EVENT (please indicate venue and date only on the cover sheet)

Unit in charge : F/5, C.1

BRIEFING NOTE

Subject: revision of the medical devices legislation

1. SCENE SETTER

CONTEXT

The existing directives covering medical devices aim to ensure the smooth functioning of the internal market and a high level of protection of human health and safety.

Medical devices are not subject to any pre-market authorisation by a regulatory authority but to a conformity assessment which, for medium and high risk devices, involves an independent third party, known as 'notified body'. Notified bodies are designated and monitored by the Member States and act under the control of the national authorities. Once certified, devices bear the CE marking which allows them to circulate freely in the EU/EFTA countries and Turkey. Studies have shown that this system allows for faster market access at equivalen safety levels when compared to a pre-market authoriation system.

The existing regulatory framework has demonstrated its merits, but has recently come under harsh criticism, notably after the fraudulent breast implants safety case involving a French manufacturer (PIP). Substantial divergences in the interpretation and application of the rules that are no longer up to date and rather weak have also emerged, together with uncertainties with regard to certain products resulting from scientific progress.

This revision aims to overcome these flaws and gaps and to further strengthen patient safety, while being supportive of innovation and the competitiveness of the medical device industry The proposed regulatory framework aims to allow for a cost-efficient market access for safe, innovative medical devices, to the benefit of patients and healthcare professionals.

POSITION OF DG ENTR

The efforts to update and strengthen the regulatory framework and therefore the safety of medical devices are most welcome by DG ENTR. The proposal enhances the requirements and obligations for all actors involved; manufacturers, testing laboratories and certification bodies, national authorities and the European Commission.

1) No need for a marketing authorisation

It was decided to reinforce the current system and adapt it with a view to technical and scientific progress,. A fundamental change to the system introducing a marketing authorisation of medical devices was not considered appropriate. This option, which

would mean the transfer of responsibility for the assessment of the safety and performance of medical devices from Notified Bodies to regulatory authorities and the replacement of the CE marking by a marketing authorisation, was widely rejected during the public consultations and the subsequent dialogue with competent authorities, manufacturers and most other stakeholders.

A decentralised marketing authorisation by Member States would have a negative impact on the internal market for medical devices because the application of the mutual recognition of national authorisations would not provide automatic access to the market of the other Member States. A central marketing authorisation at EU level would require setting up a new EU public body, with significant impact on the EU budget, on manufacturers in terms of costs and administrative burden and on innovation in terms of time to market. The competitiveness of EU medical devices industry would be at stake.

Furthermore, it is questionable that a marketing authorisation procedure would be able to prevent deliberate fraudulent practices once a product is approved for marketing.

DG ENTR therefore supports the choice of reinforcing the current regime, rather than the radical shift and associated risks for competitiveness that a marketing authorisation would represent.

2) Aims of the proposed revision and concerns of DG ENTR

The new regulations proposed by DG SANCO are meant to:

- cover legal gaps and loopholes,

- enhance the legal clarity and coordination in the field of post-market safety,

- adapt the legal requirements, taking into account technological, scientific and regulatory developments (for instance when it comes to classification rules),

- enhance legal certainty and coordination in the field of clinical evaluation and investigations, in particular those conducted in more than one Member State,

- solve "borderline" cases (e.g. whether they should fall under the medical devices or the medicinal products regulatory framework) in a cross-sectoral manner,

- provide a uniform control of Notified Bodies,

- enhance the involvement of external scientific and clinical expertise,

- clarify the obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales,

- enhance the transparency regarding medical devices on the EU market, including their traceability,

- efficiently and effectively manage the regulatory system.

DG ENTR concurs that these objectives will in general be ensured by the new legislative framework and that its tools – notably – accreditation should be used fully.

During the ISC, we **nevertheless raised concerns on the**:

- **accreditation**:

The existing measures and tools of the new legislative framework that the file claims to use are, are almost completely ignored, even though they have been approved by the European legislators not even two years ago and accepted by market actors. The Commission funds accreditation activities.

Especially accreditation which ensures a public authority control of notified bodies and their regular surveillance is not taken into account.

It is clearly pointed out in the impact assessment that a large part of the problem which could lead to the PIP scandal is the lack of resources in national ministries and the Commission to control and to properly assess notified bodies. Especially regular surveillance visits do not seem to take place in the case of many unaccredited notified bodies. Therefore the system proposed is developed.

In this context, the proposal can be seen as an attempt to return to a model that is tightly controlled by the medical authorities. Accreditation bodies are already obliged to conduct surveillance visits at regular intervals.

It is often claimed that accreditation is not specific enough for the medical devices sector as accreditation bodies work on a wide range of sectors and subjects. However, while accreditation is about the general technical competence of a body, an accreditation certificate is always issued in relation to a specific activity and product.

Accreditation assessors are usually sectoral experts. European accreditation bodies are already working on a common pool of assessors to bundle expertise. It seems doubtful that the Commission could muster the appropriate sectoral and technical expertise to go and assess a notified body using its own personnel.

Furthermore, there is the possibility to introduce accreditation schemes for specific sectors if necessary. In fact, SANCO and JRC are currently developing a sector scheme on breast cancer units. Medical devices have so far not made use of this possibility which could greatly help in further harmonising the requirements for notified bodies.

- classification of self-medication devices that are wholly or partially absorbed by the body under Class III products, as per rule 21.

The concern of the Association of the European Self-Medication Industry (AESGP) is the introduction of very strict safety controls for devices that might not need them, leading to excessive costs and bureaucratic burdens. These products are often used over a long time and without prescription. This certainly calls for adequate security checks, but this is also the case with a IIa classification. Otherwise, it might be more useful to only make these devices available under supervision and with a prescription.

- **timing of notification procedure**, which could lead to delay the market of high-risk devices (Class III devices).

A mechanism for scrutiny of certain conformity assessments is being proposed in the new regulations. The notification procedure could delay the conformity assessment process, hence the marketing of devices. It was requested to DG SANCO that this procedure is adapted so as to not unduly introduce delays, which could be detrimental to innovation and competitiveness, considering the time constraints imposed by competitive markets. DG SANCO shortened some deadlines related to this procedure, which will be in the benefit of industry and is appreciated.

The two final points that remained to be negotiated with DG were about the:

- introduction of a voluntary "pre-notification" of authorities by manufacturers before envisaged class III applications in order to raise awareness of files that might be subject to scrutiny, allowing faster reaction later on, thereby saving time

- modification of the deadline for the Medical Device Coordination Group (MCDG) to request the summary of the preliminary conformity assessment from the notified body to 21 calendar days.

These points on the notification procedure were agreed upon between DG ENTR and DG SANCO Cabinets.

2. LINE TO TAKE

KEY MESSAGES (LIMITED TO THREE)

- DG ENTR welcomes the efforts to update and strengthen the regulatory framework and therefore the safety of medical devices.

- DG ENTR supports the choice of reinforcing the current regime, rather than introducing a new regulatory procedure for pre-market authorisation.

- DG ENTR requests that full consideration is being taken of the new legislative framework, when it comes to accreditation.

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