SAFETY OF ORAL PARACETAMOL – ANALYSIS OF DATA FROM A SPONTANEOUS REPORTING SYSTEM IN POLAND

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Paracetamol (acetaminophen), active metabolite of phenacetin, probably is the most popular over-the-counter antipyretic and analgesic used in Poland. It is commonly used for the relief of headaches and other minor pains and is a major active ingredient in numerous cold preparations. Post-marketing surveillance using tools such as data mining of spontaneous (passive) reports and investigation of case reports to identify adverse drug reactions are very important in drug safety monitoring. **Aim:** Analysis of safety of oral paracetamol (Paracetamol tablets 0.5 Hasco, Paracetamol oral suspension 120 mg/5 mL). **Material and Methods:** We analyzed data obtained from monitoring of spontaneous reports of adverse effects of Paracetamol Hasco® tablets 0.5 and Paracetamol Hasco® oral suspension 120 mg/5 mL collected by the manufacturer (Hasco-Lek S.A. Wroclaw, Poland) and National Monitoring Center in Warsaw (Krajowy Ośrodek Monitorowania Niepożądanych Działań Leków) in the period from November 2000 to June 2012. The polish system is based on written reports voluntary submitted by professional health care workers mainly. **Results:** A

Total of 45 694 units of Paracetamol Hasco® tablets 0.5 and 6,048,289 units of Paracetamol Hasco® oral suspension 120 mg/5 mL produced by Hasco-Lek S.A. Wroclaw, Poland were marketed during analyzed period. There were 4 spontaneous reports regarding that medications registered in Poland in the analyzed period.

1. A 67 years old woman received 0.5 g of Paracetamol HASCO tablet during post-operative pain management. Rash and itching were observed shortly afterwards.
2. A 21 months old boy weighed 12 kg, developed generalized edema of soft tissues including eyes, face and trunk (angioedema or Quincke's edema) after the boy had been given Paracetamol HASCO suspension (7,5 mL of suspension i.e. 180 mg; 15 mg/kg) for fever on the third day of chickenpox. The edema responded well to steroid treatment.
3. A58 years old woman received 2.0 g of Paracetamol HASCO tablets during post-operative pain management. She complained of itching alone (without rash).
4. A 28 years old woman presented with vomiting of blood (hematemesis) after she had received 4.0 g of Paracetamol HASCO tablets and 200 mg of ketoprofen, an NSAID medication for menstrual pain. She required hospitalization. The adverse effect was the most likely due to ketoprofen, but causative relation with paracetamol can not be excluded completely.

Conclusions: Oral paracetamol forms are a safe medication rarely causing adverse effects. Only a few cases of adverse effects were reported in the 12 years observation period after more than 6 millions of medication units were distributed. It is possible that the existing spontaneous monitoring system of adverse effects in Poland is not sensitive enough to detect all adverse effects, and needs improvement.