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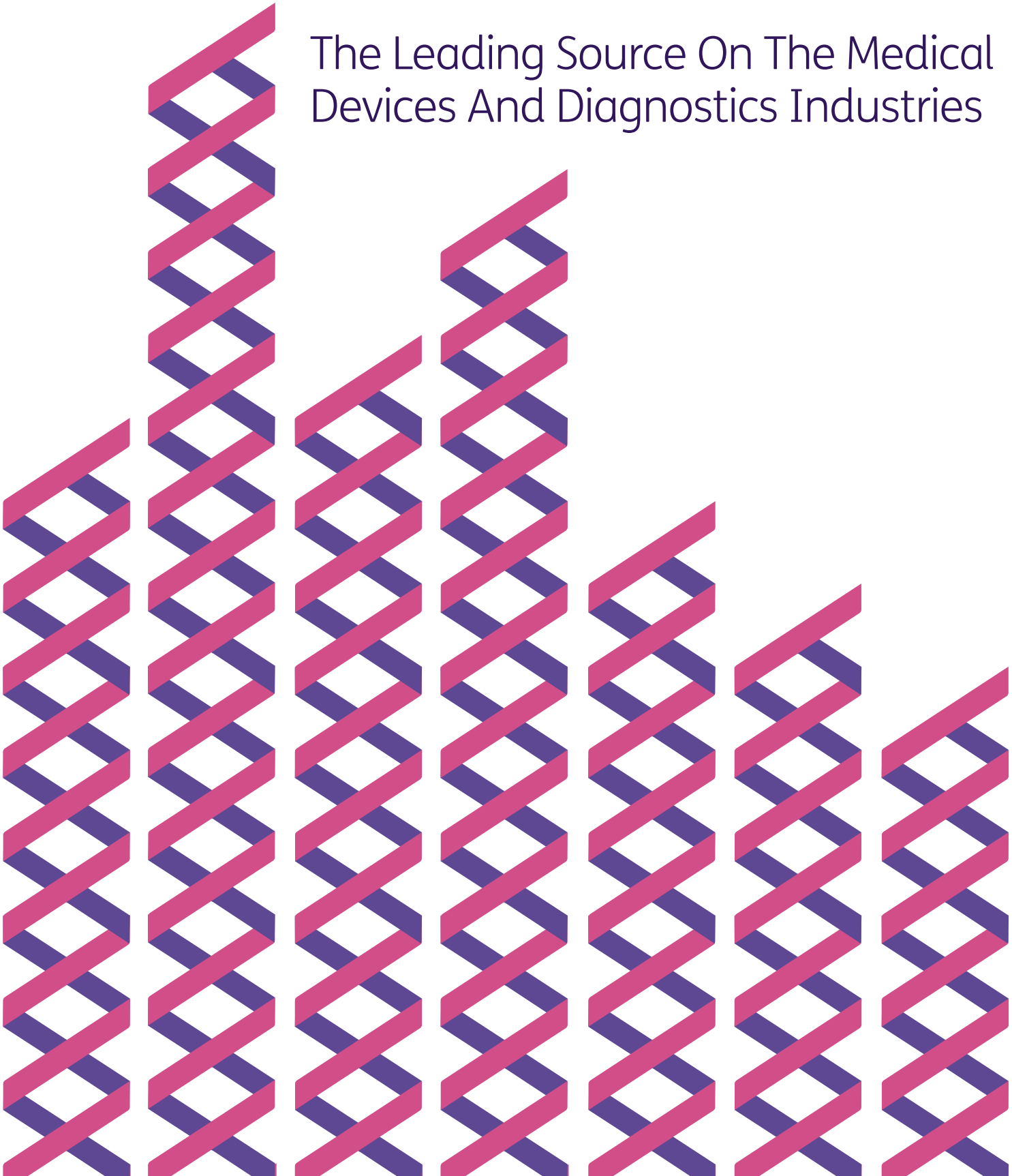

Key Vigilance Links To Safeguard Patients In Case Of Non-EU Products Now Under Threat

By Amanda Maxwell ,12 May 2016

The Council of the EU's proposals to make authorized representatives liable, under the pending Medical Device Regulation, for defective products when they are representing non-EU manufacturers continues to generate a passionate debate in the EU.

The latest argument to emerge is that the Council's proposals could threaten direct communication between the authorized representative and the manufacturer while lawyer-to- lawyer communication get underway. And this could delay vital information for patient safety being made public.

EU authorized representatives act as the lynchpin for communication between manufacturers and the authorities; they effectively act as an EU office for non-EU manufacturers who wish to trade in the EU, but cannot without having a presence here.

One of the key roles that authorized representatives play is being involved with the manufacturers' vigilance activities, including handling incidents and recalls. Although the current medical device directives do not specifically require authorized representatives to be involved in this way, the responsibility falls on these legal representatives because they are the main contact for the European authorities.

Speaking on behalf of the German authorized representative business, Medical Device Safety Service GmbH, president Ludger Möller told Clinica that next to registration of products, "vigilance is the biggest portion of our business".

Yet, should the Council of the EU's proposals be accepted by the European Parliament and Commission – and there are an increasing number of indications that this is likely to be the case – then this will mean that authorized representatives will lose this significant role they currently play, Möller believes.

This will stem from a specific Council proposal, which stipulates, as reports have indicated, that "where the manufacturer is not established in any Member State ... the authorized representative shall be legally liable for defective devices".

This situation threatens to take away the pivotal role of the authorized representative. If they have to defend themselves against potential liability situations, then the manufacturer will be reluctant to share information with the authorized representative.

This means that if the information is kept by the manufacturer abroad, then the competent authorities will have to work directly with the manufacturers to obtain it.

The authorized representative's co-operation with the competent authorities would also diminish, Möller anticipates, as it would be very difficult to discuss any relevant vigilance information with them since every incident would potentially be a liability case and there would be legal constraints to open communication on this topic.

If the medtech sector wishes transparent communication to take place between manufacturers and their authorized representatives in a manner to resolve medical device problems, then this liability clause should be removed, Möller argues, and authorized representatives should retain their current status.

Otherwise, any information referred to the authorized representative by the manufacturer would then have to be transferred to the authorized representative's lawyers. In turn, they would immediately require their authorized representative client to only share information through their lawyer who would start communicating with the liability insurer of the manufacturer.

In other words, the direct communication line and trust between the manufacturer and the authorized representative, who is supposed to be the manufacturer's outer limb in the EU, would cease; and the whole debate will be between lawyers, rather than medical device experts, with the lawyers trying to fully control the information between the manufacturer and the authorized representative.

"In the context of the current directive (as well as the German law) we would have informed the manufacturer, immediately evaluated the event, and in case of an incident, shared this with the manufacturer and the authority which, in turn, could react quickly should there be a bigger underlying problem, thereby protecting other patients in case of reoccurrence," Möller explained.

All this information would be transparent with the relevant parties, he added.

It is not clear to as why the lawmakers would reduce the pivotal communication role of authorized representatives and this level of transparency since the safety of patients may be at stake if the information flow in Europe is disrupted, he concluded.