The case for the generic labelling of infant formula in health care settings
Introduction

This report looks at the case for providing infant formula in packaging with generic labels, the implications of doing so and possible mechanisms for providing generically packaged formula in health care settings.

Infant formula has been described is a semi-medicinal food or ‘nutritional medicine’ which should only be used on the advice (and ideally under the supervision) of health workers.”

It is a processed food, based on cow’s milk or soya, intended for use when babies are not breastfed by their mothers and do not otherwise have access to breastmilk (from a donor milk bank, for example).

Breastmilk substitutes are unlike other foods in that they are the sole source of nutrition during a critical period of rapid growth and development.

Processed formulas can only ever be an imperfect approximation of human breastmilk which is a living substance that changes as the baby grows. A mother’s breastmilk contains antibodies and other protective factors that are tailored to her baby’s needs. It impossible to mimic a mother’s breastmilk, which is delivered to her baby in a uniquely safe way. In every stage of the manufacture, storage and delivery of formulas, there are countless opportunities for contamination, human error and corruption.

In addition to these problems, minor modifications and omissions in the ingredients used in these products can have major effects on infant health. "The Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae identified some of problems that have occurred with the introduction of modified infant formulae. Examples included reduced protein availability with impairment of growth; trace element deficiency with severe clinical disease; chloride deficiency with long-term neurological damage and thiamine deficiency with severe clinical disease, including neurological damage and several cases of infant death.

Breastmilk substitutes may be required when a child is orphaned, the mother is incapacitated or drugs are contraindicated (though expert pharmacists should be consulted as breastfeeding is possible with many drugs, even when the standard information indicates otherwise as a routine recommendation - contact the Drugs in Breastmilk Helpline).

In the UK, a large proportion of mothers use formula with no medical need. Indeed, the preliminary results from the Infant Feeding Survey 2010 show that nearly a fifth (19%) of babies in the UK are never breastfed. The last full published survey (2005) found that the number of babies breastfed exclusively until 6 months, as recommended by the Departments of Health and the World Health Organisation, is insignificant; only 21% of babies are still being exclusively breastfed at 6 WEEKS of age in the UK.

Mothers (and carers when the mothers are absent) who are unable or unwilling to breastfeed and do not have access to breastmilk by other means will require access to breastmilk substitutes (infant formula) when in hospital with their babies.

---

1 Infant formula and related trade issues in the context of the international code of marketing of breast-milk substitutes, health implications of direct advertising of infant formula. www.who.int/nutrition/.../infant_formula_trade_issues_eng.pdf

2 Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae SCF/CS/NUT/IF/65 Final 18 May 2003
Section One: The case for generic labelling

Composition of infant formulas - key facts:

- Any product sold as an infant formula must comply with the compositional criteria set out in legislation and the basic nutritional profile of the majority of formulas is very similar.

- There is no proven benefit from optional ingredients.

- Six nutrition claims and one disease risk reduction claim are specifically permitted for infant formulas and follow-on formulas.³

- A brand name cannot be an implied health or nutrition claim unless that claim is legally permitted.⁴

- Additional claims may be allowed for follow-on formulas and formulas and foods for older babies which may all share the same brand name as infant formula. These claims must be permitted by specific EU claims legislation.⁵

- Formulas for special medical purposes (including for low birth weight babies) are covered by separate legislation so may carry implied health and nutrition claims and promotional text.⁶

- Some babies may have an adverse reaction to certain ingredients.

- Parents may have ethical issues about certain ingredients.

- Manufacturer and composition information should be communicated to users in a factual, non-promotional manner.

- Manufacturers have the legal right to market products in the UK provided they meet EU Requirements. Regulations in other EU member states vary considerably so products that do not meet UK standards can be legally marketed in the UK.⁷ (add the chart)

- The detailed rules laid down in the Infant Formula and follow-on formula Regulations 2007, have precedence over the general food labelling rules.

- Health or nutrition claims and idealising images and text, distort parents perceptions of the nutritional value and safety of products.

---

³ The Infant Formula and Follow-on Formula (England) Regulations 2007, Section 4 Prohibition on the marketing of products other than infant formula for normal healthy infants

⁴ Summary Report of The Standing Committee on the Food Chain and Animal Health (SCoFCaH), 22 June 2012

⁵ EU Register On Nutrition & Health Claims providing an updated list of all the permitted health and nutrition claims: http://ec.europa.eu/nuhclaims/