RISK ASSESSMENT METHODOLOGY

Level of Risk and Rate of Introduction to the Market

Introduction

For the Beyond Compliance process to work effectively the level of risk inherent in a new device, modification to an existing device or an extension to a range must be assessed early on in the Beyond Compliance process. Categories of risk are set out below. From our already increasing experience we appreciate that on some occasions a device will not easily fall into one particular 'Level of Risk'. Therefore it must be clear that our recommended, numeric risk level (1-5) is by nature, to a degree, subjective.

The purpose of these numeric levels of risk are to convey our concerns or lack of concerns about a particular implant, to a manufacturer. That is to say, that a low number implies minimal risk and a high number implies major concerns. We would expect manufacturers to consider being increasingly cautious about the rate of introduction of an implant with a high numeric rating.

In our assessment of each product, the Beyond Compliance Advisory Group will discuss with the manufacturer the rate of introduction of their implant to the marketplace and the level of surveillance that is recommended.

Points to consider

- There are no pre-existing rules or explicit guidelines available for this assessment process.
- Stratifying risk has major limitations but no other method has been found which would be superior.
- The rate of introduction to the market will eventually be determined by the number of hospitals and number of surgeons wishing to take up the device. All these devices have CE marks and therefore BC can only make recommendations, it would be illegal for them to state a limit on sales etc. It is hoped that manufacturers will agree to the suggestions that Beyond Compliance makes. Beyond Compliance has the right to excuse themselves from the process if they thought that the manufacturer was taking little or no notice of the advice they were given.
- The initial cohorts of implants that are used when a new device enters the market will not be large enough to make a decision based on statistical significance. Worrying pointers will almost certainly be evident before statistical significance is achieved. Statistical advice will, of course, be available.
- There will be occasions when implants are being introduced to the home market where they have already been used in another country. In making risk assessments overseas, data will be always be helpful but its weight will depend on its quality.

Benchmarks

Risk will be assessed by comparing the implant against the performance of a well-established implant which is recognised as having a first-class track record; one having a 10A* ODEP rating.

Modifications leading to differences between the predicate and the submitted implant in areas such as changes in the working surface (the interface with the patient) and the bearing surface will attract a higher rating of risk than in some other areas of modification.

In summary, significant modifications will include:

- Change in materials
- Change in bearing surface
- Change in fixation.

Less significant modifications/changes will include changes in angles, offset, etc. Because assessments will often be subjective, where there are a series of 'minor' modifications, they may be summated to effectively be considered as a 'major change'.

GUIDELINES

LEVEL 1 RISK	The level of risk is thought to be minimal. An example would include an extension to a range of sizes
Anticipated rate of introduction	No restriction
Monitoring	Through the BC process. Data reviewed and reported 6 monthly or annually

LEVEL 2 RISK	For example, where there has been one significant change away from the benchmark implant(s)
Anticipated rate of introduction	To be agreed between the manufacturer and the rapporteurs and referenced in the assessment
Monitoring	Through the BC process. Initally 3-monthly, with tripartite meetings

LEVEL 3 RISK	For example, where there are two or more significant changes from the benchmark implant
Anticipated rate of introduction	To be agreed between the manufacturer and the rapporteurs and referenced in the assessment. It is anticipated the rate of release will be slower than with a product which has attracted a lower risk rating
Monitoring	Through the BC process. Staged release and periodic tripartite reviews

LEVEL 4 RISK	Where there is no useful benchmark implant and/or where there is a significant multiple change away from the accepted benchmark implant. In this type of analysis, it is likely there may be liaison with the appropriate notified body
Anticipated rate of introduction	Very limited introduction as agreed in the risk assessment
Monitoring	Close monitoring through the BC process and regular tripartite reviews

LEVEL 5 RISK	Where there is an absence of predicates with a satisfactory track record or where any similar implants have previously performed unacceptably
Anticipated rate of introduction	Strictly limited
Monitoring	Strictly monitored through the BC process and frequent tripartite reviews

Reviews

Following the risk assessment being agreed by all parties and contracts signed, 'Review Meetings' will be organised at prescribed intervals. The timescale for these meetings is dependent on the level of risk that has been ascribed to the device and to the anticipated up take by the market.

These meetings will be face to face meetings, if it is thought necessary otherwise they will take the form of teleconferences. It is expected that the champion surgeons for the implant will be available together with representatives of the manufacturer, representatives from Northgate Public Services and the Rapporteurs will discuss the performance of the implant up until that time. They will have a comprehensive report from Beyond Compliance available prior to this meeting.

Before the end of these meetings a recommendation will be made as to the rate at which the usage of the product can be increased or otherwise.

IMPORTANT NOTICE

The risk level (1-5) that is agreed is confidential to the Manufacturer and Beyond Compliance. It will not be seen on our public facing website. It is to be used for guidance by all parties and it is very much hoped it will be of use.