

Joint Assessments of medical devices Notified Bodies by Member States and Commission Experts

In 2012 the European Commission's Directorate-General Health and Consumers (DG SANCO) launched a 'Joint Plan for Immediate Actions' concerning, amongst other things, the performance and designation of Notified Bodies in the medical devices sector. A major objective of the plan is to ensure that only well-functioning and properly resourced Notified Bodies are designated to conduct conformity assessment in the field of medical devices and that they make full use of their existing powers (under the current EU medical devices Directives).

The Commission, in collaboration with the Notified Body Operations Group (NBOG) – comprising representatives from the national Designating Authorities of the EU Member States, European Economic Area (EEA) and European Free Trade Association (EFTA) States and Turkey – established an ad hoc NBOG coordination group. The group has devised an on-going pilot programme of voluntary joint assessments of Notified Bodies designated under the medical devices Directives. The joint assessment programme started in January 2013 and involves both the national Designating Authorities responsible for designation of Notified Bodies, national experts from Designating Authorities in other countries and Commission experts from DG SANCO's audit and inspection service – the Food and Veterinary Office (FVO). The assessments are being carried out jointly with the national Designating Authorities on a voluntary basis as there is no legal basis requiring joint assessments under the existing Directives. It is foreseen that these joint assessments will be made mandatory through an Implementing Regulation which will be adopted shortly. In the long term, the Commission has proposed to make mandatory joint assessments a part of the new Regulation on medical devices.

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. The criteria against which the joint assessments are being carried out are the existing medical devices Directives and, where appropriate, interpretive documents published by the Commission (MEDDEV Guidance) and NBOG (Designating Authority handbook and Best Practice Guide documents).

Given the voluntary nature of the joint assessments, the Commission cannot (nor has any legal basis to) publish individual joint assessment reports. However, in the course of the project, overview reports collating and summarising both examples of good practice and opportunities for improvement in Designating Authorities' performance will be produced. The overview reports will be made publicly available with a view to raising awareness among all Designating Authorities and encouraging better performance from both Designating Authorities and the Notified Bodies for which they are responsible.

In the first half of 2013, 10 joint assessments have been carried out (with at least 19 foreseen to be completed in 2013). The feedback so far indicates that both the national Designating Authorities and the Notified Bodies concerned have found this to be a useful exercise.

The practice of involving two national experts – one more, and one less experienced - from different Designating Authorities has fostered cooperation and sharing of best practice within and between the joint assessment teams and the national Designating Authorities. In addition, a first specific training of national Designating Authority assessors has been conducted, helping to further align the conduct of Notified Body assessments and designation activities.