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# Parallel Scientific Advice: a shortcut to global development

The animal health industry's ongoing 1-1-1 campaign for one dossier, one authorization and one global market seeks to reduce the time, cost and complexity of the present systems of bringing a new veterinary medicine to more than one country market. In this article, two consultants at the Triveritas contract research organisation, Dr Dave Petrick and Dr Andrew Hewitt highlight an arrangement between the US and EU authorities that can help to cut the time and cost of reaching these two market places.


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Many animal health companies, both large and small, recognize that a key factor in improving their return on investment to get their products authorized in the world's two largest markets, the United States and European Union, in the shortest possible time. With increasing pressures on R&D budgets and the rising cost of running clinical trials to current standards, it is essential to get this right the first time.

Add in the historic differences in approach between the different regulatory agencies worldwide, which are sometimes subtle, and a potential minefield can develop. With global product development becoming more common in veterinary medicine, taking advantage of the opportunities provided for advice from key regulatory bodies may provide large savings of both time and money in the R&D process.

The US Food and Drug Administration (FDA)'s Center for Veterinary Medicine (CVM) and the European Medicines Agency (EMA)'s Committee for Medicinal Products for Veterinary Use (CVMP) have a Parallel Scientific Advice (PSA) procedure in place, dating from a confidentiality agreement that was signed by both agencies in 2003 (1). The goal of this scheme is to improve the acceptability of data gathered, to minimise the duplication of studies and increase the scientific validity of results. It forms part of a wider spirit of communication and co-operation between the FDA and EMA which has been growing over recent years in both human and veterinary medicine.

Recently the two bodies reported that there is currently an average of 55 interactions between the agencies per month on a wide range of issues, and that demand for the PSA scheme is growing. Seven PSA requests were completed in the year to September 2010, with a further three accepted since then (2). While the majority of this interaction

is based around human medicinal products, the Veterinary Medicinal Products cluster is also reporting excellent cooperation, with a veterinary product PSA recently concluded.

Once an applicant (or sponsor) has decided on a joint US-EU development route, the foundations will be in place to easily facilitate a PSA procedure. In the US, an Investigational New Animal Drug Application (INAD) will be required. A written request for a PSA is required, which should be submitted to each agency separately. The applicant is encouraged to attend a meeting with both agencies separately – while this means travel to both agencies, it is very useful in getting the maximum benefit from the process. The PSA procedure poses little additional burden to the applicant over advice from either single agency: both agencies follow their standard procedures (and fee structures), but communication between the two is scheduled at appropriate points to try and reach a consensus on each point. Fee reductions or waivers are offered for EMA small and medium enterprises (SME) status or certain minor use – minor species (MUMS) products.

## Finding common ground

The EMA and FDA advise that that although they will try to find common ground on as many areas as possible, they will form their own opinion and are not bound by any advice given. Recent experience suggests that the degree of assessment and willingness to find a common solution during the PSA process is encouraging from a sponsor standpoint.

Additional benefits may be gained from submitting a PSA request. As well as providing an avenue with which to enter a constructive dialogue with the regulator about a company's product development programe, it could also facilitate a smoother protocol concurrence with the FDA where some of the scientific issues have already been discussed in depth.

Although there is a time implication to the procedure, it is no greater than getting advice from either single agency and should be easily absorbed into the planning phase of the development. It should also be offset by greater clarity in study design at the protocol concurrence and study implantation stages of the process. The greatest benefits of the PSA scheme are undoubtedly available for novel products, but the process could be useful in any scenario where there may be unanswered questions on global development. Even if an authorization is not sought simultaneously on both continents, the opportunity exists to design studies that would be acceptable for a later registration in the other market. The EMA and FDA will make an assessment of the overall value of the process to any given product development, before accepting the PSA request.

Making the most of this opportunity certainly requires knowledge of the different systems and expectations on both sides of the Atlantic. The PSA request and communications with both agencies can be handled by a veterinary product development consultancy on the applicant's behalf, which can be beneficial where experience with both regulatory agencies and an objective viewpoint is required. Ideally a consultant should have experience of the PSA procedure and a presence in both countries to allow good contacts with the two agencies.

Having access to a depth of both clinical trial and regulatory expertise in all the major veterinary markets will enable the most benefit to be obtained from the process, and helping to get the product to market sooner.

***References***


1. EMA/FDA, 2008. Confidentiality Arrangements Concluded between the European Union (EC and EMEA) and the US Food and Drug Administration/DHHS http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017956.pdf 2.

2. EMA/FDA, 2011. EMA/705027/2010 Interactions between the European Medicines Agency and U.S. Food and Drug Administration September 2009-September 2010 http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/06/WC500107900.pdf