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# Clinical insignificance of alcohol in salbutamol metered-dose inhalers—it's time to stop flogging the horse

Felix SF Ram, Elissa M McDonald

The ozone-depleting potential of chlorofluorocarbons (CFC) in metered-dose inhalers (MDI) has led to the end of CFCs being used in MDIs. Currently available generic MDIs in New Zealand (Respigen®, Salamol®, and the recently introduced SalAir®), are developed containing the less ozone-depleting hydrofluoroalkane, HFA-134a. To aid this changeover these formulations literally contain microscopic amounts of ethanol (2–5 micrograms/actuation) as a co-solvent. Anecdotal evidence suggests that community pharmacists are being misled into believing that the recently introduced (September 2015) SalAir® containing less ethanol (2 micrograms)<sup>1</sup> is clinically superior to the other similar inhalers. We wanted to inform and provide assurance to all healthcare practitioners regarding any clinical differences between these devices by reviewing the evidence to date.

Many good clinical studies<sup>2–4</sup> have shown that the actual dose of ethanol delivered per actuation is insignificant, with no evidence of any health impact in children or adults. These inhalers have been reviewed and approved as safe for use in children and adults, not only by Medsafe (Ministry of Health) in New Zealand, but by regulatory authorities in many different countries in Europe, the Middle East, Africa and the US.

PHARMAC's Respiratory Subcommittee of experts has extensively reviewed both

Respigen and Salamol, and did not report ethanol as an issue,<sup>5</sup> due to the extremely low and clinically insignificant levels present. In New Zealand, approximately 8–10 years ago, there was misinformed publicity regarding MDI and ethanol content. However, high quality clinical studies conducted in New Zealand and overseas have clearly demonstrated the insignificance of the ethanol content in these MDIs.<sup>2–5</sup> Any perceived patient issues (eg, road side alcohol breath tests), even with the MDI containing the highest level of ethanol (Salamol, 4.85 micrograms/actuation), proved insignificant during extensive repeated testing.<sup>3</sup> Furthermore, studies have shown that even non-alcohol containing salbutamol MDIs (eg, Ventolin®) have been reported as giving elevated breath-alcohol recordings, and the authors suggests that this may be due to the actual propellants used rather than the alcohol.<sup>6</sup> Any effects of ethanol in these inhalers (even with highest level) appear extremely low (if any),<sup>2–5</sup> incredibly short-lived (2–3 minutes),<sup>3–4</sup> and only localised with no long-term effects highlighted in any studies conducted to date. Based on ethanol content, there is absolutely no reason to choose one salbutamol inhaler over another, and any claims of differences based on ethanol between salbutamol inhalers remains entirely unsubstantiated.

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