Responsibilities and duties of a Beyond Compliance Rapporteur

Introduction

Rapporteur is the name given a member of the advisory group from Beyond Compliance who, usually working with one or two more colleagues, is responsible for producing the assessment of a new device following the stage 2 meeting.

Their responsibilities continue until the product gets to 3A ODEP rating, or when they terminate their relationship with Beyond Compliance.

Rapporteurs usually work in pairs and sometimes threesomes. We try to partner experienced and less experienced rapporteurs as pairs and, of course for governance purposes, it is always important that at least two people discuss the data about a company. Rapporteurs are not assigned to a particular product if there is any question of there being a conflict of interest.

The duties

- Read all the data provided by manufacturers prior to the stage 2 meeting.
- To make themselves aware of the details of any predicate the manufacturer is citing in their submission.
- To attend the stage 2 meeting in good time so as to discuss the format of the meeting and any issues that might need comment prior to the manufacturer being present.
- To listen to the submissions and ask appropriate questions before contributing to discussion about the product and the risk analysis.
- To produce the written assessment with the other rapporteur. It is generally the responsibility of the first rapporteur to complete the assessment form, but it could be the second one with agreement with the first.
- The Chairman of the advisory group or his deputy will review the assessment and may contribute to it. When the rapporteurs and the Chairman (or his deputy) are happy with the assessment it will be forwarded to Alan Needham at Northgate before being sent on to the manufacturer.
- The rapporteurs will then receive feedback from the manufacturer and discuss it amongst themselves before editing the assessment.
- When the assessment is fully agreed by the manufacturer and ourselves it will be signed off. If rapporteurs wish to lodge their electronic signature with Northgate that is entirely their decision.

  IT IS ESSENTIAL THAT THE FIRST DRAFT OF THE ASSESSMENT REACHES THE MANUFACTURER BEFORE THE NEXT BEYOND COMPLIANCE MEETING. I.E. WITHIN A MONTH.

  IT IS SUGGESTED THAT THE ASSESSMENT IS WRITTEN UP WITHIN 48 HOURS OF THE MEETING AS IT WOULD BE EASIER TO DO IT THEN RATHER THAN LATER. IT IS, THERFORE, SUGGESTED THAT RAPPORTEURS BOOK TIME IN THEIR OWN DIARIES TO COMPLETE THE ASSESSMENT, SAY BY THE SUNDAY EVENING AFTER THE MEETING.
- It is usual for the rapporteurs to visit the champion surgeon and observe the use of the product and the instruments. This will be agreed by the company.
- Rapporteurs will have their expenses paid by Beyond Compliance, including visiting the champion surgeon.

Review of meetings

Rapporteurs will have decided, in the assessment, to recommend a time period before the first review meeting.

- The details of the performance of the product will be sent by Northgate Public Services to the rapporteurs at least a week before the meeting.
- The meeting will be a telephone conference, usually at 8 pm on the appointed date.
- The rapporteurs will use an agreed agenda to cover all the points that need discussing. The rapporteurs will then be responsible for producing minutes of the meeting and sending them as a draft to the manufacturer.
- The rapporteurs will be responsible for reviewing the comments made by the manufacturer and agreeing the minutes appropriately.
- At the end of the meeting a decision will be made as to the rate of the ongoing release of the product and the date for the next review meeting.

Final Comments

The legal liability of Beyond Compliance is underwritten by NHS Supply Chain and BSA. It is, of course, essential any conflict of interest etc. is declared.

Beyond Compliance gives advice and does not make rules. The assessment we give is an opinion and it is important that the assessment reports are crafted along these lines. It is entirely up to the manufacturer as to whether they take our advice. Some people have suggested that does not constitute a firm enough directive on their marketing. I think the fact that our advice will be recorded, and thus available to lawyers etc. if the product failed, would be more than enough for most manufacturers to be very careful about not following anything that we have suggested. One has to accept the fact that the people are most likely to read our assessments with great care are going to be lawyers.

If during any of the duties that a Rapporteur has with one particular implant they have concerns they should be in touch with their colleagues and with the chair of the advisory group. I am convinced that our advice is always going to be better if our individual advices are pooled.

If anybody has any comments or concerns please contact me at ktucker77@aol.com.

I very much hope that you enjoy being a rapporteur.

Keith Tucker

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