"Development of the most effective tools to control infectious animal diseases"

Terms of Reference – Expert Groups

1. Background

The DISCONTOOLS project started as an FP 7 project involving a wide range of stakeholders including the research community, regulators, international organisations, CVO's, veterinarians, farmers and others. The aim is to provide a mechanism for focusing and prioritising research that ultimately delivers new and improved vaccines, pharmaceuticals and diagnostic tests.

The project started on the 1st of March 2008 and ended in February 2013. After wide stakeholder agreement that the project needs to be continued, in June 2014 the project was relaunched with the financial support of different national funders in the EU. The aim is to keep the information in the database actual, with a re-evaluation of the specific disease information in a 3 to 4 year cycle.

These Terms of Reference (ToR) attempt to guide Expert Groups when completing the Disease and Product analysis form and when scoring the disease. The aim is to provide guidance concerning some of the issues that may be encountered during the creation of the Expert Group and its subsequent deliberations.

2. Objectives and general scope of the scoring exercise

DISCONTOOLS is a research focused project that will provide a mechanism for focusing and prioritising research that ultimately delivers new and improved tools to control disease outbreaks. This project delivers part of the Action Plan of the European Technology Platform for Global Animal Health (ETPGAH) such as a disease database, a gap analysis and a prioritisation exercise.

It will represent a source of scientific work and will be centred on risk assessment as opposed to being centred on risk management. Political considerations are outside the scope of the exercise. The focus is purely risk assessment with the objective being to agree the most critical gaps that need to be addressed in terms of future research. As an example, DISCONTOOLS may identify animal movement as a critical mechanism for spreading a disease (risk assessment) but will express no further views concerning animal movement (risk management).

3. Guideline for the scoring exercise

a. Expert groups, range of expertise and timing

The DISCONTOOLS secretariat will contact potential leaders following the recommendations of the Working Groups. The leader should suggest a group of about 10 people to work on a particular disease and make contact with them. In discussing the make up of Expert Groups, it was suggested that the groups should include people with **laboratory expertise**, an **epidemiologist**, an **industry representative**, a **diagnostics expert** and **an individual with economic/trade expertise**. The secretariat will assist in whatever way possible (template letters, propose industry representative, organize tele-conferences etc.).

Thereafter, the Expert Group should engage in electronic communication to seek agreement on the "Disease and Products Analysis" document, gaps and scores. The timing estimated is around 3 months between the leader's invitation and the finalised documents. It is only an

indicative timeframe as the groups might have various approaches on how to deal with the work (and we leave the leader some freedom to organise timing). Over the three months, perhaps the equivalent of 3 days work may be necessary on the part of the leader. If the Expert Group decides to have a physical meeting, this would take an additional day.

b. Documents and models

One version of each of the documents described below should be filled-in by disease.

- *"Disease and Products Analysis" document (D&P)*

This document is intended to gather relevant information on each disease to assist with the scoring in relation to gap analysis and prioritisation. It is a reference document providing the information necessary to score a particular disease. It includes 23 main sections with sub-headings covering aspects such as description and characteristics of the disease, zoonotic potential, tools available, economic impact, etc.

The column headed "Gaps identified" on the right side of the table was designed to gather further information on the gaps in knowledge of the disease and products to combat it. This will help scoring in the gap analysis sheet by highlighting the most critical gaps. The Experts will be requested to put numbers from 1 to 5 on the gaps that they identify as the most important ones. An initial partially filled draft D&P will be send to each Expert Group for review and amendment as necessary. Expert Groups should reach a consensus on the final text.

- *"Products Gap Analysis scoring sheet"*

The gap analysis exercise will be carried out using a scoring sheet including 3 main sections which are: "vaccination tools" (11 criteria), "diagnostic tools" (12 criteria) and "pharmaceutical tools" (11 criteria). This document focuses on gaps in products to achieve better control of the disease. If pharmaceutical tools are not relevant for a particular disease, the section will be kept blank (no scoring). The aim of this scoring grid will be to provide details which will feed into the section entitled "Control tools" in the Prioritisation model ("Disease scoring model" document). It represents a detailed overview of the tools available to combat a disease as well as the gaps in products (vaccines, diagnostics and pharmaceuticals) available in Europe and worldwide that might exist.

The scoring scale applied is a 5-tiered system with the following scores: +2; +1; 0; -1; -2. Negatives scores are applied when products are fully developed, available and efficient. On the other hand positive scores mean that no products or not fully effective products are available or that products are not available in Europe. An interpretation guide has been developed to help decide on the score to apply to each criterion in the three sections. It describes conditions and/or states relative to each potential score in the scale proposed.

- *Prioritisation scoring – "Disease scoring model"*

The prioritisation exercise will be carried out using a scoring grid with 6 main sections as follows: "disease knowledge", "impact on wider society", "impact on public health", "impact on trade", "animal welfare" and "control tools". Scores are attributed to specific criteria that are detailed in each section of the scoring model (between 2 and 10 criteria per section). A user guide has also been developed to help the Experts decide on the appropriate scores to apply to each criterion.

The scoring scale applied is a 5-tiered system with the following scores: for the five first sections ("disease knowledge", "impact on wider society", "impact on public health", "impact on trade", "animal welfare") +1; +2; +3; +4; +5; for the last section as explained above with

regard to gap analysis ("control tools"): +2; +1; 0; -1; -2. This scoring scale was selected to highlight the differences in control tools for each disease in the sense that if for a particular disease a vaccine exists that has a high level of efficacy, quality, safety and availability, then a negative score will be attributed to the final total score of the concerned disease to diminish its priority as an effective tool is available. On the contrary, if control tools are missing, then a positive score will be added to the total score meaning that the disease will be higher in the prioritised list of diseases.

c. <u>Guidelines for scoring</u>

The geographic dimension of the project should be European with a Global perspective in mind. Naturally, where a disease is not present in Europe, a Global perspective must be taken. Expert Groups are asked to highlight and take into account strains and species where the economic impact is the highest.