ethanol and benzalkonium chloride. Opportunities for product substitution were defined as EOI-containing formulations for which an EOI-free product was reported in the survey with identical active pharmaceutical ingredient (API), galenic form and strength.

**Results**

Of 31 invited European countries 20 with 115 NICUs responded. A total of 564 trade names (TN) with 53 APIs were used in more than 10% of units. EOI containing formulations (n = 151) were used for 31 APIs, found overall in 363 TNs. Compared to parenteral forms (50/199; 25%), enteral (83/130; 64%) and topical TNs (18/34; 53%) contained EOI more frequently (OR: 95% CI 5.3; 3.3–8.5 and 3.4; 1.6–7.1, respectively). An EOI free substitution was available for 31/50 parenteral (63%), 17/83 enteral (21%) and 3/18 topical (17%) TNs. Overall, 51/151 (34%) TNs with EOI could be replaced; substitution was possible in 92/151 (61%) of cases if the requirement for identical API strength was ignored.

**Conclusions**

EOI-free formulations available on the European market could be used to reduce the number of TNs with EOI by at least a third.

**References**

Abdel-Latif ME et al. Pediatrics 2006
Wachman EM et al. JAMA 2013
Welle-Strand GK et al. Acta Paediatr 2013

**O-099**

**THE IMPACT OF BREASTFEEDING ON THE INCIDENCE AND SEVERITY OF NEONATAL ABSTINENCE SYNDROME**

1K Allergan, 2IN van den Akker. 1Neonatal Intensive Care Unit, University Hospitals Leuven, Leuven, Belgium; 2Intensive Care, Erasmus MC Sophia’s Children’s Hospital, Rotterdam, Netherlands.

**Background and aims**

In light of the current epidemic in the abuse of opioids, a major increase in neonates with neonatal abstinence syndrome (NAS) is likely. Incorporation of breastfeeding as a first pillar of treatment of NAS seems appropriate. We aimed to quantify the impact of breastfeeding on the incidence and severity of NAS.

**Methods**

Pooling of published NAS cohorts, with specific emphasis on the impact of breastfeeding on the incidence (yes/no opioid administration) and duration (duration opioids, duration hospitalisation) of NAS.

**Results**

Three studies [1–3] were retrieved and resulted in a pooled dataset of 400 neonates (218 breastfed, 54.5%). There is a significant reduction in NAS (54 vs 77%), number needed to treat 5–6. The same trends are observed when the duration of opioid treatment (difference -18 to -23 days) or the length of hospital stay (difference -4 to -10 days) are considered.

**Conclusions**

Breastfeeding is associated with a clinical significant reduction on the incidence and the duration of NAS in opioid exposure newborns. Incorporation of breastfeeding as a first pillar of treatment for relieving the NAS symptoms seems to be a very natural, and effective way of addressing this.

**References**

Abdel-Latif ME et al. Pediatrics 2006
Wachman EM et al. JAMA 2013
Welle-Strand GK et al. Acta Paediatr 2013

**O-100**

**RELATIONSHIP BETWEEN ADVERSE DRUG REACTIONS AND OFF-LABEL/UNLICENCED DRUG USE IN HOSPITALISED CHILDREN. EREMI STUDY**

1KA Nguyen, 2Y Mimouni, 3A Lajzouje, 4P Paret, 5S Malk, 6L Milliat-Guitard, 7L El-Amrani, 8C Camallian, 9AM Schott, 10Voi, 11Kassa. 1Neonatal Intensive Care Unit and Neonatology, Hospices Civils de Lyon/Hôpital Femme Mère Enfant, Lyon, France; 2Clinical Pharmacology, Hospices Civils de Lyon/EPICIME/CIC 1407/Hôpital Femme Mère Enfant/UMR 5558/CNRS/Lyon 1 University, Lyon, France; 3Pharmacovigilance Center of Lyon, Hospices Civils de Lyon/Lyon 1 University, Lyon, France

**Background and aim**

To date few studies have shown a significant association between the off-label drug use and adverse drug reactions.

(ADRs). The main aims of this study are to evaluate the relationship between adverse drug reactions and unlicensed or off-label drugs prospectively in hospitalised children and to provide more information on prescribing practice, the amplitude, nature and consequences of unlicensed or off-label drug use in paediatric inpatients.

**Methods**

In this ongoing multi-centre prospective study, the French summaries of product characteristics in Theriaque (a prescription products guide) are being used as a primary reference source for determining paediatric drug labelling. Detection of ADRs is carried out by health care professionals and research groups using a trigger tool and patients’ electronic health records. The causality between suspected ADRs and medication is evaluated using the Naranjo and the French methods of imputability.

Preliminary results for a 6 month period: 40% of the 73 detected ADRs were estimated as severe. 1498 patients have been included.

**Conclusions**

This is the first large multi-centre prospective study in France that evaluates the relationship between adverse drug reactions and unlicensed or off-label drugs in hospitalised children. This study will help to identify the risk factors that could be used to adjust preventive actions in children care, guide future research in the field and increase the awareness of physicians in detecting and declaring ADRs. This study is funded by l’ANSM (French national agency of drug security).

**References**

Abdel-Latif ME et al. Pediatrics 2006
Wachman EM et al. JAMA 2013
Welle-Strand GK et al. Acta Paediatr 2013