



Dear Stakeholder,

This is a short note to bring you up to date on the regulatory process in Europe for vCJD tests. At the present time vCJD tests are unlisted, and regulation is done via the self-declared CE mark process on a country by country basis.

As you will have read in our [Press Release \(October 25\)](#), we presented our EP-vCJD™ test at the recent European workshop on the “ADDITION OF VCJD DIAGNOSTIC ASSAYS TO ANNEX II LIST A OF THE IVD DIRECTIVE 98/79/EC”. This meeting was called to respond to the request by the United Kingdom to add vCJD tests to Annex II List A and thereby regulate it for all of the European Community. The workshop was attended by representatives from most member states of Europe. The meeting was coordinated by John Brennan, Policy Officer, Cosmetics and Medical Devices, European Commission, Enterprise and Industry Directorate-General. His final summary of the meeting was:

- “1. This issue is an important one and concerns all citizens of the EU
2. The common opinion of the attendees to the workshop is that this kind of device [a test for vCJD] would appropriately belong in Annex II List A
3. If added to List A, there would need to be an appropriate Common Technical Specification (CTS) drafted preferably available at the same time that the test is listed
4. If the test is not added, it potentially poses a public health issue and could have serious implications for public health authorities”

We were the only company to present a commercially-viable test for vCJD. Some of our competitors attended the meeting but did not present.

We took the opportunity to inform the regulatory bodies that our EP-vCJD™ test was able to properly identify 11 out of 12 positive scrapie sheep and 7 out of 8 negative normal sheep. **This is the first time anyone has been able to detect endogenous prions in a large blinded panel.** The ability to identify endogenous scrapie prions in the blood of sheep is viewed as a key milestone in the validation and certification for a blood test for vCJD.

The regulatory process will continue with additional meetings to develop a CTS applicable to all of Europe. The time to accomplish this process is undefined. The overall attitude of the representatives at the conference was vCJD “poses a public health issue” and is a “concern to all citizens of the EU”. It is anticipated the EU Commission will advance the process expeditiously.

Amorfix will continue to build a database to submit for a self-declared CE mark and will apply for the CTS-CE mark when the CTS is available and the test has been added to the in Annex II List A.

Thank you for your continued support,

All the best,

Dr. George Adams

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