Meeting animal welfare needs in a biotherapies environment—challenges for the CSL/Pfizer Animal Ethics Committee

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Introduction

The CSL Ltd/Pfizer (Animal Health) Animal Ethics Committee governs the animal use activities for two companies involved in the production of biotherapies for human and animal use. Both CSL Ltd and Pfizer (Animal Health) are based on the same manufacturing site in Parkville, Victoria. Historically CSL owned both businesses on site but it sold the animal health component to Pfizer around four years ago. A single AEC was retained to monitor both companies under contractual agreement.

AEC Membership

The continuity and stability of AEC membership is critical in maintaining compliance in all areas of animal use. The support of external members in particular is important in making sure that a properly functioning committee is upheld. A number of factors that needs to be taken into consideration in maintaining a balanced AEC membership include the following items.

1) Recruitment

i) The availability of Category C&D* members in particular may be limited.

ii) What approaches should be employed in identifying potential members? This may be through word of mouth, industry contacts, selected advertising or through contact with animal welfare organisations.

iii) Once applicants have been identified, how is the right member selected? It has been the experience of one of our external members on another AEC that the wrong type of member can obstruct constructive consensus on a committee.

2) Membership maintenance

i) Housekeeping factors such as the ease of inducting external members on to the site and the availability of car parking places are important in maintaining a spirit of commitment with external committee members.

ii) The workloads of all members at critical phases during information processing, especially before project review meetings needs consideration. The standardisation and timely presentation of information is therefore important in ensuring that matters can be properly assessed. The availability of more than one member for each category is also important in ensuring that a quorum is achieved at all meetings.

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*Category C: a person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved in the care and use of animals for scientific purposes. Veterinarians with specific animal welfare interest and experience may meet the requirements of this Category. While not representing an animal welfare organisation, the person should, where possible, be selected on the basis of active membership of, and nomination by, such an organisation; and
Category D: a person who is both independent of the institution and who has never been involved in the use of animals in scientific or teaching activities, either in their employment or beyond their under-graduate education. Category D members should be viewed by the wider community as bringing a completely independent view to the AEC, and must not fit the requirements of any other Category.

iii) The scheduling of meetings may have to be taken into consideration to accommodate the work hours of some external members.

iv) The methods of communications and conferring outside of scheduled meetings need to be well structured to ensure proper information flows.

v) There has been a limited need for conflict resolution as far as this committee is concerned. The role of the Chairperson in particular has been valuable in ensuring that items are addressed in a manner that is acceptable to all AEC members.

3) Serving the needs of two institutions

As stated previously, this AEC has served the animal welfare needs of two separate institutions since the acquisition of the animal health business by Pfizer (Australia). However, many AEC members were involved with the committee before the division of the business from CSL. Nonetheless, this change has brought about several unique considerations that include:

i) the requirement for confidentiality of internal members from the two institutions;
ii) the differences in company structure have made the documentation methods and lines of reporting more complex; and
iii) the balance of internal members is more important in ensuring that there is legitimate representation for the specific projects that are under review at that meeting.

4) Science versus animal welfare discussions

It is recognised that if the science isn't right, then the animals approved for a project will be wasted. However, at the same time the science has to be presented in a lay language so that all members of the committee can properly assess the suitability of a project. A statistician's comment is mandatory on all project applications to assure the committee that the project design is valid from this view point.

Meeting all regulatory codes

A major challenge in a biotherapies environment is addressing the requirements of not only animal welfare, but also integrating the constraints of other regulatory codes. For instance, some requirements of the Pharmacopeia compendiums may limit the scope for replacement and refinement of some Quality Control tests. The recognition and documentation of acceptable intervention points for animals on test is important to ensure that animal distress is minimised while not threatening the validity of test outcomes

Other regulations, such as quarantine and containment codes may reduce the opportunities for housing enrichment because of greater controls over the environment. Waste management codes may conflict with the provision of more comfortable exercise activity areas for larger animals due to floor surface and drainage restrictions. Looking at the bigger picture, even the specification for higher air change rates in a larger laboratory animal house has significant implications for the size of the carbon footprint arising from that facility.

On occasions the AEC also has to take into consideration the animal welfare regulatory requirements of different States in Australia. This in itself can pose administrative complexity where the types and lines of reporting in one state are different to another.

However, it must also be recognised that most commonly the different regulatory codes are complementary in their requirement for the practice of good animal welfare. For instance, it is clearly stated in the *Code of Good Manufacturing Practice* (GMP) that animal welfare responsibilities must be met and that evidence of AEC approval of all Quality Control tests requiring the use of animals must be provided to GMP regulators.

Recognition of training

In some instances, the AEC has to contend with the consideration of new investigative procedures where there is no clear definition of expertise in that field since the technique itself may be new. While these approaches may not appear to be excessively risky or harmful to the animal, the AEC still requires assurance that the specified operators are qualified to carry out such procedures.

This poses the question as to who is the best person to do the training for this procedure and what is his or her proof of expertise. Does a person's experience in a procedure necessarily confer expertise and who can be the judge of this? In such cases, the AEC has recognised the need for proper delegation of responsibility for method development and subsequent feedback to the committee on the progress and findings that are made.

The tracking of new procedures and personnel expertise through a centralised information system is important in ensuring that such efforts are not duplicated. This places a reliance on the use of an interactive data recording system that can be updated on a real time basis.

Other items

Other challenges identified by this AEC, but that will not be explored in great detail in this presentation, include the following:

i) Ensuring closure of all AEC action items including the methods that are used for the monitoring and reporting on issues relating to AEC decisions.

ii) AEC communication hurdles including:
   —the availability of investigators for personal feedback;
   —receiving appropriate feedback from the operators of animal facilities; and
   —maintaining correspondence with the executive management of two separate company executives.

   It is recognised that the roles of both the Chairperson and the Secretary are very important in ensuring that these communications occur in an effective and timely manner.

iii) The education of new project investigators on AEC requirements including:
   —their need to understand what the AEC needs to know and why this is the case; and
   —an emphasis on the use of lay language when writing applications.

In conclusion I would like to thank the members of the CSL/Pfizer AEC for their collective contributions into the content of this presentation.