PIP ACTION CAMPAIGN

PART II

The Anatomy of Institutional Harm

Fraudulent PIP Implants and the Official UK Narrative



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Introduction

For more than fourteen years, UK women affected by fraudulent PIP breast implants have fought for truthful information, recognition of their injuries and access to appropriate medical care. Women who underwent surgery in good faith—including reconstruction after breast cancer—have faced further operations, persistent illness and uncertainty about what was implanted in their bodies. They have sought answers about chemical exposure, pregnancy, breast feeding and their children's health. Across successive governments, they have repeatedly encountered an official account that acknowledges their distress while maintaining that serious long-term harm has not been established. The burden of challenging that account has fallen on the women living with its consequences. [2][4]

By February 2026, Parliament's Women and Equalities Committee had identified the continuing failures: official assurances resting on limited long-term research; inadequate records of who received PIP implants; enduring physical and psychological harm; poor follow-up; and dismissal of women's symptoms. The passage of time had neither resolved the scandal nor supplied the evidence needed to understand its full consequences. [5]

On 24 July 2026, PIP Action Campaign wrote to the Prime Minister seeking a statutory Public Inquiry within the principles of the Hillsborough accountability framework. Our letter asked for independent examination of what the authorities knew, the decisions they made, the evidence they failed to collect and the consequences for those exposed. It challenged the continued use of reassuring conclusions where the comprehensive investigation needed to establish the extent of harm had never taken place. It was an appeal for national leadership to break a pattern that successive governments had allowed to continue. [2]

The response of 5 September came from the Department of Health and Social Care's Ministerial Correspondence and Public Enquiries Unit—the department whose conduct formed part of the request for investigation. It offered no decision on that request and no reasons for declining or deferring it. Instead, it repeated the established account: the matter had been properly investigated; the regulator had fulfilled its obligations; the advice remained unchanged; and subsequent reforms demonstrated improvement. The request for scrutiny was answered with assurances from within the institutions requiring scrutiny. [1]

That response is itself evidence of the accountability failure this report examines. Our allegation is that an entrenched narrative has helped prolong the harm: women's evidence is reduced to "concerns", gaps in knowledge become grounds for reassurance, and institutional accounts of adequate performance stand in place of an independent examination of what happened. For women seeking treatment, these are consequential distinctions. An authoritative statement that harm has not been established can shape whether symptoms are investigated, whether exposure is considered and whether appropriate care follows. The cruelty lies in requiring injured and traumatized women to prove what the responsible institutions have failed adequately to investigate. [1][2][5]

Hillsborough and Infected Blood demonstrate why this pattern demands scrutiny. Bishop James Jones identified the protection of institutional reputation at the expense of accountability. The Infected Blood Inquiry found that defensiveness and repeated misleading assurances compounded the original harm; it specifically condemned the use of "no conclusive proof" where material qualifications were omitted. Those findings provide a standard against which the PIP response must now be examined. [28][29]

The Public Office (Accountability) Bill—the proposed Hillsborough Law—addresses the need for candour, assistance to inquiries and effective participation by those affected. The PIP case gives that need an immediate human meaning. Democracy depends on public explanations that can withstand examination. Women's dignity, bodily autonomy and ability to make informed decisions depend on access to truthful information and serious consideration of their evidence. These protections cannot depend on the endurance of those already harmed. [26][27]

Part I sets out the serious, potential and avoidable harms to women and children. Part II deconstructs the official narrative, sentence by sentence, exposing how omissions, selective evidence and repeated assurances sustain it. The case for a statutory Public Inquiry and enforceable public accountability arises from that record: institutions entrusted with protecting the public must be required to account for the harm, their decisions and the explanations they continue to give.

Fraudulent PIP Implants Background

Poly Implant Prothèse manufactured breast implants in France and supplied them internationally through the European Union's CE-marking system. By 2010, breast implants were Class III medical devices—the highest risk classification. That classification required scrutiny of their design, materials and manufacture. Regulatory responsibility continued after implantation: manufacturers were responsible for surveillance and clinical follow-up, notified bodies for assessing continuing conformity, and national regulators for monitoring and investigating adverse incidents and corrective action. Women were entitled to expect those protections to operate while the devices remained inside their bodies. [36]

Warnings preceded the discovery of the fraud. The MHRA had repeatedly questioned PIP about adverse incidents from 2003 onwards. Its own analysis, discussed in January 2010, identified earlier rupture than with competing implants. In France, increasing rupture reports, clinical warnings and information about the manufacturer prompted an inspection on 16–18 March 2010. Inspectors discovered the fraudulent substitution of the approved filler on 17 March. The matter was referred to prosecutors, and a police search, accompanied by regulatory staff, followed on 24 March. [9][37]

PIP had substituted its own mixtures for the Medical Grade silicone filler specified in its certification documents. The French investigation documented industrial ingredients, variable formulations, the absence of written production procedures for the substitute gels, poor or absent cross-linking—the chemical process that forms the gel— and in some cases the removal of the implant shell's barrier layer altogether. These findings concerned the composition and manufacture of devices implanted into women's bodies under an assurance of regulatory conformity. [37]

France suspended the implants' marketing and use on 29 March 2010 and publicly announced its action on 30 March, with information for women and recommendations for their clinical follow-up. The UK regulator was informed. In November 2011, the French authorities reported the death from anaplastic large cell lymphoma of a woman who had carried PIP implants. On 23 December 2011, following further assessment of the evidence, France recommended that every affected woman be offered preventive removal, including women without clinical signs of implant deterioration. Its decision identified established risks of rupture and irritation capable of causing inflammation and making removal more difficult. [9][37][38][39]

Meanwhile, in the UK, stopping further implantation was not accompanied by a comparable response for women already carrying the devices. The Howe Report records that the MHRA did not advise clinicians to contact affected women after the March 2010 discovery. Pending toxicology information, it considered that there was no additional advice to offer beyond the investigation ordinarily undertaken when a woman reported symptoms of rupture. The immediate response therefore left those women dependent on recognising a problem and seeking help, although the authorities already knew that the implants did not conform to their approved specification. [9, paragraphs 5.3–5.8]

By 21 December 2011—approximately 21 months after the French alert—the message reported by BBC News was reassurance. Its headline read: "Breast implants 'have no cancer link' says UK watchdog." The report conveyed the UK position that routine removal was unnecessary and directed concerned women back to their implanting surgeon or clinic. Two days later, France announced its national offer of preventive removal. [39][40]

The House of Commons Health Committee's 2012 PIP Report subsequently concluded that the UK's communication with affected women after March 2010 had been inadequate. It found that the scale of the problem should have prompted a substantial public response much sooner, including urgent evidence collection. These failures were therefore identified by Parliament in 2012. [11, paragraphs 25–28]

This is the political setting in which the subsequent expert assessments and government reviews must be understood. Decisions had already been made about notification, investigation, intervention and responsibility. Part II examines how scientific advice was used to sustain those decisions—and how an assessment conducted under acknowledged uncertainty became an enduring official narrative of reassurance.

The official account of PIP drew authority from two distinct assessments: a review of the conduct of public institutions and an expert assessment of the risks to women. Understanding who produced these reports, and what they were commissioned to examine, is essential to understanding the narrative that followed.

Earl Howe, then a serving health minister, led the review of the Department of Health and the Medicines and Healthcare products Regulatory Agency (MHRA), published on 14 May 2012. Departmental civil servants conducted the review and reported directly to him. MHRA and departmental officials commented on its draft findings, and ministers agreed its publication. This was an internal examination of the institutions' own conduct. Its authorship and reporting arrangements matter when its conclusions are subsequently invoked as evidence that the regulatory response was adequate. [9]

Dr Bruce Keogh, then NHS Medical Director, chaired the Expert Group assessing the health risks of PIP implants and advising on the clinical response. The Keogh Preliminary Report appeared on 6 January 2012 and the Keogh Final Report on 18 June 2012. The group brought together surgeons and specialists in toxicology, statistics and clinical ethics, including Ian Kimber, a toxicologist at Manchester University, and Anne-Marie Slowther, a clinical ethicist at Warwick Medical School. Its conclusions supplied the scientific basis for the continuing advice against routine preventive removal. [12][34]

Part II examines how these assessments came to sustain a common institutional position: that the regulatory response had been adequate and that the evidence did not justify a different clinical approach. To understand the authority attached to that position, it is necessary to examine the conditions under which the scientific judgement was reached.

Mandated science and enduring reassurance

David Spiegelhalter, then Cambridge's Winton Professor of the Public Understanding of Risk, was a member of Keogh's Expert Group and led its statistical assessment. His subsequent account provides an explanation from within the assessment of the evidence available and the constraints on its interpretation. Writing in Significance in December 2012, he described the task directly:

> *"Essentially this was 'mandated science' – a conclusion had to be drawn, using whatever material was available."*

David Spiegelhalter, with Stuart Knight and Tony Sant, Significance, December 2012. [23]

The group had to provide policy advice despite poor-quality data, conflicting sources and severe time constraints. Spiegelhalter explained that systematic biases limited what statistical analysis could establish, leaving substantial reliance on qualitative judgement. These limitations were part of the assessment itself. [23]

The evidentiary problem examined here is the continuing authority given to that assessment. The DHSC letter of 5 September 2026 relies on its conclusions without demonstrating that the acknowledged deficiencies have been repaired. An urgent judgement made from incomplete evidence cannot, through repetition alone, establish the long-term safety of women exposed to fraudulent implants. Part II examines how the Department's language maintains that reassurance while leaving the underlying evidentiary gaps unresolved. [1, sentences 13 and 36][12][23]

The Keogh Preliminary Report of 6 January 2012 supported the MHRA's position against routine removal, while explicitly acknowledging considerable uncertainty and recommending further data collection. Its conclusions were provisional. The report committed the group to reviewing new evidence and considering whether its advice should change. [34]

The House of Commons Health Committee, chaired by Stephen Dorrell MP, examined that response in its 2012 PIP Report of 28 March 2012. It identified repeated gaps in the evidence, uncertainty about implant composition and insufficient knowledge of rupture rates and their consequences. The Committee recorded Keogh's acknowledgement that "the absence of evidence is not the same as evidence of safety". It called for all available evidence—including women's reported experiences—to be gathered and analysed, and for further data collection if safety remained unresolved. These limitations were therefore known to Parliament from the outset. [11]

The Howe Report, published on 14 May 2012, addressed regulatory and departmental conduct. Earl Howe was a serving Health Minister; the review was undertaken by Department of Health civil servants reporting directly to him. Its chronology ended on 24 December 2011. Although it concluded that the

MHRA had fulfilled its obligations, its status as an internal minister-led review and the limits of its examination matter when its conclusions are subsequently presented as independent vindication. [9]

The Keogh Final Report, published on 18 June 2012, confirmed substantially higher rates of rupture or silicone leakage and acknowledged that incomplete follow-up had produced serious underestimation of failure. Nevertheless, it maintained the position against routine preventive removal. Crucially, paragraph 27 acknowledged widespread reports of systemic symptoms but declined the proposed collection of information to assess their frequency. The report therefore records both evidentiary limitations and a decision against collecting further evidence, which is central to assessing the continuing reliance on its conclusions. [12]

The Scottish Parliament's SPICe briefing, The Regulation and Governance of Medical Devices in Scotland, by Fiona Coyle, published on 29 June 2018, revisited PIP within the wider regulatory system. It recorded the history of adverse reports and the problem of regulatory conclusions drawn from incomplete information filtered through the fraudulent manufacturer. This parliamentary research briefing helps locate the PIP response within longstanding weaknesses in device regulation and surveillance. [35]

By 18 February 2026, the Women and Equalities Committee (WEC Committee), chaired by Sarah Owen MP, was still identifying limited long-term research, inadequate records, insufficient follow-up and dismissal of women's symptoms. Its findings demonstrate the continuing distance between official reassurance and the evidence needed to account for women's health. [5]

The central allegation concerns what happened to the acknowledged uncertainty. The DHSC letter of 5 September 2026 continues to rely on the 2012 conclusions without demonstrating that the deficiencies identified by the experts and parliamentary committees have been repaired. An urgent assessment became an enduring reassurance. The passage of fourteen years cannot, by itself, turn incomplete evidence into an adequate account of long-term harm. Part II examines how that transformation is sustained in the Department's own words. [1][5][12][23]

Public accountability

Within six months of the December 2011 public controversy, the Government's principal reviews had reported: the Keogh Preliminary Report in January, the Howe Report on regulatory conduct in May, and the Keogh Final Report on 18 June 2012.

By June 2012, the central elements of the UK's official narrative had been established. Responsibility rested with the fraudulent manufacturer; the regulator had fulfilled its obligations; the available evidence did not justify routine preventive removal; and serious long-term harm had not been demonstrated. The Howe Report supplied the account of institutional adequacy, while the Keogh Final Report supplied the scientific reassurance. Together, they provided the framework through which women's subsequent concerns would be answered. [9][12]

The first UK BIA-ALCL fatality was in June 2012. [41]

Despite evidence emerging in France and Australia, the acknowledged deficiencies in the evidence did not prevent these conclusions becoming the settled official UK position.

The WEC Committee's Cosmetic procedures Report challenged the evidentiary basis of that reassurance in February 2026. Nevertheless, the DHSC letter of 5 September 2026 again invokes the Keogh Final Report, cites the Howe Report as confirmation that the MHRA fulfilled its obligations, and states that its current advice remains unchanged. [1][5]

This is the continuity Part II examines: an assessment reached under acknowledged uncertainty became an enduring institutional account of safety and adequacy. Women's continuing reports of harm were received within a framework whose central conclusions had already been settled.

Part II alleges that the institutional response compounded the original PIP fraud. An official narrative of reassurance became a defence of the authorities' conduct while women continued to seek recognition, investigation and care. Hillsborough, Infected Blood, Mid Staffordshire and First Do No Harm expose the mechanisms through which institutions prolong harm: defending their reputations, dismissing those affected and repeating explanations that leave material evidence out.

Hillsborough Law and public accountability

The Public Office (Accountability) Bill—the proposed Hillsborough Law—addresses institutional evasion through duties of candour, disclosure and assistance in inquiries and investigations. Clauses 2–3 address the provision of relevant evidence and correction of errors and omissions. Clause 10 addresses ethical conduct; clause 12 proposes an offence of seriously improper, intentional or reckless misleading of the public. These provisions express a fundamental accountability principle: public bodies must help establish the truth about their conduct. [26][27]

Hillsborough: public interest before institutional reputation

Bishop James Jones's 2017 report called for public bodies to "Place the public interest above our own reputation." Its charter demanded full disclosure, honest participation in scrutiny and an end to defending the indefensible or dismissing those harmed. [28]

That principle goes directly to the PIP argument. The DHSC's letter repeats the authorities' favourable assessment of their own response. Part II challenges that account through the evidence it omits, the unresolved failures it passes over and the continuing harm it leaves unanswered. [1]

Infected Blood: reassurance that conceals the evidence

The 2024 Infected Blood Inquiry found that institutional defensiveness and repeated official explanations compounded the original harm. It examined assurances of "no conclusive proof" that omitted evidence of a recognised risk. Its finding was explicit: "It lacked candour and by not telling the whole truth was misleading." [29]

This finding identifies a central mechanism examined in Part II: uncertainty presented as reassurance, while the evidence needed to understand that uncertainty disappears from the official account. An absence of proof cannot establish safety. Repeating a conclusion cannot repair the evidence missing beneath it.

Mid Staffordshire and First Do No Harm: listening, disclosure and care

Robert Francis's Mid Staffordshire Inquiry required healthcare organisations to give truthful accounts, including public statements that do not mislead by omission. It placed openness, recognition of harm and an appropriate remedy at the centre of accountability. [30]

First Do No Harm, led by Julia Cumberlege, exposed a fragmented and defensive healthcare system in which women's accounts were repeatedly dismissed. It called for specialist care and reliable information connecting implanted devices to the people receiving them. [31]

These findings give the PIP analysis its accountability standard. Women's reports of harm require investigation. Their exposure histories must remain visible. Material omissions require correction. Claims about safety and access to care must be supported by evidence. The institutions' account of their response must answer to women's experience and the documented record.

Categories and sentence index

The 49 sentences in DHSC's response of 5 September 2026 are examined below in the original 14 categories. Each quotation is followed by its narrative function, the evidence and rebuttal, and named sources with specific locations. The categories identify how the reply maintains the official account while leaving the inquiry request and women's continuing clinical needs unanswered. [1][2][5]

Category	Key point	DHSC sentences
1	The request is returned to the institutions under challenge	1, 2, 49
2	Women's evidence is reduced to concern and distress	3, 4, 21
3	Investigative adequacy is asserted without accounting for failures	5, 7, 8
4	Manufacturing uncertainty is used as reassurance	6, 9, 10, 11
5	The limits of the 2012 clinical conclusion are omitted	12, 13
6	Toxicology findings are extended beyond what was tested	14, 15
7	Product withdrawal is substituted for informing women	16
8	Information is substituted for access to clinical care	17, 18, 45, 46
9	International agreement obscures different protective decisions	19, 20
10	Missing evidence sustains unchanged advice	22, 33, 34, 35, 36, 43
11	The Howe review is presented as independent exoneration	23, 30, 31
12	The missing cohort is detached from the registry's history	25, 26, 27, 28, 29, 32
13	Cancer classifications narrow the visibility of PIP exposure	37, 38, 39, 40, 41
14	Monitoring and later reforms stand in for a demonstrated PIP response	24, 42, 44, 47, 48

Reference numbers connect to the named source annex and full plain text URLs at the end. Quotations retain DHSC's wording, including its dates and descriptions; those claims are examined in the evidence and rebuttals.

Evidentiary annex

Category 1 The request is returned to the institutions under challenge

Allegation. DHSC substitutes its own account of existing policy for a reasoned response to the allegations referred by the Prime Minister's Office.

Purpose. Establish what the reply actually answers, identify the missing decision and distinguish departmental self-assessment from independent accountability.

Accountability alignment. Hillsborough Report — public interest and openness to scrutiny. Infected Blood Inquiry Final Report — the additional harm of institutional defensiveness. [28][29]

Sentence 1

DHSC. *"Thank you for your correspondence of 24 July to the Prime Minister about Poly Implant Prothèse (PIP) breast implants."*

Narrative function. Narrows the description of the originating submission.

Evidence and rebuttal. The subject and date are correct. The omitted context is the purpose: the 24 July letter presented allegations about regulatory decisions, ministerial advice, lost surveillance and continuing harm, and requested independent statutory scrutiny. Describing it simply as correspondence about implants permits an account of existing policy to stand in place of an answer to those allegations. PIP Action Campaign's 24 July letter to the Prime Minister remains the measure of whether the response is adequate.

Sources. DHSC response of 5 September 2026 [1] p. 1; PIP Action Campaign letter to the Prime Minister of 24 July 2026 [2] pp. 1–3.

Sentence 2

DHSC. *"Your letter has been passed to the Department of Health and Social Care, and I have been asked to reply."*

Narrative function. Places the institutional account in the hands of the department challenged.

Evidence and rebuttal. The referral places DHSC in control of the response to allegations concerning DHSC and MHRA. The resulting letter selects the evidence, describes the institutions' conduct and endorses their position. It identifies no independent assessment and no accountable decision on the request sent to the Prime Minister. The observable problem is a conflict of function: the department's explanation is presented where the submission sought scrutiny of that explanation.

Sources. DHSC response of 5 September 2026 [1] p. 1; PIP Action Campaign letter to the Prime Minister of 24 July 2026 [2] pp. 1–3; PIP Action Campaign correspondence of 28 August 2026 [3].

Sentence 49

DHSC. *"I hope this reply is helpful."*

Narrative function. Closes the correspondence without a reasoned determination of the submission.

Evidence and rebuttal. The reply contains no acceptance or refusal of the statutory inquiry request, no named minister responsible for deciding it and no reasons addressing the case submitted. It is signed by an unnamed correspondence officer. These are omissions visible in the document; they do not tell us what happened in undisclosed internal discussions. The finding is that the response delivered to the Campaign leaves the request and its supporting allegations substantively undetermined.

Sources. DHSC response of 5 September 2026 [1] closing text and signature; PIP Action Campaign letter to the Prime Minister of 24 July 2026 [2] pp. 1–3; PIP Action Campaign correspondence of 28 August 2026 [3].

Category 2 Women's evidence is reduced to concern and distress

Allegation. The response acknowledges emotional reactions while leaving the submitted evidence of physical harm and failures of care substantively unanswered.

Purpose. Restore women's injuries, clinical records and reported experience to the centre of the analysis, including the consequences of dismissing symptoms.

Accountability alignment. First Do No Harm Report — reports from women must be heard and investigated. Mid Staffordshire Public Inquiry Report — care and accountability must be judged through the experience of those affected. [30][31]

Sentence 3

DHSC. *"I appreciate your concerns."*

Narrative function. Acknowledges concern without engaging with its evidentiary substance.

Evidence and rebuttal. The problem is the response as a whole: DHSC acknowledges concern but does not answer the allegations and documents submitted by PIP Action Campaign. Women's evidence remains described as concern while the existing institutional position is restated. Acknowledgement supplies neither an investigation of the reported harm nor an answer to the institutional conduct identified in PIP Action Campaign's 24 July letter to the Prime Minister.

Sources. DHSC response of 5 September 2026 [1] pp. 1–6; PIP Action Campaign letter to the Prime Minister of 24 July 2026 [2] pp. 1–2.

Sentence 4

DHSC. *"The Medicines and Healthcare products Regulatory Agency (MHRA) recognises the distress experienced by those who received PIP breast implants and the importance of patients receiving accurate and comprehensive information on their concerns."*

Narrative function. Recognises distress and the importance of information without accounting for injury or delivery.

Evidence and rebuttal. PIP Action Campaign's 24 July letter to the Prime Minister described physical injury, repeated operations, silicone migration, lymph-node involvement and continuing illness. The WEC Committee's February 2026 Cosmetic procedures Report also recorded enduring physical and psychological harm, inadequate follow-up and dismissal of symptoms. The DHSC sentence neither answers that evidence nor demonstrates that women received timely, accurate information. Its language of distress leaves the clinical and institutional substance of the allegations unaddressed.

Sources. PIP Action Campaign letter to the Prime Minister of 24 July 2026 [2] pp. 1–2; WEC Committee Cosmetic procedures Report [5] paragraphs 14–19.

Sentence 21

DHSC. *"The MHRA recognise that people affected by PIP implants may continue to have questions or concerns."*

Narrative function. Returns continuing injury and unmet need to the language of questions and concerns.

Evidence and rebuttal. By this point, the reply has still not addressed the submitted record of physical consequences and barriers to care. Its acknowledgement leads directly into maintenance of existing advice. The findings of the WEC Committee's Cosmetic procedures Report and the originating letters require a substantive account of how harm and unmet need were assessed. Repeating a recognition of concern adds no such account and leaves the continuing clinical consequences outside the response.

Sources. DHSC response of 5 September 2026 [1] sentences 21–22; PIP Action Campaign letter to the Prime Minister of 24 July 2026 [2]; Fleur Anderson letter of 4 August 2026 [4]; WEC Committee Cosmetic procedures Report [5] paragraphs 18–19.

Category 3 Investigative adequacy is asserted without accounting for failures

Allegation. A description of MHRA's responsibilities and activity is used to convey that the PIP response was adequate, despite recorded failures in evidence gathering and gaps in the public record.

Purpose. Separate the duty to investigate from its performance, and distinguish missing manufacturer records from missing government records.

Accountability alignment. Public Office (Accountability) Bill — assistance with scrutiny and correction of omissions. Mid Staffordshire Public Inquiry Report — favourable accounts must be tested against adverse information. [26][30]

Sentence 5

DHSC. *"The role of the MHRA is to monitor all incidents that are reported to it, making sure that these incidents are investigated fully and that any necessary action is taken."*

Narrative function. Uses a statement of institutional duty as an assurance of institutional performance.

Evidence and rebuttal. MHRA's role does not establish that PIP incidents were fully investigated. The 2013 Cosmetic Review estimated that only 15–18% of expected PIP adverse incidents had been reported. MHRA's August 2026 Internal Review upheld refusal of the requested adverse-incident and health-consequence information and confirmed a manual-review estimate exceeding 167 hours. The Campaign's request reproduced in that review records MHRA's earlier disclosure of more than 2,500 PIP reports. Those are reports, not a count of distinct injured women. The Medical Devices Regulations 2002, regulation 65, required the UK to perform the Member State's Article 10 incident-recording functions. DHSC's assurance must be tested against the actual recording, evaluation, investigation and protective response, not the statement of a duty alone.

Sources. 2013 Cosmetic Review [6] paragraph 4.10; MHRA Internal Review IR2026/00843 [7] pp. 1 and 4–6, response points 1 and 5–7; EU Class III framework and Medical Devices Regulations 2002 [36] Medical Devices Regulations 2002, regulation 65 and Directive 93/42/EEC, Article 10; DHSC response of 5 September 2026 [1] sentence 5.

Sentence 7

DHSC. *"The manufacturer acted fraudulently and then ceased operation therefore there was limited scope to obtain documentation."*

Narrative function. Attributes documentary limits to the manufacturer's fraud and closure.

Evidence and rebuttal. PIP's closure does not account for the records and decisions of the regulator, Department, notified bodies or healthcare providers. The Howe Report itself contains a substantial regulatory chronology. Separately, MHRA's August 2026 FOI response says it no longer holds relevant personnel records and holds no explanation of the senior devices vacancy or assessment of its effect on PIP handling. These are public-authority record gaps. They cannot be explained away by the manufacturer's closure.

Sources. Howe Report [9] chronology; MHRA FOI2026/00792 response [10] pp. 1–2.

Sentence 8

DHSC. *"The MHRA worked with the NHS and other health partners to ensure the issue was properly investigated."*

Narrative function. Treats collaboration as proof that investigation was adequate.

Evidence and rebuttal. The House of Commons Health Committee's 2012 PIP Report criticised the delay in evidence gathering and inadequate communication, finding no significant activity between March 2010 and December 2011. The Keogh Final Report then acknowledged widespread systemic-symptom reports but decided against the proposed PIP-specific frequency study. Those findings directly qualify the assertion that the issue was properly investigated. Participation by several organisations does not establish that the relevant harms were measured or that the evidence gaps were resolved.

Sources. House of Commons Health Committee 2012 PIP Report [11] paragraphs 23–28; Keogh Final Report [12] paragraph 27.

Category 4 Manufacturing uncertainty is used as reassurance

Allegation. Unresolved variation in fraudulent PIP manufacture is presented without a reliable means of identifying what any individual woman received or what that meant for her exposure.

Purpose. Expose the unsupported step from variable samples and incomplete records to reassurance about unidentified recipients.

Accountability alignment. Infected Blood Inquiry Final Report — incomplete proof must not conceal a material safety uncertainty. [29]

Sentence 6

DHSC. *"The concerns relate to the use of non-approved silicone filler in some PIP breast implants and, in some cases, more fragile implant shells."*

Narrative function. Reduces fraudulent manufacture to unspecified subsets of filler and shell defects.

Evidence and rebuttal. SCENIHR's 2012 PIP Opinion and the French DGS/AFSSAPS Investigation Report documented fraudulent substitution of the certified filler, manufacturing variation and removal of the barrier layer. This was fraudulent manufacturing outside the certified design and production specification, not ordinary variation in an authorised Class III product. The French report records variable proportions and no written procedure for the substitute gel. Neither a sample of approved filler nor a component that passes an individual test establishes that the complete device was manufactured under the required controls. DHSC identifies no traceable, compliant whole-device category for individual women. Its word 'some' cannot identify which women escaped the consequences of the fraud.

Sources. SCENIHR 2012 PIP Opinion [8] sections 3.4.2 and 5.3, pp. 15 and 22–23; French DGS/AFSSAPS Investigation Report [37] manufacture and physicochemical analyses, pp. 123–129; EU Class III framework and Medical Devices Regulations 2002 [36] Class III conformity framework; DHSC response of 5 September 2026 [1] sentences 6 and 9–11.

Sentence 9

DHSC. *"Available evidence indicated that not all PIP implants manufactured during the affected period contained non-medical grade silicone or had more fragile shells."*

Narrative function. Invokes manufacturing variation without identifying the women to whom it applies.

Evidence and rebuttal. SCENIHR's 2012 PIP Opinion records variation in the fraudulent gels and shells. That variation does not tell a woman which material or shell she received, whether her whole device conformed to the certified specification, or what escaped from it. The French DGS/AFSSAPS Investigation Report records manufacturing inconsistency and failed process traceability. These are failures of the controls required for a Class III implant. DHSC supplies no validated method for assigning women to a compliant category. Read with sentence 11, the result is unresolved exposure uncertainty, not an identifiable group whose whole devices were shown to comply.

Sources. SCENIHR 2012 PIP Opinion [8] section 5.3; French DGS/AFSSAPS Investigation Report [37] physicochemical analyses and conclusions, pp. 123–129; EU Class III framework and Medical Devices Regulations 2002 [36] conformity assessment and essential requirements; DHSC response of 5 September 2026 [1] sentences 9–11.

Sentence 10

DHSC. *"Rupture rates can therefore vary depending on the batch received, and early rupture typically occurs within the first 5 to 10 years."*

Narrative function. Frames failure through batch variation and an apparent time window.

Evidence and rebuttal. The Keogh Final Report estimated failure, defined as rupture or significant silicone bleed, at 6–12% after five years and 15–30% after ten years. It described retrospective estimates as substantial underestimates because follow-up was incomplete and lacked imaging. DHSC omits those qualifications and provides no means of assigning a woman a reliable batch-specific risk. These figures cannot establish a period during which an individual woman's exposure was safe.

Sources. Keogh Final Report [12] paragraph 25 and summary.

Sentence 11

DHSC. *"Unfortunately, because of the fraudulent activity involved, it has not been possible to determine precisely how many implants fell into each category."*

Narrative function. Acknowledges uncertainty without explaining how it affected protection.

Evidence and rebuttal. DHSC's inability to quantify the categories limits the conclusions it can draw from sentences 9 and 10. The French DGS/AFSSAPS Investigation Report documents fraudulent, inconsistent manufacture, rather than controlled production to the certified Class III specification. DHSC does not explain how uncertainty about composition, shell integrity and exposure informed precautionary communication, clinical assessment or follow-up. Unquantified manufacturing variation cannot support individual reassurance without a method of identifying and assessing recipients.

Sources. DHSC response of 5 September 2026 [1] sentences 9–11; SCENIHR 2012 PIP Opinion [8] section 5.3; French DGS/AFSSAPS Investigation Report [37] manufacture and process traceability, pp. 123–129; EU Class III framework and Medical Devices Regulations 2002 [36] essential requirements and conformity framework.

Category 5 The limits of the 2012 clinical conclusion are omitted

Allegation. The response repeats a reassuring conclusion while omitting the failure rates, incomplete follow-up and decision against collecting PIP-specific systemic-symptom frequency data recorded in the same report.

Purpose. Read the conclusion together with the evidence that limits it, and distinguish the location of harm from its severity.

Accountability alignment. Mid Staffordshire Public Inquiry Report — statements must not mislead by omission. Infected Blood Inquiry Final Report — inherited official assurances require examination of their evidentiary basis. [29][30]

Sentence 12

DHSC. *"The MHRA worked with other international regulators at the time to investigate and it was found that ruptured PIP implants may cause local reactions around the implant area in a small proportion of women, which can result in symptoms such as tenderness or swollen lymph glands."*

Narrative function. Compresses clinical harm into a small proportion and limited local examples.

Evidence and rebuttal. 'Local' describes where an effect occurs, not how severe or persistent it is. The Keogh Final Report recorded excess local clinical signs and underestimation associated with poor follow-up; SCENIHR's 2012 PIP Opinion considered leakage as well as rupture. Published PIP studies also record tissue infiltration, extensive silicone lymphadenopathy and further surgery. Mistry and colleagues' PIP case records progressive lymph-node disease causing thoracic outlet syndrome after explantation. DHSC supplies no denominator for its 'small proportion' and compresses this clinical burden into tenderness and swollen glands. PIP Action Campaign's 24 July letter raised injuries and repeated operations requiring an account of severity, persistence and consequences.

Sources. Keogh Final Report [12] paragraphs 15–27; SCENIHR 2012 PIP Opinion [8] sections 3.4.2 and 5.3; Zambacos and colleagues 2013 lymphadenopathy study [47] PIP subgroup and findings; Mistry and colleagues 2015 PIP thoracic outlet case [61] Summary and Case report; PIP Action Campaign letter to the Prime Minister of 24 July 2026 [2] pp. 1–2.

Sentence 13

DHSC. *"While the MHRA understands the concerns some women may have, the PIP UK Expert Group concluded in their final report, available at www.gov.uk/government/publications/poly-implant-prothese-pip-breast-implants-final-report-of-the-expert-group, that PIP implants are clearly substandard although there is no evidence of a significantly increased risk of clinical problems in the absence of rupture or that local reactions cause serious long-term health issues (June 2012)."*

Narrative function. Carries the 2012 reassurance forward without its material qualifications.

Evidence and rebuttal. The Keogh Final Report itself recorded increased failure, deficient follow-up and under-reporting. Paragraph 27 acknowledged widespread systemic symptoms but rejected proposed PIP-specific frequency data collection.

PIP Action Campaign's June 2013 Literature Review assembled emerging clinical and analytical papers; subsequent published reports include systemic inflammatory disease and pulmonary silicone embolism following PIP exposure. DHSC's 2026 repetition neither evaluates those findings nor shows that the missing long-term evidence was collected. The central allegation remains the conversion of a limited assessment into enduring authority: an outcome inadequately measured cannot be presented as if long-term investigation had excluded it.

Sources. Keogh Final Report [12] paragraphs 14–27; WEC Committee Cosmetic procedures Report [5] paragraphs 18–19; Spiegelhalter, Knight and Sant 2012 analysis [23] evidence limitations; PIP Action Campaign June 2013 Literature Review [44] contents and papers 1–11 and 22–29; Chan and colleagues 2015 systemic inflammatory case [58] Abstract and Case presentation; Gopinath and colleagues 2015 PIP pulmonary case [59] published PIP pulmonary case.

Category 6 Toxicology findings are extended beyond what was tested

Allegation. Selected gel tests and a limited breast milk investigation are used to support statements broader than the substances, samples and outcomes actually examined.

Purpose. Define precisely what the tests establish and expose the unsupported extension to all cancer risks, all silicone derivatives and all infant exposure.

Accountability alignment. Public Office (Accountability) Bill — candour and correction of material omissions. First Do No Harm Report — the safety response must address women's and children's experiences. [26][31]

Sentence 14

DHSC. *"The toxicological assessment, at www.gov.uk/government/publications/poly-implant-prosthese-pip-implants-toxicology-testing/poly-implant-prosthese-pip-implants-toxicology-testing, of the non-approved silicone contained in PIP breast implants at the time of the investigation indicated that the silicone was not carcinogenic."*

Narrative function. Extends selected toxicology findings into a broad cancer assurance.

Evidence and rebuttal. The MHRA Toxicology Testing webpage describes specific genotoxicity, cytotoxicity and irritation tests, including in vitro tests of extracts from five batches. Their methods and endpoints must remain visible when describing what those tests established about the sampled gel. They did not follow the exposed women over decades or assess every mechanism involving an implant surface, capsule or inflammatory response. The French DGS/AFSSAPS Investigation Report and Beretta and colleagues' analyses of explanted PIP materials also concern the actual fraudulent formulations and containment. A gel-test conclusion cannot stand for a complete cancer assessment of the whole implant and its lifetime exposure. The broader assurance about 'other cancers' is examined separately at sentence 38.

Sources. MHRA PIP Toxicology Testing webpage [13] Additional MHRA tests; French DGS/AFSSAPS Investigation Report [37] materials and physicochemical analyses, pp. 123–129; Beretta and Malacco 2013 PIP analysis [49] comparative analytical investigation; Beretta and colleagues 2013 periprosthetic-fluid analysis [50] late periprosthetic-fluid analysis; MHRA BIA-ALCL guidance [14] cancer monitoring and data limitations; DHSC response of 5 September 2026 [1] sentences 14 and 38.

Sentence 15

DHSC. *"Available evidence at the time also concluded that no silicone or any derivates are passed to infants through breast milk."*
Narrative function.. Converts an unresolved question about chemical transfer into an absolute denial of infant exposure, concealing the silicon proxy, the limitations of the cow's milk experiment and the qualifications in the official record.
Evidence and rebuttal. Paragraph 10 of the Keogh Final Report did not establish that no silicone derivatives enter breast milk. It explicitly recognised that lower-molecular-weight siloxanes could migrate into milk and stated that the commissioned milk analysis was awaiting results. Continuing breast feeding advice was a policy judgement made while that investigation remained incomplete. DHSC presents that unresolved position as an established finding of no transfer. [12] (assets.publishing.service.gov.uk)

The subsequent MHRA cow's milk experiment measured total silicon, using an elemental measurement as a proxy for chemically distinct silicone-related substances. Silicon is not interchangeable with silicone: a total-silicon result cannot identify or separately quantify the individual siloxanes D4, D5 and D6. The investigation involved one breast milk sample from a woman with a ruptured PIP implant. MHRA acknowledged that its method had not been fully optimised and validated. Commercial semi-skimmed cow's milk, used to develop the method, contained more total silicon. That comparison did not establish the absence of implant-derived substances from human milk, equivalent chemical composition, or safety for an exposed infant. Cow's milk was not an unexposed human breast milk control. [13] (gov.uk, gov.uk)

The MHRA's own October 2012 summary directly undermines DHSC's categorical assurance. Silicon in Breast Milk states that silicon materials can be found in the sampled woman's milk and acknowledges: "A proportion of these silicon species may be siloxanes." DHSC removes that qualification and substitutes a claim that no derivatives pass to infants. The evidence cited does not establish that claim. A limited silicon-proxy experiment and a cow's milk comparison have been turned into false reassurance about the absence of infant exposure. [13] (gov.uk)

Sources. Keogh Final Report [12], paragraph 10, printed p. 7: possible siloxane migration and milk analysis awaiting results. MHRA PIP Toxicology Testing webpage [13], "Additional MHRA tests"; accompanying Silicon in Breast Milk, October 2012, p. 1: single donor sample, total-silicon proxy, method limitations, cow's milk comparison and acknowledgement of possible siloxanes.

Category 7 Product withdrawal is substituted for informing women

Allegation. The withdrawal of implants from sale and distribution of professional alerts are presented without accounting for whether women already implanted were reached.

Purpose. Keep market control, professional notification and effective communication with recipients separate, and show the consequences of the gap.

Accountability alignment. Mid Staffordshire Public Inquiry Report — information must reach the people affected. Hillsborough Report — institutions must account openly for their response. [28][30]

Sentence 16

DHSC. *"The PIP breast implants were withdrawn from the UK in 2010 and the MHRA issued a series of Medical Device Alerts, at assets.publishing.service.gov.uk/media/5485ac3ae5274a428d000295/con076500.pdf and assets.publishing.service.gov.uk/media/5485ac2bed915d4c10000299/con096758.pdf, at the time to communicate the issues with PIP breast implants."*

Narrative function. Uses the withdrawal of unused implants and alerts to healthcare professionals to imply that women already carrying PIP implants were warned. It provides no evidence that those women were identified, contacted or informed.

Evidence and rebuttal. The 2010 withdrawal and professional alerts are part of the chronology. They do not demonstrate that women already implanted were identified and informed. The House of Commons Health Committee's 2012 PIP Report challenged the reach of alerts into the private sector and the adequacy of communication with affected women. The official account must therefore distinguish the date of product control from effective notification and support. Women's access to information cannot be inferred from the existence of an alert.

Sources. MHRA PIP Medical Device Alerts [15]; House of Commons Health Committee 2012 PIP Report [11] paragraphs 20–28.

Category 8 Information is substituted for access to clinical care

Allegation. General guidance and prospective cosmetic-surgery information do not answer the submitted evidence of unmet medical need following fraudulent PIP implantation.

Purpose. Show the difference between publishing advice and providing a coordinated route to knowledgeable clinicians, diagnosis, treatment and continuing care.

Accountability alignment. Mid Staffordshire Public Inquiry Report — clear responsibility for care. First Do No Harm Report — a coordinated response to reported harm. [30][31]

Sentence 17

DHSC. *"Guidance from the MHRA in 2012 advises anyone with a PIP breast implant and who is concerned about unwanted symptoms should consult their doctor about the possibility of removal."*

Narrative function. Places the next move on the woman who recognises unwanted symptoms.

Evidence and rebuttal. The Keogh Final Report also expected providers to contact PIP recipients and made recommendations for consultation and follow-up. DHSC does not account for delivery of those measures. An invitation to consult a doctor depends on a woman knowing her implant history and recognising a possible problem. It does not establish organised identification, appropriately informed clinical assessment or continuing care. The missing account is of the system's response, not women's willingness to seek help.

Sources. Keogh Final Report [12] recommendations and provider-contact statement; House of Commons Health Committee 2012 PIP Report [11] paragraphs 27–30.

Sentence 18

DHSC. *"Guidance for patients produced by the NHS and MHRA lists the options available for removal is available at www.nhs.uk/tests-and-treatments/cosmetic-procedures/cosmetic-surgery/breast-enlargement."*

Narrative function. Directs a medical-harm submission to a general cosmetic-surgery webpage.

Evidence and rebuttal. A breast-enlargement webpage does not demonstrate a commissioned pathway for the consequences of fraudulent PIP implantation. PIP Action Campaign's correspondence raised reconstruction after cancer, repeated operations, persistent illness and barriers to care. The reply identifies no service coordinating those histories with diagnostic assessment, specialist referral and continuing treatment. The allegation is the substitution of generic information for an accountable clinical response to an existing exposure and its consequences.

Sources. NHS Breast enlargement guidance [16]; PIP Action Campaign letter to the Prime Minister of 24 July 2026 [2] pp. 1–2; Fleur Anderson letter of 4 August 2026 [4] pp. 1–2.

Sentence 45

DHSC. *"The MHRA has produced a suite of guidance webpages on the safety of breast implants including on BIA-ALCL at www.gov.uk/guidance/breast-implants-and-anaplastic-large-cell-lymphoma-alcl and on symptoms sometimes referred to as breast Implant Illness (BII) at www.gov.uk/guidance/symptoms-sometimes-referred-to-as-breast-implant-illness."*
Narrative function. Presents published webpages as evidence that women's health needs are being addressed.
Evidence and rebuttal. Official guidance also informs GPs and physicians. Reassurance without clear instructions to investigate past PIP exposure risks reinforcing dismissal, missed disease and delayed diagnosis. The **WEC Committee Cosmetic procedures Report** recorded women's symptoms being dismissed by GPs and specialists, inadequate follow-up and gaps in cancer detection. DHSC lists webpages without demonstrating that these failures have been corrected or that women receive appropriate investigation, referral and continuing care. [5] (publications.parliament.uk)

Sources. MHRA BIA-ALCL guidance [14]; MHRA BII guidance [19], "Reporting suspected problems with breast implants"; WEC Committee Cosmetic procedures Report [5], paragraphs 15–18, 29 and 39–43.

Sentence 46

DHSC. "The MHRA has also published a cosmetic breast augmentation risk awareness tool at www.gov.uk/guidance/cosmetic-breast-augmentation-risk-awareness-tool for patients to support their decision-making process when considering whether to get breast implants."
Narrative function. Answers women already living with the consequences of fraudulent implants by citing a tool for people considering cosmetic surgery.
Evidence and rebuttal. The **MHRA Cosmetic Breast Augmentation Risk Awareness Tool** addresses decisions about future surgery. It does not provide a PIP-specific pathway for women deciding whether to retain, remove or replace their implants, including women whose implants followed cancer reconstruction. DHSC identifies no coordinated provision of symptom assessment, specialist advice, continuing monitoring or support as victims of fraud. The **WEC Committee Cosmetic procedures Report** recorded refused care and removal requests, continuing harm and unresolved replacement provision. A cosmetic-surgery checklist does not answer those failures. [21][5] (gov.uk, publications.parliament.uk)

Sources. MHRA Cosmetic Breast Augmentation Risk Awareness Tool [21], "Supporting informed decisions about breast implants" and "How to use the risk information tool"; **WEC Committee Cosmetic procedures Report [5]**, paragraphs 15–19 and 22.

Category 9 International agreement obscures different protective decisions

Allegation. Broad claims of international consistency blur both the common EU Class III regulatory duties and the distinction between withdrawing products and offering preventive removal to women already implanted.

Purpose. Identify the actual policy disagreement and prevent a conclusion about universal removal from displacing the separate case concerning information, individual care and accountability.

Accountability alignment. Public Office (Accountability) Bill — objectivity and openness in the account given. [26]

Sentence 19

DHSC. *"The MHRA guidance on PIP breast implants reflected the evidence available at the time, including evidence on structural integrity, rupture, and chemical and toxicological testing, and was broadly consistent with the approach taken by other regulators and expert groups."*

Narrative function. Uses broad international consistency to smooth over a substantive policy difference.

Evidence and rebuttal. At the time of the PIP crisis, the UK was an EU Member State implementing the common medical-device framework. Commission Directive 2003/12/EC classified breast implants as Class III. Directive 93/42/EEC and the Medical Devices Regulations 2002 governed essential safety requirements, conformity assessment, incident recording and enforcement. The latter expressly provided enforcement powers for non-conforming devices whether or not the Secretary of State considered them unsafe. PIP's fraudulent substitution and uncontrolled manufacture breached the certified specification; expert reassurance did not restore conformity. DHSC's appeal to regulatory agreement must therefore be tested against common legal requirements as well as clinical choices. The House of Commons Health Committee's 2012 PIP Report records that France and the UK acted differently concerning women already implanted. Shared discussion and testing cannot answer whether the UK discharged its regulatory and protective responsibilities.

Sources. EU Class III framework and Medical Devices Regulations 2002 [36] Directive 2003/12/EC, Article 1; Directive 93/42/EEC, Articles 8 and 10 and conformity annexes; Medical Devices Regulations 2002, regulations 8–10, 13, 17 and 61–65, particularly 61(7)–(8) and 65; French DGS/AFSSAPS Investigation Report [37] fraudulent manufacture and withdrawal chronology; House of Commons Health Committee 2012 PIP Report [11] paragraphs 11–14 and 23–28; DHSC response of 5 September 2026 [1] sentence 19.

Sentence 20

DHSC. *"The Government is aware that 22 EU countries recalled PIP breast implants and issued guidance on monitoring and removal; however, international expert opinion found that there was insufficient evidence to support systematic preventative removal."*

Narrative function. Answers the narrower proposition of systematic removal instead of the submitted failures.

Evidence and rebuttal. DHSC's reference to 22 EU countries belongs within the common EU regulatory framework for high-risk Class III devices. Market recall and protective measures followed exposure of fraudulent manufacture and loss of conformity with the certified product. They cannot be reduced to national preferences or an MHRA opinion carrying greater authority than those requirements. The distinct clinical question of systematic preventive explantation does not cancel duties concerning product control, evidence, communication or the response to women already implanted. The French Ministry's 23 December 2011 recommendations offered preventive removal even without clinical signs, and provided monitoring and access to care. The House of Commons Health Committee's 2012 PIP Report challenged the UK's delayed evidence gathering and inadequate communication. An expert conclusion against universal removal answers neither those failures nor PIP Action Campaign's request for independent scrutiny and appropriate clinical care.

Sources. EU Class III framework and Medical Devices Regulations 2002 [36] essential requirements, Class III conformity, incident recording and enforcement; French Ministry recommendations of 23 December 2011 [39] pp. 1–2, preventive removal, monitoring and access; House of Commons Health Committee 2012 PIP Report [11] paragraphs 25–28; PIP Action Campaign letter to the Prime Minister of 24 July 2026 [2] pp. 1–3; WEC Committee Cosmetic procedures Report [5] paragraphs 18–19; DHSC response of 5 September 2026 [1] sentence 20.

The governing standard was the common EU Class III framework

MHRA was the UK competent authority within the EU medical-device system. Its clinical advice did not displace the binding conformity, vigilance and enforcement framework. Medical Devices Regulations 2002, regulation 8, prohibited supply of devices that failed the relevant essential requirements; regulation 13 governed conformity assessment; regulation 65 required centralised incident-recording functions. Regulation 61(7)–(8) expressly extended prohibition and warning powers to non-conforming devices whether or not they were considered unsafe. The distinction matters: proof of every subsequent disease was not a prerequisite for confronting a fraudulent, non-conforming product. [36]

For these surgically implanted Class III devices, a CE mark depended on conformity with the applicable essential requirements and notified-body assessment under the required conformity procedure. The certified design, materials and manufacturing controls had to remain consistent with the approved device. The framework required consideration of biological compatibility, chemical and physical properties, infection risks, performance and clinical evidence, with production quality assurance and continuing surveillance. Fraudulent substitution of filler and uncontrolled changes to the shell defeated those controls. A CE mark on packaging could not validate a device that departed from its certified design or production specification. [36][37]

PIP's fraudulent manufacturing escaped the controls on which Class III certification depended. The protective question therefore extended beyond whether a particular laboratory assay demonstrated toxicity. France's preventive explantation policy was a clinical and public-health measure within that regulatory setting. The same common framework governed the UK; DHSC must account for its implementation, the evidence gathered and the protection of women already exposed. [37][39][11]

Sources. EU Class III framework and Medical Devices Regulations 2002 [36] Medical Devices Regulations 2002, regulations 8–10, 13, 17 and 61–65; Commission Directive 2003/12/EC, Article 1; French DGS/AFSSAPS Investigation Report [37] French investigation report, manufacturing findings; French Ministry recommendations of 23 December 2011 [39] pp. 1–2; House of Commons Health Committee 2012 PIP Report [11] paragraphs 11–14 and 25–28.

Category 10 Missing evidence sustains unchanged advice

Allegation. DHSC maintains the existing position without reconciling the decision against proposed PIP-specific symptom data collection, the continuing reports of harm, published PIP clinical findings and diagnosed systemic illness and the parliamentary findings put before it.

Purpose. Demonstrate how the absence of an established link can become self-reinforcing when the evidence needed to investigate that link has not been collected or accounted for.

Accountability alignment. Infected Blood Inquiry Final Report — repeated reassurance and the treatment of uncertainty. First Do No Harm Report — patient reports as evidence requiring action. [29][31]

Sentence 22

DHSC. *"Its current advice remains unchanged, but it would of course consider any new and emerging evidence that might affect this position."*

Narrative function. Maintains the position while locating reconsideration in hypothetical future evidence.

Evidence and rebuttal. Material evidence was already before Government. The WEC Committee's February 2026 Cosmetic procedures Report identified limited long-term research, continuing harm, poor data and inadequate follow-up. PIP Action Campaign's 24 July letter relied on those findings. Published PIP clinical reports also include objective tissue and lymph-node pathology, systemic inflammatory disease and pulmonary silicone embolism. DHSC neither reconciles this record with unchanged advice nor identifies a fresh assessment of the case submitted. The promise to consider new evidence leaves existing evidence unanswered.

Sources. PIP Action Campaign letter to the Prime Minister of 24 July 2026 [2] pp. 1–2; WEC Committee Cosmetic procedures Report [5] paragraphs 11–19; PIP Action Campaign June 2013 Literature Review [44] June 2013 Literature Review; Chan and colleagues 2015 systemic inflammatory case [58] Abstract and clinical course; Gopinath and colleagues 2015 PIP pulmonary case [59] PIP pulmonary case; Mistry and colleagues 2015 PIP thoracic outlet case [61] Summary and Case report; DHSC response of 5 September 2026 [1] sentence 22.

Sentence 33

DHSC. *"The MHRA has received reports from people with a variety of symptoms which are sometimes referred to as Breast Implant Illness (BII)."*

Narrative function. Acknowledges reports without showing what became of them.

Evidence and rebuttal. Receiving reports is not the same as accounting for them. MHRA's August 2026 Internal Review upheld non-disclosure of PIP adverse-incident and health-consequence information; PIP Action Campaign's reproduced request records the previously disclosed total exceeding 2,500 reports. The WEC Committee's reference to around 1,000 reports potentially falling within BII concerns breast implants generally and must not be converted into a PIP total. Mechanical failure, silicone migration, pathological inflammation, diagnosed systemic illness, cancer and surgical complications require separate examination. Grouping them under BII conceals clinically different events and their investigative outcomes.

Sources. MHRA Internal Review IR2026/00843 [7] pp. 1–6, reproduced request and response points 1, 5–7; WEC Committee Cosmetic procedures Report [5] paragraph 37; PIP Action Campaign June 2013 Literature Review [44] clinical and analytical papers; Chummun and McLean 2013 PIP study [46] Results, including postoperative complications; Chan and colleagues 2015 systemic inflammatory case [58] systemic inflammatory case; Gopinath and colleagues 2015 PIP pulmonary case [59] pulmonary case; DHSC response of 5 September 2026 [1] sentence 33.

Sentence 34

DHSC. *"BII is not a recognised disease, but it is a term sometimes used by people to describe the health problems they associate with their breast implants."*

Narrative function. Allows diagnostic classification to dominate the response to clinical need.

Evidence and rebuttal. The absence of a single recognised diagnosis called BII does not dispose of actual disease. Chan and colleagues' BMJ Case Reports paper describes systemic inflammatory disease following PIP implantation, persisting after replacement and resolving following removal.

González and colleagues' published case records prior PIP and later Silimed exposure with morphea, psoriasis, Sjögren's syndrome and psoriatic arthritis. These clinical diagnoses must be distinguished from a symptom label and considered with the complete exposure history. The WEC Committee's Cosmetic procedures Report records dismissal of symptoms and inadequate follow-up. DHSC identifies no pathway that connects the reported illness, objective findings, appropriate specialists and continuing care.

Sources. Chan and colleagues 2015 systemic inflammatory case [58] Abstract and Case presentation; González and colleagues systemic-disease case [51] Case presentation, Tables 1–2 and implant-history timeline; WEC Committee Cosmetic procedures Report [5] paragraphs 18 and 37–43; MHRA BII guidance [19] MHRA systemic-symptom guidance; PIP Action Campaign letter to the Prime Minister of 24 July 2026 [2] p. 2.

Sentence 35

DHSC. *"The reports the MHRA has received is not limited to a particular manufacturer or type of implant and include silicone and saline (salt water) filled implants, smooth or textured (rough) surface implants."*

Narrative function. Broadens the population in a way that can obscure the PIP-specific question.

Evidence and rebuttal. Reports across manufacturers and implant types do not establish the safety of fraudulently manufactured PIP devices. The French DGS/AFSSAPS Investigation Report documents uncontrolled substitute formulations, deficient traceability and departure from the certified shell and gel specification. These product-specific failures must remain visible alongside class-wide questions. The FDA's Types of Breast Implants guidance confirms that saline implants also have silicone shells. González and colleagues' systemic-disease case illustrates why earlier PIP exposure must remain visible after a different brand replaces it. Neither broad reporting categories nor a current implant brand erase the earlier exposure.

Sources. French DGS/AFSSAPS Investigation Report [37] physicochemical findings and traceability, pp. 123–129; EU Class III framework and Medical Devices Regulations 2002 [36] Class III conformity requirements; FDA Types of Breast Implants guidance [24] silicone outer shells; González and colleagues systemic-disease case [51] implant history and Case presentation; MHRA BII guidance [19] MHRA systemic-symptom guidance.

Sentence 36

DHSC. "A link between breast implants and the reported health problems has not been established."

Narrative function. Uses the absence of an established link as reassurance while omitting the decision not to collect the evidence needed to investigate it.

Evidence and rebuttal. The Keogh Final Report, paragraph 27, acknowledged widespread systemic symptoms but rejected the proposed PIP-specific frequency study. DHSC cannot treat that missing evidence as a finding of no harm. [12] (assets.publishing.service.gov.uk) Published PIP reports subsequently documented systemic inflammatory disease, pulmonary silicone embolism and progressive lymph-node disease. González and colleagues reported autoimmune diagnoses following sequential PIP and Silimed exposure. [58][59][61][51] The FDA's BIA-ALCL reporting explicitly considers previous implants and warns that incomplete histories limit its data. Changing implant brands does not erase earlier exposure. DHSC's blanket statement leaves both the clinical findings and the missing research unanswered. (fda.gov)

Sources. Keogh Final Report [12], paragraph 27; Chan and colleagues' systemic inflammatory case [58]; Gopinath and colleagues' PIP pulmonary case [59]; Mistry and colleagues' PIP thoracic outlet case [61]; González and colleagues' systemic-disease case [51], implant history and Tables 1–2; FDA, Medical Device Reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma, Table 2, footnote c and "Certain Findings".

Sentence 43

DHSC. *"The MHRA will also seek independent expert advice as appropriate and if further risks are identified, and it will take action to ensure these are communicated to patients so they can make informed decisions regarding their healthcare."*

Narrative function. Makes action conditional on future findings while leaving existing evidence and requests for independent scrutiny unanswered.

Evidence and rebuttal. The WEC Committee Cosmetic procedures Report already identified limited research, continuing harm and inadequate follow-up. [5] DHSC identifies no independent reassessment of that record. In 2020, the Department confirmed that its archive contained nearly 9,000 documents relating to the Keogh review, but refused the request for its editing history on cost grounds. PIP Action Campaign has requested their preservation. The reply neither confirms preservation nor offers independent examination of how the enduring reassurance was constructed. Promising future advice leaves the evidence already held—and women's present clinical needs—unanswered.

Sources. WEC Committee Cosmetic procedures Report [5], paragraphs 18–19 and 42–46; DHSC FOI response FOI-1200036, 5 February 2020, p. 1; PIP Action Campaign Advance Letter for the 21 October 2026 Meeting, 22 September 2026, p. 3, preservation request and footnote 9; DHSC response of 5 September 2026 [1], sentence 43.

PIP adverse events and diagnosed illness must remain distinct

The evidence below separates device failure, objectively recorded pathology, diagnosed systemic disease, surgical consequences and reported symptoms. PIP Action Campaign's June 2013 Literature Review already brought together many of the early papers. Later PIP-specific reports enlarged that clinical record. These categories must not be collapsed into the single, disputed label BII. [44][46][47][58][59][61]

An adverse report, an explant-series finding, a clinical diagnosis and a confirmed cancer notification answer different questions. Their denominators and exposure histories must remain explicit. The point is to preserve and investigate the actual findings rather than make them disappear when an implant is removed, replaced or described under another manufacturer. MHRA's withheld reports also prevent a complete review of its own PIP adverse-event record. [7][42]

Adverse event or illness	Published findings	Record and interpretation
Rupture and implant failure	Quaba and Quaba's 2013 PIP explant series: 144 ruptured implants among 676 implants in 338 women; 119 women affected. This is 21.3% per implant and 35.2% per woman, not interchangeable rates.	PIP surgical series; mean implantation period 7.8 years. [45]
Gel bleed and tissue exposure without rupture	Maijers and Niessen recorded excessive gel bleed in four of eight women explanted without rupture. Beretta and colleagues analysed nonconforming explanted PIP gel and late fluid from four women with ruptured PIP implants.	Clinical and analytical findings; an intact shell does not exclude exposure. [48][49][50]
Pain, swelling and capsular disease	The Keogh Final Report recorded excess local clinical signs and reactions. González and colleagues documented grade 3 capsular contracture in the woman with previous PIP and later Silimed implants.	Clinical findings and capsule disease require assessment in their own right; the mixed implant history is retained. [12], paragraphs 15–19; [51], Case presentation.

Adverse event or illness	Published findings	Record and interpretation
Silicone lymphadenopathy and migration	Zambacos and colleagues' own 14-case series included ten women with PIP implants. Kolios and colleagues documented histologically confirmed PIP silicone lymphadenopathy extending towards the neck.	Pathologically recorded disease, distinct from a general symptom label. [47][52][53]
Progressive disease after removal	Mistry and colleagues described progressive cervical, axillary and internal mammary silicone lymphadenopathy after PIP explantation, causing bilateral thoracic outlet syndrome and requiring further surgery.	PIP clinical case with imaging, histology and neurological consequences. [61]
Cutaneous disease	Skin deep: Cutaneous manifestation of PIP implant rupture reports extensive breast-tissue involvement and cutaneous xanthomatous inflammation.	Published PIP case with a defined pathological manifestation. [60]
Pulmonary silicone embolism	Gopinath and colleagues published Chronic silicone embolism syndrome due to PIP breast implant leakage—a new entity?	A specifically identified pulmonary disease report; not ordinary BII fatigue. [59]
Systemic inflammatory disease	Chan and colleagues described systemic inflammatory illness after PIP implantation, persisting after replacement and resolving after explantation.	Published clinical course involving treatment and inflammatory response. [58]
Diagnosed autoimmune disease with prior PIP exposure	González and colleagues recorded morphea, psoriasis, Sjögren's syndrome and psoriatic arthritis in a woman with PIP followed by Silimed implants. The authors also recorded an ASIA diagnosis.	The sequential exposure and documented diagnoses remain explicit; this is not a PIP-only incidence estimate. [51]
Consequences of further surgery	Chummun and McLean recorded infection, seroma, lymphadenopathy, hypersensitive scar and wound overgranulation after PIP surgery. Malata and colleagues described prolonged, technically challenging revision with capsulectomies, granuloma/node excisions and wash-outs.	Recorded surgical morbidity and complexity, not merely cosmetic dissatisfaction. [46][54]
Reported systemic symptoms	The Keogh Final Report acknowledged generalised pain, respiratory problems, anxiety and fatigue and declined the proposed PIP frequency study.	Reported symptoms require their own investigation alongside, rather than instead of, clinical diagnoses. [12], paragraph 27.
Malignancy and complete exposure histories	DHSC acknowledged seven confirmed BIA-ALCL reports with previous PIP exposure. A published PIP case also records breast carcinoma and foreign-body inflammation. Rare capsule malignancies require distinct diagnostic consideration.	Confirmed regulatory reports, clinical cases and cancer types must remain separate. [1], sentence 40; [55][56].

Sources. PIP Action Campaign June 2013 Literature Review [44] Literature Review, contents and pp. 6–12 and 27–34; Quaba and Quaba 2013 PIP explant study [45] Results; Chummun and McLean 2013 PIP study [46] Results; Zambacos and colleagues 2013 lymphadenopathy study [47] PIP subgroup; Maijers and Niessen 2013 PIP study [48] Results; Beretta and colleagues 2013 periprosthetic-fluid analysis [50] methods and findings; González and colleagues systemic-disease case [51] Case presentation and Tables 1–2; Malata and colleagues 2013 PIP revision study [54] operative consequences; Chan and colleagues 2015 systemic inflammatory case [58] clinical course; Gopinath and colleagues 2015 PIP pulmonary case [59] PIP pulmonary case; Skin deep PIP cutaneous case [60] cutaneous case; Mistry and colleagues 2015 PIP thoracic outlet case [61] progressive lymph-node disease; MHRA Internal Review IR2026/00843 [7] response points 1 and 5–7; MHRA FOI2026/00467 response [42] response point 6.

Category 11 The Howe review is presented as independent exoneration

Allegation. DHSC describes the Howe Report as independent and selects its favourable conclusion while omitting its internal minister-led character, restricted scope and adverse findings.

Purpose. Correct the description of the review and test the claimed exoneration against the Howe Report's own methodology and findings.

Accountability alignment. Hillsborough Report — scrutiny must serve the search for truth. Public Office (Accountability) Bill — candour about relevant evidence and institutional conduct. [26][28]

Sentence 23

DHSC. *"Two significant independent reviews have identified lessons learned, the Howe Review (2012) at assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216537/dh_134043.pdf, and the Keogh Review (2013) at www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions."*

Narrative function. Assigns independence to two different exercises without distinguishing their character.

Evidence and rebuttal. The official publication page calls the Howe Report a retrospective internal review. Departmental civil servants reported to a serving departmental minister; its chronology ended on 24 December 2011. DHSC's claim that this was an independent review is false. The 2013 Cosmetic Review examined the wider cosmetic-interventions sector. It was not another PIP clinical report, and its independent designation cannot turn the Howe Report into an independent investigation. The reply uses the authority of two different exercises to endorse an institutional account without respecting their actual authorship, remit or limitations.

Sources. Howe Report [9] paragraphs 1.7–1.13, pp. 19–21; Official Howe Report publication description [33] official publication description; 2013 Cosmetic Review [6] 2013 Cosmetic Review, introduction and terms of reference; DHSC response of 5 September 2026 [1] sentence 23.

Sentence 30

DHSC. *"The Howe Review of 2012 focused on the actions of the MHRA and the Department."*

Narrative function. Invokes the subject of the Howe review without its institutional and temporal limits.

Evidence and rebuttal. The Howe Report's methodology says the work was conducted by a departmental team reporting to a departmental minister. It examined selected incident responses to understand process, rather than judging every response, and ended its chronology on 24 December 2011. Those limits matter when the review is used in 2026 to answer a challenge extending to later clinical decisions, surveillance and continuing reassurance. A review of an institution is not necessarily independent of it.

Sources. Howe Report [9] paragraphs 1.7–1.13, pp. 19–21.

Sentence 31

DHSC. *"The evidence detailed in the Howe Report shows that the MHRA fulfilled its obligations in terms of reviewing and responding to the incidents reported to them involving PIP breast implants."*

Narrative function. Selects Howe's favourable conclusion without confronting Howe's contrary material.

Evidence and rebuttal. The Howe Report recorded contradictory manufacturer reports, including rupture attributed to removal when rupture had prompted removal; offers of further evidence from two surgeons that were not pursued; and requested electron-microscopy evidence that PIP never supplied. It also explained dependence on manufacturer-supplied international data. DHSC's sentence excludes this material from its account of fulfilled obligations. The review cannot be treated as an unqualified certificate of adequate investigation while its adverse findings remain unanswered.

Sources. Howe Report [9] paragraphs 4.14–4.15, 4.23 and 4.28–4.29, pp. 33–37.

In the Scottish Parliament on 14 June 2012, Malcolm Chisholm described the Howe Report as "an internal whitewash of the MHRA".

His criticism concerned untested explants, delayed responses to clinicians and failures to inform women. This is contemporaneous parliamentary criticism attributed to Chisholm. It demonstrates that the review's adequacy was disputed from the outset. [32]

Category 12 The missing cohort is detached from the registry's history

Allegation. The reply treats the absence of a complete PIP list as an obstacle without accounting for the former registry's closure or demonstrating an organised effort to recover the historical cohort.

Purpose. Restore the 1993–2006 registry history, use 2017 for fully implemented BCIR data collection, and distinguish a registry's stated purpose from demonstrated inclusion and follow-up of PIP women.

Accountability alignment. First Do No Harm Report — traceability and the ability to connect devices to outcomes. Public Office (Accountability) Bill — transparent institutional explanations. [26][31]

Sentence 25

DHSC. *"It was difficult to contact patients who may have been implanted with the fraudulent PIP breast implants as a Registry of patients did not exist."*

Narrative function. Omits the decision history behind the missing register.

Evidence and rebuttal. The House of Commons Health Committee's 2012 PIP Report records a national Breast Implant Registry funded by MHRA from 1993 until closure in 2006. PIP Action Campaign's 24 July letter expressly raised the withdrawal of funding. MHRA's May 2026 FOI response confirms that the former registry held identifiable women's details and implant manufacturer and batch/serial information, and that after its closure MHRA had no system able to identify individual women with particular implant types. DHSC leaves that decision and its consequences out of its explanation. The absence of a registry at the crisis point was not an unexplained natural obstacle: it followed the loss of a pre-existing identification system.

Sources. Health Committee 2012 PIP Report registry findings [18] paragraphs 65–68; PIP Action Campaign letter to the Prime Minister of 24 July 2026 [2] pp. 1–2; MHRA FOI2026/00467 response [42] p. 2, response points 1(a)–(c) and 2(a); DHSC response of 5 September 2026 [1] sentence 25.

Sentence 26

DHSC. *"The Keogh Review (2013) of the Regulation of Cosmetic Interventions made a number of recommendations for improvements in this area."*

Narrative function. Foregrounds recommendations while leaving the failures that prompted them in the background.

Evidence and rebuttal. The 2013 Cosmetic Review was a review of the wider cosmetic-interventions sector, not a second PIP clinical report. It recorded severe PIP under-reporting and the importance of identifying a complete cohort for a particular implant. Its registry recommendations arose from those regulatory deficiencies. Invoking the review as evidence of improvement does not show that women implanted before the new system were recovered, followed or protected. The account must connect the recommendation to its implementation and to the historical PIP population.

Sources. 2013 Cosmetic Review [6] 2013 Cosmetic Review, paragraph 4.10, paragraphs 4.18–4.22 and Recommendations 20–21; DHSC response of 5 September 2026 [1] sentence 26.

Sentence 27

DHSC. "*The Department of Health and Social Car [sic] led a programme of work to implement the recommendations including the establishment of the Breast and Cosmetic Implant Registry (BCIR) in 2016*."

Narrative function. Presents the delayed replacement of a dismantled safety system as evidence of regulatory improvement, without accounting for the years of lost surveillance and traceability.

Evidence and rebuttal. A breast implant registry is core safety infrastructure for surgically implanted Class III devices: it connects women to their implants, enables notification when products fail and supports investigation of outcomes. The European Parliament's 2003 Breast Implants Resolution, paragraphs 23–24, urgently recommended compulsory national registration and identified registries as essential for tracing affected recipients. The UK nevertheless closed its MHRA-funded registry in 2006. [18] (europarl.europa.eu https://www.europarl.europa.eu/doceo/document/TA-5-2003-0063_EN.pdf, publications.parliament.uk)

The Health Committee's 2012 PIP Report, paragraph 69, expressly recommended compulsory inclusion. The 2013 Cosmetic Review, Recommendation 21, called for a replacement registry to be established and operational within twelve months. NHS England confirms that BCIR data collection was not fully implemented until 2017—approximately four years after that recommendation and eleven years after the former registry closed. DHSC's establishment date conceals that prolonged safety gap. [18][6][17] (publications.parliament.uk, assets.publishing.service.gov.uk, digital.nhs.uk)

The Department of Health's BCIR Direction expressly required tracing, monitoring outcomes by implant brand and notifying women when their provider had ceased trading. It also permitted registration of implants received before launch. The issue is therefore whether these protective functions were delivered, including recovery of historical PIP exposure. Citing the registry's existence supplies no account of that work. (assets.publishing.service.gov.uk)

Sources. European Parliament Breast Implants Resolution, P5_TA(2003)0063, 13 February 2003, paragraphs 23–24; Health Committee 2012 PIP Report [18], paragraphs 65–69; 2013 Cosmetic Review [6], paragraphs 4.18–4.21 and Recommendation 21, pp. 33–34; NHS England BCIR Management Information 2023 [17], "BCIR Data Collection: 2017 to 2023"; Department of Health, Breast and Cosmetic Implant Registry Direction, 6 October 2016, pp. 1–3. https://assets.publishing.service.gov.uk/media/5a80ce17e5274a2e8ab5243c/Breast_and_Cosmetic_Implant_Registry.pdf

Sentence 28

DHSC. *"The BCIR collects data on all types of breast implant and removal surgery in England, Scotland and Northern Ireland by the NHS and private providers."*

Narrative function. Describes the registry's scope without establishing complete capture.

Evidence and rebuttal. 'All types' describes the procedures within the BCIR's scope, not complete recording of every woman, provider, procedure or previous exposure. NHS England's BCIR Management Information reports activity from fully implemented data collection in 2017. The WEC Committee's Cosmetic procedures Report records that use was not mandatory and covered around 80% of breast implants. MHRA's May 2026 FOI response relies on BCIR for identifying women and capturing events, but supplies no PIP-specific coverage measure. Historic PIP exposure is recorded, connected to later operations, pathology and health outcomes across NHS and private care.

Sources. NHS England BCIR Management Information 2023 [17] BCIR Data Collection: 2017 to 2023 and coverage notes; WEC Committee Cosmetic procedures Report [5] paragraphs 20–25, especially paragraph 20; MHRA FOI2026/00467 response [42] response point 7; DHSC response of 5 September 2026 [1] sentences 28–32.

Sentence 29

DHSC. "*The aim is to help detect emerging safety issues and trace patients if necessary*."

Narrative function. Cites the registry's intended purpose without showing that women exposed to PIP have been traced, informed or followed.
Evidence and rebuttal. Detecting safety problems requires linking implant identity, clinical findings and outcomes over time. The Cancer Annex identifies NHS, pathology, cancer-registration and mortality records that could support that work. The Toxic Exposure Annex explains why follow-up must continue after removal, including retained deposits and replacement exposures. DHSC identifies no coordinated programme joining these records or reaching the historical PIP population. A stated aim supplies no evidence that these protective functions have been delivered.
Sources. Department of Health BCIR Direction, 6 October 2016, pp. 1–3; Cancer Annex, "What the NHS records can establish"; Toxic Exposure Annex, sections 7 and 9; NHS England, National Cancer Registration and Analysis Service, "What data are collected?". (assets.publishing.service.gov.uk, digital.nhs.uk)

Sentence 32

DHSC. *"It would not be feasible to contact all patients who may have been implanted with a PIP breast implant for a number of reasons including the lack of a complete list of patients who received the implants and the BCIR not being established until 2016."*

Narrative function. Uses incomplete records to declare contact infeasible without accounting for efforts to recover those records.

Evidence and rebuttal. The absence of a complete list does not establish that tracing is impossible. Fleur Anderson's letter of 4 August 2026 requested identification and contact through GP practices. MHRA's own 2021 BIA-ALCL information leaflet identifies surgeons, hospitals and GP discharge records as potential sources of implant history. DHSC provides no appraisal of those routes, surviving registry records or direct contact with women. Nor does it describe how earlier PIP exposure is recovered after replacement. The missing list is a failure requiring remedial work; it cannot, by itself, justify abandoning that work.

Sources. Fleur Anderson letter [4], p. 2; MHRA FOI2026/00467 response [42], points 1–2; MHRA/PRASEAG, Information about BIA-ALCL for people with breast implants, "I cannot remember what type of breast implant I have"; Cancer Annex, "Latency and complete exposure histories". (gov.uk)

Category 13 Cancer classifications narrow the visibility of PIP exposure

Allegation. A reassuring PIP-only zero is presented alongside seven confirmed reports involving previous PIP exposure, without demonstrating that all cancer reports and lifetime implant histories have been reconciled.

Purpose. Preserve every previous PIP exposure, distinguish reports from incidence, and ensure that missing histories remain recorded as unknown rather than being treated as no exposure.

Accountability alignment. Mid Staffordshire Public Inquiry Report — accurate performance information. Public Office (Accountability) Bill — material qualifications must remain visible. [26][30]

Sentence 37

DHSC. *"The MHRA closely monitors Breast Implant Associated - Anaplastic Large Cell Lymphoma (BIA- ALCL) a very rare form of non-Hodgkin lymphoma (cancer of the immune system)."*

Narrative function. Uses "closely monitors" and "very rare" as reassurance without establishing the completeness of diagnosis, reporting or PIP-specific follow-up.

Evidence and rebuttal. "Very rare" does not establish the lifetime risk faced by women exposed to PIP. MHRA's published estimate uses implants sold, including devices never implanted, rather than a verified population of women followed over time.

Its guidance acknowledges reporting limitations; its 2021 recipient leaflet acknowledges gaps in GP and nurse awareness. The WEC Committee Cosmetic procedures Report records concerns about missed diagnoses through inadequate capsule examination. DHSC provides no PIP-specific audit reconciling clinical findings, pathology, cancer registrations and deaths. A reporting rate cannot substitute for that investigation. [14][5] (gov.uk, gov.uk, publications.parliament.uk)

Sources. MHRA BIA-ALCL guidance [14], "Estimated reporting rate" and "Notes and limitations to the data"; MHRA/PRASEAG 2021 recipient leaflet, "What should I do if I have an implant and notice breast changes?"; WEC Committee Cosmetic procedures Report [5], paragraph 29.

Sentence 38

DHSC. *"The MHRA has not seen any evidence that PIP implants carry a greater risk of BIA-ALCL than other breast implants, or that they lead to an increased risk of other cancers."*

Narrative function. Converts missing comparative evidence into reassurance about PIP and extends it across different cancers and exposure histories.

Evidence and rebuttal. DHSC identifies no long-term PIP cohort study capable of supporting this comparison. The Toxic Exposure Annex documents the limits of sampled batches, chemical identification, extraction and selected test endpoints. Those tests cannot establish the lifetime cancer risk of the whole implant, its capsule environment or retained material after removal. The Cancer Annex also identifies capsule SCC and large B-cell lymphomas, including published EBV-positive DLBCL. Each requires appropriate investigation and complete implant histories. MHRA's own guidance warns against manufacturer comparisons using its reporting data. Unmeasured comparative risk cannot support a blanket reassurance. [14][56] (gov.uk, fda.gov, gov.uk)

Sources. Toxic Exposure Annex, sections 3–7 and 9; Cancer Annex, "The final chapter on the wider cancer spectrum and deaths", sources 12, 15 and 22–23; MHRA BIA-ALCL guidance [14], "Notes and limitations to the data"; FDA capsule-SCC Safety Communication [56], 8 March 2023.

Sentence 39

DHSC. *"The MHRA has not received any confirmed reports of BIA-ALCL occurring in patients who have only ever had PIP breast implants."*

Narrative function. Uses a narrowly defined PIP-only zero to reassure a population whose implants may have been removed or replaced.

Evidence and rebuttal. Women who received another manufacturer's implant after PIP fall outside this category despite their earlier exposure. Sentence 40 acknowledges seven confirmed reports involving previous PIP implants. Unknown histories must also remain unknown; they cannot be counted as established absence of PIP exposure. The first UK BIA-ALCL fatality in June 2012, contemporaneously reported following PIP implantation, requires reconciliation with the clinical record and MHRA's classification. The PIP-only zero answers none of these wider exposure-history questions. [1][41]

Sources. DHSC response [1], sentences 39–41; MHRA BIA-ALCL guidance [14], "History of multiple implants"; Contemporary report of the June 2012 UK fatality [41]; Cancer Annex, "Latency and complete exposure histories".

Sentence 40

DHSC. *"The MHRA has received seven (out of 122) confirmed reports of BIA-ALCL in patients who had previously had a PIP implant but at the time of diagnosis had an implant from a different manufacturer."*

Narrative function. Acknowledges confirmed cancer reports involving previous PIP exposure while placing them beside a reassuring PIP-only zero.

Evidence and rebuttal. These seven reports belong within the accounting of women previously exposed to PIP. Replacement does not erase that history. DHSC should reconcile all 122 confirmed reports cited in its letter, deduplicate to women where appropriate, and verify lifetime implant histories through clinical records and contact with living women. Records of women who died must also be examined. The audit must distinguish verified PIP exposure, verified absence of PIP exposure and unknown history. Withholding the requested multiple-exposure information prevents scrutiny of the classifications used for reassurance. [1][7]

Sources. DHSC response [1], sentence 40; MHRA Internal Review IR2026/00843 [7], pp. 3 and 5, multiple-exposure request and response point 6; Cancer Annex, “Latency and complete exposure histories” and “The penultimate chapter on withheld PIP information”.

Sentence 41

DHSC. *“This makes it difficult to ascertain which implant was associated with the development of BIA-ALCL because it can take years to develop following implantation.”*

Narrative function. Invokes latency to explain uncertainty over attribution without committing to the lifetime follow-up that latency requires.

Evidence and rebuttal. A cancer diagnosed years after replacement requires investigation of the complete exposure timeline. MHRA and FDA reporting both acknowledge incomplete previous implant histories. The Toxic Exposure Annex also explains why removal does not establish clearance of retained material. DHSC must connect original implantation, gel bleed or rupture, removal, replacement, pathology and subsequent diagnoses. Latency strengthens the need to preserve records and follow women over time. It cannot justify allowing earlier PIP exposure to disappear from the clinical or regulatory account. [14] (gov.uk, fda.gov)

Sources. MHRA BIA-ALCL guidance [14], “History of multiple implants” and “Average Time for BIA-ALCL to present”; FDA, Medical Device Reports of BIA-ALCL, prior-history notes to Table 2; Toxic Exposure Annex, section 9; Cancer Annex, “Latency and complete exposure histories”.

Category 14 Monitoring and later reforms stand in for a demonstrated PIP response

Allegation. Passive reporting, prospective improvements and newer manufacturer requirements are cited without showing active follow-up, investigation or care for the historical PIP population.

Purpose. Test what the cited measures actually do for women already exposed, and distinguish voluntary Yellow Card reporting, manufacturer device-vigilance obligations and future prevention from a functioning response to continuing harm.

Accountability alignment. First Do No Harm Report — link safety signals to coordinated action. Hillsborough Report — demonstrate institutional learning through practice. [28][31]

Sentence 24

DHSC. *“The health system has since enacted important changes.”*

Narrative function. Uses unspecified improvements to imply that the historical problem has been addressed.

Evidence and rebuttal. The test is what the changes delivered for women already exposed to PIP. New systems and information may have prospective functions, but they do not, by their existence, recover the historical cohort or establish investigation and treatment of continuing harm. DHSC provides no PIP-specific account of tracing, assessment, follow-up or outcomes. The assertion of change therefore leaves the present condition of the affected women unresolved.

Sources. DHSC response of 5 September 2026 [1] sentences 24–32 and 42–48; WEC Committee Cosmetic procedures Report [5] paragraphs 16–25.

Sentence 42

DHSC. *“The MHRA continues to monitor the safety of all breast implants including PIP implants and monitors adverse events reported to us, as well as globally published literature and other data sources, to determine whether any evidence indicates any increased or previously unrecognised risk.”*

Narrative function. Describes incoming reports and literature review as continuing PIP safety monitoring.

Evidence and rebuttal. Reading literature and incoming reports is not active follow-up of the PIP population. These activities cannot find every woman whose symptoms never became a report or supply the denominator for long-term outcomes. MHRA's May 2026 FOI response expressly accepts that Yellow Card data cannot identify all affected individuals, cannot calculate incidence and is subject to variable under-reporting. The 2013 Cosmetic Review's 15–18% estimate is a historical PIP finding, not a measured current Yellow Card rate. Regulation 65 of the Medical Devices Regulations 2002 addressed centralised incident-recording functions. DHSC must demonstrate how reports are evaluated, investigated and connected to protective action for PIP women, rather than describing receipt of information as close monitoring.

Sources. MHRA FOI2026/00467 response [42] p. 3, response point 6(a)–(c); 2013 Cosmetic Review [6] 2013 Cosmetic Review, paragraph 4.10; MHRA Internal Review IR2026/00843 [7] adverse-report information request and review outcome; EU Class III framework and Medical Devices Regulations 2002 [36] Medical Devices Regulations 2002, regulation 65; DHSC response of 5 September 2026 [1] sentence 42.

Sentence 44

DHSC. *"The MHRA strongly encourages healthcare professionals and anyone experiencing any symptoms they believe to be associated with their breast implants to report these through the Yellow Card Scheme at yellowcard.mhra.gov.uk, so that it can continue to monitor these devices closely."*

Narrative function. Places reporting duties on women and clinicians without showing investigative follow-through.

Evidence and rebuttal. Yellow Card now accepts medical-device adverse-incident reports as well as medicine reports. That shared reporting front end does not make device vigilance identical to medicines pharmacovigilance. MHRA's MORE guidance states that manufacturers must submit device incident reports through the manufacturer route; women's and clinicians' voluntary Yellow Cards do not replace those obligations. A device incident can involve gel bleed, shell failure, silicone migration, deficient instructions or a serious deterioration requiring further surgery. Investigation must connect the device and manufacturing failure with the clinical consequences and corrective action. The MHRA progress report on the Stephenson review records introduction of the Yellow Card brand for devices on 25 November 2014, after the PIP crisis. The regulatory duty to record and evaluate device incidents pre-dated that rebranding. DHSC gives no account of how PIP's defunct manufacturer's missing vigilance function was replaced, or how women's reports led to complete investigation and follow-up.

Sources. MHRA Yellow Card and MORE reporting guidance [20] MORE, How to report to the MHRA and manufacturer-only scope; Yellow Card medical-device reporting; MHRA 2015 independent-review progress report [43] Recommendation 9 progress update, Integrated Yellow Card reporting, p. 14; Howe Report [9] adverse-device-incident definition, p. 5, and paragraph 5.23; EU Class III framework and Medical Devices Regulations 2002 [36] Medical Devices Regulations 2002, regulation 65, and Directive 93/42/EEC, Article 10; MHRA FOI2026/00467 response [42] response point 6.

Sentence 47

DHSC. *"The MHRA is strengthening its regulatory framework that will ensure that patients have access to the safe and effective medical devices they need."*

Narrative function. Moves the account from past performance and present harm to future regulation.

Evidence and rebuttal. Future regulatory strengthening does not answer historical regulatory failure. The French DGS/AFSSAPS Investigation Report established fraudulent departure from the certified materials and manufacturing controls; the House of Commons Health Committee's 2012 PIP Report identified inadequate communication and delayed evidence gathering. These failures occurred under an existing EU Class III framework, not in the absence of regulation. The WEC Committee's Cosmetic procedures Report recommended regular testing of approved implants to check continued compliance. DHSC identifies no completed assessment of the failures, or evidence that the measures cited meet PIP women's present needs.

Sources. French DGS/AFSSAPS Investigation Report [37] inspection, materials and manufacturing controls; House of Commons Health Committee 2012 PIP Report [11] paragraphs 25–28; EU Class III framework and Medical Devices Regulations 2002 [36] Class III conformity and enforcement framework; WEC Committee Cosmetic procedures Report [5] paragraphs 34–36; DHSC response of 5 September 2026 [1] sentence 47.

Sentence 48

DHSC. *"In June 2025, the MHRA launched new regulations on post market surveillance, and it continue to develop future medical device regulations to further support the proactive safety monitoring of devices."*

Narrative function. Invokes a newer manufacturer regime without explaining its scope for historical PIP devices.

Evidence and rebuttal. MHRA's Post-market Surveillance Requirements guidance applies the new Great Britain requirements to devices placed on the market or put into service from 16 June 2025. It excludes discontinued and earlier individual devices from those new requirements while retaining earlier surveillance requirements. PIP devices withdrawn in 2010 are not brought into the new regime by this reform. The common EU framework and Medical Devices Regulations 2002 already governed the PIP response. A later manufacturer regime neither repairs those historical failures nor supplies a manufacturer able to investigate continuing PIP exposure. Northern Ireland has a separate current framework. DHSC's future-regulation claim leaves the historical population and the performance of the earlier duties unanswered.

Sources. MHRA Post-market Surveillance Requirements guidance [22] Introduction and scope: discontinued devices, earlier devices and Northern Ireland; EU Class III framework and Medical Devices Regulations 2002 [36] regulatory framework governing the PIP crisis; DHSC response of 5 September 2026 [1] sentence 48.

Device vigilance and the Yellow Card

The medical-device framework addresses failures of a regulated product and the resulting or potential serious harm. It requires more than counting symptoms: device identity, the event, clinical consequences, evaluation, investigation and corrective action must be connected. The Howe Report's adverse-incident definition includes malfunction or deterioration and conditions requiring medical or surgical intervention to prevent serious deterioration. The medicines Yellow Card tradition began with suspected drug reactions; the common Yellow Card front end was extended to devices in November 2014. Sharing the front end did not abolish device-specific responsibilities. [9][36][43]

Current MHRA MORE guidance separates manufacturers' mandatory incident submissions from reporting by women, clinicians and other users through Yellow Card. MHRA's May 2026 FOI response accepts that the latter is voluntary, incomplete and unsuitable for identifying the full population or calculating incidence. Device vigilance therefore cannot be demonstrated simply by inviting women to make a Yellow Card. For PIP, the missing manufacturer, unreliable historical information and absence of an identified cohort made an organised regulatory and clinical response more necessary. [20][42][9]

Issue	Device adverse-incident vigilance	Voluntary Yellow Card reporting
Regulatory purpose	Identify, record and evaluate incidents involving device malfunction, deterioration or other failures with actual or potential serious consequences.	Receive suspected safety problems through an accessible common reporting channel.
Reporter and obligation	Manufacturer obligations arise under the device framework and approved conformity system. Current manufacturer incident submissions go through MORE.	Reports by women and healthcare professionals are voluntary; MHRA's May 2026 FOI response expressly acknowledges this.
Required follow-through	Device identity, event details, severity, investigation, outcome and corrective action. Clinical records and pathology may be essential.	A submitted report is an input into vigilance; submission itself does not establish investigation, clinical care or a completed corrective response.
Population and frequency	An identified cohort and linked outcomes are needed to assess completeness and long-term rates.	MHRA accepts Yellow Card data cannot identify all affected individuals or calculate incidence, and are subject to under-reporting.

Issue	Device adverse-incident vigilance	Voluntary Yellow Card reporting
Historical PIP relevance	The manufacturer's closure created a vigilance gap recorded in the Howe Report. Earlier regulatory duties still require an account.	The device Yellow Card brand began in November 2014; present invitations to report cannot demonstrate fulfilment of duties during or after the 2010 crisis.

Sources. Howe Report [9] p. 5, definition of an adverse device incident; paragraph 5.23, manufacturer closure and vigilance gap; EU Class III framework and Medical Devices Regulations 2002 [36] Medical Devices Regulations 2002, regulation 65 and device conformity/enforcement provisions; MHRA 2015 independent-review progress report [43] p. 14, Integrated Yellowcard reporting; MHRA Yellow Card and MORE reporting guidance [20] manufacturer-only scope and How to report; MHRA FOI2026/00467 response [42] p. 3, response point 6(a)–(c).

What the sentence by sentence record establishes

The strongest contradictions arise within the official record itself. DHSC describes the Howe Report as independent despite its published internal methodology. Its categorical breast milk assurance exceeds the limits described in the Keogh Final Report and MHRA's Toxicology Testing webpage. A PIP-only cancer zero appears beside an acknowledgement of seven confirmed reports involving previous PIP exposure. The BCIR establishment date obscures data collection not being fully implemented until 2017. Later regulatory reform is invoked without showing what it delivered for women exposed to fraudulent PIP implants. [1][9][12][13][17][22][33]

The record also restores the governing law. The UK response occurred within the common EU Class III medical-device framework, implemented through the Medical Devices Regulations 2002. Fraudulent departure from the certified specification was a regulatory matter in its own right. The existence of disagreement about preventive surgery did not suspend conformity, incident-recording, investigation or enforcement responsibilities. MHRA's authority had to be exercised within that framework; it was not a substitute for it. [36][37][11]

The architecture of the embedded narrative

The narrative is embedded because its assumptions are carried inside otherwise routine explanations. Institutional duties appear as evidence of fulfilled duties. An internal review acquires the authority of independence. The withdrawal of unused products stands in for informing women already implanted. Publishing webpages stands in for access to knowledgeable clinicians and coordinated care. Prospective reforms stand in for accounting for historical failure. Each substitution removes a material question from the account while keeping the conclusion of adequacy in place. [1][9][11][17][22]

The evidentiary structure is circular. The former registry's closure helps create a missing population. Under-reporting and incomplete follow-up leave the health consequences inadequately measured. The Keogh Final Report declines further PIP-specific symptom-frequency collection. Published clinical diagnoses are compressed into a general BII discussion, while reporting data and full exposure classifications remain inaccessible. The resulting absence of an established population-level link is then presented as a reason to retain the advice. Missing evidence becomes a defence for the institutional position whose failures helped produce the deficit. [18][12][7][42][44][51][58][59]

Institutional purpose and practical effect

PIP Action Campaign's analysis identifies the institutional purpose advanced by this account: preserve the settled policy, defend the authorities' previous performance and contain the demand for independent scrutiny. The practical purpose of an embedded narrative is to govern which facts appear relevant, which evidence is treated as sufficient and which action appears necessary. It achieves that through selection, omission, classification and repetition, without needing to refute every woman's record individually. [1][2][3][5]

In this reply, women's injuries become concerns; uncontrolled fraudulent manufacture becomes unspecified batch variation; missing identification becomes infeasibility; unknown incidence becomes reassurance; previous PIP exposure loses visibility behind a current manufacturer or PIP-only category; and voluntary reporting becomes the apparent answer to continuing harm. The letter's practical conclusion is unchanged advice. It gives no accountable decision on the statutory Public Inquiry request and no demonstrated PIP-specific clinical response. That is the observable institutional direction and effect of the text. [1][2][4][7][42]

The consequences reach clinical practice. The official account influences whether past PIP exposure is recorded, whether disease is investigated as an exposure-related possibility, whether women reach appropriate specialists and whether pathology and outcomes enter surveillance. A narrative that narrows what is recognised also narrows what is measured. Women can then be required to supply the proof that the system has failed to assemble, while waiting for the care and independent examination they requested. The WEC Committee's 2026 findings show that those failures remain consequential. [5][44][46][47][51][58][59][61]

Attribution and public accountability

The authorship and approval record is needed to establish who selected and authorised the assurances, what contrary information was available and why it was omitted. The relevant records include the preparation of the 5 September response; evidence and advice used to maintain the policy; incident investigation and follow-up; registry funding, retention and tracing decisions; complete implant and cancer histories; and referral, refusal, diagnosis and treatment records. These arise from the analysis as evidentiary subjects for independent scrutiny. [1][7][9][10][18][42]

Hillsborough, Infected Blood, Mid Staffordshire and First Do No Harm supply the accountability standard: public interest before institutional reputation; honest disclosure of the material record; attention to reported harm; and a response capable of delivering care. The Public Office (Accountability) Bill expresses the same need for candour, assistance and effective participation. Part II demonstrates why the official account must be examined against that standard rather than accepted on its own authority. [26][28][29][30][31]

The PIP fraud was the original crime. The embedded narrative concerns the institutional response that followed and the continued use of an account that does not answer its failures. A statutory Public Inquiry is required to connect the decisions, the missing and restricted evidence, and the consequences for women. The clinical response must proceed alongside that scrutiny. Repetition of reassurance cannot discharge either responsibility. [2][3][4][5]

Sources. DHSC response of 5 September 2026 [1] sentences 5–48 and closing; Howe Report [9] paragraphs 1.7–1.13 and 5.23; Keogh Final Report [12] paragraphs 10 and 27; MHRA PIP Toxicology Testing webpage [13] Additional MHRA tests; NHS England BCIR Management Information 2023 [17] BCIR Data Collection: 2017 to 2023; MHRA Post-market Surveillance Requirements guidance [22] Introduction and scope; EU Class III framework and Medical Devices Regulations 2002 [36] Class III conformity and regulations 61–65; MHRA Internal Review IR2026/00843 [7] response points 1 and 5–7; MHRA FOI2026/00467 response [42] response points 1–2 and 6–7; WEC Committee Cosmetic procedures Report [5] paragraphs 18–25 and 37–43; PIP Action Campaign June 2013 Literature Review [44] clinical papers; Public Office (Accountability) Bill [26] clauses 1–3, 10 and 12; Hillsborough Report [28] institutional accountability; Infected Blood Inquiry Final Report [29] Volume 1; Mid Staffordshire Public Inquiry Report [30] paragraphs 1.176–1.183; First Do No Harm Report [31] Chapter 2 and Recommendations 5 and 7.

Named source annex and plain text links

Full document names and identifying details are given below. Page references use printed numbering where available; paragraphs and named sections are the preferred locators. Correspondence and held Campaign records without a public URL are identified by title, date and document reference. The numbering is consistent throughout Part II.

[1] DHSC response of 5 September 2026

Department of Health and Social Care, Your correspondence of 24 July, 5 September 2026. Primary reply analysed here; 49 sentences. Supplied correspondence; no public URL.

[2] PIP Action Campaign letter to the Prime Minister of 24 July 2026

PIP Action Campaign, Prime Minister 24 July 2026, statutory Public Inquiry request, 3 pages. Supplied correspondence; no public URL.

[3] PIP Action Campaign correspondence of 28 August 2026

PIP Action Campaign, PM Meeting RQ 28 August, 10 pages, and Kevin Lee 28 Aug. Follow-up correspondence supporting the inquiry and meeting requests. Supplied correspondence; no public URL.

[4] Fleur Anderson letter of 4 August 2026

Fleur Anderson MP, letter headed Dear Prime Minister, 4 August 2026, 2 pages. Supplied file: Letter to Andy Burnham – Poly Implant Prothèse (PIP) breast implants (2) (1). Identification, contact and clinical-care requests; no public URL.

[5] WEC Committee Cosmetic procedures Report

House of Commons Women and Equalities Committee (WEC Committee), Cosmetic procedures, HC 869, 18 February 2026. PIP findings: paragraphs 11–19; registry: 20–25; cancer and testing: 28–36; systemic symptoms and care: 37–43.

https://publications.parliament.uk/pa/cm5901/cmselect/cmwomeq/869/report.html

[6] 2013 Cosmetic Review

Department of Health, Review of the Regulation of Cosmetic Interventions, April 2013 (chaired by Keogh). This is the 2013 Cosmetic Review, not a further PIP clinical report. Paragraph 4.10: under-reporting; 4.18–4.22 and Recommendations 20–21: registry and implementation.

https://data.parliament.uk/DepositedPapers/Files/DEP2013-0717/Review_of_the_Regulation_of_Cosmetic_Interventions.pdf

[7] MHRA Internal Review IR2026/00843

MHRA, Internal Review IR2026/00843, 27 August 2026, 7 pages. Pages 1–4 reproduce PIP Action Campaign's request; pages 4–6 give MHRA's response. Section 12 refusal, manual-review estimate and requests concerning adverse incidents, health consequences, BCIR and multiple exposure. Held Campaign document; no public URL.

[8] SCENIHR 2012 PIP Opinion

Scientific Committee on Emerging and Newly Identified Health Risks, The Safety of PIP Silicone Breast Implants, 1 February 2012. Sections 3.4.2 and 5.3, printed pages 15 and 22–23.

https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_034.pdf

[9] Howe Report

Department of Health, Poly Implant Prothèse (PIP) Silicone Breast Implants: Review of the actions of the Medicines and Healthcare products Regulatory Agency (MHRA) and Department of Health, May 2012, published 14 May. Methodology: 1.7–1.13; adverse findings: 4.14–4.15, 4.23, 4.28–4.29; communication: 5.3–5.8; manufacturer closure: 5.23.

https://assets.publishing.service.gov.uk/media/5a7c88ffed915d48c24106a2/dh_134043.pdf

[10] MHRA FOI2026/00792 response

MHRA, FOI2026/00792 response, 19 August 2026, 2 pages. Personnel-record retention, senior devices vacancy and absence of held explanation or impact assessment. Held Campaign document; no public URL.

[11] House of Commons Health Committee 2012 PIP Report

House of Commons Health Committee, PIP breast implants and regulation of cosmetic interventions, HC 1816, 28 March 2012. Chapter 3, particularly paragraphs 8–14 and 23–30: evidence, international responses, delayed collection and communication.

https://publications.parliament.uk/pa/cm201012/cmselect/cmhealth/1816/1816.pdf

https://publications.parliament.uk/pa/cm201012/cmselect/cmhealth/1816/181607.htm

[12] Keogh Final Report

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