BFLG-UK submission to Department of Health and Social Care (DHSC) Open consultation on disclosure of industry payments to the healthcare sector

Submission closing date: 16 October 2023


Consultation description (from the website)

“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.”

Background to the Baby Feeding Law Group (BFLG-) UK

The BFLG-UK is coalition of UK health professionals and consumer and public health non-governmental organisation (NGOs) that was founded in 1997, the year after the adoption of the World Health Assembly (WHA) Resolution 49.15, the first of several Resolutions calling for Conflict of Interest safeguards in matters relating to Infant and Young child feeding and monitoring. The aim of the BFLG-UK 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 low-and-middle-income-countries (LMIC) where UK policies have impact. To this end, addressing Conflicts of Interest amongst our members and ensuring that health policy setting is protected from undue commercial influence is an ongoing and central aspect of our advocacy. BFLG members were instrumental in exposing the lack of transparency and conflicts of interest in the EU’s Scientific Committee for Food (SCF) in 2000 that had led to loopholes in EU legislation that undermined child health. The SCF was subsequently closed down and the EU Scientific advisory system was reformed. The European Food Standards Agency (EFSA) was created with the intention of being at arm length from the political process.

The BFLG-UK therefore 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. In our experience, the undue influence of commercial funding on UK and global policy setting is profound and grossly under-estimated and that regulation in this area is overdue. For this reason, the UK Government must not 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 public relations budget, not least because the trust-worthy, responsible public image conveyed diverts attention from harmful practices. Institutions can also perpetuate this problem when adopting weak policies that do little to address fundamental and unacceptable conflicts of interest that distort/subvert their policy and practice.

We submit the following suggestions in order to increase the chance that the initiative will achieve its objective of safeguarding public health policies and practice both in the UK and the wider world. We do so on the understanding that 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.

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 of Marketing of Breastmilk Substitutes and subsequent World Health Assembly resolutions (hereafter referred to as ‘The Code’) 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 safely if needed. Their purpose is not to pressurise parents to breastfeed but to protect everyone from misinformation and commercial promotion. When properly implemented they protect both breastfed and artificially fed babies. They are not just for resource poor countries, where they are often a lifeline, but are minimum requirements for ALL countries.

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 Code universally ‘in all contexts’. The Code and WHA Resolutions are embedded in many global declarations, standards and strategies, including the Codex Code of Ethics, and the UN Political Declaration and Framework for Action.

References

- 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; Some of the 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
- Codex Code of Ethics for International Trade in Food CAC/RCP 20-1979 4.4: National authorities should be aware of their obligations under the International Health Regulations (2005) with regard to food safety events, including notification, reporting or verification of events to the World Health Organisation (WHO). They should also make sure that the international code of marketing of breast milk substitutes and relevant resolutions of the World Health Assembly (WHA) setting forth principles for the protection and promotion of breast-feeding be observed.
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?

- Agree
- Disagree
- Don’t know
- I have an alternative suggestion

Please explain your alternative suggestion (maximum 100 words).

Full response:
We welcome the inclusion that businesses manufacturing or supplying borderline substances need to publish information disclosing industry payments to the healthcare sector. This is critically important however, the list of businesses that need to publish information disclosing industry payments to the healthcare sector must be expanded to include a category of products in addition to the 3 listed, namely all manufacturers and suppliers of products within the scope of the International Code of the Marketing of Breastmilk substitutes and subsequent relevant WHA Resolutions (ICDC, 2022). This will include manufacturers of:

- breastmilk substitutes (BMS)/ commercial milk formula (CMF) including those for pregnant and breastfeeding women, where BMS/CMF includes any formulas or milks, bottles, teats and foods marketed for infants and young children to the age of 3 years
- feeding bottles and teats
- dummies/pacifiers
- formula preparation machines
- breast pumps
- nipple shields and creams for breastfeeding women
- commercial baby foods or supplements marketed for infants and young children up to 36 months
- any commercial formula or food product cross-branded or cross-promoted with BMS/CMF targeting children

Since specialist CMF (i.e., formulas for allergies, preterm/low weight etc) are already on the borderline substances list, and there is considerable scope for brand cross-promotion, there is a need to include all CMF/BMS, as an additional category.


100-word response:
The list of businesses needing to publish information disclosing industry payments to the healthcare sector must be expanded to include an additional category, namely all manufacturers and suppliers of products within scope of the International Code of the Marketing of Breastmilk substitutes and subsequent relevant WHA Resolutions, including any breastmilk substitutes (BMS)/ commercial milk formula (CMF) including any formulas or milks, bottles, teats and commercial foods or drinks marketed for infants and young children to the age of 3 years and dummies/pacifiers, formula preparation machines and breast pumps. [https://tinyurl.com/CodeandRes](https://tinyurl.com/CodeandRes)
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?
• Agree
• Disagree
• Don’t know
• 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.

Reference:

Question: Do you or your business currently make payments or provide other benefits to registered healthcare professionals and healthcare provider organisations?
• Yes
• No
• Don’t know

Question: Do you or your organisation currently receive payments or receive other benefits from manufacturers or suppliers of healthcare products?
• Yes
• No
• Don’t know

Additional explanation: The Baby Feeding Law Group UK (BFLG-UK) is a group of 33 organisations and individual members. The BFLG-UK as an alliance does not receive any payments or benefits from manufacturers or suppliers of healthcare products. However, as Secretariat for the BFLG-UK, we do not know all payments and benefits that members or individuals may receive.

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

For the sub-group “medical or clinical research organisations”, this is a particularly important category, where some 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.

The recent Lancet Breastfeeding Series (published in February 2023) documents how the BMS/CMF industry has captured science to serve their aims, through funding research and sponsorship of journals and health professional associations (Rollins, et al., 2023). Examples include selective reporting, substantial industry influence and little independence and transparency with industry-funded research. When journals and professional associations receive sponsorship from BMS/CMF manufacturers, articles sponsored by the CMF industry in scientific and public health journals can be hard to recognise as commercial advertisements.

In addition to the organisations listed, we further recommend the inclusion of: universities, academic 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 includes 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
• Disagree
• Don’t know
• I have an alternative suggestion
Please explain your alternative suggestion (maximum 100 words).

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
- Every 6 months
- Every 3 months
- Don’t know
- Other, please specify

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
- Disagree
- Don’t know

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?
- Agree
- Disagree
- Don’t know

Question: Do you currently report any payments to Disclosure UK, a voluntary scheme run by the Association of the British Pharmaceutical Industry (ABPI)?
- Yes
- No
- Don’t know

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?
- Yes
- No
- Don’t know

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)
- None of the above
- Don’t know
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 1 year
- At least 3 years (√)
- At least 5 years
- Don’t know
- Other - please specify

Questions: Should compliance with the requirements be monitored?

- Yes (√)
- No
- Don’t know

How often should compliance with the requirements be monitored?

- Every 3 months
- Every 6 months (√)
- Every 12 months
- Every 24 months
- Don’t know
- Other - please specify

Who should monitor compliance?

- Trade body
- Government (√)
- Don’t know
- Other - please specify

Additional explanation: We acknowledge that government currently does not have adequate capacity or resources for comprehensive monitoring of existing legislation and therefore, for this 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, if it important that compliance and tracking is state funded and protected from commercial influence, possibly a collaborative effort between the DHSC and BEIS (Department for Business, Energy, and Industrial Strategy).

Questions: How should suspected non-compliance be reported?

- Contactable phone line
- Email
- Online platform (√)
- Through official checks only
- Don’t know
- Other - please specify

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 (√)
- No
- Don’t know
- Other - please specify

Question: What triggers should be used to determine whether a case is fully investigated?
The national and global impact of commercial influence on public health and environmental policy setting is largely undocumented and grossly under-estimated. The impact on maternal, infant, and young child health is a clear example of how lack of policy coherence and the absence of and non-compliance with transparency and conflict of interest safeguards has undermined health, food safety development. The impact on the food system and the environment must also be recognised. Corporations are never held financially responsible for the harm they cause and the ‘costs’ are too often externalized to governments, families, and our planet.

**Question:** Do you consider that financial penalties would be an effective and fair deterrent for non-compliance?
- Yes
- No
- Don’t know
- Other - please specify

**Question:** Please share further comments or feedback relating to enforcement if you have any (maximum 500 words).

Our previous experience with enforcement of health-related legislation is that the responsibility for enforcement lies with local authorities and this means Trading Standards and their officers. Trading Standards Officers (TSOs) have a wide remit and a large number of areas of work to monitor and enforce. There have also been recent cuts to the numbers of TSOs. The result is that when we have previously submitted violations of nutrition related legislation, these complaints take months to years to be processed and are often not fully resolved, with no penalties imposed on companies that repeat violations. For the reasons and impact stated above, a government-wide effort is required to improve enforcement of all health-related legislation.

**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?

- Agree
- Disagree
- Don’t know

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
- Don’t know

If you answered yes, please explain why you believe small and/or microbusinesses should be exempt (maximum 250 words).

If you answered no, please explain why you believe small and/or microbusinesses should not be exempt (maximum 250 words).

Any business involved in healthcare, if they receive payments from the industry should be required to report on this.

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 (maximum 500 words).

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? Please provide an estimate.

N/A

Question: Are there any other issues or comments you would like to provide feedback on? (maximum 500 words)

We are concerned that, to get around this, industry companies might rather 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. Therefore, there should be a definition of "payment" provided that includes cash but also gifts, donations, payments of expenses, 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 (maximum 500 words).
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 (maximum 500 words).
We don’t know of any.

Question: Do you think the proposals will change patient relationships with their healthcare professionals?
- Yes
- No
- Don’t know
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
- No
- Don’t know

Question: Would you access and use the published information to make decisions on your healthcare?
- Yes
- No
- Don’t know

Question: If this published information had been available to you in the past, would you have used it?
- Yes
- No
- Don’t know

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).

Full response:
Justification for expanding the scope of business that would need to disclose industry payments to include all manufacturers and suppliers of BMS/CMF, including all products within the scope of the International Code of Marketing of Breastmilk Substitutes:
The reason for this recommended expansion is that the undue, conflicted, and problematic involvement of the industry from these types of companies and businesses in the healthcare sector in the UK has been documented many times (van Tulleken, 2018). The UK has endorsed the Code, which bans the advertisement of BMS/CMF and has provisions relevant to bottles, teats and commercially produced foods marketed as being suitable for infants and young children from the age of 6 months to 36 months (UNICEF, 2023). However, companies have been found to target the health sector in the UK through funding, research, education, supplies, and materials. In 2018, the Channel 4’s Dispatches documentary The Great Formula Milk Scandal found NHS doctors promoting BMS:

This involvement has potential negative implications for the most vulnerable groups of society, namely infants, young children, and pregnant and breastfeeding women. This has also led to some organisations such as the British Medical Journal (BMJ) and the Royal College of Paediatrics and Child Health (RCPCH), amongst others, stopping taking funding from companies that manufacture commercial formula (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.

References:
- Van Tulleken. Overdiagnosis and industry influence: how cow’s milk protein allergy is extending the reach of infant formula manufacturers. BMJ 2018;363: k5056. https://doi.org/10.1136/bmj.k5056

250 word response
The reason for recommending expanding the scope of business that would need to disclose industry payments to include all manufacturers and suppliers of BMS/CMF is that the undue, conflicted, and problematic involvement of the industry from these types of companies and businesses in the healthcare sector in the UK has been documented many times (van Tulleken, 2018). The UK has endorsed the Code, which bans the advertisement of BMS/CMF and has provisions relevant to bottles, teats and commercially produced foods marketed as being suitable for infants and young children from the age of 6 months to 36 months (UNICEF, 2023). However, companies have been found to target the health sector in the UK through
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https://www.bmj.com/company/newsroom/bmj-calls-time-on-formula-milk-adverts/
https://doi.org/10.1136/bmj.l743
https://www.corporateaccountabilitytool.org/conflict-of-interest

Baby Feeding Law Group UK Members:
Association of Breastfeeding Mothers (ABM), Association for Improvements in the Maternity Services (AIMS), Baby Milk Action, Best Beginnings, the Breastfeeding Network (BfN), Breastival, Code Monitoring Northern Ireland, the Community Practitioners’ and Health Visitors’ Association (CPHVA), Doula UK, The Fatherhood Institute, First Steps Nutrition Trust, GP Infant Feeding Network (GPIFN), HENRY, Hospital Infant Feeding Network (HIFN), the Human Milk Foundation, Institute of Health Visiting, Lactation Consultants of Great Britain (LCGB), La Leche League GB (LLLGB), Leicester Mamas, Centre for Lactation, Infant Feeding and Translational research (LIFT), Local Infant Feeding Information Board (LIFIB), Midwives Information and Resource Service (MIDIRS), National Breastfeeding Helpline, NCT (National Childbirth Trust), Royal College of Midwives (RCM), Save the Children, UK Association of Milk Banking (UKAMB), Unicef UK Baby Friendly Initiative, Unison, Women’s Environmental Network (WEN), World Breastfeeding Trends Initiative (WBTi) UK, Dr Robert Boyle, Natasha Day, Dr Clare Patton, Dr Ernestine Gheyoh Ndzi (independent members).