

MAKING A MEAL OF IT

In order to provide accurate information and advice to parents, are you updated on the various formula milks available on the market? Katherine Sykes, of the British Specialist Nutrition Association, overviews the recent shifts in their regulation, innovation and prescription.

Breastmilk is unequivocally the best source of nutrients for a healthy infant but it is easy to forget that reasons such as difficulty nursing i.e. latch and milk supply, as well as surgery, illness and medication might mean that breastfeeding is not an option. This is before consideration is even given to the modern day pressures of work and financial commitments, and the diversity of the modern family unit.

Modern feeding practices range from exclusive breastfeeding, to topping up while the milk comes in, to night feeds, right through to exclusive bottle feeding. It is therefore imperative that parents and other carers can be reassured that should exclusive breastfeeding not be possible, there are products they can turn to that are safe, suitably designed, highly researched and tightly regulated and controlled.

There are three types of standard formula:

Infant formula is designed to fully satisfy the nutritional needs of babies from birth to six months old, when a mother can't or chooses not to breastfeed

Follow-on formula is designed to satisfy the nutritional requirements of infants from six to 12 months old in conjunction with complementary foods, as part of a mixed weaning diet

Young child formula is suitable for young children from 12 to

36 months as a supplement to a normal diet based on family foods

In addition, more specialised formulae (known as 'foods for special medical purposes' or iFSMPs) are available on prescription for infants' specific medical conditions, such as cow's milk protein allergy (CMPA) and lactose intolerance.

STRICT LEGISLATION

Formula milks (1) are among the most strictly regulated of all foodstuffs (2) and rightly so. Legislation incorporates the principles and aims of the World Health Organisation (WHO) Code on Breastmilk Substitutes, and is strictly enforced.

In the last year, there has been an increasing focus on the regulatory environment. In May 2016, a resolution proposed at the World Health Assembly (WHA) called for the banning of advertising of all formulae for the first three years of life. However, although the resolution (WHA69.6) was 'welcomed with appreciation' by member states, it was not 'endorsed'. Following extensive debate, member states concluded that it went too far in its proposals to prohibit contact between healthcare professionals and the industry, to further restrict funding and to consider foods given to a child up to 36 months as breastmilk substitutes.

The decision of the WHA not to endorse the resolution has not stopped some anti-industry groups

from continuing to claim or imply otherwise however: and indeed, BSNA has written both to the Lancet and the British Medical Journal (BMJ) to correct articles that falsely stated that WHA69.6 was effectively 'endorsed'.

Following a consultation in June 2016, the membership of the Royal College of Paediatrics and Child Health (RCPCH) decided that the college should continue to accept funding from formula milk companies – though only within strict pre-specified conditions. (3) This decision reflected the belief of RCPCH members that there is a need for an open exchange of information between manufacturers and healthcare professionals relating to clinical research and product innovation, including iFSMPs. The members also recognised that a significant amount of research goes into the development of such products and the RCPCH has a role in facilitating transparent and accountable collaborations between clinicians, researchers, and manufacturers.

In late 2016, Alison Thewliss MP introduced a bill to the House of Commons, 'Feeding Products for Babies and Young Children (Advertising and Promotion)'.

However, the bill was based on a number of serious factual errors and assumptions, and has made no progress. In particular, in the mistaken belief that the formula milk industry is either self-regulated or not regulated at all, it aimed to establish an agency (the

'Infant and Young Child Nutrition Agency') to set, monitor and evaluate compositional, safety and quality standards, labelling, and nutritional claims in formula milks for babies and young children. In fact, such an agency would duplicate those remedies already available to existing official organisations under the existing law. Formula milks are among the most strictly regulated of all foods.

FORMULA MILKS ARE SAFE AND INDEPENDENTLY MONITORED

Infant formula is the only safe alternative to breastmilk. All manufacturers are required to ensure that their food products are safe in accordance with General Food Law and standards are in many respects even tighter for formula milk, compared with foods for the general population. The nutritional content of infant formula and follow-on formula is laid down in Regulation EU No 2016/127: this is based on the expert opinion of European Food Safety Authority (EFSA) scientists and the European Commission. All ingredients used in formula milk must be proven safe, and undergo rigorous clinical testing.

Formula milks are subject to independent review. The detailed nutritional content and the ingredients of formula are clearly stated on the label and additional information is made available to

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government agencies on request such as the Food Standards Agency (FSA), Trading Standards and the Department of Health. New or reformulated infant formulae must be notified to the Department of Health who review the labelling and substantiation for any new ingredients. The FSA works closely with local authority enforcement officers to make sure food law is applied throughout the food chain.

REGULATION IS STRICT; INNOVATION IS CONSTANT

In order to reflect our ever-increasing knowledge of infant nutrition, regulations are subject to change. As would be expected, there is often a time lapse between the development of our scientific knowledge and implementation of new regulation.

One example is the decision to include docosahexaenoic acid (DHA, an Omega-3 fatty acid) in the list of mandatory ingredients from February 2020. Clinical research conducted during the past 20 years or so has clearly demonstrated the benefits of DHA for non-breastfed infants; in fact, this is a clear example of where industry funding and collaboration with the healthcare profession has resulted in advancement of science and product innovation for the benefit of babies who are not fed with breastmilk.

COMPANIES NEED TO COMMUNICATE WITH HEALTHCARE PROFESSIONALS

Article 7.2 of the WHO Code specifically permits formula milk companies to communicate with healthcare professionals. Ongoing research and development in paediatric nutrition results in regular product innovation and development.

Consequently, companies communicate with healthcare professionals to share and discuss such development and innovation and any reasons for the changes to their products.

SPECIALIST INFANT

FORMULAE ON PRESCRIPTION ARE UNDER THREAT

iFSMPs are specialised products specifically formulated, processed and intended for the exclusive or partial feeding of infants and young children, for the dietary management of specific diseases, disorders or medical conditions.

The choice of the most appropriate iFSMP for each patient will vary as every clinical situation is different and requires specific nutritional considerations.

They should be used under medical supervision, making sure that the infant and/or child is receiving the appropriate nutritional support to ensure optimal growth and development, either in an acute clinical situation or for chronic conditions. These conditions can vary greatly in terms of their permanence, severity and impact on day-to-day life. Their age of introduction also varies, with some medical conditions being detected at birth by newborn screening e.g. PKU, to others which may have a later on-set or diagnosis, e.g. between six to 12 months, such as cow's milk protein allergy (CMPA) and lactose intolerance.

Due to advances in ante-natal care, an increasing number of pre-term babies are surviving. These babies are vulnerable, and specialist paediatric dietitians have a critical role to play in making sure that these infants' diets are effectively managed. Expressed breastmilk supplemented by a breastmilk fortifier is the preferred method of feeding. However, mothers of pre-term infants may be under particular stress, which may affect their milk supply. If so, a specialist ready to feed pre-term formula may be required, (4) which typically contains higher levels of energy, a higher protein to energy ratio and higher levels of key micronutrients, such as iron and vitamin D, compared with standard formula.

These pre-term formulae are designed to support the increased metabolic requirements of pre-term infants.

As infants have relatively high nutritional needs and growth

trajectories, their nutritional support should be constantly monitored by a healthcare professional. One size does not fit all: as children grow and develop, their nutritional needs change, therefore they may need different nutritional inputs at different times. Moreover, some conditions are characterised by periods of relapse and remission, e.g. Crohn's disease, which makes on-going monitoring even more important. The value of good paediatric dietetic advice in these situations cannot be underestimated.

Not only is a medical condition stressful for the infant, it can be very upsetting for parents too. Conditions such as lactose intolerance and CMPA can be significantly distressing and frightening for the parents of children who suffer from them. (5) Any concerned parent should be encouraged to see their doctor to make sure that the appropriate feeding options are discussed, including specialist formulae, so that the condition can be professionally managed.

Against this background, some Clinical Commissioning Groups (CCGs) in England have recently considered whether to restrict the prescription of specialist formula on the grounds of cost. It's imperative that infants are diagnosed and managed with the most appropriate formula, be that an amino-acid based formula (AAF) or extensively hydrolysed formula (eHF) (as in the case of CMPA), as stated by NICE and the MAP Guideline. (6) (7)

There is a real risk that short term financial savings may negatively impact on patient outcomes and effectively cost the NHS more money in the long-term.

CONCLUSION

Formula milks are strictly regulated and safe to use and consume. In order to advise parents appropriately, it's essential that healthcare professionals keep themselves updated on the various formulae available on the market. Short-term cuts to prescriptions may negatively impact the health

of vulnerable infants and young children and cost the NHS more money in the medium to long-term.

ABOUT THE BRITISH SPECIALIST NUTRITION ASSOCIATION

BSNA is the trade association representing the manufacturers of products designed to meet the particular nutritional needs of individuals: these include specialist products for infants and young children (including infant formula, follow-on formula, young child formula and complementary weaning foods), medical nutrition products for diagnosed disorders and medical conditions, parenteral nutrition and gluten-free foods on prescription.

For more information, visit www.bsna.co.uk or tweet @BSNA_UK.

REFERENCES

1. In this document, the term 'formula milks' is used generically to include infant formula; follow-on formula, young child formula and infant foods for special medical purposes (iFSMPs)
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