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Vaccination of cattle against bovine TB, used in conjunction with existing TB control measures, could have benefits in reducing the prevalence, incidence and spread of TB in the cattle population and could also reduce the severity of a herd breakdown regardless of whether infection is introduced by wildlife or cattle.

Developing effective cattle TB vaccines is a high priority for Defra. Since 1998, we have invested more than £23 million on research and development on cattle vaccines and associated diagnostics, and over the next 4 years plan to invest a further £9.3 million.

**The science about vaccination and the use of BCG**

BCG (*Mycobacterium bovis* Bacille Calmette-Guérin) is currently the most suitable cattle TB vaccine candidate. Experimental studies show that BCG vaccination reduces the progression, severity and excretion of TB in cattle (1-5) and field studies show that it can reduce transmission of disease between animals (6-7). Development of alternative vaccines is a longer-term research goal.

**How efficacious is BCG in cattle?**

As vaccination of cattle in the field is currently prohibited under EU legislation, the cattle vaccine and associated diagnostic test have been developed in experimentally infected cattle. These studies cannot provide a definite figure for vaccine efficacy when administered to cattle under field conditions in the UK. Small-scale field studies have been carried out recently in Ethiopia(6) and Mexico(7) and depending on the parameters selected the protective effect of vaccination was between 56% and 68%. It is not clear what effect BCG vaccination of cattle would have in reducing the incidence of TB herd breakdowns.

BCG vaccination of cattle, as with BCG vaccination in other species, is not 100% effective in preventing TB. Rather, it provides a spectrum of protection:

- Some cattle will be fully protected;
- Some cattle will suffer a less severe form of disease (and be less likely to affect other animals);
- Some cattle will get no protection from vaccination.

As far as we know BCG does not have a therapeutic effect in already infected animals.

BCG vaccination of cattle could be a valuable tool when used alongside other TB control measures in the UK.

**Progress on licensing BCG in cattle**

Licensing studies demonstrating the safety and efficacy of BCG have now been completed by Defra's Animal Health and Veterinary Laboratories

**Links:**

- ▶ AHVLA disease alert subscription service
- ▶ AHVLA local offices
- ▶ Disease prevention for livestock farmers – GOV.UK
- ▶ Imports and exports of animal and animal products

Agency (AHVLA) and in January 2012 an application for marketing authorisation (required to place a veterinary medicinal product on the market) was submitted to the UK's Veterinary Medicines Directorate (VMD) for assessment. The assessment process may take up to a year to complete and providing it is satisfied with the safety, efficacy and quality data, VMD will be able to confirm that requirements to obtain a marketing authorisation have been met. However, VMD will only be able to grant a marketing authorisation for BCG once the existing EU prohibition on vaccination of cattle against TB is lifted.

### **Differential diagnosis of BCG-vaccinated animals from TB-infected animals**

Vaccination of cattle with BCG results in a proportion of animals becoming positive to standard TB diagnostic tests (both to the tuberculin skin test and the conventional interferon-gamma blood test) and can therefore lead to false positive results in BCG-vaccinated but TB-uninfected cattle (8). In parallel with developing cattle TB vaccines, AHVLA is also developing a test to differentiate infected from vaccinated animals (the so-called DIVA test (8-10)). This test, a modification of the current interferon-gamma blood test, can be used alongside the tuberculin skin test in vaccinated animals where necessary, to confirm whether a skin test positive result is caused by vaccination or TB infection.

### **Barriers to vaccination of cattle against TB and what is being done to change the law**

Vaccination of cattle against TB is currently prohibited by EU legislation, in place principally because BCG vaccination of cattle can interfere with the tuberculin skin test which is the recognised primary diagnostic test for TB in cattle.

Vaccinating cattle in the UK against TB but without a Marketing Authorisation for the vaccine runs the risk that live cattle and cattle product exports could be banned by other countries. While the export market for live cattle is relatively small, the value of our meat and dairy exports is much greater. Our dairy exports alone grew by nearly 20% in 2011, to more than £1.1billion.

Defra has discussed with the European Commission the steps that would be necessary to change the current legislation and allow TB vaccination of cattle combined with use of a test to differentiate infected from vaccinated animals (so-called "DIVA" test – see below) to be used as a trade test. One of the most difficult barriers will be to get international validation of the DIVA test, which will depend on being able to satisfy the World Organisation for Animal Health (OIE), on the basis of solid scientific evidence, that the test is effective and safe. That process is in train, but is likely to take years, rather than months, to complete. AHVLA's data has been shared with other OIE reference laboratories and with the EU Reference Laboratory for bovine TB for their views.

An opportunity to provide a future legal basis for vaccination of cattle against TB is likely to be created by the proposed new European Animal Health Law, which is currently under consideration by the European Commission.

The [EU commissioner for health and consumer policy wrote to the Secretary of State](#) (PDF) on 14 January 2013 setting out a tentative timeline for possible use of a TB cattle vaccine.

### **Further cattle TB vaccine and DIVA research and development**

Further research in progress includes continued vaccine development to improve the efficacy of a BCG-based vaccine and development of vaccines

that do not sensitise cattle to the tuberculin skin test (non-sensitising vaccines). Computer modelling is also being developed to assess how efficient a vaccine for TB will have to be to provide protection to herds and the benefit vaccination may provide to different types of farm businesses. Modelling will also assess the likely interaction of vaccination with routine surveillance and help us to recommend optimal schedules for vaccine delivery.

## Preparing for deployment

As the science becomes clearer Defra will be in a firmer position in the coming months to begin to discuss with farmers, vets and other interested parties about how the vaccine and the associated DIVA test can be used in the field and the likely implications on different types of farm business.

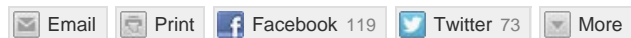
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24 January 2013

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