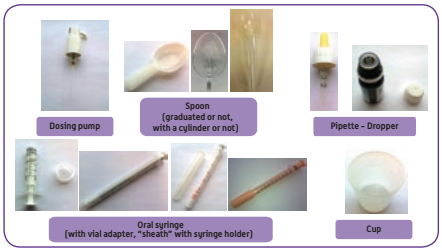


Figure 5: ME attributable to the Human errors : causes



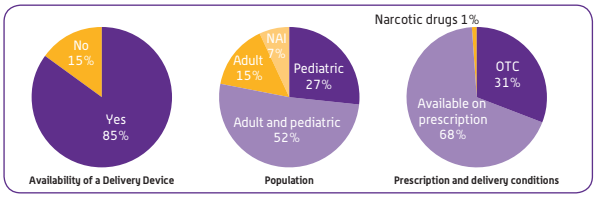
2. ANALYSIS OF THE LIQUID ORAL MULTIDOSIS PRODUCTS AVAILABLE ON THE FRENCH MARKET (SYRUPS, ORAL SOLUTION ETC.)

Figure 6: variety of different Delivery Devices available



The variety of DD is wide. They have the status of medical devices, meaning they need to meet the essential requirements of the 93/42/CEE Directive and be CE marked if necessary.

Figure 7: characteristics of the 410 products available as liquid oral multidosis form



3. CURRENT RECOMMENDATIONS ON THIS TOPIC (NON URGENT INFORMATION TO EUROPEAN MEMBER STATES, BIBLIOGRAPHY)

In order to have information on current recommendations at an European and International level on this topic :

- a Non-Urgent Information (NUI) was sent on February 2013 to European Member States : no specific recommendation have been made,
- an international literature review was conducted in November 2012 : 2 major Guidances have been identified, the FDA's Guidance for Industry "Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products" and the European Medicines Agency's "Guideline on pharmaceutical development of medicines for paediatric use".

4. RISK MINIMISATION MEASURES

The ANSM decided to set up risk minimisation measures in accordance with the experience of healthcare professionals of medication errors working group :

- 17 Practical recommendations to MAH for safer DD (adopted after a step of public consultation on our website);
- Communication to healthcare professionals highlighting the risk of ME related to DD;
- Poster to raise awareness concerning this issue for patients and caregivers: "Don't mix up the cups".

CONCLUSION

This analysis highlights that given the number of products involved and the number of reports, implementing general measures to minimize this kind of medication errors is necessary.

It would be essential to measure the effectiveness of the modifications an the impact to reduce medication errors.