THE GOVERNMENT'S RESPONSE TO THE HOUSE OF COMMONS HEALTH COMMITTEE: SIXTEENTH REPORT OF SESSION 2010-12

PIP BREAST IMPLANTS AND REGULATION OF COSMETIC INTERVENTIONS

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by command of Her Majesty

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PIP BREAST IMPLANTS AND REGULATION OF COSMETIC INTERVENTIONS

1. The government welcomes the Health Committee's thoughtful analysis of the problems arising out of the fraudulent use of non-medical grade silicone in the breast implants manufactured by the French company Poly Implant Prothèse (PIP) and of the wider implications for the regulation of cosmetic interventions.

2. The government's consistent approach, since the fraud was first uncovered in March 2010, has been to seek out the best available evidence and scientific advice; to base policy firmly on the evidence, and not on hearsay and anecdote; and to offer support and help to those many women who received PIP implants in good faith and are now, understandably, worried and distressed at the possible implications for their health.

3. We welcome this opportunity to reiterate the government's position:

i on the basis of the evidence available to the expert group in January, there is no clear evidence that PIP implants represent a materially greater risk to health than the recognised risks of other brands of silicone gel breast implants. We therefore do not recommend that women with PIP implants should, as a routine precaution, seek to have their implants removed;

ii we do recommend that all women in this position, whether they were originally treated in the NHS or in the private sector, should seek clinical advice (if possible from their original provider) and should discuss the options, informed where appropriate by a scan;

iii the NHS will support removal of PIP implants if, informed by an assessment of clinical need, risk or the impact of unresolved concerns, a woman with her doctor decides that it is right to do so. The NHS will replace the implants if the original operation was done by the NHS;

iv we expect private providers to offer the same after-care to their patients. If however a provider is no longer in business, or refuses to meet its moral and legal obligations to its patients, the NHS will offer removal (but not normally replacement) of the implants;

v we are continuing to collect evidence on the potential health risks of PIP relative to other implants, and to work closely with other governments and regulators. Sir Bruce Keogh's expert group will continue to assess this evidence and we will update our policy and our health advice as needed.

4. We welcome the Committee's endorsement of the main elements of the Government's policy, and their many helpful suggestions for the work of the two reviews the government announced on 11 January, a retrospective review of the actions of the Department of Health and the Medicines and Healthcare products

Regulatory Agency (MHRA) to be carried out by Earl Howe, and a prospective review of the regulation of cosmetic interventions to be carried out by Sir Bruce Keogh. All these points are being covered by the two reviews.

5. There are however two points on which we must differ from the Committee's recommendations. First, the Committee have suggested that the Department and the MHRA failed to give sufficiently urgent attention to the need to gather evidence and communicate health advice following the discovery of the PIP fraud in March 2010. The report of Earl Howe's review, published today[1], documents in detail the work that the MHRA in particular undertook in this period to assess the risk to women and to give appropriate advice. The report recommends a number of improvements to the current system and its operation but concludes that, in general, the actions of the MHRA and DH were reasonable and proportionate.

6. Secondly, the Committee have suggested that we should find a way of enabling women who received PIP implants from a private provider, and are now looking to the NHS for support, to pay a "top up fee" for fitting replacement implants at the same time as receiving NHS surgery to remove the PIP implants. In our view, this would raise serious issues both of principle and of practicality. It would cut across guidance on co-payments issued in 2009[2]. Our reasons are given in more detail below, but in summary:

i it is vital to ensure as clear a separation as possible between NHS and private treatment, to ensure that patients do not have to pay for elements of treatment that should be available on the NHS or conversely that the NHS does not subsidise private treatment. To do otherwise would undermine one of the founding principles of the NHS;

ii if NHS providers were to carry out a replacement breast augmentation, they would become responsible for all the associated aftercare including the high probability of further replacement operations in subsequent years;

iii offering what would in effect be a subsidised breast augmentation for non-clinical purposes would mean that the NHS would become the provider of choice for many women with PIP implants. This would risk putting significant pressure on NHS breast reconstruction services and delays to women who have a clinical need for breast augmentation, for instance after breast cancer.

Advice from Sir Bruce Keogh's expert group makes clear that, for most women, there is no clinical need for re-augmentation after removal of a breast implant, and that any excess risk associated with undergoing separate operations for removal and replacement of the implants is low for this group of patients.

7. The government's response to the Committee's individual recommendations is set out in the following paragraphs.

Evidence on the risks of PIP implants

Recommendation 1. *All possible evidence, including patient-reported experiences, must be gathered and analysed in order to inform the policy response to this issue. We look forward to seeing what new evidence has been made available to the Expert Group since the publication of its interim report. If this new evidence does not allow for a conclusive view on the safety of PIP implants, we recommend that the Department brings forward a proposal for gathering the necessary data. (Paragraph 13)*

Recommendation 2. *Since the publication of the Expert Group's Report some further evidence has been emerging about the inflammatory properties of the PIP implants whether ruptured or not, and the increased difficulty of removing ruptured PIP implants. Evidence on these issues should be examined carefully and urgently – if it is found that the removal of ruptured PIP implants involves significant complications, then this would be an argument for recommending early removal of PIP implants. (Paragraph 14)*

8. Since publication of the Expert Group's interim report, the MHRA has been working closely with other national regulators to improve the evidence base on the potential health risks of PIP relative to other silicone gel breast implants. In the UK, the main initiatives have been

i. the systematic collection of data on clinical findings at explantation for all explantations of breast implants (both PIP and other makes) over the period 2001-2011. This includes information on ruptures, gel bleed, local inflammation, diffusion of the gel material outside the implants and serious health events such as cancers. Analysis of the data will enable the expert group to compare the time-to-event curves ("survivorship curves") of PIP and other implants;

ii. a programme of further testing for the potential toxicity of the filler material for a sample of PIP implants manufactured at various times between 2001 and 2010. This will complement the results of tests already carried out in the UK[3], France[4] and Australia, and additional testing in Australia[5]. It will also add to the findings of the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) published on 1 February 2012[6]. These showed that, on the basis of the data so far available, women with PIP breast implants are not at significantly different risk to women with other types of breast implants.

The Expert Group will continue to meet as the results of this work become available and will issue further advice as needed.

9. The Expert Group has considered carefully the feasibility of collecting patient-recorded experience. The information which has been collected informally, for instance through social networks, suggests that the systemic health outcomes most commonly reported – generalised pain, headaches, lack of energy – are widely prevalent in the general population. Interpreting such data therefore requires an appropriate control group and attention to the many possible sources of bias (for

instance, the possibility that women with PIP implants are more likely to report health concerns than a matched sample in the general population). A number of careful studies of this kind were undertaken in the early 2000s[7] in response to previous concerns over breast implants and have shown how difficult it is to demonstrate a causal connection for this kind of self-reported data.

Action before March 2010

Recommendation 3. *The Committee is concerned that, given what was known about PIP implants and the issues raised by the MHRA, there wasn't greater vigilance, especially when PIP implants were significantly cheaper and were not the implant of choice for surgeons. Earl Howe's Review should seek to address whether the MHRA had information that ought to have prompted them to act sooner. (Paragraph 19)*

10. Earl Howe's review has carefully examined the actions taken by the MHRA in relation to its responsibility for surveillance of CE marked devices. The record shows that the MHRA was diligent in following up adverse incident reports with the manufacturer and, when the replies were unsatisfactory, with the German notified body. MHRA only had anecdotal evidence at the time from a handful of surgeons who had decided not to use PIP implants, as is common with devices where clinicians' preferences may vary for many reasons. The wider lessons for the regulatory system as a whole, in particular the need for greater user of unannounced inspections, are being taken up with the European Commission in response to its review of the Medical Devices Directives.

Action between March 2010 and December 2011

Recommendation 4. *"Sincere hope" is not an adequate basis for regulation. There needs to be a more reliable method of communicating Medical Device Alerts to the private sector, that requires a positive response that the instruction has been received and acted upon in the same way as in the NHS. Sir Bruce Keogh's review into the regulation of cosmetic interventions must set out how this could best be achieved. Using the professional associations as channels of communication will not cover all surgeons. (Paragraph 22)*

11. All private providers registered with CQC have been encouraged to register for Medical Device Alerts either with the MHRA or with the Department's Central Alerting System. However, we accept that current arrangements do not guarantee that all providers are registered on one or both systems. Earl Howe's review therefore recommends that MHRA should work with private providers to establish a network of Medical Device Liaison Officers, mirroring that which exists in the NHS, to provide a focus for communication and local action on device regulation and vigilance issues.

Recommendation 5. *It is surprising that urgent action to gather evidence and communicate with affected women only gathered pace in December 2011, following the announcement of the French Government. Given the fact that 40,000 women were known to have received sub-standard implants, the very scale of the problem alone should have provoked a high-profile policy response much sooner, including urgent action to gather evidence that would allow the risks of these implants to be properly assessed. Earl Howe's review must examine why action was not taken sooner. (Paragraph 26)*

Recommendation 6. *The action taken to communicate with affected women after March 2010 was inadequate. The Committee recognises that private clinics had a duty to contact their patients directly, but the MHRA and the Department of Health also had a duty to raise public awareness. A more creative approach should have been used. Earl Howe's review should determine when the Department of Health and the MHRA contacted NHS patients directly, and the adequacy of strategies to communicate with the far greater body of private patients. (Paragraph 28)*

12. See para 5 above. Earl Howe's review has concluded that the action taken by MHRA and DH, following the discovery of the fraud in March 2010, was reasonable and proportionate. In particular, MHRA took prompt action in commissioning tests of the potential toxicity of the PIP gel material as soon as it became clear that the tests by the French regulator AFSSAPS were being delayed. As a result, patients in the UK and worldwide had access to the results of these tests at least 6 weeks before would otherwise have been the case. The MHRA used all available routes to disseminate the information, and continued to monitor UK and other sources of evidence in order to ensure that the health advice remained up to date.

13. The significant media interest and the additional concern generated in implanted women in December 2011 was triggered by the decision of French ministers – unsupported by the advice from their own national institute for cancer (INCa)[8] or from the "comité de suivi" (monitoring committee) set up to advise them[9] – to recommend routine, precautionary explantation. To date, the French authorities have failed to publish any evidence to support their action[a] other than the increase in the reported rates of adverse reactions following the discovery of the fraud in March 2010.

14. The MHRA's alert notice of 4 October 2010 asked health providers to contact their patients to inform them of the reassuring results of the toxicology testing and to offer advice. It would not be feasible or proportionate for MHRA or DH to follow up every alert notice and to investigate whether it has been carried out to the letter by every individual provider. Nor is it feasible for MHRA or DH to contact individual women, as they do not hold the confidential patient-level information that would be required to undertake such an exercise.

15. That said, Earl Howe's review also found there is room for improvement in MHRA's communications capability. In particular, it recommends that MHRA should rapidly establish the capacity to issue regular updates to patients, professionals and the media in relation to medical device alerts or related issues of concern.

The NHS offer

Recommendation 7. *Private clinics used PIP implants in good faith because of the CE mark. Nevertheless, the Committee agrees with the Department of Health that private clinics have an obligation to provide care and should mirror the NHS offer. (Paragraph 37)*

[a] AFSSAPS published a positive finding in a "dermal irritancy test" as part of their "topical report" in June 2011(see reference 4). Subsequent tests on a variety of samples in Australia and France have failed to replicate this finding.

16. We welcome the Committee's endorsement of the Department's view that private providers have a moral and legal obligation to offer appropriate after-care to all their patients.

Recommendation 8. *The Department of Health has been very clear about the moral imperative – it would have been welcome to have had a clearer statement of the extent of the legal obligation on private clinics. The argument of a moral imperative may be compelling, but it is difficult to enforce. Sir Bruce's review should provide a clear statement of the legal responsibility of providers to meet their duty of care and to supply an appropriate product. The situation must be clear and consistent. It is unacceptable that there should be uncertainty when it comes to responsibility for a device implanted into the body. (Paragraph 38)*

17. All healthcare providers have an obligation under the Supply of Goods and Services Act 1982 to replace, free of charge, any "unsatisfactory" goods they have supplied to their patients in the previous 6 years. Legal advice available to the Department suggests that this would apply to the supply of implants which, in the event, have turned out not to conform to the requirements of the CE mark. However, the circumstances of individual cases would need to be tested in the courts and any women contemplating joining the current legal action against providers should seek their own legal advice.

18. All healthcare providers carrying out a "registered activity" (including all forms of invasive cosmetic surgery) are required by law[10] to "protect service users ... against the risks of inappropriate or unsafe care...". As part of Sir Bruce Keogh's review, we will consider whether the wording of this regulation could be strengthened in order to make explicit the obligation of healthcare providers to provide clinical support and advice to patients after, and not just before and during, their treatment. We will seek views on whether this responsibility to provide after-care should be indefinite or should have a defined period.

Recommendation 9. *The NHS offer must take into account matters of capacity. The overall number of women affected is significant, and single providers are responsible for a significant proportion of that number. There is no point having a policy stance if it cannot reasonably be carried through. The capacity to undertake the surgery must be assessed and the policy response tailored accordingly. The Committee asks the Department of Health to identify how to make the best use of any spare capacity, whether public or private. (Paragraph 39)*

19. The Department recognises that some private providers may need to make use of spare capacity in other providers in order to fulfil their obligations to their patients. We do not consider that it is appropriate for the Department to broker such arrangements, or to place additional demands on NHS capacity which is required for the treatment of patients with clinical needs such as breast reconstruction after breast cancer.

Recommendation 10. *The Committee agrees that replacement implants for private patients should only be provided on the NHS where there is a clinical need. Nevertheless there is a particular problem for women whose original clinic no longer exists or refuses to provide treatment. (Paragraph 47)*

Recommendation 11. *Given the number of women likely to find themselves in this situation, and the potential risks for women undergoing two surgical procedures in rapid succession, a framework must be developed to allow women whose original clinic no longer exists or refuses to provide treatment to be able to pay for private fitting of privately-paid for implants in the course of the same surgery that begins with the NHS removal of the implants. It must be made clear to the patient that the implants are being fitted under a private procedure and that the NHS bears no responsibility for their future care. Such a procedure should, of course, not be carried out if the PIP implant has left the breast cavity in such a condition that it is not advisable to replace the implants immediately. (Paragraph 51)*

Recommendation 12. *We appreciate that this step will need to be carefully thought through if it is to fit within existing structures and in order to avoid setting unhelpful precedents, but we invite the Department of Health to propose how it could be achieved. Barriers posed by accounting and administration should not be the cause of women putting themselves through two operations in quick succession. (Paragraph 52)*

20. We have carefully considered the Committee's recommendations, and fully understand the concern of women who – after considering the risks and benefits – have decided to have their PIP implants both removed and replaced. We believe that policy in this difficult area should be based on the following considerations :

i in most cases, there is no *clinical* need to replace a breast implant. Members of the Expert Group have searched the literature and find no evidence that a woman who has had a breast implant removed is at risk of infection or other health consequences (over and above the risk inherent in the explantation itself);

ii we recognise that there is a slightly greater clinical risk associated with two operations rather than one, but consider that this is likely to be small for the great majority of women in this position;

iii any proposed solution to the dilemma must recognise the fundamental principle that NHS treatment should be free at the point of treatment and that NHS treatment should not cross-subsidise any associated private treatment. This is not just an accounting convention, but a founding principle of the NHS enshrined in legislation;

iv the benefits of any NHS actions taken to help women who wish to have a breast re-augmentation for non-clinical reasons need to be weighed against the possible impact on NHS services for people who have a clinical need for treatment.

21. The general principles for the provision of supplementary procedures not routinely available on the NHS were set out in "Guidance on NHS patients who wish to pay for additional private care" which was published in March 2009[11] in response to a review commissioned in 2008 by the then Secretary of State for Health and conducted by Professor Mike Richards CBE, the National Cancer Director. The

guidance makes clear that the private and NHS components of treatment must be clearly separated so that

i there is no possibility of cross-subsidisation (in either direction) and

ii responsibility for aftercare for the private component clearly falls on the provider in its private capacity (even if the provider is an NHS hospital).

Normally this should be achieved by separating the NHS and private elements of care or treatment in both time and place. This principle derives from the basic legislative framework governing the provision of NHS services, as set out in the NHS Act 2006 and enshrined in the NHS Constitution. Departing from the principle of separation can only be considered in exceptional circumstances – "where there are overriding concerns of patient safety, rather than on the basis of convenience". In the light of the advice from the Expert Group, we are clear that this test is not met in the case of the replacement of breast implants.

22. We have considered whether the normal principles as set out in the 2009 guidance could be modified in these unusual circumstances. Quite apart from the likelihood that hospitals carrying out combined private and NHS treatments in a single operation could be held to be acting unlawfully, we believe that there are two compelling practical reasons against such an arrangement:

i if this possibility is offered, many women with PIP implants are likely to turn to the NHS as the provider of choice (especially as the cost of the "top up fee" may well be less than the cost of a separate breast augmentation). We think there is a serious risk that the resulting demand would overwhelm NHS breast reconstruction services, to the detriment of women with a clinical need for breast augmentation (for instance, following breast cancer);

ii there are other similar examples in which, from the perspective of the individual patient, a combined NHS/private operation would be desirable. One example, which is explicitly ruled out in the 2009 guidance, is a patient who seeks a multifocal lens (not normally available on the NHS) as part of an NHS cataract operation. We think it would be difficult to construct a rationale for allowing combined removal/replacement operations for breast implants without transparent unfairness to other groups of patients.

23. Finally, we have considered a variant in which the combined procedure is carried out by a *private* provider but the NHS commissioner pays a reasonable amount for the removal part of the operation. This would not directly impact on NHS clinical capacity. However, as with the option considered in the previous paragraph, if this NHS-supported option is offered many women with PIP implants are likely to pursue this route. While this would not affect NHS capacity directly, it is likely that it would result in a significantly larger financial impact than current policy and would thus (within fixed NHS budgets) reduce the funding available for patients with clinical needs. In addition, the same legal principles apply to this as to the use of top-up payments in NHS facilities, since for legal purposes "NHS treatment" means any

treatment funded by the NHS, whether it is provided by an NHS hospital or by a private provider.

Recommendation 13. *Any additional costs incurred by the NHS in the course of this, or any other procedure that ought rightly to have been carried out by a private provider, must be recouped from that provider. (Paragraph 53)*

24. The NHS Cost Recovery Scheme enables the NHS to recover costs on a fixed tariff for any treatment given to a patient who makes a successful claim for personal injury[12]. We will ensure that costs are recovered from private providers in such circumstances. However, this is dependent on the woman choosing to pursue and achieve a successful claim for personal injury and the costs that can be recovered may well be lower than the actual costs incurred by the NHS.

CE Mark

Recommendation 14. *Procedures for the follow-up of the CE mark certification have been shown to be inadequate by what has happened in this case. Sir Bruce's review should examine how to strengthen the CE mark system—for example by ensuring that certified devices are subject to routine review. There must be a procedure whereby the concerns of national regulators regarding implants manufactured in another European country can be acted upon and investigated. (Paragraph 63)*

25. The Medical Devices Directives, as they apply to Class III devices such as breast implants, already require the "Notified Body" to carry out routine checks that the manufacturer is continuing to comply with the requirements for certification. National regulators can and do bring concerns to the attention of the Notified Body; the report of Earl Howe's review shows that the MHRA wrote to TÜV Rheinland in 2007 to express its concerns over possible issues with PIP implants and received written reassurance following TÜV's recertification review of PIP. However, we agree that the arrangements can be further strengthened, in particular by increasing the number of unannounced visits and by closer cooperation between national regulators and Notified Bodies, and Earl Howe's review has made a number of concrete recommendations in this area. We will be taking forward these recommendations in discussion with the European Commission. They will be addressed in the context of the short-term actions recently set out by the European Commission[13], which have already been the subject of a discussion between the Secretary of State for Health and Commissioner Dalli, as well as the longer-term work underway to revise the medical devices directives. A key area of improvement identified in both these initiatives concern the operation and oversight of Notified Bodies, as well as taking steps to improve collaboration and co-ordination concerning oversight of the devices regulatory system across the EU.

Register of implants

Recommendation 15. *Sir Bruce's review should pursue the creation of a register of implants, to improve reporting of adverse incidents, allow better monitoring of outcomes, and allow swift communication with affected parties in the event of a problem being found. Inclusion on the register should be compulsory. (Paragraph 69)*

26. As the Secretary of State made clear in his statement to the House on January 11, we strongly favour the principle of establishing a register of all significant forms of implants, and Sir Bruce's review is tasked with establishing its feasibility and cost. The potential value of registry information is underlined by Earl Howe's review. Whether the public interest in establishing an effective register should outweigh the normal presumption that individuals have a right to opt out of the inclusion of their personal data on a register is an issue which the review will need to address.

Informed consent/responsibilities of provider organisations

Recommendation 16. *In the light of these issues, the Committee believes that these events prompt some serious concerns which need to be addressed both by provider organisations and the medical profession, and by their professional regulators. (Paragraph 79)*

Recommendation 17. *Sir Bruce's review should look into how to improve reporting of adverse incidents and examine the procedures in place in provider organisations for the reporting of such incidents. All providers in both the public and private sectors should have consistent and obligatory procedures for reporting adverse incidents to the MHRA. Sir Bruce's review should assess the quality and consistency of record keeping in the both the public and private sectors; and should review the actions taken to communicate with patients following the withdrawal of the CE mark in March 2010. Providers also have a responsibility to ensure that their patients are aware of the risks and commitments involved in their procedures. Sir Bruce's Review should assess the quality of consent procedures and investigate how it can be ensured that patients have been given the time and information they need to reach an informed decision. (Paragraph 80)*

Informed consent

27. We agree that informed consent to treatments of a cosmetic nature is one of the most important issues to be addressed by Sir Bruce Keogh's review. In the first instance, we see this as a requirement to be placed on provider organisations, which are responsible for setting up the clinical governance systems within which their clinicians should operate. The requirements for registration with the CQC already make clear the need for fully informed consent[14] and a more detailed code of practice have been drawn up by the Independent Healthcare Advisory Services (IHAS)[15]. However, we know from the NCEPOD report "On the Face of It" published in 2010[16] that many of the smaller cosmetic providers are unable to demonstrate their compliance with these standards and the review will need to consider whether the regulatory framework needs further strengthening.

Record keeping, audit, reporting and communication

28. We agree that all provider organisations should have clear procedures within their clinical governance framework for maintenance of patient records, for audit of clinical outcomes, for local analysis of adverse events, for communicating information on potential health risks to patients, and for reporting adverse events to the National Reporting and Learning System and (where devices are concerned) to the

MHRA. Sir Bruce's review will consider how these requirements can be strengthened, building on the Committee's recommendations and those made by Earl Howe's review.

29. We will ask the review team to consider the feasibility and value of a (possibly selective) audit of the communications between providers and patients following the Medical Device Alert in March 2010.

Professional responsibility of medical professionals

Recommendation 18. *Medical professionals should be alert to adverse incidents and ought to ensure that these are reported to the MHRA. They ought also to satisfy themselves that treatment is only provided to a patient who has given fully informed consent. (Paragraph 81)*

Recommendation 19. *Sir Bruce's review should look at how well surgeons are respecting these professional obligations. The Committee also believes that the GMC should review medical professionals' performance of these obligations in the light of these events. (Paragraph 82)*

30. We agree that healthcare professionals have an ethical responsibility to report adverse events, and Earl Howe's review makes recommendations on this issue. Professionals also have a responsibility to ensure that patients are given the information to give fully informed consent, over and above the clinical governance arrangements in the organisations within which they work. This is perhaps particularly important for some of the smaller provider organisations within the cosmetic surgery sector. The NCEPOD report referred to above noted that this was a difficult area in which to ensure a proportionate degree of regulatory oversight and the review team will wish to discuss with the GMC, CQC and other stakeholders what more could be done in this area.

Recommendation 20. *The Committee believes that both Sir Bruce and the GMC should review the ways in which information about risks related to medical devices is drawn to the attention of surgeons who are not members of the relevant professional associations. The fact that many of these operations are taking place in the private sector does not change the nature of the professional obligation on medical professionals. (Paragraph 83)*

31. All healthcare professionals have an individual responsibility to keep up to date with developments in their own field of practice, and this will in future be assessed (subject to final decisions by ministers) as part of medical revalidation. Clinicians working in private cosmetic surgery providers are responsible for ensuring that they receive copies of all safety alerts sent to the provider. Sir Bruce Keogh's review will be considering whether cosmetic surgeons should be on an appropriate specialist register, which would help to ensure that they are in touch with professional developments in their field of practice.

Insurance

Recommendation 21. *Sir Bruce's review must look into how existing insurance arrangements in the sector, which apply to both providers and medical professionals, protect the interests of patients and how such insurance arrangements may need to be strengthened for the future. (Paragraph 88)*

32. We agree this recommendation and will ensure that the Association of British Insurers is able to make a full contribution to the work of the review team on this aspect.

Advertising for cosmetic surgery

Recommendation 22. *In certain cases, cosmetic surgery has been commercialised and trivialised. Advertising is sometimes inappropriate and fails to make clear the commitment and aftercare involved. Advertising should not be targeted at under-18s, and the Review should consider how to ensure this. (Paragraph 90)*

33. Codes on the advertising of cosmetic surgery have been drawn up by the Advertising Standards Authority[17] (the "CAP Code" published in 2010) and by the Independent Healthcare Advisory Services[18]. The review team will wish to take evidence on how effectively these codes have been implemented within the sector and on whether further measures are needed to ensure more effective protection for those who may be considering cosmetic surgery.

Reference

[1] Department of Health *Poly Implant Prothèse (PIP) silicone breast implants: Review of the actions of the Medicines and Healthcare products Regulatory Agency and the Department of Health* (Department of Health, May 2012)
[2] Department of Health *Guidance on NHS patients who wish to pay for additional private care* (Department of Health, March 2009) at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_096428
[3] MHRA press release (September 2010) at http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON093706
[4] Agence Française de sécurité sanitaire des produits de santé (AFSSAPS) *Topical report* (AFSSAPS June 2011) at http://www.ansm.sante.fr/var/ansm_site/storage/original/application/39acdab927235584ccfa340e4a9d3896.pdf
[5] See for example the updates on the website of the Australian Therapeutic Goods Administration at http://www.tga.gov.au/safety/alerts-device-breast-implants-pip.htm
[6] European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) *The Safety of PIP Silicone Breast Implants* (European Commission February 2012) at http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_034.pdf
[7] See for example Fryzek et al "Self-reported symptoms among women after cosmetic breast implant and breast reduction surgery" *Plastic and reconstructive surgery* **107** 206 (2001); Brinton et al "Risk of connective tissue disorders among breast implant patients" *American Journal of Epidemiology* **160** 214 (2004)
[8] Institut National du Cancer (INCa) *Propositions de conduite à tenir pour les femmes porteuses de prothèses mammaires PIP : avis d'experts* (INCa December 2011) at http://www.e-cancer.fr/toutes-les-actualites/360/6737-protheses-mammaires-pip-avis-du-groupe-dexperts-coordonne-par-linca
[9] See Secretariat d'Etat àla Santé/ Agence Française de sécurité sanitaire des produits de santé *Etat des lieux des contrôles opérés par les autorités sanitaires sur la société Poly Implant Prothèse* (summary and complete reports) at http://www.sante.gouv.fr/xavier-bertrand-et-nora-berra-ont-recu-les-conclusions-du-rapport-sur-les-protheses-mammaires-poly-implant-prothese-realise-par-la-dgs-et-l-afssaps.html
[10] The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (SI 2010/781) especially regulation 10(1), at http://www.legislation.gov.uk/uksi/2010/781/contents/made
[11] See reference 2
[12] See http://www.dh.gov.uk/en/Managingyourorganisation/NHSInjuryCostRecovery/index.htm
[13] European Commissio Press Notice "Medical devices: European Commission asks for further scientific study and draws first lessons from the recent fraud on breast implants" at http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/96&format=HTML&aged=1&language=EN&guiLanguage=en
[14] See reference 10, regulation 18
[15] Independent Healthcare Advisory Services (IHAS) *Good Medical Practice in cosmetic surgery / procedures* (IHAS May 2006)
[16] Goodwin, Martin et al *On the face of it: A review of the organisational structures surrounding the practice of cosmetic surgery* (National Confidential Enquiry into Patient Outcomes and Death, September 2010) at http://www.ncepod.org.uk/2010cs.htm
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