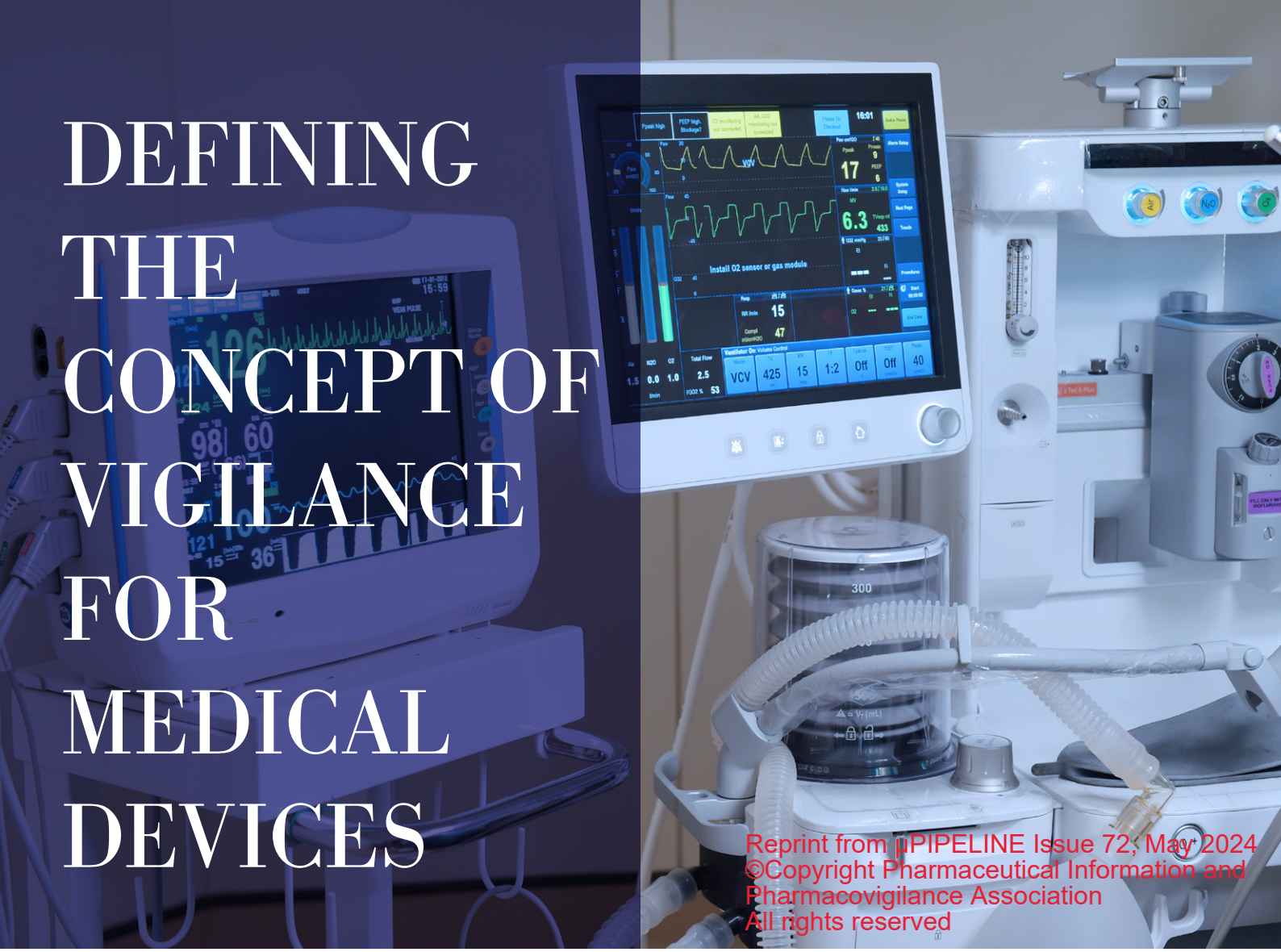
DEFINING THE CONCEPT OF VIGILANCE FOR MEDICAL DEVICES



The concept of 'vigilance', as it applies to medical devices, relates to the identification, reporting and trending of serious incidents as well as any corrective actions related to safety[1]. It is distinct but related to the supporting post-market surveillance processes which focus on the monitoring of information to provide periodic confirmation that the benefit of a medical device outweighs the risk. These are not new concepts, however the requirements for vigilance and post-market surveillance were not clearly delineated or articulated within the original Medical Device Directive (MDD) or In Vitro Diagnostics Directive (IVDD).

With the introduction of the European Medical Device Regulations (MDR 2017/745)[2] and In Vitro Diagnostic Regulations (IVDR 2017/746)[3], it appears that the regulator has taken inspiration from its pharmaceutical counterpart with regards to definitions. Now, both MDR and IVDR more clearly specify the requirements for both the post-market surveillance processes and outputs, as well as implementing stricter reporting requirements and increasing the visibility of manufacturers' reports of device performance and safety[4].

In particular, knowledge of the two industries finds that the post-market practices for pharmaceuticals and medical devices share the following common features:

- Requirement for receipt, triage and quality, clinical (medical) and/or regulatory assessment of complaints and incidents for reportability determination.
- Establishment and definition of processes and workflows for post-market surveillance activities.
- Vigilance activities to detect emerging negative trends. For example, increases in frequency or severity of incidents.
- Requirement for Periodic Safety Update Reports (PSURs[5]).
- Upload of PSURs to a centralised database (EUDAMED[6]).
- Risk-based approach.

However, there are also some key differences. Of particular note is that for medical devices, the manufacturer is required to establish, within a degree of certainty, whether an adverse event or incident is related to, or is likely to be related to, the use of the device[7]. This informs the decision of reportability. This is in contrast to pharmaceuticals, which do not require the establishment of the causal relationship to necessitate reportability[8]. In addition, the pathways and timelines for reporting of incidents and vigilance activities are also unique for pharmaceuticals and medical devices.

These differences are primarily a factor of the inherent differences in the mode of action between pharmaceuticals and devices (chemical/pharmacological versus physical), which can make it impossible to definitively confirm a causative relationship between a drug and an event[8]. Despite the differences, the aim of medical device vigilance and pharmacovigilance remain the same – to improve patient care and ensure the ongoing safety of pharmaceuticals and medical devices to end users.

The changes to post-market surveillance and vigilance processes for medical devices also addresses some of the concerns and limitations of the previous regulatory framework.

Under the medical device and IVD directives, the focus for notified bodies was on ensuring that manufacturers had available sufficient data to support the positive benefit to risk ratio for their devices, with little emphasis or definition as to how this was intended to be monitored and maintained over time.

The updated regulations aimed to specifically address this with the introduction of the post-market surveillance processes of post-market clinical follow-up (PMCF) for medical devices and post-market performance follow-up (PMPF) for IVDs, as well as periodic safety update reports (PSURs)[9],[10]. These processes aim to ensure that products are made available to the end user in as timely a manner as possible, whilst still allowing the regulator to ensure the continued collection of data to support ongoing monitoring of the risk/benefit profile of the products. The overall objective is improved patient treatments and outcomes, as well as ensuring that users have access to the latest technology without compromising patient or user safety.

Although Europe is taking a lead with medical device vigilance and post-market monitoring, post-market oversight of medical devices amongst other global regulators has intensified, with many adopting more stringent processes and requirements to provide assurance of the safety and effectiveness of medical devices[11,12].

The definition and standardisation of the terms within vigilance and post-market surveillance processes across jurisdictions remains limited. However, the concept for ongoing monitoring and reporting of device incidents is largely the same.

The challenge now is for manufacturers to adopt and implement vigilance and post-market processes that address the variabilities between requirements, as well as staying on top of the ever-evolving global regulations.

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