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ADVISORY COMMITTEE ON DANGEROUS PATHOGENS

Secretariat Report for the 96th meeting of the ACDP, and matters arising from previous meetings

1. This paper includes reports on progress made with matters arising from the last meeting, reports from ACDP Working Groups and other relevant advisory committees as well as other items that may be of interest to members.

Matters Arising from the 95th meeting:

Griffin Committee Enquiry into *E.coli* 0157 outbreak at Godstone Farm

2. The report from this enquiry was published on 15th June 2010 and can be accessed at http://www.griffininvestigation.org.uk/

   A multi-agency working group, led by the Health Protection Agency, has been set up to consider the recommendations and to take matters forward as appropriate. This will be discussed in more detail under Agenda Item 6.

Xenotropic murine leukemia virus-related virus (XMRV)

3. At the June 2010 ACDP meeting members were informed that a subgroup had been convened by the National Expert Panel for New and Emerging Infections (NEPNEI) in May 2010 to review available data on XMRV. The minutes of this meeting and its conclusions are available on the Department of Health website at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_118427.pdf

   In summary, the subgroup concluded that:

   - XMRV can infect humans but there is currently no evidence that it causes human disease;
   - Development of a reliable test to accurately detect infection is required, as is further work to study the virus in more depth, investigate the possible mode of viral infection, the epidemiology of infection, whether the virus can cause

disease, and thus whether there is any public health significance to XMRV infection;

- Based on the available evidence, no public health action is required at this time.

Studies published since then have not changed the conclusions of the meeting as none has provided evidence of an association with human disease.

4. People with myalgic encephalomyelitis (ME)/chronic fatigue syndrome (CFS) have long been excluded from donating blood. In November 2010 this advice was simply changed to include persons who have ever had ME/CFS. This change was made on the grounds of donor safety as these are relapsing conditions, and this exclusion is in line with other similar conditions. These exclusions are for the benefit of donors, so as to avoid any risk of there being any association between blood donation and a subsequent coincidental exacerbation of donors' illness. These decisions were in no way due to any findings of XMRV or HMRVs in humans.
5. Both the HPA and National Blood Service take all potential risks to the blood supply from viruses very seriously. Preliminary studies have been conducted on more than 500 blood samples and have failed to show the presence of the viruses in UK blood donors. As a further preliminary precaution, a range of further studies to develop validated diagnostic tests are underway.
6. The importance of careful validation of tests is highlighted in recent papers on the subject; a series of 4 papers and an editorial were published in the journal *Retrovirology* on 20/12/2010. (These are available online at http://www.retrovirology.com/.) Researchers have for some time feared that the high rates of detection of XMRV in studies which used nucleic acid methods to detect the virus could be due to inadvertent contamination with mouse DNA (containing virus sequences), either of the human samples being tested or of laboratory reagents used in the testing. These 4 new papers provide evidence that contamination of samples or testing methods with ubiquitous mouse DNA has indeed occurred in a variety of ways, with the implication that previous study results that suggested the presence of XMRV in the human population may be incorrect.

Blood borne viruses

7. The BBV guidance is expected to become live on HSE's website in March of this year. Publication will take the form of a web page with live links to other documentation and references where appropriate. The Secretariat will meet with the Chair and members of the working group to review the web site test page during February, prior to the site going live.

The new regulatory framework - Safe work with biological agents and genetically modified pathogens

8. Chris Grayling, the DWP minister has asked HSE to proceed with work on the Legislative Reform (Contained Use of Animal Pathogens) Order (LRO) that will give HSE powers to regulate contained use work with animal pathogens under the Health and safety at Work etc Act 1974. This was consulted on in March 2010. The aim is for the LRO to be in place by summer 2011, subject to parliamentary scrutiny procedures. This will not in itself change any requirements on those working with human and animal pathogens or GMMs.
9. HSE will then be able to introduce new Regulations to simplify regulatory requirements and we expect that these will be in the form of a single set of regulations to encompass contained use work with human and animal pathogens and GMMs (as previously discussed with ACDP). However, the detail is not yet finalised and there remains a possibility that we will be asked to take a different approach. ACDP will be kept informed of any further developments and there will be further opportunities for stakeholders to provide comments on changes to the proposals.

Reports from ACDP Working Groups

ACDP TSE Working Group

10. The TSE Working Group has met twice since the June 2010 ACDP meeting, on the 7th July 2010 and 3rd November 2010

Annex A2 – Distribution of infectivity in animal tissue and body fluids

11. Annex A2 was updated to reflect the recently revised WHO guidelines on Tissue Distribution of Infectivity in TSE. The revised Annex A2 was published in August 2010 at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_118443.pdf

Surgical subgroup

12. To address concerns about the risk of transmitting vCJD during surgical procedures involving medium risk tissue (for example liver transplants, mastectomy and block dissection of the neck), the TSE Working Group set up a subgroup. The question first arose when a haemophiliac who received multiple blood transfusions went on to develop hepatitis C and subsequently required a liver transplant. Surgeons were concerned about what precautionary measures to take as liver transplantation

involves cutting through gastrointestinal lymphoid tissue and this patient was at risk of vCJD.

13. The first meeting of the Surgical subgroup was held on October 21st 2010 and was attended by a number of surgeons representing gastrointestinal, liver transplant and general surgery. The practicalities of current guidance for general and liver surgery were discussed and a number of conclusions were agreed. These will be reflected in a new Annex entitled "Managing vCJD risk in surgery involving medium infectivity tissue" which is currently being drafted.

Procedures involving the dura

14. Dura mater has recently been reclassified as low infectivity tissue; however, procedures conducted on intradural tissues (i.e. brain, spinal cord and intracranial sections of cranial nerves) or procedures in which human dura mater is implanted in a patient remain high risk. Annex A1, Part 4 and Annex J of the TSE Working Group guidance have been updated in light of this.

Other matters

Pet Travel Scheme

15. The UK's Pet Travel Scheme (PETS) has been in operation for 10 years. The controls currently in place under UK PETS reduce the risk against the introduction of rabies into the UK by pet cats, dogs and ferrets, and additionally protect against the risk of certain diseases being introduced that are transmitted by ticks or caused by tapeworms. The EU introduced its own Pet Travel Scheme (EU PETS) in 2003, which has less stringent requirements in relation to rabies protective measures and no requirements for tick and tapeworm controls. The UK, along with Ireland, Malta, Sweden and Finland, were allowed to maintain their additional controls under a derogation from harmonised EU pet travel rules. This derogation from the harmonised rules expires at the end of 2011. In seeking its last extension to its derogation, the UK signalled its willingness to harmonise with EU pet travel rules on the understanding that the rabies risks would continue to decrease across Europe and subject to risk assessment of other non-rabies diseases.
16. A meeting was convened on 11th November 2010 to bring together relevant experts to consider the public health risk from diseases other than rabies associated with pet cats, dogs and ferrets entering the UK under PETS, and whether such risks warrant the continued application of additional controls under PETS. The group agreed that the retention of tick controls for travelling pets provided a prudent and proportionate public health protective measure against the risk of introduction of exotic tick species,

and of tick-borne diseases. The group also agreed that tapeworm controls should be retained as an important public health protection measure against a very serious health threat, and that the proposed 0-72 hour treatment window was acceptable on the basis that better compliance would be likely to be achieved. The minutes of the meeting are attached (see paper **ACDP/96/P4/Annex 1**).

Botulism vaccine supply issue

17. The VMD recently reported to Ministers and CVOs that there is a supply problem with a botulism vaccine for veterinary use in the UK. Botulism has been reported in cattle, sheep and goats in the UK and is potentially fatal.
18. There are no animal vaccines against botulism authorised for use in the UK or EU. Due to the animal health and welfare risks associated with the disease, the VMD has permitted the importation of Singvac from Australia for use under the VMD's Special Treatment Certificate (STC) Scheme.
19. The manufacturer, Pfizer Animal Health, recently advised that this vaccine is no longer available for supply to the UK. Due to the clinical need for a botulism vaccine for veterinary use in the UK, the VMD is investigating the feasibility of sourcing an alternative product. We have at the moment pending applications to import alternate vaccines and subject to receipt of some additional data relating to safety we hope to be able to approve the import of these vaccines through the STC scheme into the UK market soon. The VMD will advise stakeholders once an alternative vaccine has been assessed as suitable for importation.
20. Veterinary surgeons have already been advised that it is possible to submit STC applications for alternative suitable vaccines to the VMD with each application being assessed on merit to ensure its safe use in the UK.
21. The Advisory Committee for Microbiological Safety of Food (ACMSF) recently considered the potential public health risk associated with botulism in cattle, sheep and goats. The botulinum toxin strains identified in cattle, sheep and goats (C and D) have rarely been associated with disease in humans (which is most commonly associated with types A, B and E). In addition, Animal By-Product controls require prompt and safe disposal of carcases, whilst affected animals will rapidly show clinical signs (or be found dead) and thus be kept out of the food chain. In addition, the active toxin is broken up in the act of bonding at the neuromuscular junction and so is in effect no longer able to cause re-intoxication following consumption of meat or milk from affected cattle, sheep and goats. For these and other reasons the Committee concluded that the risk to consumers was negligible and there was, therefore, no reason to prevent the sale of meat or milk from clinically healthy animals from farms

where there have been clinically suspected cases of botulism in animals. The FSA has implemented this advice and will review it if new evidence emerges that the botulinum toxin types that affect humans (such as A, B and E) cause any outbreaks in cattle, sheep and goats or vice versa.

22. This means that any temporary non-availability of a vaccine for veterinary use should be regarded principally as an animal health and welfare problem, rather than a public health issue.

Charging for HSE's regulatory activities

23. HSE has been asked to look at all areas for which we currently charge for our activities including notifications of work with GMMs and at those areas for which charging may be introduced. As part of the consultation for the single regulatory framework HSE indicated that a cost recovery scheme would be introduced for work to review notifications, inspect laboratories and carry out investigations. We expect this to go ahead as previously discussed, however it is now clear that this is an important priority for the Government and so we will need to introduce cost recovery whatever else might change.

New structure of ACDP

24. The Government's review of Advisory Non-Departmental Public Bodies (ANDPBs), announced on 14th October 2010, concluded that ACDP should lose its ANDPB status and become an expert committee of DH. ACDP will continue its functions as a tripartite committee, advising Defra and the Health and Safety Executive (in future it will also provide advice for FSA on TSE issues) but in future will do so through officials. The review also concluded that SEAC should no longer be an ANDPB, be abolished and that its functions be transferred to DH and delivered in the future by ACDP. The rationale for this is that much has been achieved by SEAC and the need broadly embraces that of SEAC. It is recognised that TSE issues remain of high importance and it will be necessary to take independent expert scientific advice on both risk assessment and risk management.
25. The proposal for the transfer of SEAC's functions to DH and the delivery of these by ACDP is as follows:
    - Advice on TSE risk management issues continues, as currently, to be provided by the ACDP TSE Working Group;
    - TSE risk assessment issues to be considered by a new group to be convened by ACDP on an *ad hoc* basis. This group to comprise experts in risk assessment and modelling and TSE experts with clinical, academic and research experience

covering human health, veterinary and food safety input. Precise membership of the *ad hoc* group will be determined by the specific risk assessment topic to be considered;

- The Chair for the *ad hoc* risk assessment group, to retain the direct link with main ACDP, should be a member of the Advisory Committee;
- The Chair of the ACDP TSE working group (currently Professor Don Jeffries) be a member of the *ad hoc* risk assessment group;
- The terms of reference and membership of the ACDP and its TSE working group will be reviewed to reflect future work priorities and required expertise. It is proposed that FSA and Defra (as current sponsors of SEAC) be invited to all meetings of the *ad hoc* group, and of the TSE Working Group, and be invited to attend ACDP meetings as they see fit.

Secretariat
January 2011