

# Protecting patients and the NHS through full transparency in industry-NHS collaborations

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The Government faces a key balancing act: growing a world-leading life sciences sector while safeguarding patients from the risks posed by financial conflicts of interest between pharmaceutical and medical device companies and the NHS, its staff, and professional bodies.

Ensuring full transparency of these financial ties is essential, but the current disclosure system in England, created and overseen by the industry, does little to address these risks. Independent research and the *Independent Medicines and Medical Devices Safety (IMMDS) Review* have highlighted its failures. In addition, cases of avoidable patient harm and instances of major companies failing to disclose their payments to the NHS and its staff underscore the urgent need for reform. Nevertheless, the Government's proposals in late 2023 offered only modest improvements.

This policy brief recommends legislative changes in three key areas based on patient experience, international best practices, and research evidence. These reforms will promote transparency by being comprehensive, enforceable, and actionable. In doing so, they will support the Labour Government's core missions to strengthen the NHS and drive investment in life sciences. Following the scope of the *IMMDS Review*, the proposed reforms focus on England, but their core transparency principles are relevant for all devolved administrations within the UK.



# Policy recommendations: Priority areas for transparency reform in healthcare

Drawing on research, international practices, and documented cases of patient harm from conflicts of interest in the NHS, this policy brief highlights areas for legislative reform. Based on the core principles of **comprehensive**, **enforceable**, and **actionable** transparency, these reforms aim to protect patients, ensure responsible use of public funds, and uphold trust in the NHS. The focus of these recommendations is on England but the three core principles are applicable across all devolved administrations as the challenges posed by conflicts of interest are systemic and affect all countries within the UK.

#### 1. Full disclosure of all industry payments.

All payments (cash or in-kind) made by pharmaceutical and medical device companies in relation to prescription-only products must be fully disclosed. The following categories are especially important as they are not covered by the current industry-run disclosure system, although they have been successfully addressed in other countries with appropriate legislative provisions.

- Payments related to drug/medical company research. Payments to individual researchers and research institutions amount approximately to two-thirds of all payments drug companies make in the UK, yet their recipients are not publicly identified, increasing the risk of bias in medical research, policy advice, and clinical commissioning.
- Ownership and investment interests. Any financial stakes healthcare
  professionals and decision-makers hold in pharmaceutical or medical
  device companies (e.g., equity, investments) must be publicly disclosed.
  These interests can lead to biased clinical recommendations and
  procurement decisions.
- Hospitality payments. Free food and drinks despite their relatively small value compared to other payment categories have been shown to influence medical decision-making, leading to unnecessary, expensive, and even harmful treatments. A low disclosure threshold, such as £10, is necessary to monitor impact.

## 2. Centralised, government-run disclosure database.

A single, comprehensive, government-managed database should be established to store all payments made to all professionals, institutions, and patient organisations. This database must be accessible to patients, regulators, policymakers, and the public, and subject to rigorous quality checks. It will serve as the central and authoritative source of information on financial ties within the healthcare system.

#### 3. User-friendly database interface.

The disclosure database should be designed for ease of use by all stakeholders. It must allow patients, carers, and professionals alike to search and interpret data without requiring significant time or expertise. Tools to visualise payment flows should be included to enable quick and informed decision-making.

# Delivering the transparency reform: Two legislative routes

To implement these recommendations, the Government has two viable routes. These are grounded in international models, allowing them to address the risks of conflicts of interest.

- Bespoke sunshine legislation. Similar to laws in the US and France, dedicated transparency legislation can specifically focus on financial disclosures in the healthcare sector.
- 2. Expanded health legislation. Following the examples of Denmark, Portugal, and Slovakia, the Government could integrate transparency provisions into existing health laws, such as the Health and Care Act 2022, which already provides the legal framework for requiring disclosures.

**Both legislative routes** are consistent with the recommendations to the Government made in the *IMMDS Review* by creating a legal obligation that prevents healthcare professionals from refusing their payments to be included in public disclosure databases. In addition, each approach has its unique advantages, and therefore the choice of the preferred option will depend on the Government's broader legislative agenda in healthcare.

However, international experience **does not support** the **'mixed' system** proposed during a <u>consultation held in 2023</u> by the previous Government, which favoured expanding the pharmaceutical industry-run Disclosure UK database. The key shortcoming of such mixed systems is that they leave significant payments outside public scrutiny.

# Addressing conflicts of interest in the NHS: Key priorities for reform and legislative solutions

Collaborations between the NHS, its staff, and drug and medical device companies can lead to innovation but can also generate **conflicts of interest** risking patient harm, undermining medical research, wasting taxpayers' money, and weakening public trust in the NHS.<sup>1,2,3</sup>

The current disclosure system in England is insufficient because it is industry-led, lacks reliable and comprehensive data, and allows healthcare professionals to opt out of disclosures. It therefore does not address risks posed by the financial ties which have been documented in a landmark parliamentary inquiry into the influence of the pharmaceutical industry<sup>4</sup> and the recent seminal *IMMDS Review*.<sup>5</sup>

In response to these concerns, in late 2023, the Government <u>ran a consultation</u> on improving the current system for disclosing these financial ties to the public.<sup>6</sup> However, the proposed solutions would offer only minor changes to the current self-regulatory transparency system.<sup>7,8,9,10</sup>

Considering these challenges, this policy brief outlines three key priority areas for legislative reform seeking to deliver **comprehensive**, **enforceable**, and **actionable** transparency:

- Full disclosure of all financial ties between industry and the healthcare sector, covering payments for research, ownership interests, and hospitality.
- A centralised, government-run disclosure database ensuring reliable, high-quality payment data for patients, regulators, and policymakers.
- 3. A user-friendly interface and tools to allow all stakeholders to search and interpret financial flows and identify potential conflicts of interest.

These reforms will not only allow the Government to protect patients and the NHS but also **boost investment** in the life sciences sector by fostering trust and accountability. Clear and enforceable transparency standards will create a competitive advantage for genuinely innovative companies while **minimising regulatory burdens** by leveraging existing reporting infrastructure.

To deliver these reforms, the Government has **two clear routes**, with the choice of the preferred one depending on its broader legislative agenda in healthcare:

- Bespoke sunshine legislation that focuses exclusively on transparency in healthcare.
- 2. **Expanding existing health legislation**, such as the Health and Care Act 2022, to integrate robust transparency provisions.

# Balancing corporate investment and public health

Pharmaceutical and medical companies have **extensive collaborative ties** to the healthcare sector across the UK.<sup>11</sup> These partnerships, promoted by successive governments as drivers of better healthcare and economic growth, <sup>12,13</sup> include grants, sponsorships, and consultancies for NHS institutions and staff.<sup>11,14,15,16,17</sup> For example, from 2015 to 2022 pharmaceutical companies paid £4.5bn to support their collaborations with healthcare professionals and organisations across the UK.<sup>18</sup> In addition, available data from 2015 suggests that the main focus of these partnerships is England, as demonstrated by the value of payments made (even when adjusted for the population size), the number of companies making payments, and the number of healthcare organisations receiving them.<sup>11</sup>

However, these collaborations can also generate **conflicts of interest** that undermine healthcare professionals' and organisations' **primary duty** to patient health.<sup>1,3,19,20,21,22,23</sup> The harm and waste generated by poorly managed conflicts of interest can far outweigh any potential benefits that can arise from industry collaborations. Research evidence, coming primarily from the US, where relationships between manufacturers and healthcare providers are most comprehensively documented, thanks to the government-run Open Payments database, shows that when conflicts are poorly managed, they can lead to:

- Compromised clinical judgement. Healthcare professionals may prescribe medications or make recommendations based on financial incentives rather than patient needs. These treatments can harm patients as they are not always necessary and carry additional risks and side effects.<sup>24,25,26</sup> For example, payments received by physicians were significantly associated with higher prescribing of opioid products and increased risk of patient deaths from overdoses.<sup>26</sup>
- Increased healthcare costs. Receiving industry payments may result in a preference for newer, more expensive treatments over equally effective, cheaper alternatives, placing additional strains on public resources.<sup>27,28,29</sup> To illustrate, a study looking at several commonly prescribed medications found that payments received by physicians were linked to the prescription of products that had less expensive but no less effective alternatives.<sup>27</sup>
- Bias in medical research. Funding by manufacturers can skew research outcomes, which, further down the line, may result in the approval of unsafe or ineffective products for use in patients.<sup>1,30,31</sup> Notably, researchers with conflicts of interest are more likely to choose study comparators that favour desired outcomes, report results selectively, or publish conclusions that are not supported by the study results.<sup>31</sup>
- Influence on treatment guidelines. Conflicts of interest can shape treatment guidelines, affecting standard care practices, and potentially influencing care delivered to thousands of patients.<sup>32,33,34</sup> For instance, a study found that guidelines for the prescription of opioids 'were at risk of bias because of pervasive conflicts of interest with the pharmaceutical industry.'<sup>34</sup>

The links between receiving industry payments and poor clinical, research, and advisory practice have not been traced in the UK because the payment data made available by the industry is incomplete and has low quality, as this policy brief demonstrates below. Nevertheless, there are strong indications that such an association exists at least in three critical areas.

Practitioners in England found that 'The pharmaceutical industry was the most frequently used information source and there was an evident association between the evidence distilled from representatives and prescribing initiation.'35 Importantly, General Practitioners may be influenced by the industry despite (or perhaps because of) their widespread belief about the 'immunity to commercial marketing activities.'36 In addition, changes in the pattern of prescription of a specific product have been interpreted as connected to its marketing by the manufacturer.'37

- Bias in medical research. Concerns about bias in medical research were widespread in the evidence submitted as part of the Health Committee's investigation into the influence of the pharmaceutical industry.<sup>4</sup>
- Cases of patient harm. The UK has seen a string of high-profile cases in which significant patient harm was reported as being associated with unaddressed financial conflicts of interest, such as involving pelvic mesh implants,<sup>5</sup> the antidepressant medication Seroxat (Paroxetine),<sup>38</sup> breast implants,<sup>39</sup> and the influenza treatment Tamiflu (Oseltamivir).<sup>40</sup>

However, these examples likely represent only **the tip of the iceberg**. The broader impact that conflicts of interest are having on everyday patient care is probably significantly greater and could be captured more accurately if comprehensive and high-quality payment data were available, a key motivation behind this policy brief.<sup>8,14,16</sup> For example, extensive research conducted in the US demonstrates that **even small payments**, such as a free lunch, have led to patients being prescribed **more expensive or unsafe drugs**.<sup>29,41,42</sup> A key case in point is the ongoing **opioid crisis**, which has claimed hundreds of thousands of lives, and placed severe pressure on public services and social cohesion in the US.<sup>26,43,44</sup>

# Industry self-regulation: Transparency-in-name only

The current disclosure system operating in England and other UK countries is driven by industry self-regulation and fails to address the risks posed by financial conflicts of interest in the NHS. Pharmaceutical and medical device companies decide which payments to disclose, how, when, and for how long. 14,16 Essentially, they are both setting and marking their own 'transparency homework'.

This self-regulatory system has resulted in several **major transparency** gaps.

- Insufficient disclosure of research payments. Payments related to pharmaceutical companies' research activities are reported without named recipients.<sup>8</sup> For example, in 2019, payments related to companies' research amounted to €435m or over two-thirds of all payments made in the UK the highest level among the 14 studied European countries.<sup>8</sup>
- Omission of key financial interests. Pharmaceutical companies have decided not to disclose important financial interests held by healthcare professionals, such as stock ownership and investments.<sup>7</sup>

- Incomplete disclosure of hospitality payments. While the pharmaceutical industry bans hospitality payments related to food and drink above £75, there is no requirement for detailed disclosure of smaller payments below this threshold. Yet even these smaller payments have been shown to influence clinical decision-making.<sup>29,41,42</sup> Without full disclosure, it is impossible to understand the extent of their impact on prescribing patterns within the NHS.
- Opt-out from disclosure. Individual healthcare professionals can ultimately refuse to have their payments included in drug company disclosures citing 'privacy concerns.' 14,45 This opt-out results in healthcare professionals with potentially the most significant conflicts of interest escaping appropriate scrutiny.

Given these transparency gaps, less than 25 per cent of the £4.5bn reported by drug companies between 2015 and 2022 is traceable to specific healthcare professionals or organisations.<sup>8,18</sup> Medical device company payments are even less transparent.<sup>46</sup>

Even where disclosures are made, the data available to the public is **incomplete** and **unreliable**.

- Missing details. Even when recipients' names are provided, other key information is often missing, including the nature or purpose of projects being funded or their links to any products being promoted by companies.<sup>7,8</sup> Therefore, it is unclear whether industry payments benefit the NHS or patients or have been purely promotional.<sup>15,17</sup>
- Inconsistent implementation. Because industry guidelines for disclosure are often imprecise, companies implement them inconsistently, making the payment data hard to understand. This undermines its value as a potentially vital resource for managing conflicts of interest that might affect clinical and policy decisions within the NHS.<sup>7,16,47</sup> For example, the same organisation or individual may appear under many names in different disclosures, obscuring their potential conflicts.
- Non-compliance. Some companies do not adhere to their self-regulatory obligations by failing to disclose their payments to clinicians, hospitals, and other stakeholders influencing NHS decision-making and processes. 47,48,49 A striking example involves Novo Nordisk, which has a dominant share of the UK's obesity care market. 50,51 Between 2020 and 2022, it failed to disclose approximately 500 payments, worth £7.8m, to over 150 recipients across the UK between 2020 and 2022. Without robust enforcement, the true scale of payments escaping disclosure and their potential impact on the NHS and its staff remains unknown.
- Poor accessibility. Patients and professionals find it very difficult to engage with industry disclosures.<sup>7,8</sup> A key case in point are payments to patient organisations, which are often very significant and can involve

serious conflicts.<sup>53,54</sup> These payments are reported separately by each company on its website, meaning stakeholders must potentially visit well over 100 company websites and inspect all available reports to build a complete picture.<sup>47</sup> This lack of accessibility places an unreasonable burden on NHS decision-makers, patient organisations, their members or supporters, and members of the public interested in how patient organisations manage their financial relationships with the pharmaceutical industry.

## Promoting transparency through legislation: International best practices

In addressing conflicts of interest in healthcare, countries have pursued two main legislative approaches.<sup>7,8,9,10</sup>

- 1. Bespoke sunshine legislation. Countries such as the US and France have enacted specific sunshine laws mandating companies to disclose payments in public databases. These sunshine laws have brought important benefits to healthcare and the public. For example, the US Sunshine Act has enabled:
  - Documenting payment influence: Revealed how payments made to doctors influence prescribing practices in ways that can compromise good clinical judgement.<sup>29,41,42,43</sup>
  - Exposing hidden financial ties: Uncovered conflicts of interest not disclosed to the public.<sup>55,56,57</sup>
  - Identifying corruption: Provided evidence of corrupt practices between some doctors and companies.<sup>58,59</sup>

In France, the **Loi Bertrand** has enabled journalistic investigations into the conflicts of interest in clinical trials and hospital practices.<sup>60</sup>

The **key advantage** of bespoke legislation is its tailored focus on transparency while considering privacy and commercial confidentiality concerns. It allows for the development of specialised enforcement mechanisms and draws attention to the issue of transparency from healthcare professionals, the industry, and the public.

2. Expanded health legislation. Countries like Denmark, Portugal, Romania, and Slovakia have integrated new transparency provisions into existing health legislation, such as medicines or pharmacy acts. These provisions are specified in secondary legislation, such as Lithuanian and Romanian

ministerial ordinances which detail exactly how and where companies must make their disclosures.

Embedding transparency of industry payments in existing legislation offers several **important advantages**, including a shorter legislative process and smoother implementation as stakeholders are familiar with the overall legal framework.

Both bespoke sunshine legislation and expanded existing health legislation can ensure complete, high-quality payment data, helping to trace conflicts of interest. Most importantly, unlike self-regulation, they do not grant individual healthcare professionals the right to withdraw their payments from the disclosure records based on privacy grounds.

In England, the *IMMDS Review* resulted in <u>a clause included in the Health and Care Act 2022</u>, granting the Secretary of State for Health and Social Care the power to make regulations requiring pharmaceutical and medical device companies to publish or report information about the payments and other benefits to the healthcare sector. Regulations set out in future secondary legislation could potentially meet the list of requirements above.

# A caution against 'mixed' disclosure systems

There is also a third option – a 'mixed' system in which the state supports currently existing disclosure databases run by the industry. This seemed to be the Government's preferred option in the 2023 consultation of Disclosure UK. However, mixed systems fail to provide the comprehensive transparency needed to manage conflicts of interest effectively.

International experience shows that these systems, such as those in Belgium, Spain, and the Netherlands, leave **significant shares of industry payments undisclosed**.<sup>7,8</sup> Most notably, payments related to companies' research activities, which make up a majority of all payments made, <sup>8</sup> are effectively excluded from disclosure. In addition, the 'mixed' system proposed by the Government in 2023 suggested £50 as the threshold for disclosure of industry payments (if the annual value of payments per recipient does not exceed £500). <sup>6</sup> This is similar to the threshold from the Dutch 'mixed' system (€50), but considerably higher than thresholds included in the US (\$10) and French (€10) sunshine legislation. <sup>6</sup> At least in the US, the low threshold for disclosure has enabled capturing the impact of small payments, such as free lunches, on clinical practice, as noted above. <sup>29,41,42</sup>

### **Core principles for legislative reform**

To ensure meaningful transparency, whether through bespoke sunshine legislation or expanding existing health laws, the Government must follow three core principles: **comprehensive**, **enforceable**, and **actionable** transparency:

#### 1. Comprehensive transparency

- Companies making payments: Ensure uniform provisions apply to both pharmaceutical and medical device manufacturers.
- Payment recipients: Cover the entire healthcare system, from policymakers to frontline healthcare workers.
- Payments: Mandate disclosure of all payments related to prescriptiononly products, including payments related to companies' research and development, ownership and investment interests, and hospitality payments above a low threshold (e.g. £10), consistent with the sunshine legislation in the US and France.

#### 2. Enforceable transparency

- Reporting guidelines: Require all companies to follow consistent definitions for payments, companies, and other aspects of reporting.
- Monitoring: Establish continuous and transparent monitoring by the Department of Health and Social Care.
- Compliance: Implement significant financial penalties for companies not complying with the disclosure requirements. Any fines collected should contribute towards to costs of maintaining the disclosure system.

#### 3. Actionable transparency

- Accessibility: Ensure payment data is searchable and downloadable by patients, healthcare professionals, and policymakers.
- User-friendliness: Present data in a format suited to the needs of patients and members of the public, allowing for ease of exploration and interpretation.
- Interconnectedness: Ensure that the disclosed data can be connected
  to existing NHS datasets to monitor the potential influence of payments
  on prescribing and device procurement.

### **Boosting investment**

Enhanced transparency in industry payments is not only essential for protecting patient health and responsible financial management within the NHS but also for promoting medical technology investment, a key Labour Government priority.<sup>61</sup>

- Transparency as a competitive advantage. Full transparency will
  establish clear, predictable, and enforceable standards for acceptable
  company behaviour. This will allow companies to enhance their
  reputation with policymakers, the NHS, and the public.
- Innovation through accountability. Full openness about financial
  ties with the healthcare sector will encourage companies to invest in
  collaborations that can withstand public scrutiny and bring forward
  genuine innovation.
- Level playing field. By mandating transparency for all companies, more robust transparency will ensure a level playing field where ethical practices are the norm. This will prevent unethical companies from gaining an unfair advantage and promote healthy competition based on product quality and efficacy.
- Risk management. Transparent disclosure of financial ties will help companies manage risks to shareholders by identifying and addressing potential conflicts of interest before they escalate into scandals. This proactive approach can protect companies from legal and reputational damage.

### **Minimising regulatory burdens**

The proposed legislative reforms will not create significant regulatory burdens for the NHS or industry. Pharmaceutical companies will report payments using mechanisms similar to the existing self-regulatory system. Medical device companies will need to expand their reporting infrastructure as their current reporting is very limited and is of very poor quality.<sup>46</sup>

Oversight by the Department of Health and Social Care will also involve minimal costs for pharmaceutical companies as the reforms will leverage existing infrastructure and expertise.

#### **Provenance**

This policy brief has been developed by an interdisciplinary team of international academic researchers in collaboration with UK-based civil society advocates.

The academic researchers who worked on this policy brief have an established track record of internationally comparative research on transparency and conflicts of interest in healthcare. In addition to the research evidence, Dr Ozaki provided key perspectives as a senior practicing physician familiar with the practice of collaborations between healthcare professionals and organisations and the life sciences sector in Japan.

The authors representing Sling the Mesh UK have led extensive advocacy efforts seeking to prevent patient harms by enhancing the transparency of financial ties between industry and clinicians and hospitals. This has involved providing evidence to the *Independent Medicines and Medical Devices Safety Review*, contributing to the Government's consultation on conflict-of-interest disclosure, and engaging with ministers and parliamentarians on these issues.

### **Conflicts of interest declaration**

Dr Mulinari's partner is employed by ICON, a global Contract Research Organisation whose customers include many pharmaceutical companies.

Dr Ozieranski's former PhD student was supported by a grant from Sigma Pharmaceuticals, a UK pharmacy wholesaler (not a pharmaceutical company).

Dr Ozaki received personal fees from MNES, Kyowa Kirin Inc., Becton, Dickinson and Company, Pfizer, Daiichi Sankyo Inc and Taiho Pharmaceutical Co., Ltd., outside the scope of this policy brief. Regarding non-financial conflicts of interest among the study authors, Dr Ozaki is engaged in ongoing research examining financial and non-financial conflicts of interest among healthcare professionals and pharmaceutical companies in Japan.

Ruth MacLeod is a member of the Sling the Mesh campaign group, currently works as a health policy advisor at the Royal National Institute for the Deaf, and previously worked for the MS Society.

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Other authors have nothing to declare.

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