

Supply of BCG vaccine.

Briefing advice provided to Deputy Minister by Welsh TB Policy Team in support of statement made on 1st December 2015.

## Supply of BCG vaccine

### Current situation

- The supply of the BadgerBCG vaccine, which is used to vaccinate badgers in Wales, has been interrupted due to problems with its production. It is not known if or when the situation may be resolved.
- If we are to continue to vaccinate badgers in Wales against bovine TB, in the absence of custom-made BadgerBCG vaccine, we would have to use human BCG vaccine, subject to additional licensing requirements. The standard human BCG vaccine contains the same material as the BadgerBCG vaccine. Each vial is a single badger dose, but equates to 10 adult human or 20 infant human doses.
- However, there is currently a global shortage of BCG vaccine which is affecting supplies and resulting in a prioritisation of use in humans. I do not consider it appropriate to source human BCG vaccine for use as part of the badger vaccination projects underway in Wales, while the supply for use in humans is so unstable.
- While our badger vaccination projects are important in the context of our TB Eradication Programme, human health must remain our priority. As such, I have decided to suspend the sourcing of BCG vaccine for use in badgers in Wales, until such a time when the supply situation for humans resolves.
- For use in badgers, we are limited to the vaccine produced by one supplier (Danish company, Statens Serum Institute (SSI)) by the terms of the Limited Market Authorisation. SSI have had numerous problems over the last couple of years in meeting the orders for vaccine.
- Due to supply issues this year and last year, the UK Government has had to negotiate extensions to the shelf life of existing stocks in order to bridge gaps in supply. Therefore, supply issues have not previously impacted on our badger vaccination projects.
- Defra procures badger BCG on behalf of the UK for a number of reasons; there are economies of scale in one bulk order. Defra provide a single point of contact for supply in addition, it allows for the flexibility in distribution of vaccine between the Devolved Administrations. The Animal and Plant Health Agency (executive agency of Defra) carried out all of the preparatory work that supported the application that led to the limited marketing authority to the UK.
- Unless the situation resolves early next year, there could be implications for the fifth and final year of vaccinating badgers in the Intensive Action Area as well as the other vaccination projects underway in Wales. Of course, the situation could change and the human supply could stabilise and at this stage the Welsh Government would review the decision.

- We have just completed the penultimate year of vaccinating badgers in the IAA and there are a number of ongoing private projects vaccinating badgers through the Badger Vaccination Grant initiative. I would like to express my thanks for the hard work, co-operation and commitment shown by all those involved. I have asked officials to write to those who will be directly affected by this decision.
- We do not know when the supply of vaccines for humans will stabilise, so I am not able at this stage to indicate when badger vaccination is likely to resume in Wales. In the interim, I have commissioned modelling work to assess the potential impacts of suspending badger vaccination and following consideration of the results, I will explore options for next steps.
- The modelling work aims to investigate the likely impact of these changes on the vaccination project and to assess a number of potential scenarios. Existing work to evaluate the impact of interventions, including vaccination, undertaken in the IAA will continue.
- I will provide further updates in due course.

#### **Next steps for IAA**

- We will consider any information coming from the cull areas of England over the next few months but that will be assessed alongside our ongoing review of the effectiveness of badger vaccination in the IAA. A decision to change our wildlife policy will not be taken until I have reviewed all of the evidence.
- The next IAA annual report will be available in mid-2016. This will allow time for all tests to be undertaken and for results to be verified and compiled into the necessary format.

#### **Staffing**

- The Welsh Government will be exploring ways of avoiding compulsory redundancies and minimising the number of employees affected. We will consult with all affected employees and representatives of affected employees in due course. Measures which it may take to avoid redundancies include looking for suitable alternative employment elsewhere within the organisation.

#### **Global shortage**

- Over the past three years, there has been a decline in global availability of BCG vaccine. During this time more and more countries that had previously procured their own BCG vaccines have turned to UNICEF for assistance because of the difficulty in accessing global supplies.
- UNICEF reports that 180 million doses are required to meet their Supply Division demands, and only 107 million doses have been made available from manufacturers. This results in a shortfall of around 70 million doses.

- UNICEF procures BCG vaccines from suppliers whose vaccines have been prequalified by the World Health Organisation (WHO).
- Prequalification assures UNICEF that the vaccine meets WHO-prescribed international standards for quality and safety. The main reasons for the decline in global availability are:
- The number of suppliers with prequalified vaccine is very limited. There are currently only four suppliers of prequalified BCG vaccine.
- A number of suppliers who did not have prequalified BCG vaccine have exited the market, leading to an increased demand from the remaining global suppliers. Some suppliers of prequalified vaccines have experienced manufacturing problems that have reduced quantities of vaccines produced by 50 to 80 percent.

### **Human Health**

- There is currently no shortage of BCG vaccine in the UK for the NHS and health practitioners in Wales can order the supplies they need to protect at-risk individuals.
- Due to on-going constraints with the global supply of BCG vaccine, the Welsh Government supports the call from the World Health Organisation to prioritise vaccine for use in humans, to ensure that countries with highest TB rates receive priority and to target individuals who will benefit most from BCG vaccination.
- Health practitioners have been encouraged to organise the administration of BCG vaccinations in ways that optimise the use of multi-dose vials of vaccine.

### **Protection of Badger Act 1992**

- Badgers and their setts are protected under the Protection of Badgers Act 1992.
- It is illegal to kill, injure or take badgers or to interfere with a badger sett although there is provision in the legislation to allow action to be taken under a licence.

### **Background:**

The Protection of Badgers Act 1992 consolidates previous badger legislation to protect the welfare of badgers. Badgers are widespread in the Welsh Countryside but are subject to cruel treatment from badger baiting and therefore have received additional welfare protections.

Badgers are not considered to be endangered in Wales and are not listed as a species of principal importance for conservation of biological diversity. The level of protection that the Act gives badgers is unique for a wild mammal that is not considered rare.

The Protection of Badgers Act 1992 Act created a number of offences. For example, except if permitted by or under the Act, it is an offence to wilfully kill, injure or take a badger; to interfere with a sett by damaging or obstructing it or by disturbing a badger when it is occupying a badger sett, with intent or recklessly.

Land, Nature and Forestry Division of the Welsh Government may grant licences for the purposes of:  
preventing serious damage to land, crops, poultry or any other form of property, preventing the spread of disease, maintenance or improvement of drainage works or flood defences or any agricultural or forestry operation.

Natural Resources Wales may grant licences for the purposes of:

- science or education,
- conservation of badgers,
- development,
- any zoological garden or collection,
- ringing and marking badgers,
- preservation or archaeological investigation of scheduled monuments or
- investigating any offences.

The prevention of badger persecution is one of Wales's Wildlife Crime Priorities. These priorities are reviewed periodically by the Wales Wildlife Crime Enforcement Group which is made up of the four Welsh police forces, the National Wildlife Crime Unit, Natural Resources Wales, Welsh Government and Welsh Fire Services.

### **Positive**

- We have successfully delivered over 5,000 doses of the vaccine in the IAA over four years.
- We will continue to work with the agriculture industry, wider rural communities, veterinary profession, Eradication Boards, and the Industry Advisory Group in the Intensive Action Area.
- Wales has been at the forefront of international efforts to fight bovine TB and has had a comprehensive eradication programme in place since 2008. We are proud of our achievements and of the badger vaccination project which was/ is the largest project of this nature ever undertaken.
- The vaccination of badgers within the IAA is only one of a range of different measures, including tackling the disease in wildlife, animal testing across Wales, strict biosecurity protocols and cattle movement restrictions.
- This was the first time a project of this scale has been undertaken to assess whether the vaccination of badgers would reduce the number of bovine TB cattle herd breakdowns.

- The Science Review concluded in 2011 that repeated vaccination was likely to result in a gradual build-up of immunity in the badger population thus reducing the risk to local cattle from badger-to-cattle transmission in the medium to long term.

### **Defensive**

- We are four years into a five year programme in the Intensive Action Area; if we do have to suspend badger vaccination next year as a result of these global factors, then it does not mean that the hard work of the previous four years goes to waste. We have successfully administered more than 5,000 vaccine doses during that time.
- It must be remembered that vaccination is far from the only tool in our armoury in combatting bovine TB. A whole suite of measures are in place as a result of our programme, including additional farm biosecurity and Pre-Movement Testing, for example. These will continue.
- I feel that we must act responsibly and ethically and prioritise the health of humans over that of animals.
- I believe that the decision to suspend the sourcing of BCG vaccine for use in badgers until the human supply stabilises is the most responsible and appropriate response given that reports from UNICEF indicate a world wide shortage of over 70 million human BCG doses and predict constraints continuing next year.
- My officials have been in contact with Public Health Wales officials who endorse the decision to prioritise BCG vaccine for human use.
- This shortage of the BCG vaccine for humans has prompted the World Health Organisation (WHO) to issue guidance on the prioritisation of vaccine. Although Public Health Authorities currently estimate that there is sufficient BCG vaccine available for the re-prioritised UK programme of human vaccination.
- I come back to a very important issue, and that is that the global shortage of BCG vaccine covers both humans and badgers. A single vaccination for a badger takes ten doses which could be given to adults, or twenty for infants. Important though animal health is, in a situation as stark as this one, human health must be our first priority.
- While there remains a global shortage for use of the vaccine in humans, it would be wholly inappropriate to utilise human stocks to vaccinate badgers.
- The BCG vaccine is a live biological product and its manufacture is a very complex process. Any problem during any part of the process could potentially cause the entire batch to fail.

- The UK order of BadgerBCG vaccine for 2016 was for 5,295 doses. It is unlikely that the supplier will be able to honour the order for BadgerBCG. If standard vaccine was sourced for badger vaccination purposes, the 5,295 doses would equate to 52,950 adult doses/ 105,900 infant doses. Given my decision to suspend sourcing of the vaccine, this now means that these doses will be made globally available for use in at risk humans.
- This does not reflect on our commitment to eradicating bovine TB from Wales.

**When did WG first become aware of the problem and what did it do?**

- Earlier this year, SSI (Statens Serum Institute), the Danish State owned Health Research Institute which is the sole manufacturer of BadgerBCG vaccine, indicated that due to production problems it would be unable to deliver BadgerBCG vaccine ordered by Defra on behalf of the UK for summer 2015 delivery. The previous year in May 2014 we were advised by Defra Officials of a delay in delivery of the vaccine expected in June 2014, caused by Quality Control issues at SSI.
- Officials worked closely with counterparts in Defra and the vaccine was eventually delivered. Fortunately, in relation to vaccination in 2014 the batch of BadgerBCG vaccine was granted an extension to its shelf life by the Veterinary Medicines Directorate (VMD). This followed lobbying by WG, and APHA, the vaccine Marketing Authorisation Holder, to get them to seek an extension with VMD. This enabled the badger BCG vaccination projects to be completed.
- Similarly the vaccine which was delivered late last year was given an extended shelf life, which in the absence of a 2015 delivery, enabled completion of the 2015 badger vaccination projects in Wales prior to the vaccine's 31/10/15 expiry date. We are now in a position where there is no remaining stock of in date Badger BCG vaccine in the UK.

**If the world is millions of doses short for humans in 2015, why did you vaccinate badgers this year?**

- We extended the shelf life of existing stocks of BadgerBCG vaccine due to issues with the supply of BadgerBCG. To date in Wales we have not used any BCG licensed for use in humans to vaccinate badgers.