EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (AMENDMENT) REGULATIONS 2007

2007 No.400

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health, and is laid before Parliament by Command of Her Majesty.

2. Description

2.1. The Medical Devices (Amendment) Regulations 2007 ("the Regulations") amend the Medical Devices Regulations 2002 ("the 2002 Regulations") to implement Commission Directive 2005/50/EC on the reclassification of hip, knee and shoulder joint replacements The Commission Directive provides for the reclassification of hip, knee and shoulder total joint replacements from Class IIb to Class III medical devices.

2.2. The Regulations also increase the time limit for bringing criminal proceedings in respect of contraventions of the 2002 Regulations and ensures that the 2002 Regulations apply to in-vitro diagnostic devices and active implanatable devices which incorporate human blood, blood products, plasma or blood cells of human origin, or which consist of, incorporate or are derived from certain tissues or cells of human or animal origin.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 There are none.

4. Legislative Background

4.1 The Regulations are made in order to implement the provisions of Commission Directive 2005/50/EC, which provides for the reclassification of hip, knee and shoulder joints from Class IIb to Class III medical devices. . They amend the Medical Devices Regulations 2002, which implement various European Community Directives on the safety of medical devices (including the Medical Devices Directive 93/42/EEC) and include provisions governing the classification of medical devices in the UK.

4.2 Under the Medical Devices Directive 93/42/EEC, medical devices are classified as Class I, Class IIa, Class IIb or Class III. Class I is for the more simple devices and Class III for the most complicated devices posing the greater safety risks. The classification determines the nature of the procedure which must be followed by a manufacturer before he places device on the market. The procedures are designed to ensure that devices meet the safety and performance requirements specified in the Directive.

4.3 A Transposition Note for Commission Directive 2005/50/EC is attached at Annex A. The Regulations transpose the Directive by amending the 2002 Regulations; in particular, they insert the definition of "hip, knee and shoulder replacement" used in the Directive, and implement the relevant transitional periods by disapplying, in the specified cases, the provisions of regulation 13, which sets out the procedures for affixing CE marking to general medical devices which must be applied to devices marketed in the UK.

4.4 The UK and France had submitted a proposal on 5th November 2002 for the reclassification of Hip, knee and total joint replacement at the Council Working Group meeting held on 24th February 2003. The rationale being, that such devices should be placed into the highest category of regulatory control and scrutiny by the notified body.

4.5 The EU Commission produced a Draft Directive which had gained general support throughout the Member States at a meeting on the reclassification issue on 25th November 2003. The Draft Directive had then been put before the Article 7 Regulatory Committee in order to allow Member States to decide whether or not they agreed with the Draft Directive and its objective in February 2004. An agreement of the Draft Directive had been formalised through the Article 7 committee and passed through the customary EU legislative processes.

4.6 As part of parliamentary scrutiny of the proposal both an Explanatory Memorandum and an initial Regulatory Impact Assessment were presented to the EU Scrutiny Committees on the 4th July 2004 and clearance was given.

4.7 The Directive was then formally published on 11th August 2005, with a view to the implementing legislation being made and published before the 1st March 2007 with a coming into force date of 1st September 2007.

4.8 These Regulations also amend regulation 3, so as to ensure that, in accordance with the provisions of Directive 98/79/EC and Council Directive 90/385/EEC, the 2002 Regulations apply to in-vitro diagnostic devices and active implanatable devices which incorporate human blood, blood products, plasma or blood cells of human origin, or which consist of, incorporate or are derived from certains tissues or cells of human or animal origin. Regulation 6 provides for the increase in time limits for commencing criminal proceedings in respect of a contravention of the Regulations.

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy Background

Policy

7.1 Over the years there have been some problems with hip, knee and shoulder joints which have led to some medical devices being voluntarily removed from the market. The number of notices issues during the period between 2001-2005 by the Agency was seven and the number of adverse incidents received was 880. Hip, knee and shoulder replacements should be distinguished from other total joint replacements, due to the particular complexity of the joint function to be restored and the consequent increased risk of failure due to the device itself.

7.2 This culminated in an investigation into the 3M Capital Hip System and a report published in July 2001 by both the Department of Health and the Royal College of Surgeons which demonstrated that the Capital Hip System exhibited a poor short-term performance. The main recommendation of the report was a need for enhanced evaluation of data of new or modified design for such devices. This as well as other instances created an impetus for the eventual introduction of the Commission Directive to reclassify such products in order to ensure the highest level of scrutiny by the notified body. It should be noted that hip and knee replacements are weight-bearing and extremely sophisticated implants, for which the risk of revision surgery is significantly greater than for other joints.

7.3 Manufacturers must follow certain specified procedures for assessing conformity with the requirements of the Medical Devices Directive 93/42/EEC. The type of procedures which are applicable to a particular product are determined by the product's classification. Devices are divided into Classes I, IIa, IIb and III – Class I being the more simple devices and Class III for the most complicated devices posing the greater safety risks. The rules for determining the classification of a product are set out in Annex IX to Directive 93/42/EEC; but these may be adapted or modified by further Commission Directives, in the light of technical progress and new information in relation to adverse incidents (see Article 9.3 of the Directive). Commission Directive 2005/50/EC is one such directive and provides that hip, knee and shoulder joint replacements be classified as Class III devices, rather than Class IIb devices

7.4 Placing these joint replacements in this higher risk category increases the level of scrutiny the Notified Body (an independent third party certification body) will have to undertake before issuing the manufacturer with an EC Certificate of Conformity. Currently the verification undertaken by the Notified Body is usually restricted to assessment of the manufacturing facilities. Under the requirements of the reclassification Directive, Notified Bodies will be required to also verify that each type of hip, knee and shoulder joint replacement placed on the market meets the new requirements. The new Directive will ensure this risk assessment for these products will be within the highest risk category and, thus be subject to the most stringent conformity assessment procedure

7.5 The reason for the reclassification of hip, knee and shoulder joint implants is that Member States including the UK have been concerned that the products are placed on the market without adequate assessment of the design of the product and/or adequate supporting clinical data. The reclassification should go some way to require a more thorough examination of the devices at the pre-market phase thus helping to ensure public health

and safety. It is estimated that over 85,000 people receive hip, shoulder and knee joint implants each year in the UK.

7.6. In addition to transposing Directive 2005/50/EC the current exercise is also making two additional changes to correct operational difficulties and anomalies. These are:-

i). The Medical Devices Regulations have been in place for over ten years and during that period the Agency (and its predecessor) has undertaken an active market surveillance programme. Our experience to date has shown that we, at times, have difficulties in starting criminal proceedings because we have become time barred. When the then three main medical device Regulations were consolidated in 2002 we included a provision that we could take action within 12 months from the time when the offence was committed. We have since discovered that that is still not sufficient in some cases so we are proposing to amend regulation 61 of the 2002 Regulations to provide a time limit of 3 years from the date of the commission of the offence, or one year from the discovery, whichever is earlier. It is proposed that the increased time limit will apply only to offences committed after the regulations come into force. This Is in line with the provision of the General Product Safety Regulation.

ii) During the consolidation exercise in 2002 the revised regulations were drafted so as to provide that the 2002 Regulations did not apply to devices consisting of, or containing or derived from, tissues or cells of human origin, or devices consisting of or containing or derived from viable tissues or cells of animal origin. An unforeseen consequence was to also apply this exclusion to the *in-vitro* diagnostic medical devices and active implantable medical devices. The In-Vitro diagnostic Directive (Directive 98/79/EC) and the Active Implantable Medical Devices Directive (Directive 93/385/EEC) do not contain any exclusions for devices which consist of, incorporate or are derived from human or animal material.

Consultation

7.8 The MHRA consulted with Policy Divisions within the Department of Health and other Government Departments such as the DTI as well as the United Kingdom Representation to the European Union (UKREP) as the proposal for the reclassification of hip, knee, and shoulder joint replacements developed through the EU legislative processes.

7.9 The12 week public consultation on the implementing Regulations commenced on the 31st August 2006 with relevant stakeholders and concluded on the 30th November 2006. Three responses were received from industry and one from a notified body. As a result, a number of points had been raised in terms of implementation .

8.0 For example, it had been suggested by industry, that the draft regulations are amended in order to allow notified bodies to continue to evaluate design dossiers submitted before 1st September 2009 (the end of the transition period) so that a formal decision can be taken at a later stage. This is not in accordance with the Directive. Other points related to the conduct of reviews, resources attributable to the notified bodies concerned, reviews of

current procedures in undertaking assessments, and the issue of proportionality as to the introduction of the new requirements.

8.1 Some of the points raised, for example, longer transitional arrangements, cannot be incorporated into the draft regulations, as the current transitional arrangements as found in the Directive, have to be given effect through national legislative measures and cannot go beyond its scope.

Guidance

8.2 Due to the concerns expressed by industry as to the Directive's scope in terms of it possibly applying in relation to hip, knee or shoulder joint replacement to an implantable component part of a total joint replacement, but not ancillary components, guidance is currently being developed to clarify the Directive's interpretation. This guidance will be accordance with guidance being developed at the European level.

8.3 This will confirm our interpretation of the Directive in that it will apply to implantable components which are part of a total joint replacement system. The key wording is total which we have interpreted as meaning to replace both opposing artificial surfaces in each compartment of the joint being replaced. Once finalized, this will be made available on MHRA's website.

Consolidation

8.6. The Regulations are the third amendment of the 2002 Regulations The previous amendments were in 2003 and 2005 to give effect to two further community directives that reclassified breast implants and products that utilize tissues of animal origin as well as restoring to Trading Standards (TS) the ability to continue to enforce the regulations in respect of consumer products.

8.7 The 2002 regulations was a consolidating measure of all the previous regulations enacted in order to give effect to the three main Community Directives as they relate to general medical devices (wheelchairs), active implantable medical devices (pacemakers), and in-vitro diagnostic medical devices (pregnancy test kits) as well a further amending Directive which relates to medical devices that incorporate stable derivatives of human blood or human plasma as it applies to both in-vitro diagnostic and active implantable medical devices, which the above amendment regulations is designed to restore. The 2002 Regulations also consolidated the medical devices fees regulations which enabled the Competent Authority and Notified Bodies to charge for certain of their functions.

8.8 This consolidation was last effected on 13th June 2002. At present, a proposal for revision of the Medical Devices Directive 93/42/EEC is being discussed in the Council of Minister's Working Group and negotiations which commenced with the Austrian Presidency are on-going at the European level during the course of the German Presidency. Once agreement has been reached and at the stage when the UK begins the process of transposition, necessitating amendment to the main Regulations, we will again consider whether further consolidation is necessary.

9. Impact

9.1. A Regulatory Impact Assessment has been prepared as to the costs resulting from the reclassification of hip, knee and shoulder replacements Directive is attached.

`10. Contact

10.1 The contact for further information on these Regulations is:

R.M. Gutowski,
Room 8/2 -I03,
MHRA,
Market Towers,
1 Nine Elms Lane
London, SW8 5NQ

Tel: (+44) (0)207 084 3253

Email: richard.gutowski@mhra.gsi.gov.uk

Full Regulatory Impact Assessment

1. The Medical Devices (Amendment) Regulations 2007

Implementation of the European Commission Directive 2005/50/EC on the Reclassification of hip, knee and shoulder total joint replacements within the framework of Directive 93/42/EEC on Medical Devices under the Medical Devices (Amendment) Regulations 2007 which amend the Medical Devices Regulations 2002 for the purposes of implementation.

2. Purpose and intended effect of measure

(i) Objective

The Medical Devices (Amendment) Regulations 2007 amends the Medical Devices Regulations 2002 ("the principal regulations") in order to give effect to the Commission Directive 2005/50/EC on the reclassification of hip, knee and shoulder total joint replacements into UK law.

The purpose of the Commission Directive is to provide by way of derogation from the general classification rules of Annex IX of the Medical Devices Directive 93/42/EEC, for the reclassification of hip, knee and shoulder total joint replacements to be regulated as class III medical devices. (Such devices are currently Class IIb devices). This will assign to these devices the highest level of regulatory control and ensure that the design dossier of hip, knee and shoulder replacements is examined in detail by the Notified Body (a third party independent certification organisation) before these devices are placed onto the market. This will help ensure the highest level of safety and performance for such devices.

The Directive provides for two transitional periods for existing products. This is dependent on the conformity assessment route the manufacturer has previously adopted or followed for a class IIb medical device under Article 11 of the Medical Devices Directive 93/42/EEC.

From 1st September 2007, new joint replacements will be required to undergo the conformity assessment procedures for Class III medical devices. A device which has been assessed before that date as a Class IIb device using the EC type-examination procedure combined with either the EC verification procedure or the production quality assurance procedure will not require further assessment, as the same procedures are sufficient for Class III devices. Other devices that have been previously assessed will be required to undertake further conformity assessment procedures by the end of the relevant transitional period. Devices which have previously been assessed under the full quality assurance system, as it applied to Class IIb devices, will have until 1st September 2009 to undertake a complementary conformity assessment and obtain an EC design examination certificate. Devices which have been previously assessed under the EC type- examination procedure combined with the product quality assurance procedure will have until 1st September 2010 to undertake conformity assessment for Class III device – (i.e. EC type-examination procedure combined with either the EC verification procedure or the production quality assurance procedure) or submit an application for an Annex III EC type-examination procedure coupled with an Annex IV EC verification or Annex V production quality assurance procedure.

Under Article 3(4) of the Commission directive devices that have been assessed under the EC-type examination procedure combined with the product quality assurance procedure before 1st September 2007 and then placed on the market before 1st September 2010, but without being subject to further conformity assessment procedures, may still be put into service after 1st September 2010.

The Medical Devices (Amendment) Regulations 2007 also amend the Medical Devices Regulations 2002 and make certain other amendments to correct certain anomalies which have arisen:-

i) During the consolidation exercise in 2002 the revised regulations were drafted so as to provide that they did not apply to devices consisting of, or containing or derived from, tissues or cells of human origin, or devices consisting of, or containing or derived from viable tissues or cells of animal origin. An unforeseen consequence was to also apply this exclusion to *in-vitro* diagnostic medical devices and active implantable medical devices. However, the In-Vitro Diagnostic Directive (Directive 98/79/EC) and the Active Implantable Medical Devices Directive (Directive 90/385/EEC) do not contain any exclusions for devices which consist of or derive from human or animal material. As a consequence an amendment to Regulation 3 of the Medical Devices Regulations 2002 ("the principal regulations") will be made in order correct this anomaly. This is anticipated to have no significant cost implications in that industry already complies with the requirements of both the Directives as they related to in-vitro diagnostic medical devices and active implantable medical devices.

ii) When the three main medical device regulations were consolidated in 2002 we included a provision that we could start criminal proceedings within 12 months from the time when the offence was committed. This was an increase of 6 months from that specified in the Consumer Protection Act 1987. Experience has since shown that this time period is still not sufficient in some cases. Accordingly we are proposing to amend regulation 61 of the 2002 Regulations so as to increase the limit to 3 years from the date of the offence or 12 months from the discovery of the offence by the prosecutor, whichever is earlier (see draft regulation 6). Please note that these time limits would apply only as respects offences committed after 1st March 2007 and that they would be the same as the time limits for prosecution under the General Product Safety Regulations 2005 (S.I. 2005/1803).

(ii) **The Background**

Hip, knee and shoulder total joint replacements are regulated across Europe as medical devices under the Medical Devices Directive (93/42/EEC) which was transposed into UK law by the Medical Devices Regulations 2002http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=370. The Medical Devices Directive 93/42/EEC requires manufacturers to meet certain safety and performance criteria before placing their products on the Community market. Manufacturers of joint replacements are required to ensure that their products meet such requirements

Over the years there have been some problems with hip, knee and shoulder joints which have led to some medical devices being voluntarily removed from the market. Seven safety notices were issued by the Agency between 2001 and 2005 and 880 adverse incidents were received.

In July 2001 the Department of Health and the Royal College of Surgeons published a joint report of an investigation into problems with the 3M Capital Hip System. The main recommendation of the report was a need for enhanced evaluation of data of new or modified design for such devices by the Notified Body prior to the device being marketed. However, as a Class IIb device this evaluation was not always required to be carried out.

However, placing these joint replacements in this higher risk category increases the level of scrutiny the Notified Body (an independent third party certification body) will have to undertake before issuing the manufacturer with an EC Certificate of Conformity. Currently the verification undertaken by the Notified Body is usually restricted to assessment of the manufacturing facilities. Under the requirements of the reclassification Directive, Notified Bodies will be required to also verify that each type of hip, knee and shoulder joint replacement placed on the market meets the new requirements.

Accordingly the UK along with France requested that the Commission set in train the formal procedure in the Medical Devices Directive for these devices to be re classified.

(iii) **Rationale for Government intervention**

This Directive is the result of that formal approach from the UK and France for the products to be reclassified. This is due to certain problems experienced over the years, leading to some devices being voluntarily removed from the market. Hip, knee, and joint shoulder replacements should be distinguished from other joint replacements, due to the complexity of their function and the increased risk of failure as well as the greater risk of revision surgery due to such devices being weight bearing and extremely sophisticated implants.

The consequences of non implementation are the following:-

- Hip, Knee and shoulder joint replacements would not be subject to the higher levels of conformity assessment via a notified body and could potentially pose a greater risk.

- Failure to implement would mean that the UK is in breach of its obligation under European Community law.

At present these products are regulated by the Medical Devices Directive which has a requirement for a risk assessment built into it. The new Directive will ensure that this risk assessment will be within the highest risk category and, thus, be subject to the most stringent conformity assessment procedure.

In addition re classification should go some way to require a more thorough examination of the devices at the pre-market phase thus helping to allay concerns that some products are

placed on the market without adequate assessment of the design of the product and/or adequate supporting clinical data. It is estimated that over 85,000 people receive hip, shoulder and knee joint implants each year in the UK

3. Consultation

(i) Within Government

The MHRA has consulted with Policy Divisions within the Department of Health and other Government Departments such as the DTI as well as the United Kingdom Representation to the European Union (UKREP) as the proposal for the reclassification of hip, knee, and shoulder joint replacements developed through the EU legislative processes.

(ii) Public Consultation

A 12 week public consultation exercise on the implementing Regulations commenced on the 31st August 2006 with relevant stakeholders and concluded on the 30th November 2006.

Three responses were received from industry and one from a notified body. As a result, a number of points had been raised in terms of implementation, in particular via option 3.

For example, it had been suggested by industry, that the draft regulations are amended in order to allow notified bodies to continue to evaluate design dossiers submitted before 1st September 2009 (the end of the transition period) so that a formal decision can be taken at a later stage. This is not in accordance with the Directive. In any event manufacturers and Notified Bodies will, by the end of the transition periods, have had over ten years knowledge of the introduction of the new requirements. Other points related to the conduct of reviews, resources attributable to the notified bodies concerned, reviews of current procedures in undertaken assessments, and the issue of proportionality in the introduction of the new requirements.

4. Options

Option 1:
Do Nothing. There are no benefits in that this would disadvantage the UK medical devices industry as procedures would not be uniform throughout the Community. Failure to implement would be in breach of the UK's obligations under European Community law, resulting in infraction proceedings and potential claim for damages. In addition this would retain the status quo thus negating the original UK decision to approach the Commission in order that these implants be reclassified.

Option 2:

Introduction of voluntary arrangements and guidance. The introduction of voluntary arrangements and guidance may not constitute adequate implementation of the Commission Directive, which also poses the risk that the UK could be in breach of its EC obligations and could result in infraction proceedings and potential claim for damages. In addition national voluntary agreements and guidance could lead to different requirements being imposed on manufacturers by individual Member States. It could also lead to an inconsistent approach in a single market measure. If such an approach was adopted it could also lead to different compliance costs across the Community thus putting manufacturers at a financial disadvantage.

Option 3:
Implement the Directive by an amendment to the Medical Devices Regulations 2002. By introducing the Regulations we are ensuring that hip, knee, and shoulder replacements are Class III devices under UK legislation and that UK complies with it's obligations under Community law. The new requirements should be of benefit to manufacturers in the long term, as it should lead to greater confidence in the products by patients and clinicians. It would also mean that the UK would not be subject to infraction proceedings by the Commission or by individual manufacturers who may well have felt disadvantaged in some way by non-implementation by the UK.

5. Costs and Benefits

(i) Sectors and groups affected

Manufacturers or their designated authorised representatives and distributors of hip, knee and shoulder joint implants who are responsible for ensuring that their products are placed on the market as Class III medical devices.

At present there are less than 10 UK manufacturers of hip, knee and shoulder joint implants and authorised representatives and distributors of approximately 10 non-UK manufacturers. In addition 4 UK Notified Bodies are designated to issue EC Certificates for hip, knee and shoulder total joint implants.

(ii) Costs and Benefits of Option 1: Do Nothing

Option 1 would incur no costs to manufacturers of these devices or to Notified Bodies. We do not know precisely what costs could stem from infraction proceedings by the Commission, but the possibility of such proceedings and the consequences that this could entail, means that implementation of the Directive as provided by option 3 is the most appropriate means of ensuring compliance with Community law as well as helping to ensure increased levels of safety in the use of such devices.

(iii) Costs and Benefits of Option 2: Introduction of voluntary arrangements and guidance

Option 2 The classification of medical devices in the UK is subject to the provisions of the Medical Devices Regulations 2002. If hip, knee and shoulder replacements are to be

reclassified as Class III devices in the UK, an amendment to the Regulations is required; voluntary arrangements and guidance would not be sufficient. Furthermore, although we do not have precise estimates, we have no information as to whether manufacturers would sign up to voluntary arrangements or comply with guidance. This option would in any event clearly generate a cost to manufacturers (see figures under Option 3). What we are not able to quantify is what additional costs may be incurred by manufacturers if there is no a uniform application of the provisions across all Member States.

(iv) Costs and Benefits of Option 3: Implement the Directive by an amendment to the Medical Devices Regulations 2002

Option 3

Benefits

Option 3 (together with Option 2) could potentially be of benefit to patients in reducing the number of revision surgeries and injuries that stem from malfunctioning hip replacements. Whilst it is difficult to quantify the potential benefits, we anticipate that due to such products being placed into the higher classification, this will have an impact upon the number of revision surgeries to be performed.

The figures based upon data from the National Joint Registry for England and Wales for January- December of 2004 are as follows:-

- total number of hip replacement operations = 48987
- number of primary hip replacement operations = 44262 (90.4%)
- number of revision operations = 4516 (9.2%)
- number of re-operations (other than revision) = 209 (0.45%)

A report from the National Audit Office (NAO) in 2003 stated that in 2002, the average cost of a primary hip replacement was £4,274 which ranged between £2,266 to £7,456. The report also goes onto state that during 2002, the cost of a revision hip replacement was £5,756, which ranged between £2,260 to £11, 489. This is indicative of the costs that can stem from premature failure of such devices. In terms of the overall cost to the NHS, this is difficult to quantify, but the high level of failure, coupled with significant costs, indicates a significant percentage of revisions having to be carried out because of premature failure of the device in question, which have little or no clinical data to demonstrate short or longer term safety and performance. Whilst it is difficult to quantify the potential benefits, we anticipate that due to such products being placed into the higher classification, this could have an impact upon the number of revision surgeries to be performed.

If option 3 is adopted, the implementation of the Directive will ensure that the manufacturer has to provide adequate clinical data to support the CE marking of the device and that data will be more extensively scrutinised by the notified body, who will review the manufacturer's design dossier. The result should be that less inadequate and poorly functioning devices reach the UK market. The change should ensure higher levels of safety in the use of such devices.

Administrative costs

Option 3 would create a cost on Notified Bodies to undertake the additional assessment of revised deign dossier applications. Manufacturers would also generate a cost in having to prepare the dossier to submit to their Notified Body. For existing products this information would already exist but would need to be collated into a format to enable the Notified Body to be able to undertake its assessment. The Notified Body would recoup any additional cost from the manufacturer in terms of the fees charged.

The Directive will impact on manufacturers or their designated authorised representatives and distributors of hip, knee and shoulder joint implants. No charities or voluntary organisations are believed to be affected by the Directive in that they do not manufacture or market hip, knee and shoulder joint implants. As far as healthcare institutions are concerned the cost of an operation will not be affected.

The costs falling to the manufacturers are those relating to assembling the information in a suitable format to enable it to be reviewed by a Notified Body. There are less than 10 UK manufacturers who make hip, knee and shoulder joint implants and it is estimated that meeting the new requirements will be negligible in terms of the overall cost in bringing such a product to the market. The manufacturer will also be required to pay an additional fee to the Notified Body for assessing the additional information.

The cost falling to the Notified Bodies are those relating to an increased level of scrutiny and reassessment. The original anticipated cost per product type for the Notified Body design dossier review was estimated at between £2,500 and £7,000 depending on the complexity, with the average cost at around £4,000.

Notified Body	Cost of new Design Examination (£)	Cost of Review of Change to class III (£)	Cost of 5-year Design Dossier Renewal
SGS	2,500-3,500	850.00	**850-1,700**
LRQA	2,000-3,000	1,000	**1,000**
BSI	6,000-7,000	1,500-2,000	**1,500-2,000**
AMTAC	**3,000-5,000**	**500-1,500**	**1,000**

Having consulted with industry and notified bodies during the course of the public consultation, it has emerged that the cost for a new design examination ranges between £2,500 and £7,000, cost of review of change to existing dossier ranges from £850 to £2,000 above.

In addition industry have costed the preparation of an upgraded dossier at £8k on average.

1. Cost of upgrading existing dossiers	2. Cost of preparing dossiers for new products.	3. Notified Body Costs
Number of dossiers estimated at 500 based on 10 Manufacturers having on average 50 such dossiers. Average cost £8k x 500 = £4m.	Number of new dossiers estimated at 10 per year. Average cost £8k x10 = £80,000	Cost of assessing dossiers based on 500 current dossiers at an average assessment cost of £4k = 2m. Cost of assessing new dossiers based on 10 per year = £40,000 per year.

Further costs may also impact on the UK economy. Products falling under this Directive produced by non-UK manufacturers but consumed within the UK may be liable to an increase in price, which will impact the NHS in terms of a cost increase. This is because manufacturers are likely to pass on the extra administrative burden to consumers of the products, so as not to experience a loss of profit. Passing on all the extra cost to consumers will only be possible if there is no reduction in the quantity of products consumed. This is a reasonable assumption given the nature of the product.

In order to determine what the likely impact of this is, it would be necessary to know the total amount of products falling under the Directive consumed in the UK. Unfortunately this information is not available, and therefore this element of the costs is not possible to estimate. It should be noted however that additional costs in the form of small price increases of the products may arise in the future.

Notified Bodies have given an indication, that such costs may be reduced where design submissions for comparable devices and processes have been previously reviewed by them, but for new joints, involving particularly novel features, costs are likely to higher, as indicated above, which would reflect the level of work undertaken by the notified body.

It should be noted that major manufacturers would have approximately 50-60 design dossiers that will require upgrading during the transitional period in order to meet the requirements as a result of reclassification. In addition, in respect of new devices, the average number of design dossiers submitted to the Notified Bodies, would be approximately 10 per year.

Policy costs

Total compliance costs are expected to be insignificant due to the relevant companies already placing their products on the market having already gone through a conformity assessment procedure as a medium high risk product. The compliance costs are therefore the extra work that needs to be undertaken by a Notified Body to verify the design specification of the hip, shoulder and knee implants.

6. Consultation with Small Business: The Small Firms' Impact Test

All companies manufacturing hip, knee and shoulder joint implants are in the main well established national or multi-national. The UK companies are divided roughly equally between national and international. The major UK suppliers are similarly mixed. For these reasons the Small Business Section (SBS) is content that a small firm's impact test was not needed.

7. Competition Assessment

Although the regulation will slightly increase barriers to entry in this market, the fact that the costs are low, are in proportion to the number of products manufactured, and apply equally to all products, there is unlikely to be any impact on competition. Given the small and specialist nature of the market and the fact that the requirements are fairly minimalist it is not felt that the Directive will have any significant effect on competition. A competition assessment showed that the proposal is likely to have little or no effect on competition.

8. Issues of Fairness and Equity

The proposals covered in this RIA have been considered in accordance with the duties contained in the Race Relations (Amendment) Act 2000. It is not anticipated that they will have any discriminatory or adverse effects on black and minority ethnic communities.

9. Enforcement and Sanctions

The Medicines and Healthcare Products Regulatory Agency enforce the current Medical Devices Directives and the changes brought about by the reclassification of hip, knee, and shoulder joint replacements will not significantly affect their current work.

In addition, during the transposition of the Directive, we have sought to amend Regulation 61 of the Medical Devices Regulations 2002 in respect of the time limit to commence proceedings for those offences which are summary under the Consumer Protection Act 1987. The Regulations are safety regulations for the purposes of the Act, and offences that are prosecuted under the Act are summary and can only be tried before the Magistrates Court.

Where such offences are summary only, they are subject to an express time limit in which proceedings must be brought. The Medical Devices Regulations have been in place for over 10 years and during that period the Agency (and its predecessor) has undertaken an active surveillance programme. Previous experience has shown that at times, we have had difficulty in commencing summary proceedings, because these are time barred. When the Regulations had been consolidated through the 2002 Regulations, we included an extension so that we could take action within 12 months from the time the offence has been committed. We have since discovered, this too has caused us difficulties in terms of enforcement, so we have proposed to amend Regulation 61 of the 2002 Regulations to provide a limit of 3 years from the date of commission or one year from the date if discovery, whichever is the earlier period. This will ensure a more effective enforcement regime of the Regulations.

10. Monitoring and Review

The proposed reclassification Directive does not incorporate a review provision but the implementing Regulations will be periodically reviewed as part of normal practice.

11. Summary and Recommendations

Option 3 best meets the objective of the reclassification of hip, knee, and shoulder total joint replacements as class III medical devices outlined in the Directive and would ensure that manufacturers more stringent conformity assessments via notified bodies before the placing their products on the market. This will lead to a consistent approach as a single market measure that will benefit the UK medical devices industry. This will also enable the UK to meet its European obligations in terms of transposition of the Directive.

As a result guidance will be published prior to the provisions coming into force. This guidance will be in line with guidance being produced at a European level.

It is proposed that the regulations would be made by 1st March 2007 and come into force on 1st September 2007 (the latter date for the provisions implementing the Directive).

In addition, we propose to include in the implementing regulations other amendments to the Medical Devices Regulations 2002 which are as follows:

- To alter the time limit for prosecutions to 12 months from the date of discovery of the offence. The present provision starts from 12 months from the date the offence occurred.

- To amend Regulation 3 which excludes devices incorporating human blood, blood products, plasma or blood cells of human origin as well as transplants or tissue cells of human origin, or products incorporating or derived from tissues or cells of human origin currently from Directive 93/42/EEC in order to clarify that In-vitro diagnostic medical devices as defined under Directive 98/79/EC are not included within the scope of the current exclusion. This is anticipated to have no significant cost implications in that industry already complies with the requirements of both the Directives as they related to in-vitro diagnostic medical devices and active implantable medical devices and ensure conformity assessment procedures for both products are adhered to, which consist of, incorporate or are derived from tissues or cells of human and animal origin.

Option	Benefits	Costs
1	There are no benefits associated with this option.	There are no costs associated with this option.
2	Possibly better clinical data to support safe usage of devices, but unknown due to unknown take up.	Possible costs due to a) upgrading existing dossiers, b) additional assessments, and c) costs of increased prices. However, this is not known due to unknown rate of voluntary take up.
3	Better clinical data to support safe usage of devices. Possible savings	a) Cost of upgrading an existing dossier has been estimated by industry at on average £8k. With each of the 10 manufacturers having say 50 such

	related to revision operations, the costs of which total £2.7m per annum. However, this is not possible to quantify and is unlikely to be significant.	dossiers this gives a figure of £4m. b) Cost of preparing new dossiers is based on: number of new dossiers estimated at 10 per year. Average cost £8k x10 = £80,000 c) Notified body costs: cost of assessing dossiers based on 500 current dossiers at an average assessment cost of £4k = 2m. Cost of assessing new dossiers based on 10 per year = £40,000 per year. **Total administrative cost= £4,120,000**

12. DECLARATION

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs.

Signed: Philip Hunt

Date: 15th February 2007

Minister of State, Department of Health.

Contact Point: R M Gutowski
Policy (Devices)
Room 8/2 – 103
Ext: 3253