The European Association of Medical devices Notified Bodies

Team-NB Position Paper

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TRANSPARENCY

The MDR IVDR 2.0 proposal (https://health.ec.europa.eu/publications/proposal-regulation-simplify-rules-medical-and-vitro-diagnostic-devices_en) requests Notified Bodies to plan and conduct risk based and proportionate surveillance activities such as technical documentation assessments, PSUR reviews, unannounced audits and even to determine the certificate validity period.

Team-NB supports the goal to make surveillance proportionate, and risk based over the whole lifecycle under both MDR and IVDR. We propose that the intensity, frequency and modality of surveillance audits, unannounced audits, technical documentation sampling and batch testing can be adjusted based on objective, documented criteria such as incident history, PMS/Vigilance data, QMS maturity and effectiveness of corrective actions. We also welcome emphasis to simplify and make information available digitally. We welcome the Commission's proposal to meet these objectives while ensuring patient safety.

Risk-based regulatory oversight depends on timely access to comprehensive regulatory information. To exercise the greater discretion envisaged by the proposal, Notified Bodies must have access to the same high-quality information on safety, clinical performance and market experience that underpins proportionate regulatory decision-making.

However, Notified Bodies are currently lacking access to crucial information available in EUDAMED.

Current legislation only allows Notified Bodies access to the following modules for information related to the manufacturers that they work with:

- **Market Surveillance** (released in production in 2026) – module used by Competent Authorities for product non-compliance procedures – Notified Bodies have access to records related to their clients.
- **Vigilance** (available in playground, mandatory use planned in 2027) – module dedicated for manufacturers' reporting (MIR, FSCA, FSN, PSUR, MTR, PSR). Notified Bodies should have access to reports uploaded by their clients.
- **Clinical Investigation / Performance Studies** (module under development, not available yet in playground). Notified Bodies should have access to investigations / studies when a CE marked device from a manufacturer that they work with is used.

Providing Notified Bodies with direct access to these systems would create a single, authoritative source of safety, performance and state of the art information, would enable a more efficient, risk-based oversight and reducing the need to consult multiple national and international databases. Today, Notified Bodies devote considerable resources to identifying

and evaluating information on device safety, including incident characteristics, affected components, root causes, patient outcomes, and the frequency of similar events.

Beyond initial certification, Notified Bodies play a critical role in post-market surveillance, determining the scope and timing of surveillance activities and assessing whether new information affects the validity of issued certificates. To fulfil these responsibilities, Notified Bodies audit manufacturers, suppliers and subcontractors, review scientific and clinical evidence, and monitor vigilance data to remain current with the he generally acknowledged state of the art.

On going clinical investigations and performance studies provide an additional and indispensable source of evidence. These studies may reveal rare adverse events and help establish the evolving state of the art by informing comparison with benchmark devices, available therapeutic alternatives, accepted clinical practice, and advances in technology and patient management.

A single, integrated source for incident reports and ongoing clinical investigations / performance studies would substantially reduce the time and effort for both initial and ongoing conformity assessment throughout a device's lifecycle. Increasing the efficiency of conformity assessment and surveillance activities, would help ensure that patients gain timely access to safe, novel, and innovative medical devices while preserving robust regulatory oversight and public confidence.

To enable Notified Bodies to fulfil these enhanced responsibilities effectively and consistently, the legal framework should provide direct access to the relevant electronic regulatory systems.

We therefore propose the following amendment to MDR Article 106, that we think will support these objectives for both MDR and IVDR Notified Bodies:

The EMA **and the Notified Bodies** shall have access to EUDAMED and any electronic system referred to in Article 33(2) or Regulation EU 2017/745 or Article 30(2) or Regulation EU 2017/746 that is not included in EUDAMED.

The table below illustrates the fragmented nature of current vigilance and safety communications across jurisdictions, highlighting the need for a single, European, integrated source of information accessible to Notified Bodies.

Country	**Vigilance**	**Information to Healthcare Professionals / Patients**
Australia	Australia's Therapeutic Goods Administration (TGA) has a publicly visible database called Database of Adverse Event Notifications (DAEN). Visible to the public for medicines since 1971 and for medical devices since 2012.	Information about all devices on the market and a summary including manufacturer, classification, nomenclature, intended purpose and some information on how the device got to market is visible to the public. This can be further refined to search specific to

	https://www.tga.gov.au/safety/adverse-events/database-adverse-event-notifications-daen	biologicals, medical devices, medicines or other therapeutic goods. https://www.tga.gov.au/resources/artg Australia makes clinical trials visible to the public. Australian Clinical Trials https://www.anzctr.org.au/
Brazil	Brazil's National Health Surveillance Agency (ANVISA) has a digital portal for reporting pharmacovigilance and technovigilance. eNotivisa has collected medical devices adverse events since 2006. There is some information visible to the public in Portuguese. https://enotivisa.anvisa.gov.br/perfil	Information about all devices on the market is visible to the public. https://consultas.anvisa.gov.br/#/saude/ Brazil makes clinical trials visible to the public; however the information is limited to what can be reviewed. https://www.gov.br/anvisa/pt-br/assuntos/produtosparasaude/pesquisa-clinica Consultas - Agência Nacional de Vigilância Sanitária
Canada	Health Canada has a publicly visible database for pharmaceuticals and medical devices. Mandatory Problem Reports for MD have been visible to the public since 2014. https://hpr-rps.hres.ca/mdi_landing.php	Regulatory Decision Summaries including pre-market approvals and scientific rationales behind safety decisions are visible to the public. https://dhpp.hpfb-dgpsa.ca/review-documents Canada makes clinical trials visible to the public. https://clinical-information.canada.ca/search/ci-rc
Japan	Japan's Pharmaceutical and Medical Devices Agency (PMDA) has a publicly visible database for adverse events. This is available in Japanese language.	Information about devices on the market, classification, intended use, nomenclature, safety information, materials, risks and many other details are made visible to the public.

	These are categorised by Yellow Letter (Emergent Safety Communications) or by Blue Letter (Rapid Safety Communications). https://www.pmda.go.jp/english/search_index.html	https://www.pmda.go.jp/english/search_index.html https://www.pmda.go.jp/PmdaSearch/kikiSearch/ In Vitro Diagnostic Pharmaceuticals Package Insert Information Search | Pharmaceuticals and Medical Devices Agency Japan makes clinical trials visible to the public. https://jrct.mhlw.go.jp/search?language=en
USA	Incidents in the USA are called Medical Device Reports (MDRs). Manufacturer and User Facility Device Experience (MAUDE) database has made MDRs visible to the public since 1993. In 2026 an updated database called Adverse Event Monitoring System (AEMS) was launched with even more visible to the public. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm	US FDA make all devices available on the market visible to the public through a number of databases. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases It is possible to see the regulatory decision making for all devices. 510k https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm PMA https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm De Novo https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm Humanitarian Device Exemption

		https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm USA makes clinical trials visible to the public. https://clinicaltrials.gov/
Singapore	Singapore's Health Sciences Authority (HSA) has a publicly visible database for Medical Devices Adverse Events since 2010. https://share.hsa.gov.sg/medics/PublicListing/Smdr	The Singapore Medical Device Register (SMDR) makes information on all devices, classification, manufacturer and nomenclature visible to the public. https://www.hsa.gov.sg/ Clinical Trials are registered and visible to the public. https://clinicaltrials.sg/about-us#ctsg
South Korea	Korea's Ministry of Food and Drug Safety (MFDS) make Adverse Events visible through a portal called Korea Patient Safety Reporting & Learning System (KOPS). https://www.koiha-kops.org/main.do	The Integrated Medical Devices Information System makes information on devices and is very valuable tool for all user of the platform. It separates information out by digital medical device information, clinical trial approval status. Medical devices subject to tracking requirements, current supply status of medical devices and also gives an overview of medical devices subject to recall! https://emedi.mfds.go.kr/ Clinical Trials are registered and visible to the public through the Clinical Research Information Service (CRIS). https://cris.nih.go.kr/cris/search/listDetail.do