National Institute for Health and Clinical Excellence

Health Technology Appraisal

Continuous subcutaneous insulin infusion for the treatment of diabetes (review)

Comment 1: the draft scope

Section	Consultees	Comments	RESPONSE
Background information	Roche Diagnostics	The background information was accurate and complete.	-
	Aberdeen HTA Group	Mostly fine. In paragraph 4, it is not quite right to say that type 2 diabetes results from reduced insulin production, because in the early stages there is often, due to insulin resistance, an increased level of insulin production. In paragraph 5, the suggested 1 million undiagnosed is probably an over-estimate.	Wording has been amended accordingly
	DH	We feel that the background information should include the critical role that self-management makes in the management of all types of diabetes. It is a central tenet of the Diabetes NSF, where specific recommendations are made about the service components, which should support this including structured education and care planning. We think these should be acknowledged as standards components of routine care. In addition, structured patient education has also been recommended for everyone in NICE technology appraisal no 60.	Technology appraisal (TA) 60 is now referred to in scope.
	ABCD (PH)	The draft scope for the appraisal looks fine.	-
	ABCD (SB)	A statement about the difficulty in achieving good control of diabetes on insulin ie due to the risk of hypoglycaemia or severe insulin resistance could be discussed.	Reference to difficulty in achieving glycaemia control now added to background.
	RCN	Seems appropriate	-

Section	Consultees	Comments	RESPONSE
	BDA	Some of the sentences need re-wording, as they are very long and difficult to read. May be useful to say type 1 diabetes is a condition of greater blood glucose instability than type 2 diabetes and that insulin absorption via subcutaneous injection is often erratic.	Comment noted.
	Diabetes UK	Inhaled insulin is not referred to and is an option for some people with diabetes	Text in scope has been amended accordingly
	INPUT	No comment	-
	Medtronic	Accurate and complete	-
	RCP (Edin)	Some comment on the inadequacy of conventional insulin regimens in achieving physiological insulin replacement would help put the assessment in context. In other words, it is not easy to reach current glycaemic control targets with existing treatment. Given that the main emphasis is on type 1 diabetes, some of the material on type 2 diabetes could be cut.	Reference to difficulty in achieving glycaemia control now added to background. The appraisal will consider the use of CSII for the treatment of people with either type 1 or type 2 diabetes.
The technology/ intervention	Roche Diagnostics	Disetronic is now part of Roche Diagnostics Ltd, whose current pump range comprises: Accu-Check Spirit and Accu-Chek D-TRONplus. (Older Disetronic pumps, which are no longer sold, include: H-TRON and D-TRON.)	Scope updated accordingly.

Section	Consultees	Comments	RESPONSE
	Aberdeen HTA Group	Yes. You might wish to note emerging research linking continuous blood glucose monitoring systems to pumps; too early for appraisal yet but something for the future.	Scopes do not include this type of detail. The assessment Group (AG) may wish to consider emerging technologies in the appropriate section of the Assessment Report (AR).
	ABCD (SB)	Satisfactory	-
	BDA	As far as the BDA is aware, this is a true description of what is available in the UK. However, other pumps – such as reservoir patches are available in the US.	This appraisal will be limited to devices available to users of the NHS in England and Wales.
	Diabetes UK	No comment	-
	INPUT	Fairly, it could be expounded upon	Comment noted.
	Medtronic	Yes	-
	RCP (Edin)	Brief, but adequate.	Comment noted.

Section	Consultees	Comments	RESPONSE
Population	Roche Diagnostics	We believe the overall scope of types 1 and 2 diabetes is correct. We believe the evidence review will highlight the importance of considering each of the following patient populations separately: ▪ Adults with type 1 diabetes ▪ Paediatrics ▪ Pregnancy and preconception ▪ Patients for whom insulin injections are unsuitable for their quality of life or lifestyle, such as: o Severe fear of hypoglycaemia or other quality of life difficulties o Co-morbidities (e.g. Cystic Fibrosis) o People whose lifestyles cause unpredictable daily insulin requirements (e.g. ambulance drivers who work shifts) Severe insulin resistance	This appraisal review will consider all recommendations of TA 57 under its original remit. Subgroups will be considered in the appraisal, but are not specified at this stage.
	Aberdeen HTA Group	The last guidance restricted CSII to type 1 diabetes. Subgroups this time may include gestational diabetes, and children with type 1 diabetes. There is now more evidence in children (see for example, Nabhan et al 2006; Sulli and Shashaj 2006; Fox et al 2005; Jeha et al 2005; McMahon et al 2004).	This appraisal review will consider all recommendations of TA 57 under its original remit (that is type 1 and type 2 diabetes). Comment on new evidence noted.
	ABCD (SB)	Appropriate	-

Section	Consultees	Comments	RESPONSE
	BDA	Children, adolescents, pre pregnancy and pregnancy and those with gastroparesis and severe lipohypertrophy should be considered separately. Need to consider pre/pregnancy separately as difficult to achieve required control without severe hypos – don't want to have to try MDI first. Patients who experience mild, but frequent hypos affecting their daily life. Patients who are scared to tighten control because of fear of hypos feel more in control when using a pump. Small children with T1 – to reduce the pressure on parents when the child refuses to eat. Patients who are for consideration of islet cell transplants, should be treated with CSII therapy initially. Patients who are regularly partaking in intensive sports regimens. Patients who's quality of life is reduced secondary to T1. Patients with complications: • Gastroparesis – due to digestion problems, a pump is useful to match the insulin delivery to food absorption • Over used injection sites in patients with **long standing** T1 DM. Many of these patients struggle to take insulin 4-5 times per day, as injection sites over used • Insulin allergies – small doses of insulin may help with sensitisation • Patients with severe complications who are struggling to improve glyceamic control, but do not have severe hypos Although there is less evidence for pregnancy and possibly children, there needs to be consideration of the quality of life benefits, as we are all aware the glycaemic improvements are negligible from trials.	Subgroups will be considered in the appraisal, but are not specified at this stage.

Section	Consultees	Comments	RESPONSE
	Diabetes UK	Consideration should be given to examining children and adolescents with T1 diabetes separately. This is due to the different experiences and problems faced by children with Type 1 diabetes and their parents. Ie different from adults. Also services for children with diabetes are organised differently and specific problems accessing pump therapy and funding locally. Research looking at effectiveness of use by children and young persons is now more widely available, which may or may provide different outcomes/experiences/costs to adults with diabetes. Although Diabetes UK is not aware of a vast amount of research about use of pump therapy and Type 2 diabetes, it would be useful to investigate further in relation to those with Type 2 diabetes using multiple injection therapy.	The scope is not limited to specific subgroups. Subgroups will be considered in the appraisal, but are not specified at this stage.
	INPUT	No Comment	-
	Medtronic	Yes (see response to questions)	Information conveyed to NICE technical team and AG (see below).
	RCP (Edin)	There has been some use of CSII in patients with type 2 diabetes, but the case for this on a large scale is not strong. The main emphasis should be in type 1 patients, and that would include young and adolescent patients and children in whom there is now significant published experience, as well as females who are either pregnant or considering conception. These groups should probably be considered separately.	This appraisal review considers all recommendations of TA 57, and its original remit. No emphasis on Type 1 or Type 2 diabetes is intended in the scope. Subgroups will be considered in the appraisal, but are not specified at this stage.

Section	Consultees	Comments	RESPONSE
Comparators	DH [Submitted in response to invention section of scope]	We are of the opinion that the standard comparator should now be insulin therapy without the use of CSII, *which meets the criteria outlined in the Diabetes NSF and NICE HTA number 60.* (see next paragraph). Therefore we think the comparator for CSII should therefore be *'insulin therapy without the use of CSII in individuals who have had structured education in diabetes and the use of insulin, which meets the recommendations of this national guidance'.* The working group on education is being reconvened after Christmas to review what needs to be done to provide guidance for those not falling within the remit of the initial reports. A formal RCT comparing best practice diabetes management *including structured education to the recognised standard* with CSII has been submitted as part of the current round of NIHR programme grants (using DAFNE – the programme specifically mentioned in HTA number 60).	Scopes do not include this type of detail. Technology appraisal 60 is now referred to in scope (as above). Patient education is referred to within economic analysis section. This information will be conveyed to the NICE technical team and AG through this consultation. The Institute would be interested in being updated on progress with this research, if relevant to this appraisal and provided through the usual submission and consultation processes. DAFNE is to be included as commentator.
	Aberdeen HTA Group	I would expand the current entry a little to "Intensive insulin therapy without the use of CSII, such as multiple daily injections of insulin or inhaled insulin "	Text in scope amended accordingly

Section	Consultees	Comments	RESPONSE
	ABCD (SB)	In adults multi injection therapy using long acting analogues. In children , intensifying therapy with multiinjection therapy would not be appropriate and CSII would be the suitable option for intensifying treatment	Comment noted.
	BDA	Insulin Detemir and Insulin Glargine used as a once/twice daily dosage in addition to fast acting analogues	Included in the current scope.
	Diabetes UK	Detemir also needs to be included.	Included in the current scope.
	INPUT	Multiple Daily Injections	Included in scope.
	Medtronic	Yes	-
	RCP (Edin)	Because successful use of CSII requires frequent testing of blood glucose and adjustment of insulin dose along with carbohydrate counting, the appropriate comparison is with multiple dose insulin regimens where quick acting insulin is taken with meals and long acting insulin is given once or twice daily to provide a basal or "background" insulin. It is unlikely that patients would move from a simple twice daily insulin regimen with low intensity testing to CSII.	Comment noted.
Outcomes	Roche Diagnostics	We are aware of new evidence (in submission for publication and to be shown at this December's IDF) defining which measures of quality of life are most appropriate for CSII: ▪ World Health Organisation Quality of Life abbreviated questionnaire (WHOQOL BREF) ▪ Problem Areas in Diabetes Scale (PAID) ▪ Hypoglycaemia Fear Scale (HFS) ▪ Insulin Delivery System Rating Questionnaire (IDSRQ) Furthermore, we are currently working with Leeds University to pull together pump data on a multi-centre register that should contribute to an understanding of the aforementioned patient populations.	Comment noted. The Institute would be interested in being updated on progress with this research, if relevant to this appraisal and provided through the usual submission and consultation processes.

Section	Consultees	Comments	RESPONSE
	Aberdeen HTA Group	Yes.	-
	DH	We think this should include maintenance of the therapy at 1, 5, 10 years, and pattern of use over that time, and sustainability of improvements.	Compliance/adherence to treatment is captured in other outcomes such as glycaemic control.
	ABCD (SB)	Ability to work, sick days, and mental state should be considered. In children days off from school and grades, as well as behavioural problems should all be considered.	Impact on employment outside the reference case for technology appraisals. Mental state may be captured within quality of life (QoL).
	BDA	Yes, Need to collate these nationally, as many centres find the benefits greater in selected patients, than those from research trials It is very important that measures of glycaemic control do not focus entirely on HbA1c. Some measure of glucose variability is needed to assess whether someone would benefit from a pump and to assess whether the pump improves glucose stability	Outcomes not limited to glycated haemoglobin A_{1c} (HbA_{1c}) and may be captured within 'measurement of glycaemic control' outcomes.

Section	Consultees	Comments	RESPONSE
	Diabetes UK	**Hypoglycaemic episodes** should be reviewed in terms of total frequency and variation in blood glucose levels, not just in relation to severity. Evidence is emerging of the benefits to those prone to frequent hypoglycaemia and significant variability in day-to-day blood glucose levels. Assessment should also include a review of effectiveness in reducing the dawn phenomenon of rising blood glucose levels. Incidence of **diabetic emergencies** will need to also include hypoglycaemic events requiring hospitalisation. The criteria to assess health **related quality of life** should include the following: patient preferences, flexibility of lifestyle, independence, control, improved sleeping patterns, confidence and motivation as these have been identified as significant benefits for people with diabetes. Less worry/concern of parents has also been reported as improving quality of life of the parents or children using pump therapy. **Measures of glycaemic index**- it is agreed that this is an important outcome, however measurement and variation in blood glucose levels impacting on overall HbA1c should also be assessed. A further outcome measure to be reviewed is that of reduced insulin requirements.	These specific measures are accommodated within glycaemic control outcomes. QoL outcomes are to be included in appraisal, but scopes do not normal include this level of detail.
	INPUT	Add. Less time off work due to diabetic events.	The reference case specifies that appraisals take a NHS and PSS perspective.
	Medtronic	Yes	-

Section	Consultees	Comments	RESPONSE
	RCP (Edin)	The outcomes specified are generally appropriate. However, the long term complication related issues eg mortality, occlusive vascular events, are unlikely ever to be assessed in a study which is large enough or goes on long enough. However, assessment of control through a measure like glycated haemoglobin is a very good surrogate with a strong evidence base that it relates to future complications. Quality of life measures are given much emphasis in expert patient programmes for chronic disease management, and it is surprising that some measure is not included.	Comment noted – mortality and long term outcomes are important and will be included in appropriate data are available. These specific measures are accommodated within glycaemic control outcomes. QoL outcomes are to be included in appraisal.
Economic analysis	Aberdeen HTA Group	It is unlikely that there will be any studies long enough to report on complications of diabetes, and HbA1c over a few years (or less) will suffice.	Comment noted (see above).
	DH	We would consider it helpful if this also included the costs of referral and management of diabetes by specialist services rather than primary care services. Since the publication of the previous guideline, the direction of government policy has been to encourage patients to receive routine care closer to home. There are now a number of examples of this being successfully achieved for Type 1 as well as type 2 diabetes with a wide variety of local models that enable people to access specialist expertise without necessarily attending secondary care. The current Department of Health, Diabetes UK working group set up to reduce variation in the implementation of the current guidance will acknowledge the important principles of pump therapy but leave configuration up to local decision (the principle of a devolved NHS). This report should be available for the current Review and may make it more possible to assess the economic implications of guidance.	This level of detail is outside the remit of this scope. The AG has not been specifically requested to investigate local models of care, but will be informed of this comment through this consultation. The Institute would appreciate being informed of process with any reports and as consultee/ commentator, DH will receive early access to the assessment report and appraisal documentation.

Section	Consultees	Comments	RESPONSE
	ABCD (SB)	Cost of sick days, ability to hold a job, need for carers, ability to keep a license and its impact on jobs should all be considered. For children, the parent's ability to take on work again may be worth considering.	The reference case specifies that appraisals take a NHS and PSS perspective. All health effects are included in the appraisal.
	DBA	There is a possibility of reduced complication rates in the long term, secondary to improved control	Long term outcomes such as occlusive vascular events, microvascular complications are included in the scope.
	Diabetes UK	It is unclear if the review will examine direct and indirect costs will be considered. Both are important to NHS and Personal social services and people with diabetes.	The reference case specifies that appraisals that will examine direct costs. Furthermore, section 5.3.3 states: "If the inclusion of a wider set of costs or outcomes is expected to influence the results significantly, such analyses should be presented in addition to the reference case analysis"
	INPUT	There are a lot of new studies published, several on QALE and the economics of CSII	Comment noted.
	Medtronic	Appropriate perspective/proposed analysis	-

Section	Consultees	Comments	RESPONSE
Other considerations	DH	We are concerned that NICE HTA Number 60: 'Patient education models in diabetes' has been omitted and this was not seen as relevant by the NICE scoping group. We also have concerns that the importance of this aspect may therefore not be taken into account in constituting the Review Committee.	Technology appraisal 60 is now referred within the scope. Experts nominated by consultees will be invited to contribute to this appraisal.
	Aberdeen HTA Group	The use of soluble short-acting versus short-acting analogue insulins in CSII might be considered.	Included in the current scope.
	ABCD (SB)	Severe insulin resistance in Type 2 diabetes, Insulin allergy, Severe painful neuropathy not responsive to standard therapy should all be considered	Population considered in appraisal is not limited in the current scope.
	BDA	It might be useful to specify the "common core of advice" that patients should expect to be covered. If different types of pumps are going to be available guidance is required for which types of pump should be used for which patients – e.g. The new MiniMed augmented pump and sensor – could be useful in patients who continue to experience regular severe hypos despite CSII.	The role of combination devices including continuous glucose monitoring may be considered, if evidence allows.
	Diabetes UK	Consideration should be given to reviewing any new evidence of use of pump therapy worldwide in babies, particularly those with Type 1 diabetes and are premature. Continuous blood glucose monitoring is a new method of monitoring day to day blood glucose levels in real time. Its effectiveness has been reported as being favourable when used in conjunction with insulin pump therapy. Consideration should be given about use of self monitoring of blood glucose levels and new technologies available when reviewing pump therapy evidence. The current guidance recommends use of pump therapy when use of insulin (glargine) has failed. Detemir is now widely available and will also need to be considered.	Population to be considered in appraisal is not limited in the current scope. The role of combination devices including continuous glucose monitoring may be considered, if evidence allows. Comparators not limited in the current scope.

Section	Consultees	Comments	RESPONSE
Questions for consultation	Aberdeen HTA Group	In some centres, the DAFNE system of education for people with type 1 diabetes is used for all people going on to CSII.	Comment noted.
	ABCD (PH)	*1. What are the appropriate comparators to CSII in current clinical practice?* MDI, including long-acting analogue based regimens, for adults; for children CSII may be the only means of intensifying insulin therapy and so should be compared to any alternative regimen *2. In clinical practice, which subgroups should be considered in the appraisal of CSII?* Adults with type 1 diabetes; children and adolescents with type 1 diabetes; those with type 2 diabetes and severe insulin resistance; preconceptual and pregnant women with either type of diabetes; those with hypoglycaemia unawareness; those with insulin allergy; young children with extreme insulin sensitivity; those with specific quality of life issues; those with severe symptomatic autonomic or peripheral neuropathy *3. Is there sufficient evidence to consider adults, children, adolescents and pregnant women?* There is certainly sufficient published evidence to consider for the first three groups. There is little useful published evidence for pregnancy, although we have published in abstract our experience in Harrogate, which is large compared with previously published data. I am hoping to publish our experience shortly and can let NICE have our data. Obviously this is observational and not RCT data! *4. Should any other device manufacturers/suppliers be included in the appraisal?* Cozmo Deltec	1. Comment noted. 2. Population considered in appraisal is not limited in the current scope. 3. Comment noted 4. Cozmo Deltec has been added to scope and matrix.

Section	Consultees	Comments	RESPONSE
Additional comments on the draft scope.	DH	1 We consider it particularly important that all 'biomedical' interventions in diabetes are now seen in the context of a holistic set of treatment and management options. The outcomes of management depend on the interaction of the many components of this 'complex intervention'. 2 We do not think that there is a strong evidence base for attempting to either isolate individual component (controlling for others) or looking at the interdependences of the various elements. Q We think it would be helpful if the Review Group made judgements about how the evidence that is available – on the limited technical intervention- might be best incorporated in the complex environment. We would consider it critical that the review group specifically includes individuals who are known to practice (as well as comment) on a holistic approach to care. It would be encouraging to see those with specific behavioural expertise, and expertise in patient empowerment and education on the review group even if they have no specific knowledge of the technical intervention. 3 Please note: A joint Department of health / Diabetes UK working party report on the implementation issues arising from the first NICE recommendations will be published shortly and may be of interest to this NICE Review group.	1. Comment noted. 2. A range of experts are invited to contribute to the appraisal (through invited submissions, advising the AG, consultation and attendance at committee meetings). 3. The Institute would be interested in being updated on progress with this research, if relevant to this appraisal and submitted through the usual submission and consultation processes.

Section	Consultees	Comments	RESPONSE
	RCN	Insulin pumps are not quick, easy fixes and are relatively expensive, and so there should be some sort of triaging through secondary care to make sure patients have been offered support with conventional regimes first. From the experience of one PCT, an audit of the patients who are being supported with funding for their pumps is being undertaken – it is interesting to see that there are patients who despite this treatment, have no change in their HbA1c than when they were on injections (although some may not have hypos so that is a benefit). Some have brilliant results and the pump funding is very clearly justified. There is, however, disparity across settings, in primary care, it appears that some PCTs struggle to identify funding for new pumps every year where as in secondary care colleagues are not finding enough people to use the funding! It is hoped that the appraisal will address the issue, it should not be making it any more difficult to get patients put on a pump, but it needs to make sure the right patients are being funded.	Comments noted.

Section	Consultees	Comments	RESPONSE
	Diabetes UK	Related NICE recommendations not included in the scope specifically: NICE Technology Appraisal The clinical effectiveness and cost effectiveness of patient education models for diabetes TA60. No reference is currently made within the scope to supporting implementation of the guideline. Implementation criteria should also be incorporated to ensure appropriate access to the therapy and services including: • This should include requirements for PCTs and LHBs to have transparent, consistent and equitable protocols and funding in place covering: - assessment, referral, follow-up, ongoing support, education, support during initiation, supply of consumables, discontinuation, staff training and competencies. • Appropriate infrastructure should be in place to support people with Type 1 diabetes using pump therapy. This includes requirements that staff in specialist adult and paediatric diabetes care teams should be able to access continual professional development, education and training about CSII. Furthermore teams supplying pump therapy services should establish databases for audit, quality assurance and adverse events reporting.	TA 60 is now referred within the scope. Development of implementation tools is undertaken by a separate dedicated NICE programme. The NICE Implementation programme will work with guidance resulting from this appraisal.

Section	Consultees	Comments	RESPONSE
	INPUT	The existing broad recommendations have been interpreted differently by different PCTs who are not providing pump services in a uniform manner across the NHS in England. Access is also variable because clinicians interpret the guidance differently and funding can depend partly on PCT policy but also on the capacity of enthusiasts to generate funding from other sources. The organisation of the supply chain for consumables and the geographical proximity to teams who can support individuals have all frustrated implementation. Not all patients who come within the guidance are benefiting. INPUT are unhappy with the use of the term "failure of multiple dose injection therapy" in the current guidelines and were aware that clinical interpretation differed widely, reflecting local interest and expertise. NICE should consider whether additional guidance can be provided that would help to reduce this variability. INPUT would also make strong representations that a number of other indications should be included: • Quality of life for adults, including more than 5 injections daily being required to achieve control, frequent sick days, marked glycaemic swings or dawn phenomenon, impaired exercise capacity, and difficulties with shift work or travel across time zones • Quality of life for children, including school performance, inability to fully integrate into school life, behavioural issues e.g. meal times, and impact on family dynamics • Pregnancy including women contemplating pregnancy • Neuropathy • Hypoglycaemic unawareness • Extreme insulin sensitivity • Needle phobia • Insulin allergy • Severe insulin resistance • The question of hyperglycaemia should also be addressed	Comments (paragraphs 1 and 2) noted. Development of implementation tools is undertaken by a separate dedicated NICE programme. The NICE Implementation programme will work with guidance resulting from the current appraisal. Some outcomes (sick days) are not specified within the reference case. The population is not limited in the current scope.

Section	Consultees	Comments	RESPONSE
	Medtronic	W.r.t. questions asked, MDI is appropriate comparator, there is variance in the quality and quantity of evidence available to consider adults, children, adolescents and pregnant women. I am working on a lit review which will give clarification to this question when complete. I am not aware of any other companies who need to be involved. W.r.t. the consultees, we believe that the Guys and St Thomas' NHS Trust (contact name Prof J Pickup) should be invited. The trust has a large pump service and therefore has a wealth of experience regarding pump therapy in a naturalistic setting. I note the DoH is already included and assume that the diabetes pump working group will be directly involved.	The Institute would be interested in being updated on progress with this research, if relevant to this appraisal and submitted through the usual submission and consultation processes. Suggestion of expert noted. The DH has contributed to this consultation.
	RCP (Edin)	A major concern with the current guidance is that it is far too restrictive and limits patient choice. CSII is presently recommended as an option for those with type 1 diabetes in whom multiple dose insulin has failed, and provided those receiving the treatment have the commitment and competence to use it effectively. One can agree with the second part, but the first is problematic. Failure of MDI is defined as "impossible to maintain haemoglobin A1c no greater than 7.5% (or 6.5% in the presence of microalbuminuria or adverse features of the metabolic syndrome) without disabling hypoglycaemia …". In turn, disabling hypoglycaemia means for the purposes of the guidance "repeated and unpredictable hypoglycaemia … requiring third party assistance". This severe level of disability is a high hurdle indeed, and puts patients' lives into danger before they are considered for CSII. We suggest "significant problems with control or lifestyle" or something comparable would be appropriate.	The purpose of the current appraisal is to review the existing guidance. The Appraisal committee will consider a range of evidence before making its determination.

Comment 2: provisional matrix of consultees and commentators

Suggested additions:

AHTA	Scottish Study Group for the Care of Diabetes in the Young (SSGCDY)
DH	Dose Adjustment for Normal Eating **(**DAFNE) Steering Group
DH	Diabetes Education and Self Management for Ongoing and Newly Diagnosed (DESMOND) Steering Group
ABCD (SB)	The Insulin Pump Working Group (DH working group)
INPUT	Starlet, Starbridge Systems Ltd (CE Marking pending)
ABCD	Deltec Cozmo, Smiths Medical, UK (CE marking awarded)

Comment 3: Regulatory issues

Section	Consultees	Comments	Action
Remit			
Current or proposed marketing authorisation			

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

WAG
J&J (but directed a communication to the Institute)