Child health, infant formula funding and South African health professionals: Eliminating conflict of interest

To the Editor: Lake *et al.*[1] refer to the Allergy Society of South Africa (ALLSA) as an example of a professional body that may be fostering transgressions of regulation R991 (R991) of the Regulations Relating to Foodstuffs for Infants and Young Children.[2] They also infer that the low breastfeeding rate (BFR) in South Africa (SA) is a direct result of aggressive breastmilk substitute (BMS) marketing and transgressions of R991 and call for a total dissociation between BMS suppliers and healthcare professionals.

ALLSA actively encourages exclusive breastfeeding and supports all rational attempts to achieve it. The significant negative downstream health effects that BMSs (especially during the first 4 months of life) may have on immune dysregulation is a frequent discussion point in our journal and at our congresses.

However, ALLSA must also acknowledge that BMSs are necessary for some normal children whose mothers cannot breastfeed, and for children suffering from conditions where feeds of special medical composition are required. We are therefore concerned about some of the points that the authors raise (or fail to raise). We are particularly concerned about the manner in which the information regarding the cancelled BMS company-sponsored symposium at a recent ALLSA congress was obtained, and that the facts were not verified before publication. The advertisement (Fig. 1 in the article[1]) did not originate from ALLSA and was not approved or distributed by ALLSA. ALLSA also required confirmation from the BMS company involved regarding R991 adherence, and a legal opinion regarding compliance with the legislation was provided in writing. The conflicting interpretation of R991 by different legal advisers must therefore be questioned and should have been obtained prior to publication. ALLSA adheres to its position statement on BMS products and the Society's relationship with suppliers.[3] An uncritical condemnation of all companies that manufacture and market BMS products is not supportable, as we have a role to play in guiding the appropriate use of BMS products.

A focus on other, and probably more important, reasons for failed breastfeeding will go further in advancing the BFR than a simple blanket condemnation of BMS products. In the SA private sector, up to 90% of women are delivered by caesarean section.[4] This proportion differs from that in other countries, and data implicate caesarean section delivery (especially scheduled caesarean section delivery) as a highly significant risk factor for failed breastfeeding.[5] Breastfeeding support is key to breastfeeding success.[6] The quality of support offered in public and private hospitals (as reflected by the low achievement of World Health Organization Baby-Friendly Hospital status) can be questioned. SA is a country of diversity, and differences in social, economic, perceptual and ethical reality may contribute to the low BFR. Is it fair to obstruct advice on BMS formulas in the face of hypoglycaemia or dehydration after elective caesarean section delivery and insufficient breastmilk production?

Quality research is needed into the true reasons for the low BFR in SA, and we should direct our energy towards addressing scientifically identified issues instead of simply pursuing a refusal of association with the BMS industry. ALLSA will continue to promote rigorous monitoring of R991.

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1. Lake L, Kroon M, Sanders D, et al. Child health, infant formula funding and South African health professionals: Eliminating conflict of interest. S Afr Med J 2019;109(12):902-906. https://doi.org/10.7196/SAMJ.2019.v109i12.14336
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To the Editor: It is with concern that we took note of the article by Lake *et al.*,[1] in which there are numerous factual inaccuracies, gross generalisations and misleading statements. We address some of these below.

The article creates a negative image of the breastmilk substitutes industry in its totality without any nuances, substantiation or referencing of contraventions to the law.

'Aggressive marketing' is alleged without substantiation or by relating what is alleged to the 1939 and 1974 sources referred to.[2,3] The generalisation made is that these alleged contraventions cause conflict of interest among healthcare professionals and ultimately harm infants.

The law prohibits the promotion of designated products.[4,5] It does not prohibit technical and scientific communication between industry and healthcare professionals. The authors correctly state that Regulation 991 (R991) allows industry to participate in scientific meetings and pooled sponsorships, but fail to substantiate why exhibitions at conferences violate the law.

The authors quote exclusive breastfeeding rates, yet fail to add that the overall 6 months exclusive breastfeeding rate in South Africa (SA) increased from 7% in 1998 to 32% in 2016.[6]

The actual provisions of R991 are not referenced. The article leaves the reader with the impression that R991 contains provisions that it does not. R991 covers:

- labelling requirements (regulations 2 - 6)
- sale and promotion (regulation 7), but research grants and other financial support are allowed
- gift packs, samples and low-priced products are prohibited (regulations 8 - 9)
- display of designated products and educational material with a brand or company name or product description is prohibited (regulation 10)
- material directed at healthcare professionals is permitted (regulation 11).

In the concluding paragraph of their article,[1] the authors call for a total prohibition of sponsorship at academic meetings and a disclosure of funding sources. The latter is already in force, and sponsorship prohibition would require a legislative change.

The law allows for complaints and enforcement. It remains unclear whether the authors had indeed reported the alleged contraventions listed. The authors also claim unsubstantiated similar experiences at other universities. Also unsubstantiated is their statement that 'funding … has the potential to undermine health workers' fiduciary duty to protect and promote child health'.

The Cochrane review[7] referred to by the authors relates to medicines and devices and concludes: 'Sponsorship … by the

manufacturing company leads to more favorable efficacy results and conclusions than sponsorship by other source … industry bias … cannot be explained by standard "Risk of bias assessment".

As the Infant Feeding Association of South Africa (IFA), we agree with intensified efforts to promote breastfeeding. We also support vigorous monitoring of R991. However, the IFA warns against action that exceeds the ambit of the law or amounts to generalisations, and/or unsubstantiated allegations.

The IFA has been and still is open to any constructive engagement in this field to ensure the best possible health outcome of infants in SA.

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Lake *et al*. respond: We thank Dr Van Niekerk and Ms Khan for their comments.

The reference to the Allergy Society of South Africa (ALLSA) conference in our article[1] was not intended as an attack on that organisation, but rather as an example of where industry attempted to contravene Regulation 991 (R991) at a health worker (HW) conference. Dr Van Niekerk questions whether marketing of breastmilk substitutes (BMSs) is a major reason for the low breastfeeding rate (BFR) in South Africa (SA), and states that we called for total dissociation of healthcare professionals from the BMS industry.

We agree that BMS marketing is not the only reason for the low BFR, and our abstract and first paragraph acknowledge that greater investment in promoting and supporting breastfeeding is required.[2] BMS marketing is, however, recognised as a major negative influence, hence our article's focus.[3,4] A recent World Health Organization report concluded: 'protecting the health of children and their mothers from continued misleading marketing practices should be seen by countries as a public health priority and human rights obligation'.[5] Recent decisions by international (Royal College of Paediatrics and Child Health, *BMJ*) and local organisations (South African Paediatric Association, University of Cape Town Department of Paediatrics and Child Health) no longer to accept funding from BMS companies acknowledge the need to protect mothers and HWs from BMS marketing.

The primary concern of BMS companies is profit, while HWs must promote health and development, and these divergent priorities lead to conflicts of interest.[6] We called on HWs to reconsider their relationships with industry and refuse all BMS funding – not dissociate totally, because (Dr van Niekerk is correct) BMSs are used, and HWs need to know their constituents, indications and evolution. R991 does not intend to limit counselling provided by independent HWs or women's feeding choices. It aims to remove the influence of industry from these choices and counselling.

Ms Khan (an industry representative) alleges 'factual inaccuracies, gross generalisations and misleading statements' without identifying what these are. Fig. 1 in our article[1] details each contravention, referencing the actual R991 provision. For example, making specific nutritional or medicinal claims, or claims of a strong similarity between the product and breastmilk, is prohibited.

She is correct: exclusive breastfeeding in SA has improved – yet 32% falls far short of the 2025 Global Nutrition Target of 50%.[7]

Despite R991[8] and the National Department of Health (NDoH) Guidelines to Industry and Health Care Personnel,[9] the BMS industry still finds ways to influence HW audiences. The Nestle Nutrition Institute advertised the cancelled breakfast symposium on breastmilk sugars and human milk oligosaccharides by email to delegates. Regulation 7(3) stipulates that industry is not allowed to provide 'gifts' in cash or kind to HWs. Meals and refreshments are specifically included in the definition of gift, so the NDoH deemed that the symposium contravened R991.

Much of Ms Khan's response is based on what is legally required. Our argument is that HWs should practise what is best scientifically and ethically, not merely what is compliant with the law. This demands that every practitioner and organisation reflect on the determinants of poor breastfeeding practices and their own actions and activities that potentially undermine ideal behaviour.

Growth in formula milk sales is currently greatest in low- and middle-income countries.[3] A new Lancet Commission calls for stronger regulation to protect children from commercial marketing, including of formula milk.[10] Individuals, institutions and governments involved in child health (policy, research, training and service) need to act independently and with integrity in the best interests of children.

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