eurolab aisbl

The European Federation of National Associations of Measurement, Testing and Analytical Laboratories

Special Briefing No. 04 – April 2017

EUROLAB Special Briefing

Updates on the Votes in The European Parliament Plenary Session

During the first week of April, the European Parliament held its plenary session where MEPs discussed and voted on the several legislative texts, among which, the Regulations on In vitro Diagnostic Medical Devices (IVDR) and Medical Devices (MDR), Approval and Market Surveillance of Motor Vehicles and their Trailers and the Recommendation following the Inquiry into Emission Measurements in the Automotive Sector (EMIS).

Medical Devices

The European Parliament endorsed the new Regulations on In vitro Diagnostic Medical Devices and Medical Devices on Wednesday, 5 April 2017. The MEPs backed the stricter rules to ensure that medical devices such as breast or hip implants are traceable and comply with EU patient safety requirements; The laws to tighten up information and ethical requirements for diagnostic medical devices, e.g. for pregnancy or DNA testing, were approved as well by the MEPs. Both proposals had been informally agreed with the Council.

Among others, the rules provide for[1]:

- random inspections of producers' facilities after devices have been placed on the market,
- stronger post-market surveillance, more information to patients,
- stricter controls on notified bodies, which will have to employ medically skilled people,
- an additional safety checking procedure for high risk devices, such as implants or HIV tests. Not only a notified body, but also a special committee of experts, will check that all requirements are met,
- an "implant card" for patients, enabling patients and doctors to track which product has been implanted,
- clinical evidence of medical device safety to be provided by manufacturers (as for medicines), especially in the case of higher risk classes.

Source: http://www.europarl.europa.eu/news/en/news-room/20170329IPR69055/medical-devices-more-safety-more-traceability

Next steps

The official timings for the transition period start 20 days after the new laws are published in the Official Journal, expected in early May. This means that an official transition starting date is around 1st June. The medical devices regulation will be fully applicable three years after publication, and that on in vitro diagnostic medical devices five years after publication.

The European trade association representing the medical technology industries, from diagnosis to cure, MedTech Europe, mentioned in a Press Release published on Wednesday, 5 April 2017, that they welcome the final vote of the European Parliament endorsing the new Regulations on IVDR and MDR. *'Governing two different types of essential health technologies for citizens, for example blood screening tests (in vitro diagnostics) and pacemakers (medical devices), this vote is the last step in a near eight-year process to update legislation first written in the 90's.'*[2] http://www.medtecheurope.org/index.php/node/993

[1] European Parliament Press Release, *Medical devices: more safety, more traceability,* Plenary Session, Public health − 05-04-2017.

[2] MedTech Europe, Press Release, *EU Parliament adopts new diagnostics and medical device regulations, focus now shifts towards implementation,* 5 April 2017.

Automotive Emission Measurements

The European Parliament (EP) adopted the Recommendations of the Committee of Inquiry into the Emission Measurements in the Automotive Sector (EMIS) on Tuesday, 4 April 2017.

The key recommendations are[3]:

- all work on drafting on air quality and emissions legislation should be placed within the portfolio of a single Commissioner and Directorate-General, to improve oversight and focus,
- EU legislation on real driving emissions should be adopted swiftly, with tests covering a wide range of driving conditions, but also with non-predictable variations to detect illegal defeat devices,
- car buyers affected by the scandal should be financially compensated by the car manufacturers involved. The Commission should also propose rules for a collective harmonised EU redress system, strengthening consumer protection,
- new type approval rules should be adopted as quickly as possible, to introduce new EU oversight of the system, with clearly defined responsibilities.

Approval and market surveillance of motor vehicles and their trailers

In a separate vote, the European Parliament approved changes to the European Commission's proposal on the revising the type approval framework to strengthen the control of the work done by testing centres and national authorities who approve vehicles for sale.

Even though some MEPs expressed their support for the creation of an EU Vehicle Surveillance Agency, during the plenary vote the proposal of the Agency was rejected with 351 MEPs voting against and 309 in favour.

MEPs stated in their recommendations that, *"the European Commission and member states were already aware, more than a decade ago, that diesel cars' nitrogen oxide (NOx) emissions in laboratory tests differ markedly from those measured on the roads, they failed to act appropriately to protect air quality and public health."*[4]

According to the text, every year EU member states would have to test at least 20% of the car models placed on the market in their country in the previous year, and fines imposed by the Commission on car manufacturers who falsify test results could be up to €30,000 per vehicle. In addition to that, the revenue from the fines should be used to support market surveillance, benefit affected consumers or for environmental protection.

The amended type approval proposal was approved by 585 votes to 77, with 19 abstentions. The Council needs to agree its position on this file before trilogies with Parliament and Commission can start.

Source: http://www.europarl.europa.eu/news/en/news-room/20170329IPR69052/car-emissions-meps-urge-eu-commission-and-member-states-to-clean-up-their-act

Should you have any comments or questions, please do not hesitate to contact Laura Martin at laura.martin@eurolab.org or Zeynep Yildizeli at zeynep.yildizeli@eurolab.org

[3] European Parliament Press Release, Car emissions: MEPs urge EU Commission and member states to clean up their act – 04-04-2017

[4] Ibid