Ministry of Health, Welfare and Sport

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All correspondence addressed to the postal address quoting date and reference of this letter.

Date
Subject Your letter of the 24th of November

Dear Mrs W , rapporteurs,

Thank you very much for your letter of the 24th of November in which you stress the urgency of reaching a deal on the medical devices dossier.

With this letter I would like to express my appreciation for the priority given by the European Parliament to this dossier and your intentions to work exceptionally hard to ensure we can conclude negotiations.

I agree with you that the considerable time and effort that Council has invested has not lead to great progress and that this is not beneficial for the system of medical devices in Europe and, most of all, not for patient safety.
In that respect, I too hope that the Council and the European Parliament can soon work together to contribute to common goals: increased safety and innovation for the European patients.

Since 2012 the Netherlands has been actively involved in the negotiations in the Council. Although the content of these future regulations is rather complex, we do think that the negotiation process should become more efficient and focus on output. The Netherlands will certainly try to foster a swifter process.

As you are aware of, the Netherlands has been confronted very recently with media attention, raised by a Dutch television programme, on the subject of notified bodies. The television-programme produced a fake dossier of a mesh device based on a mandarin net.
The involved notified bodies already reflected on this television -programme and clearly stated that a certificate would not have been given for this fake product.
Even though I take into consideration these first responses of the notified bodies involved, the tv-programme illustrated that the system needs to be further improved for patient safety and restoring confidence.

Most importantly the future regulations should be much more effective. In the case of high risk devices: they should always be properly assessed before being

placed on the market. In that respect, I am convinced that it is necessary to increase the quality of clinical data as early as possible in the system. This is why The Netherlands has proposed in the Council that manufacturers of high-risk devices should consult experts prior to any clinical investigation. This will contribute to better clinical data on the device, but also to a better clinical review by the notified bodies during the conformity assessment procedure. Additionally, clinical reviews by the notified bodies should alsobe part of the joint assessment of notified bodies by member states and the European Commission.

Besides increasing clinical expertise overall , the system of oversight of notified bodies and market surveillance should be intensified. However the focus needs to be on where risks for patients are highest. For this, post-market surveillance is key as this enables manufacturers to follow their products and improve and respond as fast as possible in case of changes of performance. We are pleased that our proposal to this end has lead to widespread support in the Council. Finally, I'd like to underline the importance of transparency and traceability throughout the system through a bar-code system. This has a very high urgency.

For the short-term I think it is important to see if we can undertake additional measures within the framework of the current legislation, perhaps under the action plan of the European Commission. Furthermore, the Netherlands will start collecting data on high risk implants in a register by the end of last year. Also in preparation of the regulation we are discussing mutual agreements on bar coding with stakeholders. It is crucial that we connect with a European system as soon as possible.

Last but not least, safety needs to be improved, but we must not lose sight of the other benefit to patients: the availability of safe, innovative devices for unmet medical needs.

Yours sincerely,

Ms. E.I. Schippers

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