Table 1 Comparison between indications reported in summary product characteristics (SPC) and those in the British National Formulary (BNF) of oral paracetamol and pre-dosed spray salbutamol

Drug	SPC*	BNF
Paracetamol, oral suspension (250 mg/5 ml)	<1 year: 2.5 ml (60 mg) every 4–6 h 1–4 years: 2.5–5 ml (60–120 mg) every 4–6 h >4 years: 5–10 ml (120–240 mg) every 4–6 h	1–3 months: 30–60 mg every 8 h 3–12 months: 60–120 mg every 6–8 h 1–5 years: 120–150 mg every 4–6 h 6–12 years: 250–500 mg every 4–6 h 12–18 years: 500 mg every 4–6 h For severe symptoms: 1–3 months: 20 mg/kg as a single dose, then 15–20 mg/kg every 6–8 h 3 months–12 years: 20 mg/Kg every 6 h 12–18 years: 0.5–1 g every 4–6 hours
Salbutamol, pressurised metered-dosed spray (1 puff/ 200 μg)	1–2 puffs up to 4 times/day "…a maximum of 2 puffs at a time are recommended, which should not be repeated for at least 4 hours …"	For acute mild to moderate exacerbations of asthma "give 1 puff every 15–30 seconds up to a maximum of 10 puffs; repeat dose after 20–30 minutes if necessary"

*Information for paracetamol is taken from the SPC of Tachipirina produced by Angelini, and for salbutamol from the SPC of Ventolin produced by Glaxo Wellcome.

A further aspect of OL use in paediatrics is the over-cautious attitude of drug companies in formulating their summary product characteristics (SPC). We have encountered this problem in Italy where, with some drugs, there is an impressive difference between the information given in the SPC and that given in the National Formularies and/or existing guidelines, leading to substantial under-dosage. This situation is clearly demonstrated by two very commonly used drugs, which are often administered independently by parents: paracetamol and salbutamol. These two drugs have been previously found to be among the five drugs most frequently used OL in Europe.[3] We compared the information given in their SPC with those in the British National Formulary.[4]

As shown in table 1, when prescribing or using a paracetamol suspension according to the SPC indications, there is a high risk of administering a low dosage, since posologies are given for very wide age ranges. As an example, in the SPC a dosage of 2.5 ml (60 mg) every 4–6 h is recommended for children less than 1 year of age. This dosage is appropriate for children between 4 and 6 kg but not for those weighing 10 kg. The risk of under-dosage is even more evident for a pre-dosed salbutamol spray where there is a wide difference between SPC and BNF recommendations (table 1). Following the posologies given in the SPC of an Italian pressurised metered-dosed salbutamol spray may have serious deleterious consequences when managing a severe asthma attack.

These two examples demonstrate how OL use regarding the dosage of paracetamol and salbutamol in Italy may in fact be good practice.[5] We could call these types of OL drugs "wrong-label" since their SPC do not reflect current evidence or recommendations given in the guidelines, leading to an ineffective and hence dangerous usage of these medicines. In Italy there are two types of SPC: those compiled by the drug companies and then approved by the European Medicines Agency (EMEA), and those compiled by the Italian Ministry of Health. To ensure clear and concordant information in all SPC, uniform criteria applied by all regulatory bodies are warranted both at national and European levels, as the problem of "wrong-label" drugs may not be specific to Italy.

Review of "wrong-label" SPC in order to reflect current evidence would be another fundamental step to ensure safer drugs for children.

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CORRECTION

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N P Iyer, R Srinivasan, K Evans, *et al*. Impact of an early weighing policy on neonatal hypernatraemic dehydration and breast feeding (*Arch Dis Child* 2008;**93**:297–9). The second line of the Results section should read: "The incidence of NHD in pre- and post-policy groups was 5 and 7.4 per 1000 live births, respectively."