Baby Milk Action/ IBFAN submission to Department of Health and Social Care (DHSC)
Open consultation on disclosure of industry payments to the healthcare sector

16 October 2023 (Corrected/Revised version)

https://www.gov.uk/government/consultations/the-disclosure-of-industry-payments-to-the-healthcare-sector

Consultation description: "*This consultation aims to seek views on the possible introduction of regulations mandating the disclosure of industry payments to the healthcare sector. We want to seek views on the possible introduction of new secondary legislation to place a duty on manufacturers and commercial suppliers of medicines, devices and borderline substances to report details of the payments and other benefits they provide to healthcare professionals and organisations. This consultation aims to address the second part of recommendation 8 contained in the Independent Medicines and Medical Devices Safety (IMMDS) Review, regarding real and perceived conflicts of interest in the health system. Gathering views through the consultation is an important step in the development of policies in this area. The proposals will enable respondents to share views on: the information they would need to provide, recipients in scope, payments that would potentially need to be reported. timing and content of reporting*
The consultation also seeks views on alternatives to regulation.

Introduction – why this consultation is relevant to IBFAN's work

Baby Milk Action/IBFAN UK, is the UK member of the International Baby Food Action Network (IBFAN) a network of over 300 citizens groups in more than 100 countries that was founded in 1979. Since then, IBFAN has worked in collaboration with WHO and UNICEF and civil society partners to improve maternal and infant and young child health through the **protection**, **support** and **promotion** of breastfeeding and optimal complementary feeding. We have helped many governments bring in legislation to control harmful marketing, based on the global recommendations adopted at the World Health Assembly in 1981, namely the International Code of Marketing of Breastmilk Substitutes We have also helped governments adopt WHA Resolutions that keep pace with science and marketing developments. There are now 20 Resolutions and Decisions that clarify and strengthen the 1981 Code, alongside the Convention on the Rights of the Child adopted in 1989.[1]

Breastfeeding constitutes one of the single most effective ways to reduce inequalities, to fulfil the child's right to life and to the enjoyment of the highest attainable standard of health. The International Code and Resolutions are designed to ensure that all parents receive objective and truly independent information, to remove obstacles to breastfeeding and ensure that breastmilk substitutes are used appropriately. Addressing Conflicts of Interest and ensuring that health policy setting is protected from undue commercial influence has been and continues to be a cross-cutting and critically important aspect of IBFAN's advocacy.

Baby Milk Action founded the Baby Feeding Law Group (BFLG) in 1997, the year after the adoption of the World Health Assembly Resolution 49.15, the first of several Resolutions calling for Conflict of Interest safeguards in matters

[1] The UK has ratified the *Convention on the Rights of the Child* (CRC) Article 24 of which calls on governments to provide parents with information on nutrition and breastfeeding. The CRC General Comments Nos. 15 and 16 stress the obligation for States to protect, promote and support breastfeeding through the implementation of the World Health Assembly *Global Strategy for Infant and Young Child Feeding* (GSIYCF) and set a direct obligation that companies abide by the IC and Resolution universally '*in all contexts'* The International Code and WHA Resolutions are embedded in many global declarations, standards and strategies, including the *Codex Code of Ethics,*[1] and the UN *Political Declaration and Framework for Action.*

relating to Infant and Young Child Feeding and monitoring.[2] The aim of the BFLG has been to bring UK and EU legislation into line with WHA Resolutions and Recommendations to protect maternal and child health in the UK and globally, including in LMICs where UK policies have impact.

Transparency and the establishment of the European Food Safety Authority (EFSA). As part of our continuing efforts to bring in and strengthen European legislation to protect child health, in 2000, IBFAN (backed by the BFLG and many health NGOs) helped expose the lack of transparency and conflicts of interest in the EU's Scientific Committee for Food (SCF). Poor SCF advice had, for many years, led to serious loopholes in EU legislation and the adoption in 1999 of the seriously problematic Directive on Foods for Special Medical Purposes.[3] The SCF was subsequently closed down and replaced by the European Food Safety Authority (EFSA) whose new Conflict of Interest rules aimed to keep the agency at arms length from the commercial and political process. IBFAN was consulted by the EU Commission regarding the formation of the transparency and COI rules and some of our suggestions were taken up.[4,5]

In later years the Commission acknowledged that the FSMP Directive had caused problems: *"Over the past years, Member States' national competent authorities have reported increasing difficulties with the enforcement of the legislative framework applicable to FSMP. Member States' experts have in particular flagged that an increasing number of products are placed on the market as FSMP in their territory, but that doubts arise in certain cases as to whether the products really correspond to the definition of FSMP and therefore correctly fall within the scope of the FSMP legislation."* [6]

In our experience the influence of commercial funding on UK, EU and global policy setting is profound and grossly under-estimated and is an important justification for regulation in this area. [7] With this in mind we consider that it would be a great mistake for the UK Government to fall back of voluntary/self-regulation, which numerous studies have shown to be not only ineffective, but subversive. Voluntary systems have multiple commercial advantages, especially for transnational corporations with extensive PR budgets, not least because the trustworthy, responsible public image conveyed diverts attention from the harmful practices. Institutions can also perpetuate this problem by adopting weak policies that fail to address serious conflicts of interest that distort /subvert their own policy and practice. While increased transparency is an important first step, for true impartiality of clinical decision-making it is essential that financial conflicts of interest are not only regulated - but when found to be inappropriate – avoided.

IBFAN warmly welcomes this consultation on the possible introduction of new secondary legislation that would place a duty on manufacturers and commercial suppliers of medicines, devices and borderline substances to report details of the payments and other benefits they provide to healthcare professionals. *We strongly support the BFLG justification for expanding the scope of businesses covered, and would go further to stress that while especially health-harming commercial entities - can be consulted - they should never be allowed to influence health policy or practice.*

Responses to the Questions

Businesses that may need to publish information
Question: The government proposes to make the following businesses subject to this reporting duty - the manufacturers and commercial suppliers of: medicines, medical devices, borderline substances
Do you agree or disagree with this proposal? I have an alternative suggestion

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[2] 1996 WHA Res 49.15: Preambular para: "*Concerned that health institutions and ministries may be subject to subtle pressure to accept, inappropriately, financial or other support for professional training in infant and child health"* 3.urged Member States:….(2) *to ensure that the financial support for professionals working in infant and young child health does not create conflicts of interest, especially with regard to the WHO/UNICEF Baby Friendly Hospital Initiative*; (3) *to ensure that monitoring the application of the International Code and subsequent relevant resolutions is carried out in a transparent, independent manner, free from commercial influence;* Other WHA Resolutions calling for transparency and Conflict of Interest Safeguards: 2002 WHA Res 55.25, 2004 WHA Res 57.17, 2005 WHA Res 58.32: 2012 WHA Res 65.6 2014 WHA Res 67(9) 2016 WHA Res 69/9

[3] COMMISSION DIRECTIVE 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1999L0021:20070119:EN:PDF BFLG Brifing:http://www.babymilkaction.org/wp-content/uploads/2022/06/FSMP-Briefing-Tuesday.pdf

[4] European Voice, Renee Cordes: *Clamour for Action to bolster Union Scientists' credibility*, 13-19 Jan 2000, Vol 6, No 2, *Scientists bow to call for more transparency*., 16-22 March, 2000, Vol 6, No 11.

[5] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety https://www.legislation.gov.uk/eur/2002/178/contents

[6] Commission Notice on the classification of Food for Special Medical Purposes (FSMP) (2017/C 401/01)

[7] *Interference in public health policy: examples of how the baby food industry uses tobacco industry tactics*, 2017 https://worldnutritionjournal.org/index.php/wn/article/view/155

We welcome the inclusion that businesses manufacturing or supplying borderline substances. This is critically important. However, the list of businesses that need to publish information disclosing industry payments to the healthcare sector must be expanded. Ideally the list should be expanded to include health-harming entities such as tobacco, arms, ultra-processed food, alcohol etc, because funding from all these entities can have a detrimental impact on clinical judgement.

But at the very least the list must include manufacturers and suppliers of products within the scope of the *International Code of the Marketing of Breastmilk substitutes* and subsequent relevant WHA Resolutions.[8] This would include all manufacturers and distributors of commercial milk formula (CMF) including formulas for pregnant and breastfeeding women, infants and young children to the age of 3 years, feeding bottles, teats, dummies/pacifiers, formula preparation machines, breast pumps, nipple shields and creams, commercial baby foods, supplements marketed for infants and young children and beyond, We assume that specialist CMF (i.e., formulas for allergies, preterm/low weight etc) are already on the borderline substances list, and since there is considerable scope for brand cross-promotion, all CMF/BMS should be included as a separate category, along with any product that is cross-promoted/branded with breast-milk substitutes

Recipients in scope
Question: The government proposes to require information about payments or other benefits provided to registered healthcare professionals, healthcare provider organisations and organisations connected to the provision of healthcare to be published, with regulations making no distinction between public or private sectors.
Do you agree or disagree with this proposal? Other - please specify

We recommend that recipients in scope should also include any payments made also to healthcare professional and their associations' publications, charities and patient organisations, magazines and journals, as well as scientific and peer-reviewed journals with head offices in the UK. It has been highlighted and documented that sponsorship of high-profile scientific journals has unduly influenced published content and that this creates a conflict of interest (Pereira-Kotze, et al., 2022). While the best practice would be for "*all scientific journals and publishers to refrain from accepting funding from manufacturers and distributors of breast-milk substitutes or commercial formula products, in accordance with the Code*" (International Code of Marketing of Breastmilk Substitutes), the next best step would be that if journals or publishers do accept payments from these businesses, it should be disclosed.

Question: Do you or your business currently make payments or provide other benefits to registered healthcare professionals and healthcare provider organisations? No

Question: Do you or your organisation currently receive payments or receive other benefits from manufacturers or suppliers of healthcare products? Yes

Question: The government proposes to require information about payments or other benefits provided to any organisation involved in medical research or training to be published. Payments to charity arms of hospitals or similar organisations linked to healthcare providers should also be in scope.
Which of the following organisations do you think should be included in the scope of these regulations? (Select all that apply)

- Charity arms of hospitals
- Medical or clinical research organisations (including medical research charities)
- Professional bodies responsible for the core training of healthcare professionals (for example royal colleges, Membership of the Royal Colleges of Physicians (MRCP))
- Other medical education or training providers
- Patient advocacy organisations
- Don't know
- Other - please specify

The sub-group "medical or clinical research organisations" is a particularly important category where complex funding mechanisms exist – for example, Knowledge Transfer Partnerships (KTPs) where funding is mixed, and can include a combination of funding from Innovate UK, UKRI and/or funding from industry, in the form of health related businesses. In addition to the organisations listed, we further recommend the inclusion of: universities, academic

[8] Compilation of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA Resolutions. Updated 2022. https://www.babymilkaction.org/wp-content/uploads/2023/05/Code-Resolutions-2022pdf-1.pdf

journals, scientific publications and health care professional publications or magazines; professional associations; health care alliances or charities (not only charity arms of hospitals) involved in research and charities that support healthcare or provide commissioned services. There are many examples where health-related publications accept payments for advertising which then include information (targeted to healthcare professionals) that is not scientific and factual and therefore, in the case of infant and young child feeding information provision is currently illegal yet continues (FSNT, 2019; Hickman, et al., 2021). There are also many examples of health care professional associations that accept funding from related industries that create a conflict of interest.

Operation of the duty. Reporting frequency
Question: The government proposes to require businesses to publish payment information on their websites with a link in a prominent place on the website's UK homepage.
Do you agree or disagree with this proposal? Agree

Question: The government proposes to require businesses to publish details of relevant payments and benefits annually on their websites with a link in a prominent place on the website's UK homepage.
What should the reporting frequency requirement be? Every 12 months

Businesses in scope for only part of the year
Question: The government proposes to require businesses to report all relevant payments and benefits provided over the full year, if they supplied a product in scope at the beginning of the reporting cycle.Do you agree or disagree with this proposal? Agree

Submission to other portals or systems
Question: The government proposes to allow businesses to comply by exception with the reporting requirements through reporting through a third-party scheme. Only schemes meeting regulatory standards would be designated by the Secretary of Health and Social Care. Do you agree or disagree with this proposal? Disagree

Question: Do you currently report any payments to Disclosure UK, a voluntary scheme run by the Association of the British Pharmaceutical Industry (ABPI)? No

Question: Would you consider participating in or launching a similar scheme if this meant you or your members could be exempt from the legislative duty to report payments on your own website? No

Information to be published. Data protection
Question: The government proposes to require publication of a register of payments with entries containing the name of the recipient, the annual sum value of payments and benefits made, and a complete list of reasons for each payment and benefit. If the recipient is an individual, we would require businesses to publish their employer and professional registration number (if applicable and published by the professional body).

What information do you think should be published?
- Name of the recipient
- The annual sum value of payments and benefits
- Complete list of reasons for each payment and benefit
- If the recipient is an individual, their workplace and professional registration number (if applicable and published by the professional body)

Question: The government proposes to require declarations to remain in the public domain for at least 3 years. Please choose your preferred timescale from the following options. At least 5 years

Questions: Should compliance with the requirements be monitored? Yes

How often should compliance with the requirements be monitored? Every 12 months

Who should monitor compliance?
- Trade body
- Government
- Don't know

Questions: How should suspected non-compliance be reported?
- Contactable phone line. Email Online platform

Where non-compliance is reported directly or flagged through the monitoring process, an investigation of compliance with the requirements could be triggered. Should all cases identified as potentially non-compliant be reviewed in full? Yes

Question: What triggers should be used to determine whether a case is fully investigated?

- Financial value of the case
- Prior instances of non-compliance

If you answered other, please provide more information: The national and global impact of commercial influence on public health policy setting is largely undocumented and grossly under-estimated. The impact on maternal, infant and young child health is an example of how lack of policy coherence and the absence of and non-compliance with transparency and conflict of interest safeguards has undermined health and development. While increased transparency is an important first step, for impartiality of clinical decision-making it is essential that financial conflicts of interest are not only regulated - but when found to be inappropriate – avoided. In all matters, while commercial entities can be consulted, commercial entities, especially health-harming entities should not be allowed to influence health policy or practice.

Question: Do you consider that financial penalties would be an effective and fair deterrent for non-compliance? Yes

Question: Please share further comments or feedback relating to enforcement if you have any: IBFAN has extensive experience with enforcement of health-related legislation in many countries and has also assisted governments in training enforcement personel. This can very important. UK enforcement lies with local authorities and Trading Standards officers (TSOs) who have a wide remit and have faced funding cuts. The result is that previously submitted complaints about violations of nutrition related legislation, take months to years to be processed and are often not fully resolved, with no penalties imposed on companies that repeat violations. To be effective, resource and capacity needs to be increased and allocated. There also need to be clear lines of accountability and levers to act. While businesses have a responsibility to monitor their own practices. it is important that compliance and tracking is state funded and protected from commercial influence.

Payments out of scope. Minimum threshold. Question: The government proposes to exempt businesses from reporting payments below £50 where the total annual value of payments does not exceed £500 for that recipient. What minimum value of payment do you think should be exempt from these regulations?

- Below £10 where the total annual value of payments does not exceed £100
- Below £50 where the total annual value of payments does not exceed £500
- Below £100 where the total annual value of payments does not exceed£1,000
- Don't know
- Other - please specify

Since commercial influence is pervasive and long-lasting and occur in all forms we do not believe that there should be any minimum value of payment that should be exempt from these regulations

Research and development

Question: The government proposes to exempt businesses from reporting payments which may disclose commercially sensitive information under the condition that they publish their rationale for using the exemption and declare that they have applied the exemption.

Which, if any, of the following options do you agree with?

- I agree with the government proposal - that exemptions are permitted, the rationale for using the exemption should be given for every use and there should be a public declaration that the exemption has been applied
- I agree in part with the government proposal - exemptions should be permitted, and there should be a standard disclaimer published that the exemption has been applied to some payments
- I disagree with the government proposal - there should be no exemption, all payments should be reported
- A redacted version of the payments should be reported
- Don't know

Question: The government proposes to exempt businesses from reporting payments and benefits made under contractual obligations where the healthcare provider organisation pays the business at fair market value, including discounts on prices that meet these criteria.

Do you agree or disagree with this proposal? Disagree

Impacts and monitoring
Impact of mandatory reporting on industry
Question: Do you think small and micro businesses should be exempt from the duty?

- Yes, exclude small businesses (up to 50 employees)
- Yes, exclude micro businesses (up to 10 employees) only
- No, don't exclude businesses based on size

If you answered no, please explain why you believe small and/or microbusinesses should not be exempt:
Any business involved in healthcare, if they receive payments from the industry should be required to report on this.

Rationale: Small or micro businesses can still have a harmful impact and it also difficult to establish whether small businesses are linked/owned in some way to multi-national corporations who inevitably have a global impact. Indeed, some of the largest corporations present themselves as SMEs.

Question: How much time and cost do you expect to incur in joining or setting up an alternative third-party reporting scheme? Please provide an estimate by types of cost you expect, for example IT set-up N/A

Question: How much (additional) time and cost do you expect to incur each year to declare payments, including to collect, review and publish the information? Please provide an estimate. N/A

Question: If available, how many in-scope payments do you expect to make each year?.N/A

Question: Are there any other issues or comments you would like to provide feedback on? (maximum 500 words)
We have many examples where companies provide health care professionals or individuals with gifts instead of payments, or pay expenses such as flights or accommodation instead of providing the person with a direct payment. The law should include a definition of "payment" that includes cash, gifts, donations, expense payments, etc.

Realising the benefits of proposals
Question: Thinking about the proposals outlined in this consultation, are there any other options for payment reporting which would achieve similar aims which the government should explore? You may choose as many of the options below as you wish.

- Voluntary compliance with government-issued guidance
- Voluntary publication of information currently required to be held by any trade association you are a member of
- Other

If you answered other, please provide more information (None – no other payment reporting options).

Question: Please provide details of any current reporting systems in the UK which may result in duplication if this new duty is introduced. This could be either voluntary or mandatory, industry or official reporting, excluding overseas requirements. We don't know of any.

Question: Do you think the proposals will change patient relationships with their healthcare professionals? Yes
If yes, how do you think these proposals would change patient relationships with healthcare providers?

- I think it would improve the relationship
- I think it would be detrimental to the relationship

Question: Do you think these proposals would increase impartial decision-making from healthcare professionals and organisations? Yes

Question: Would you access and use the published information to make decisions on your healthcare? Yes

Question: If this published information had been available to you in the past, would you have used it? Yes

Question: Reflecting on the answers given to our proposals, please share any thoughts and further information to help us understand your views, especially where you disagree with proposals (maximum 250 words).

As already mentioned in our introduction, the problems caused by the undue influence of the baby feeding products industry in UK, EU and global health policy governance, planning and practice has been documented many times [9] and more than justifies their inclusion in the scope of businesses covered by the new legislation. In the UK, organisations such as the British Medical Journal (BMJ) and the Royal College of Paediatrics and Child Health (RCPCH), amongst others, have stopped taking funding from companies that manufacture commercial formulas (BMJ, 2019; Mayor, 2019), furthermore, in 2016, the World Health Assembly recommended, through resolution WHA 69.9 that *"companies that market foods for infants and young children should not create conflicts of interest in health facilities or throughout health systems"* providing examples of situations that could create conflicts of interest.

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- *Russ K, Baker P, Byrd M, et al. What you don't know about the Codex can hurt you: how trade policy trumps global health governance in infant and young child nutrition. International Journal of Health Policy and Management 2021;* ***10****(12): 983-97. Baker et al. Globalization and Health (2021) 17:58. Advocacy at Work During the Codex Committee on Food Labelling Meeting*
- INTERVENTIONS AT WTO AND CODEX RELATED TO NATIONAL IMPLEMENTATION OF THE WHO INTERNATIONAL CODE OF MARKETING OF BREASTMILK SUBSTITUTES. Katheryn Russ*
- *The political economy of infant and young child feeding: confronting corporate power, overcoming structural barriers, and accelerating progress. BREASTFEEDING| VOLUME 401, ISSUE 10375, P503-524, FEBRUARY 11,* https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01933-X/fulltext
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For further information please contact: Patti Rundall, Policy Director, IBFAN Global Advocacy. prundall@babymilkaction.org

[9] Interference in public health policy: examples of how the baby food industry uses tobacco industry tactics, 2017 https://worldnutritionjournal.org/index.php/wn/article/view/155

'[Individual] conflicts of interest are defined as circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest.'
'Institutional conflicts of interest arise when an institution's own financial interest or those of its senior officials pose risks of undue influence on decisions involving the institution's primary interests.'
1 Lo, B. and M. Field, Inst of Med. (US) Committee on Conflict of Interest in Medical Research, Education and Practice, Eds. (2009) Conflict of interest in medical research, education and practice. Washington DC, National Academics Press, cf.