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COMMISSION STAFF WORKING DOCUMENT

Implementation of the Joint Plan for Immediate Actions under the existing Medical Devices legislation

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1. BACKGROUND

1.1. Introduction

Over many years PIP (Poly Implant Prothèse Company) fraudulently made use of industrial silicone instead of the approved medical grade silicone in many of the breast implants manufactured. The fraud remained undetected until 2010 as no laboratory tests of implants were done and as audits conducted by notified bodies were always pre-announced. Investigations were finally triggered by an unusually high short-term breast implant rupture. The product was thereafter withdrawn from the EU market.

On the basis of available data, it is estimated that up to 400 000 women received PIP silicone breast implants worldwide. These implants were available in nearly all European Union Member States - in particular they were widely used in the United Kingdom, France and Spain, where it is estimated that respectively around 40.000, 30.000 and 18.500 women were implanted with PIP silicone breast implants. PIP exported many of its implants, with a large share of the export going to Latin America, in particular Brazil and Venezuela.

Following this scandal, a number of questions were raised in media and at political level on the effectiveness of the medical devices regulatory framework, dating back to the 1990s, and its implementation in Europe. Even though the Commission in 2003, in order to reinforce the level of control, reclassified breast implants in the highest risk class[1], there were questions whether the control exercised by Member States on notified bodies that are in charge of the assessment for medium and high-risk devices and the assessment conducted by those bodies was sufficiently coherent within the EU. The scandal highlighted weaknesses in the post-market control by notified bodies, as well as in the market surveillance by competent authorities. The traceability of devices on the market was deficient and the system was perceived as not transparent enough. As an example, the power given to the notified bodies by the legislation to perform unannounced audits of manufacturers had never been used and the rule followed was always to announce the inspections in advance.

As an immediate response to the PIP crisis, the Commission, in February 2012, took the initiative of agreeing with the Member States a Joint Plan for Immediate Actions aimed at tightening controls and at restoring patient confidence in the regulatory system on the basis of existing legislation, pending the adoption by the co-legislator of the new legislation and its subsequent entry into application.

[1] Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4.2.2003, p.43).

Two years after the launch of the Joint Plan, this Commission Staff Working Document communicates the achievements of the plan. It also proposes some aspects that should be continued and intensified.

1.2. The PIP breast implants scandal

According to information available, PIP had declared using silicone gel approved for medical use in the conformity assessments of its product carried out by a notified body. It is not clear at what moment and during which periods PIP started using industrial grade silicone instead of medical silicone.

A high number of ruptures of PIP implants however occurred. Only a limited number seemed to have been reported to the competent national authorities, in particular to the Agence française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) and the UK's Medicines and Healthcare products Regulatory Agency (MHRA). On the basis of incident reports from healthcare professionals AFSSAPS could nevertheless establish a trend of higher than usual ruptures of PIP implants.

On 29 March 2010 AFSSAPS adopted a decision to recall PIP silicone breast implants from the market and to suspend their placing on the market, distribution, export and use. On 9 April 2010 AFSSAPS formally notified the Commission of their decision and on 26 April 2010, the Commission officially informed all EU Member States about the situation and requested them to take the necessary measures to prohibit any placing on the market, distribution, or use of the PIP implants as well as to alert the healthcare professionals. In the following weeks and months, Member States adopted measures at national level to withdraw the devices from their markets.

On 23 December 2011 AFSSAPS published a recommendation concerning the follow-up to be given in case of implantation of PIP implants.

Following the publication of this recommendation, exchange of views between the Member States were organised by the Commission, in particular within the framework of the Health Security Committee, and information was exchanged at international level. There has however not been a common approach in terms of risk management among the Member States. Some of them advised to explant PIP breast implants preventively, while others recommended close monitoring of women who have received these implants.

1.3. The reaction to the scandal on EU level

1.3.1. Assessment of health risks

As an immediate reaction to the December 2011 AFSSAPS recommendation, the Commission asked the relevant Scientific Committee for an assessment of the potential health impact of faulty PIP silicone breast implants.

The report of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[2] of 1 February 2012[3] concluded that the limited clinical data, along with the absence of epidemiological data on PIP silicone breast implants, provided insufficient evidence to warrant a conclusion that women with such implants have a greater risk to their health than women with breast implants from other manufacturers. The Committee however recommended further work to be undertaken to further analyse the situation.

The Commission subsequently requested from the SCENIHR a more in-depth investigation based on data from investigations by Member States. In its second opinion of 15 May 2014[4], the Committee concludes that there is currently no convincing medical, toxicological or other data to justify removal of intact PIP implants. Implant removal in the absence of malfunction may be considered for women who are experiencing significant anxiety because they have a PIP breast implant. However, the decision to remove an intact PIP implant for this reason should in the view of the Committee be based on an individual assessment of the woman's condition by her surgeon or other treating physician after consultation.

1.3.2. *Stress test in the context of the revision of the medical devices legislation*

The PIP case was used for a "Stress test" during the preparation of the Commission proposals for the new medical devices legislation in order to check if the texts envisaged were robust enough to respond to the weaknesses identified[5]. The stress test contributed to optimise the proposals for a revised regulatory framework for medical devices that were adopted on 26 September 2012[6].

1.3.3. *The Joint Plan for Immediate Actions*

The plan, put forward in February 2012, proposes to the Member States joint actions aimed at tightening controls on medical devices in the framework of the current legislation. It covers actions by the Commission (e.g. adoption of clearer rules on designation of notified bodies), Member States (e.g. re-assessment of notified bodies), and notified bodies (e.g. undertaking unannounced audits).

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2 Set up by Commission Decision No 2008/721/EC setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC (OJ L 241, 10.9.2008, p. 21).

3 "The Safety of Poly Implant Prothèse (PIP) Silicone Breast Implants" available under http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_034.pdf

4 Opinion on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants Update of the Opinion of February 2012 available on http://ec.europa.eu/health/scientific_committees/emerging/opinions/index_en.htm

5 "Analysis of the PIP breast implants case in the light of the envisaged revision of the EU Regulatory framework for medical devices ("Stress test")", published as appendix 11 to the Commission Staff Working Document "Impact assessment on the revision of the Regulatory framework for Medical Devices" (SWD(2012) 273 final of 26.9.2012) available on http://ec.europa.eu/health/medical-devices/files/revision_docs/revision_ia_part3_appendices_en.pdf

6 Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM(2012) 542 final of 26.9.2012) and Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices (COM(2012) 541 final of 26.9.2012). See further; http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm

Discussions at the informal Health Council in April 2012 demonstrated that there was broad agreement on the need for urgent improvements and that the Joint Plan provided a good framework for coordinated efforts.

The importance of this plan was further accentuated by increasing concern on other types of devices such as large metal-on-metal hip implants and vaginal meshes.

The Joint Plan aims at bridging the gap by tightening the controls under the existing legal framework. As several of the actions of the plan mirror parts of the revision proposals the plan paves the way for an early implementation of some of the forthcoming requirements and will substantially facilitate their application.

However, as the plan is based on the current legislation, it can only provide a partial answer to the weaknesses identified. For some of them, new legal provisions in the context of the revision are needed.

1.4. Main actions contained in the Joint Plan

1.4.1. Functioning of notified bodies

The plan aims to reach a uniform high standard for both the designation by the Member States of the notified bodies and the functioning of these bodies.

This followed indications of significant divergences as regards, on the one hand, the designation and monitoring of the notified bodies and, on the other hand, the quality and depth of the conformity assessment performed by them, in particular in relation to the assessment of the manufacturers' clinical evaluation and the use of their existing powers such as unannounced factory audits or product checks. Notified bodies themselves acknowledged these differences, which ultimately could lead to varying levels of protection of patients' and consumers' safety. In addition, they can distort competition between manufacturers of similar products and between notified bodies.

Member States were therefore asked to revisit their designated notified bodies and to provide the Commission with an updated list of the notified bodies designated for class III medical devices.

It is crucial for the functioning of the system that the authorities responsible for the designation and monitoring of notified bodies exercise a close, independent and consistent control to ensure that these bodies are designated only for the assessment of devices or technologies which correspond to their proven expertise and competence. Joint audits of notified bodies by teams consisting of auditors of several Member States and the Commission were therefore foreseen in the plan.

The requirements currently laid down in the medical devices directives are very general. Therefore an implementing measure (Commission Regulation) to ensure a consistent application of the criteria to be met for the designation of notified bodies by the Member States was announced in the plan.

In addition, all notified bodies were required to make full use of the powers given to them under the current directives, in particular in terms of unannounced audits of the

manufacturers' premises. A Recommendation clarifying what is expected by notified bodies when they carry out audits of manufacturers was therefore envisaged.

To allow notified bodies to assess the impact of vigilance data on the certificates they have issued, Member States were asked to ensure that the communication of vigilance reports to the notified bodies is part of the contractual arrangement between the manufacturers and their notified bodies. The possibility for notified bodies to be granted access to vigilance reports contained in Eudamed, subject to confidentiality principles, was to be considered.

1.4.2. Market surveillance

The plan contains a request to Member States, based on Regulation (EC) No 765/2008[7], to reinforce their market surveillance which should include appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples and, when necessary and justified, visit the premises of economic operators and take the necessary samples of products.

Member States were asked to report back to the Commission on how they fulfil their information and organisational obligations with regard to market surveillance and to provide information on the powers, resources and knowledge they make available for the proper performance of their market surveillance activities.

1.4.3. Coordination

To avoid duplication of tasks and to share scarce resources, Member States were invited to better coordinate their activities.

The plan envisages a more coordinated analysis to take place when an increased frequency of vigilance reports is identified by a Competent Authority and/or by the Commission for a certain device or a certain type of device to be able to detect and address problems more rapidly and efficiently.

Coordinated inspection on the market and in the premises of manufacturers / importers of such devices established on the European territory by the concerned Competent Authorities should according to the plan be organized, when appropriate, followed by the adoption of the necessary corrective actions.

The plan foresees increased coordination, in particular in the field of audits and market surveillance, to be established in the framework of the confidentiality arrangements signed with international partners.

1.4.4. Communication and transparency

Finally, the plan takes into consideration the issue of an improved traceability of medical devices and their long term monitoring in terms of safety and performance. This includes:

[7] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

– guidance to Member States that are in the process of establishing unique device identification (UDI) systems to ensure that these systems are compatible with each other and with the future European system which is foreseen in the proposals for the future legislation. The Commission therefore undertook to adopt a Recommendation providing general guidance to Member States regarding the establishment of UDI systems.

– initiatives aiming at an effective collection of mid- and long-term data on the safety and performance of implantable medical devices, such as implant registers, set up in cooperation with the medical professional societies. Systematic checks on registers is considered important in order to monitor certain devices (in particular implants), to identify signals and contribute to an independent evaluation of the long-term safety and performance. The Commission services undertook to engage in a dialogue with healthcare professionals and Member States about implantation registers.

The PIP scandal demonstrated the need to strengthen the provisions on reporting by healthcare professionals and patients, as the fraud could have been discovered faster with better reporting. There should therefore be systems in place at national level ensuring that healthcare professionals report incidents, and that patients are empowered to do so as well. For this reason the plan asks Member States to request healthcare professionals and encourage patients to report incidents involving medical devices to their Competent Authority.

2. THE IMPLEMENTATION OF THE JOINT PLAN FOR IMMEDIATE ACTION

2.1. Designation, monitoring and functioning of notified bodies

2.1.1. Controls by the Member States of the scope of designation of the notified bodies in charge of conformity assessments for high-risk devices

Nearly all countries with notified bodies dealing with high-risk devices had by the end of 2012 reported that they had re-assessed and confirmed the designations of their respective bodies. This had resulted in corrective measures or limitations in the scope of activities of notified bodies in at least 8 of these countries. One notified body had asked for the designation to be withdrawn.

2.1.2. Pilot project of joint audits of notified bodies by teams consisting of auditors of several Member States and the Commission

The overall objective of the pilot project of joint audits of notified bodies was to ensure that the legal requirements concerning these bodies were applied and implemented effectively in all Member States in a consistent and efficient way.

The voluntary joint assessment pilot programme started in February 2013 involving 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 were carried out jointly with the national Designating Authority on a voluntary basis as there was no legal basis requiring joint assessments under the existing Directives. It was only through the Commission Regulation (mentioned

under point 2.1.3 below) that these joint assessments were made mandatory. In the long term, the Commission has proposed to make joint assessments mandatory as a part of the future legislation on medical devices.

The voluntary pilot programme was designed to assist the 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 performance of such assessments. The criteria against which the joint assessments were carried out were provided for in the existing medical devices Directives and, where appropriate, interpretative documents published by the Commission and the relevant Member States working group.

The pilot voluntary joint assessment scheme delivered until May 2014 joint audits of a notified body in 22 out of the 23 countries (including 20 Member States) having notified bodies of any category[8]. In a few countries several notified bodies were assessed on the request of the Designating Authority. In the remaining country, an assessment is foreseen in the third quarter of 2014. 22 out of the 23 countries have made assessors available for the joint assessments. A training of national assessors in June 2013 gathered 58 participants from 24 countries.

As the voluntary joint assessments have included also Member States having notified bodies only dealing with lower risk class devices, the joint assessments have gone further than what was envisaged in the Joint Plan that only mentions joint audits of notified bodies responsible for Class III medical devices.

The first overall report of the joint assessments concludes that the process was proving 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 also helps to raise performance standards across the sector, and the experience gained would facilitate the implementation of the mandatory joint assessments from 2014 onwards.

The joint assessments identified best practice examples for Designating Authorities but also weaknesses with some of them that at least in one case led to a rapid action by the Member State improving the capacity and competence of the authority.

All assessments resulted in the identification of non-conformities (between 5-20) in the operation of the notified body audited. Major non-conformities (between 1-6) were identified with the notified body assessed in about half of the countries. To be able to keep their designation the notified bodies were obliged to undertake corrective actions with regard to the shortcomings identified and, in serious cases, a temporary suspension or limitation in the scope of activities sometimes combined with other actions such as re-assessments of all certificates issued by the notified bodies were imposed. In one case a complete de-designation of the notified body followed. During 2013, several other notified bodies stopped their activities without or prior to any joint assessment being announced.

The most common problems identified with regard to notified bodies relate to the:

[8] Through different agreements also the non-EU countries Norway, Switzerland and Turkey have notified bodies recognised under the EU medical devices legislation.

– evidence of staff qualifications;

– thoroughness of the review of manufacturers clinical evaluations and

– sampling of technical files for class IIa and IIb devices.

2.1.3. Commission Regulation on the designation and the supervision of notified bodies

A Commission Implementing Regulation on the designation and the supervision of notified bodies was adopted on 24 September 2013[9].

Examples of the measures laid down in the Implementing Regulation are:

- A Member State shall only designate or re-designate a notified body after a joint assessment conducted with experts from the Commission and other Member States. The assessment reports shall be made available to all other Member States.

- Member States are required to carry out surveillance and monitoring of the notified bodies at certain intervals to ensure that they continuously live up to the requirements. If this is not the case, the Member State must withdraw the designation as notified body.

- Knowledge and experience requirements of the staff of the notified bodies are clarified.

Until April 2014 five mandatory joint assessments under this regulation had been carried out. One of these resulted in a negative decision on an application for a designation of a new notified body. Around 20 mandatory joint assessments under the Regulation are expected in 2014.

2.1.4. Commission Recommendation providing guidance to notified bodies when they perform audits and assessments.

A Commission Recommendation on the audits and assessments performed by notified bodies in the field of in the medical devices sector was adopted on 24 September 2013[10].

Examples of the measures laid down in the Recommendation are:

- Notified bodies should randomly perform unannounced factory audits and, in this context, check adequate samples from the production.

- Where risks might be caused by the substitution or adulteration of raw-materials (such as in the PIP-case), a notified body should check that the quantity of finished products corresponds to the quantity of the crucial raw material purchased.

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9 Commission Implementing Regulation (EU) No 920/2013 of 24 September 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 (OL L 253, 25.9.2013, p. 8).

10 Commission Recommendation No 2013/473/EU of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices (OJ L 253, 25.09.2013, p. 27).

- The composition of the notified body assessment teams should ensure continuous objectivity and neutrality including a rotation of auditors at appropriate intervals.

2.1.5. Unannounced audits of manufacturers by notified bodies

Even though notified bodies were entitled to carry out unannounced audits, at the time of the PIP-scandal, in most cases, those audits did not take place.

About half of the Member States reported in the autumn of 2012 that they were asking their notified bodies to carry out unannounced audits while others informed that they would only request unannounced audits once the Commission Recommendation mentioned in the point above had been adopted. This situation is illustrated by the fact that out of 22 notified bodies assessed in joint assessments in the one year period from February 2013 to February 2014 only five had carried out unannounced audits. Out of the remaining 17 notified bodies 14 had provisions for conducting such audits included in contracts with manufacturers, in their general terms and conditions or in certificates, but had not made use of these.

Since the adoption of the Recommendation in the autumn of 2013, the system of unannounced audits is gradually becoming more common. In meetings in April 2014[11] all but one of the 42 notified bodies present reported that they had been asked by their national authorities to take consideration of the Recommendation on unannounced audits. All had or were finalising procedures and most were launching trials or had carried out real audits.

2.1.6. Communication of vigilance reports to the notified bodies and possibility for notified bodies to be granted access to vigilance reports contained in Eudamed, subject to confidentiality principles.

Most Member States have reported that they have requested their notified bodies to include in their contractual arrangements with their customers the obligation to transmit vigilance reports to their notified bodies.

Due to data protection requirements, it has not been possible to grant notified bodies access to vigilance reports stored in the Eudamed database. Notified bodies have however indicated a preference for receiving targeted information from national authorities on problems identified. A pilot project using a template developed for this purpose by a Member State was launched in the relevant Commission expert group and is now regularly used by numerous Member State authorities. It is expected that this can be an alternative and more user friendly approach to ensure that notified bodies react to problems identified.

The possibilities to grant targeted Eudamed access to notified bodies will ultimately be re-assessed in the course of the re-design of Eudamed under the future legislation. The proposed new Regulations contain specific provisions on the access for notified bodies.

2.1.7. Voluntary measures by notified bodies

Although outside the formal scope of the Joint Plan, it should be noted that the approximately 30 notified bodies (representing a majority of the certificates issued in the EU) that are voluntary members of the notified bodies organisation "Team NB"

[11] Meetings of NB-MED and Team NB in Brussels, 15-16 April 2014.

have on their own initiative further developed their internal Code of conduct adding additional elements linked to the PIP experience and have made the adherence to the Code obligatory for all their members. An internal mechanism for verifying the implementation of the Code by the members has been put in place.

2.2. Market surveillance

According to the information provided by the Member States to the Commission services in 2012, market surveillance is diverging widely in terms of practice, intensity of surveillance, targets of controls, types of measures taken and resources available.

There are differences concerning the types of products and the items checked, the reasons triggering checks and the measures taken.

Some countries focus exclusively on products of manufacturers or authorised representatives registered on their territory.

Some countries considered the control at the occasion of the registration of the products into national registries as a formal market surveillance check.

Some Member States focus on labelling and packaging, while others examine all possible fields of non-conformity. Some decide on priorities for surveillance taking vigilance data into account among other elements, but for others vigilance data are almost the exclusive basis. Some cooperate closely with customs, most do not.

Many of the Member States recognised that because of a shortage of resources, market surveillance is only reactive and that no proactive surveillance is carried out.

2.3. Coordination

2.3.1. Coordinated analysis when an increased frequency of vigilance reports is identified for a certain device or a certain type of device

The current legal framework provides that serious incidents and proposed corrective actions are evaluated by Member States and, where appropriate, information is disseminated among them (in the form of a National Competent Authority Report, NCAR).

Two main actions have been taken to develop the coordination of the analysis further:

(a) Monthly vigilance teleconferences with the competent authorities, chaired by the Commission, were launched in July 2012. Through these teleconferences, information is shared and it can be determined whether further strengthened coordination on specific issues is needed.

In addition to discussions on individual high priority cases the teleconferences also aim at identifying incident report trends and safety signals of concern.

On average 23 countries have participated in the teleconferences. Nearly half of the Member States have participated in more than 75% of these. Five countries have never participated. 72 specific cases have been presented for co-

ordination in the conferences until April 2014. Although the discussions on follow-up involve in general all participants, four Member States accounted for 75% of the cases proposed for discussion.

In 2013, Member States exchanged 1029 National Competent Authorities Reports (NCARs), an increase of nearly 50% compared to 2011, but the number differs hugely between Member States. Two Member States accounted for 60% of the NCARs.

Since the launch of the teleconferences a monitoring system on the follow-up and a dedicated web space for storing background documents have been put in place.

(b) A pilot project on analysis of medical devices incident reporting was launched by the Joint Research Centre (JRC) of the European Commission in the summer of 2013. The objective is to identify mechanisms for a more effective detection of signals, trends and increased incident frequency. Such mechanisms could serve as an example to be applied throughout the medical devices sector.

As a part of this project, JRC is conducting a metadata analysis of the NCARs submitted to the Commission during the past decade and a screening of publicly available sources with regard to the safety of medical devices relevant for the European market.

Based upon these results, the JRC will provide recommendations on the use of modern statistical techniques and software for an effective detection of signals and trends in the EU incidence reporting data and give recommendations for the data structure for incident reporting in an EU electronic system. The JRC report is foreseen for mid-2014.

2.3.2. Coordinated inspection on the market by the concerned Competent Authorities

Coordination between Member States of inspection on the market has traditionally been limited to method development and exchange of information of planned and on-going activities on national level. The Member States Compliance and Enforcement Working Group (COEN) made efforts to launch joint market surveillance projects between Competent authorities. A major pilot project finalised in the summer of 2013 had limited success with only ten Member States responding to the call and six of these finally being able to provide full reports on the outcome of the project on national level.

The analyses indicated problems with regard to agreement on the selection of projects and sharing and distribution of the workload, in particular in relation to the coordination. Problems relating to translation, confidentiality and follow up measures were highlighted as well.

2.3.3. Coordination, in particular in the field of audits and market surveillance with international partners

A program for exchange of information about recalls and other safety corrective actions and for exchange of information about investigations being undertaken, the "National Competent Authority Report (NCAR) Exchange Program", was

established in the context of the Global Harmonization Task Force (GHTF), that has now become the International Medical Device Regulators Forum (IMDRF)[12].

A review to ensure that the NCAR program can better facilitate timely information exchange of relevant post-market safety information on medical devices with global distribution and to ensure that the system could trigger rapid adoption of corrective actions in all concerned jurisdictions is on-going in the context of IMDRF. The proposed streamlined system could be agreed by the IMDRF members in the autumn of 2014.

The exchange of information is however sometimes still delayed or hampered because of confidentiality issues. There may be a need to analyse further the implications of these issues and to consider further bilateral or multilateral confidentiality agreements.

2.4. Communication and transparency

2.4.1. *Recommendation providing general guidance to Member States regarding the establishment of a unique device identification system (UDI)*

The Recommendation on a common framework for a unique device identification (UDI) system in the EU[13] was adopted by the Commission on 5 April 2013. This is a result of the work carried out in the framework of the European UDI Ad Hoc Working Group, which took into consideration the guidance developed in the framework of GHTF and its successor IMDRF[14].

The aim of the Recommendation is to provide those Member States who would decide to develop their own UDI mechanisms with general guidance to facilitate the compatibility of UDI mechanisms developed at national level with each other and with the future EU UDI system.

Pending the establishment of this EU level UDI system, the Recommendation proposes the data elements that Member States could include in national UDI databases and conditions to be fulfilled by economic operators, health professionals, and professional users regarding for instance marking, verification and electronic record keeping of device UDI information.

It recommends that Member States follow a risk-based approach to the implementation of national UDI systems, starting with highest-risk devices. As the Recommendation is consistent with the approach developed at international level, which should help minimize implementation costs for manufacturers and facilitate traceability and free movement of goods internationally, the principles of the Recommendation should be applied by the Member States.

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12 IMDRF is a voluntary group of the medical device regulators of Australia, Brazil, Canada, Europe, Japan, China, the Russian Federation and USA. The World Health Organization (WHO) is an official observer.

13 Commission Recommendation No 2013/172/EU of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union (OJ L 99, 9.4.2013, p.17).

14 Final document adopted 9 December 2013 available at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance.pdf

2.4.2. Dialogue with healthcare professionals and Member States about implantation registers

Currently, the legislation leaves it to the Member States to decide whether they wish to put in place implant registers or not.

In order to develop knowledge and establish priorities, the Commission has consulted the relevant expert groups and engaged in dialogues with registry representatives, national and EU wide, and with professional organisations in fields such as arthroplasty and angioplasty.

The consultations indicated that there is a plethora of registers of different types at national level, some of them including implantable devices. A mapping of existing registries and a development of methodologies aimed at enabling cross border use of registry data have been identified as priorities under the plan.

For this purpose, the Joint Action on Cross-border PAtient REgistries iNiTiative (PARENT)[15], set up in the context of Directive 2011/24/EU on patients' rights in cross-border healthcare[16], was identified as a vehicle to develop these aspects. The project, led by Slovenia, started in 2012 and will end in October 2014.

It is envisaged that other Joint Actions will be designed under the third Programme for the Union's action in the field of health (2014-2020)[17] to further develop the aspects relating to medical devices.

2.4.3. Reporting of adverse incidents involving medical devices by healthcare professionals and patients to their Competent Authority

As the legislation leaves to the Member States to decide whether they wish to put in place a reporting obligation for medical practitioners or medical institutions and no provision relates to the reporting by patients, the Commission has undertaken a mapping of the situation in Member States.

Of the 22 answers received, 19 Member States indicated that there is an obligation for healthcare professionals to report incidents involving medical devices to the Competent Authority. Almost half of the respondents indicated that patients are encouraged to report incidents involving medical devices.

On the basis of these replies, the Commission has suggested a number of actions which could be taken by the Member States under the present legislative framework to facilitate reporting by healthcare professionals and patients, such as further measures on national level to encourage reporting and the development of standard web-based structured forms.

The consultation indicated that both Member States and most stakeholders have concerns as to the usefulness of the establishment of a new set of reporting forms. However the association of patients was in favour of a possible improvement of the

15 For further information see http://www.patientregistries.eu/Stranky/Home.aspx

16 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

17 Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC (OJ L 86, 21/03/2014, p. 1).

forms for patient reporting along the model of the web-based forms for pharmaco-vigilance.

Overall, the comments received from both Member States and stakeholders point to potential problems in introducing changes to the current system prior to the entry into force of the revised legislative framework. Therefore, it was concluded to leave this issue to actions at Member State level pending the new legislation.

3. CONCLUSION

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

- Member States have re-assessed the qualifications of the notified bodies in charge of assessing high-risk devices, thus the vast majority of notified bodies. Member States have, in many cases, modified the scope of the activities of the notified bodies;

- A majority of Member States have requested their notified bodies to carry out unannounced audits and have asked notified bodies to ensure they are informed about incident reports. Notified bodies have reported that they are in the process of launching the unannounced audits;

- 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 is scheduled for the remaining. The voluntary joint audits have been judged as very useful by all parties involved;

- 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. Five such audits have been carried out until April 2014. About 20 mandatory joint audits are foreseen for 2014;

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

- 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;

- The Commission Joint Research Centre (JRC) has started a metadata analysis in the field of vigilance reporting and is conducting a screening of publicly available sources with regard to the safety of medical devices relevant for the European Market;

- 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;

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

The positive progress in the implementation of the plan has been discussed between Health Ministers in several EPSCO Councils[18].

Many Member States and stakeholders have underlined the importance to continue and intensify the work on certain aspects of the Joint Plan. The focus should be on problematic issues identified during the implementation of this plan that are not yet resolved, such as:

- **Market surveillance**

  The information received under the Joint Plan and the national market surveillance programmes[19] indicate great divergences between the Member States with regard to resources attributed and how market surveillance is carried out. Many Member States recognise that because of a shortage of resources, market surveillance is only reactive and that no proactive surveillance is carried out.

  These differences in approaches influence decisions on which products are concretely checked and on which aspects they are checked. Experience has shown that national competent authorities sometimes react in different ways to the same problems. A consequence is that whilst in some Member States the placing on the market or putting into service of a given device is banned or restricted, it may freely circulate in other Member States.

  Some of the 20 actions for safer and compliant products for Europe outlined in a Commission communication of last year[20] can be a source of inspiration for the concrete actions to be undertaken, in order to address those issues and to develop best practices (for example, a best practice would be to develop a common understanding of market surveillance and better co-ordination and communication on surveillance data, as set out in paragraph 3 of that Communication) .

  On the international level, the activities carried out within IMDRF could contribute to an increased coordination.

- **Functioning of notified bodies**

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18 Lunch discussions in the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) meetings on 7 December 2012 and 10 December 2013.

19 National programmes are available at http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/market-surveillance/index_en.htm

20 Product safety and market surveillance package: Communication from the Commission to the European parliament, the Council and the European Economic and Social Committee: 20 actions for safer and compliant products for Europe; a multi-annual action plan for the surveillance of products in the EU (COM(2013)76 final).

The Joint Plan has led to the establishment of a new structure for the designation and supervision by Member States of notified bodies. Also guidance to notified bodies in their performance of audits and assessments has been given through a Recommendation. Assessment standards should also be improved through the own measures taken by many of the notified bodies in the Team NB framework.

There are clear signs of the positive effect of these measures, justifying the continuation of these efforts.

- **Communication and transparency**

  The next steps on UDI and reporting of incidents from healthcare professionals are foreseen to be taken following the adaption of the new legislation.

  The work on making best use of registers for providing data and identifying problems with devices that has been launched under the Joint Plan should be pursued under the current PARENT Joint Action and in follow up actions envisaged.

  The proposals of the JRC project on identifying and developing recommendations for mechanisms to detect signals, trends and increased incident frequency more effectively should allow reducing the number of problems at the source and thus more effectively allocate the scarce resources attributed to market surveillance and vigilance. The results, that should become available mid-2014, should allow for discussions with Member States and stakeholders on the improvements in this respect.

- **Sharing of knowledge and good practices**

  The actions undertaken under the Joint Plan have demonstrated the value of sharing knowledge and best practices between Member States. The experiences of the joint assessments of notified bodies have been very positive in this respect. In this context a joint training has been undertaken and more are foreseen. It could be beneficial to make use of this practice of joint training in other fields of activity.

The measures described above can all be undertaken under the framework of the Joint Plan and within the existing legislation. For other important aspects, it is not possible under the current legal provisions to reach the desired objectives.

Therefore the proposed new Regulations contain provisions which aim 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,
- obligations of economic operators,
- 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.

Each of these points is pivotal towards ensuring patient and consumer safety and restoring confidence in the regulatory framework.