Joint Assessments of medical devices Notified Bodies by Member States and Commission Experts – Interim Overview Report

This interim overview report describes the outcome of the first joint assessments carried out in ten countries between January and July 2013 which were undertaken in the framework of the voluntary 'joint plan for immediate actions' concerning the performance and designation of Notified Bodies in the medical devices sector. In each of the individual assessments within this programme the joint assessment teams comprised Commission experts from DG SANCO's audit and inspection service – the Food and Veterinary Office (FVO) – and national experts drawn from national Designating Authorities of other countries. The joint assessment teams accompanied the respective country's Designating Authority responsible for designation of Notified Bodies during a surveillance assessment of a Notified Body in that country.

The objective of this pilot programme is to assist national Designating Authorities in the conduct of their surveillance, designation and re-designation assessments of Notified Bodies and to identify and document, where appropriate, opportunities for improvement in the Designating Authorities' performance of such assessments. Given the voluntary nature of this exercise and the absence of any legal basis to publish the outcome of these reports, the individual reports of the joint assessments are not being published.

On the basis of the experience gained during the first ten joint assessments, the Commission, and the national expert assessors involved (14 assessors from 12 countries), consider that the process has been beneficial – not just for each of the national Designating Authorities as a support to their assessments, but also to the national expert assessors from other Designating Authorities who, through this process, have been able to exchange views and opinions with their peers. There have been no substantial areas of disagreement between the joint assessment teams and the Designating Authorities. Overall, it is considered that each of the assessments has provided an accurate picture of the performance of Notified Bodies regardless of whether opportunities for improvement in the Designating Authorities' performance were identified. Such opportunities concerned elements such as the planning, scope and depth of surveillance activities. In one case however, the standard of the Designating Authority's assessment and overreliance on accreditation required follow-up activities to be initiated by the Commission services.

It was also the case that a number of good practices in Designating Authorities' performance were identified during the joint assessments and, if these were to be adopted also by other Designating Authorities, they could enhance the effectiveness of surveillance assessments and strengthen confidence in the current regulatory system.

With regard to the performance of the Notified Bodies assessed, there was, generally, a satisfactory level of compliance with legal requirements and best practices. Nevertheless, the joint assessment process has identified weaknesses which were common to a number of Notified Bodies in the areas of organisational requirements and quality management systems. More importantly, a number of Notified Bodies could not provide sufficient evidence that the staff employed for conformity assessment activities were appropriately qualified and experienced for the task. Another recurring issue concerned the thoroughness of the Notified Bodies' review of manufacturers' clinical evaluations.

In all cases, the Notified Bodies in question were requested to put in place necessary measures to rectify the shortcomings identified. In several cases, the seriousness of the findings led to the Designating Authorities requiring urgent corrective actions from the Notified Bodies with restrictions and sanctions being imposed in the interim period and further surveillance assessments being conducted by the national Designating Authority.

Overall, the joint assessment process is proving itself to be a useful instrument to gain a global view on the performance of both Designating Authorities and Notified Bodies in the medical devices sector. It is also helping to raise performance standards across the sector, and the experience gained will facilitate the implementation of the new joint assessments being required by Commission implementing regulation (EU) No 920/2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices [(1)].

[1] OJ L. 253, 25.9.2013, p. 8.