Analysis of European Parliament's ENVI Vote

Outcome of the ENVI Committee's Vote on the Proposed IVD Regulation

Yesterday, the European Parliament¹s Committee on Environment Public Health and Food Safety (ENVI) voted on the proposed IVD Regulation. The vote is important as it gives the first opinion of the Parliament on the matters at hand. It is not the end of the discussions with there being at least another round of voting in plenary session and the opinion of the Council. If no agreement is reached between the Parliament and the Council, a second reading with a new round of discussions both in the Parliament and the Council will be necessary. Additional information on the legislative framework can be found below.

At this stage it is important to assess the preliminary results from the vote in Parliament, as there are many specific aspects that need to be addressed:

Transition Period: Parliament has voted to shorten the transition period of the IVD directive from five to three years in order to align it with the MD transition. Additionally they have staggered the implementation so that different parts of the legislation will be put in place following a clear schedule. For instance, implementing acts will need to be put in place within 12 months to allow manufacturers time to comply. Given the large changes which the IVD Regulation introduces, EDMA will continue to advocate for the five year transition time.

Class D devices: The compromise proposal adopted by the Commission includes the concept of special Notified Bodies, which would at least in part, be supervised by EMA and would need to report regularly on their activities. Only special notified bodes would be able to handle class D IVDs. It also introduces a very complex committee structure, in the form of the Assessment Committee for Medical Devices (ACMD), which includes numerous subcommittees for experts. Though not explicitly stated, the Commission does not have sufficient resources to manage such a complex committee structure and could only effectively be handled by an agency. This replaces the Commission¹s proposal on the scrutiny mechanism, which would have been a lot less burdensome for the IVD industry.

Transparency: A problem arises with the proposal from the Parliament to potentially make the clinical performance study reports public under certain situations. There are substantial concerns that revealing the full content of the clinical performance study reports would result in significant competitive disadvantage. EDMA has instead advocated been arguing for the public release of a summary of reports, which would not reveal critical data to the competition.

In house exemption: Parliament has focussed on ensuring the safety of in-house assays, and that the in-house exemption not be used to circumvent the requirements of the IVDR. Commercial laboratories will not be able to benefit from the exemption at all. Some class D devices may be able to benefit from the exemption but will be subject to heightened scrutiny from authorities. Moreover, if there is a CE-marked device available there can be no in-house assays for Class D devices. Furthermore, the Parliament rejected the idea that an entire healthcare system could be considered a health institution. Overall, this is a favourable approach to in-house assays. However, the question of companion diagnostics as in-house assays remains an unresolved issue. The ENVI Committee also included a clause that enables Member States to implement even tighter controls of in

house assays.

Companion Diagnostics: Parliament has somewhat simplified the conformity route for in-house assays. However, it rejected the concept of using common technical specifications to control in-house assays, and reaffirmed the need to consult the European Medicines Agency for each individual companion diagnostic test. More discussions on this subject are sure to follow, both in the Parliament and the Council.

Reference Laboratories: Here, the Parliament adopted the concept that reference laboratories will need to play a key role in supporting the market surveillance activities of Notified Bodies and competent authorities. However, the Parliament has also maintained a role, to be defined through implementing measures, of reference laboratories in the batch release of class D IVDs.

Interventional Studies: The ENVI Committee has recognised the problem with using an open ended concept of ³risk² when defining what type of studies would need to comply with the requirements for interventional studies. The Commission has been tasked with developing a list of procedures that would not trigger an interventional study, it is likely that such a list would be based on current practice in various Member States.

Point of care testing: POCT has been recognised as a type of device separate from self-tests. POCTs will be regulated according to their individual classification that is independent from the fact that they are POCT. This is in line with the concerns of the industry.

Devices with a measurement function: The ENVI Committee has removed the provisions for devices with a measurement function from the proposal, as all IVDs are in one way or another devices with a measurement function.

Single use devices: Single-use devices are maintained as a concept by the ENVI Committee, even though the question of multiple-use and single-use devices never been a real issue in the field of IVDs.

Liability insurance: Parliament has introduced the concept of liability insurance for manufacturers. One of the key questions had been what exactly would need to be covered by this insurance; it has been made clear that the liability insurance will cover damage caused by manufacturing defects.

Stakeholder involvement: The question of how stakeholders, such as industry, would provide input into the regulatory processes, had been left unanswered by the Commission. The ENVI Committee has specifically called for the creation of a Medical Devices Advisory Committee (MDAC not to be confused with the ACMD!) that would include all of the concerned stakeholders (industry, clinicians, patients, civil society groups etc.). The MDAC would be consulted on questions of classification of borderline products and development of CTS.

Qualified Person: The ENVI Committee was concerned with the effect that the Qualified Person requirements from the Commission would have on SMEs. They have simplified the requirements of the Qualified Person, who can now have a broader potential background and needs to have three (as opposed to five years) of experience in IVD regulatory fields.

In addition to these changes, directly impacting the IVD industry, the ENVI Committee passed a series of amendments to better control Notified Bodies as a whole. There were extensive additions to address how IVDs are used.

In particular, these additions addressed the ethical use of IVDs, informed consent in international trials, the role of ethics committees and the handling of consent and information to minors and those who are otherwise incapacitated.

sions will now continue in preparation of the plenary vote in the Parliament, is tentatively scheduled for October 22nd. The engagement with the Council come critical as they will review the proposals and questions raised by the nent, and also address issues that the Parliament has not tackled. In lar, it is known that the Council wants to discuss the details of the ication system for IVDs, clinical evaluations, and the details of the safety rformance requirements.

The revision process of the new IVD Regulation is thus still very much a work in progress to which EDMA remains firmly committed. Members should expect further information and details on how to continue to engage in the revision process in the near future.

Additional information such as the EDMA voting recommendations, compromise and consolidated amendments can be found here. Should you have any specific questions on the situation, do not hesitate to contact the EDMA Secretariat.

Framework of the Legislative Procedure A Look Back, A Look Forward

The European Commission submitted a Proposal for a Regulation on in vitro diagnostic medical devices to the European Parliament and Council on 26 September 2012. This move officially kicked off the first reading, whereby the Council and the European Parliament have an unlimited timeframe to come to a consensus on the piece of legislation. Though in principle the review takes place in parallel at both bodies, the Regulation has been progressing much faster at the European Parliament level, where it has been assessed by the Internal Market and Consumer Protection (IMCO), Employment and Social Affairs (EMPL) both of which issued a responsive opinion and the Environment and Social Affairs Committee (ENVI), responsible for the final report.

The opinions of IMCO and EMPL, along with their proposed amendments, were voted on 18 June and 21 June 2013, respectively. The passed amendments were then moved to the final text subject for review by the lead committee - ENVI. This vote, which occurred on 25 September 2013, thus included amendments from Members of the European Parliament (MEPs) sitting on the committee, those already approved by IMCO and EMPL, as well as 28 compromise amendments. From the early analysis, it is already clear that all of the IMCO amendments have been passed, as have all but one of the compromise amendments. Consolidated amendment 28, which did not receive approval in the ENVI Committee, dealt with the availability of clinical performance data, intending to introduce alignment with the medical devices report. This, and all other amendments which did not receive approval in ENVI, will not be included in the final report submitted for voting in the plenary session on 22 October 2013.

Prior to the plenary vote, the MEPs sitting on the ENVI Committee may submit additional amendments, as may a political group or a consensus of at least 40 MEPs. The deadline for the IVD Regulation amendments is currently set for 15 October.
If the Council agrees to the opinion of the European Parliament in full as made evident by a qualified majority vote, the legislative act is adopted. As this is rather unlikely due to the different areas of focus of the two bodies, the result will be a Position of the Council. This document is shared with the Parliament and European Commission, whereby a deadline for review is

introduced in order to facilitate an early agreement in the 2nd Reading. Considering the representation of the current EDMA position, it is critical that the Secretariat, with the help of the membership, continue working at both the European Parliament and Council levels to ensure that our interests are even better represented in any subsequent changes made to the text, enhancing both patient safety and industry innovation.