Summary of the Commission staff working document on the implementation of the Joint Plan for Immediate Actions under the existing Medical Devices legislation

Progress achieved

Substantial progress has been made in the implementation of the Plan. In particular the following achievements can be noted:

- Member States have re-assessed the qualifications and the scope of activities of their notified bodies; This resulted in corrective measures or limitations in the scope of activities of notified bodies in at least 8 countries;

- Voluntary joint audits of notified bodies by teams involving auditors from several Member States and the Commission (FVO) have until May 2014 been carried out in 22 out of 23 countries having notified bodies and one is scheduled for the remaining. The voluntary joint audits have been judged as very useful by all parties involved. All assessments have resulted in the identification of non-conformities (between 5-20) in the operation of the notified bodies audited. Major non-conformities (between 1-5) were identified with the notified body assessed in about half of the countries. In addition to corrective actions sometimes a temporary suspension or limitation in the scope of activities or a re-assessment of all certificates issued were required. In one case a complete de-designation followed. Several other notified bodies stopped their activities in 2013 without or prior to any joint assessment being announced;

- Two Commission measures, respectively to ensure a consistent application of the criteria to be met for the designation of notified bodies and on the items to be verified by the notified bodies during an audit were adopted in September 2013. The first of the two measures has made the joint audits mandatory for new designations and re-designations of notified bodies. 20-25 such audits are foreseen for 2014;

- The Commission measures recommend that notified bodies shall carry out unannounced audits of manufacturers. Notified bodies have reported that they now are carrying out or are in the process of launching such audits; reliable data on the extent of unannounced audits is not yet available;

- Monthly vigilance teleconferences with Member States, chaired by the Commission services, have been launched and become regular. The teleconferences have proved to be a very efficient means of ensuring/ improving coordination between Member States. On average 23 countries have participated in the teleconferences. More than 70 specific cases have been presented for coordination;

- The Commission Joint Research Centre (JRC) has started to analyse trends on incidents;

- A Commission Recommendation on the use of a specific system for traceability of medical devices (UDI) was adopted in April 2013;

- Dialogues with Member States are on-going on product registers;

- Most Member States have reported on their market surveillance activities. This information is used as a base for assessing the need for further improvement;

- With regard to incident reporting from medical practitioners and patients, Member States prefer to develop systems at national level.

Follow-up

The analysis shows that on certain aspects of the Joint Action Plan progress has been limited and continued work is needed in the period leading up to the application of the new legislation. These aspects relate to all four pillars of the initial Joint Action Plan, but concern in particular stricter market surveillance:

- Continued application of the new systems for designation and operation of notified bodies and improved access of notified bodies to vigilance data;

- Development of a common understanding of market surveillance and better co-ordination and communication on surveillance data;

- upgraded coordination at the international level within IMDRF;

- Assessment of how to make best use of registers for providing data and identifying problems on the long term with devices;

- Identification of mechanisms to detect signals, trends and increased incident frequency more effectively based on a JRC project to be presented mid 2014;

- Assessment with Member States of the need for and possibilities of organising peer training programmes.

Limitations of the Joint Action Plan

The detailed analysis also showed that for some important aspects, it is not possible under the current legal provisions to reach the desired objectives. Therefore the adoption of the proposed new Regulations is necessary to solve in particular the problems relating to:

- the scope of the legislation,

- the governance of the system and its transparency,

- certain obligations of notified bodies, in particular in relation to mandatory unannounced audits,

- clinical evaluation,

- the risk classification of devices and the safety and performance requirements,

- the obligations of economic operators,

- the reporting of incidents by users and patients to the Competent Authorities,

- certain aspects relating to vigilance system and market surveillance,

- the role and the functioning of the database Eudamed and the access of notified bodies to Eudamed, and

- the traceability of devices.