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General Secretariat

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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Medical Devices)
N° prev. doc.:	ST 7254/26
N° Cion doc.:	ST 16919/25 + ADD 1
Subject:	Regulation to simplify rules on medical and in vitro diagnostic devices - Commission presentation on cluster 4 - Post-market surveillance, vigilance and generation and documentation of evidence

Delegations will find in annex the presentation by the Commission services at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 21 May 2026.

MDR/IVDR revision
Commission Proposal

DG SANTE Unit D3, Medical devices



European Commission

#HealthUnion

Agenda – Cluster 4

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1. Post-market surveillance and vigilance

Topics: PMS, PSUR, vigilance reporting, reporting of actively exploited vulnerabilities and severe cybersecurity incidents, analysis of vigilance reports, trend reporting (Legal references: MDR+IVDR: Chapter VII, Sections 1 and 2, Annex III)

2. Generation and documentation of evidence

Topics: clinical evidence, clinical evaluation, clinical investigations, non-clinical data, clinical data, SSCP, PMCF, combined studies, technical documentation (Legal references: MDR: Article 2(48) and (73), Article 32, Chapter VI, Annex II, Annexes XIV-XV; IVDR: Article 2(75))

Revision of the medical devices regulations

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Overall objective of the MDR / IVDR revision:

Simplify the rules to **reduce administrative burden,** increase **predictability, shorten processes, improve cost-efficiency and effectiveness**, while keeping the **high level of patient safety** and **ensuring the availability** of devices.



- Revision proposal (covering MDR/IVDR, their annexes)
- supported by two Staff Working Documents: targeted evaluation and cost-savings analysis

The revision will make the sector **more competitive,** in the internal market and globally, **by supporting innovation for better patient care.**

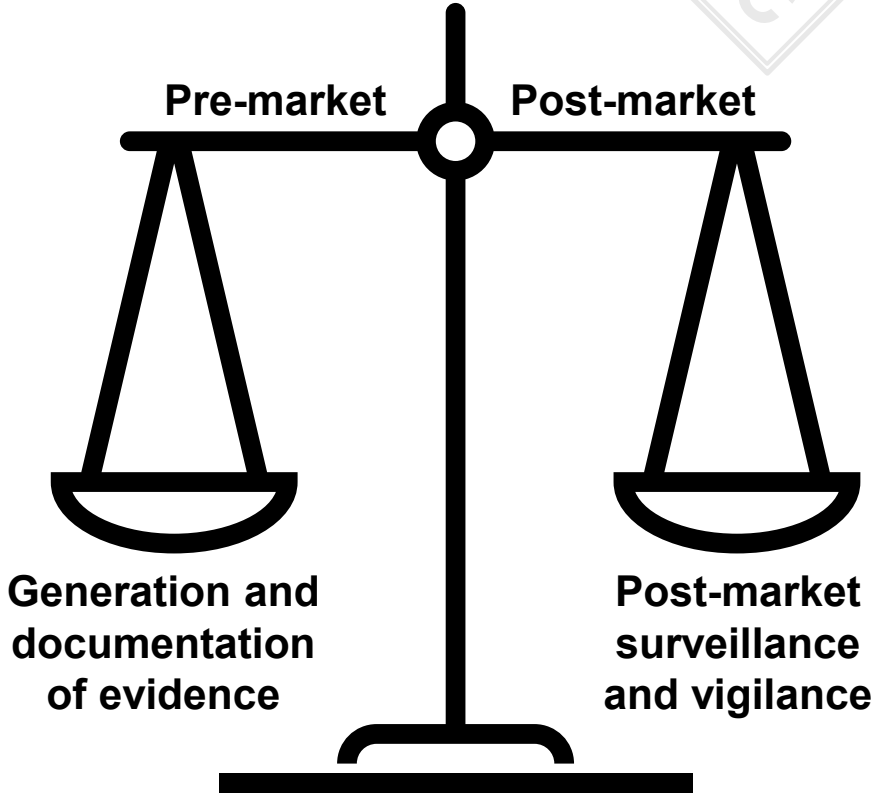
Need for proportionate pre- & post- market provisions

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- €125k–1.5M for establishing clinical evidence[1]

↓

- Disproportionate requirements for low- and medium-risk class devices
- Decreased competitiveness of the EU for clinical research



- > 20% increase in serious incident reporting, but >1% increase in field safety corrective actions[2]
- Cost per report: 200-600€ → Aggregated cost: €50M[1]
- Unclear responsibilities and duplication of work between NCAs and NBs

↓

- Increased administrative burden and inefficiency

[1] Data from the Cost-Savings Analysis.

[2] Data from the targeted national competent authority survey as part of the Targeted Evaluation.

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Post-market surveillance and vigilance

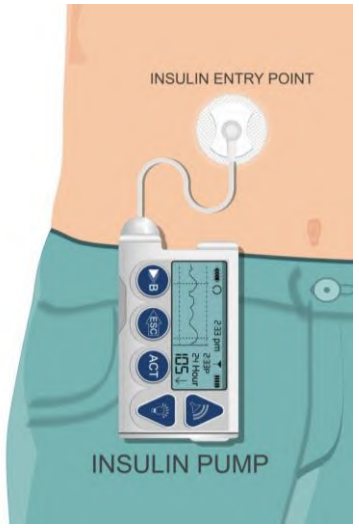
Legal reference: Chapter VII, Article 83 MDR/ 78 IVDR

Post-Market Surveillance (PMS) System

*'**post-market surveillance**' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.*

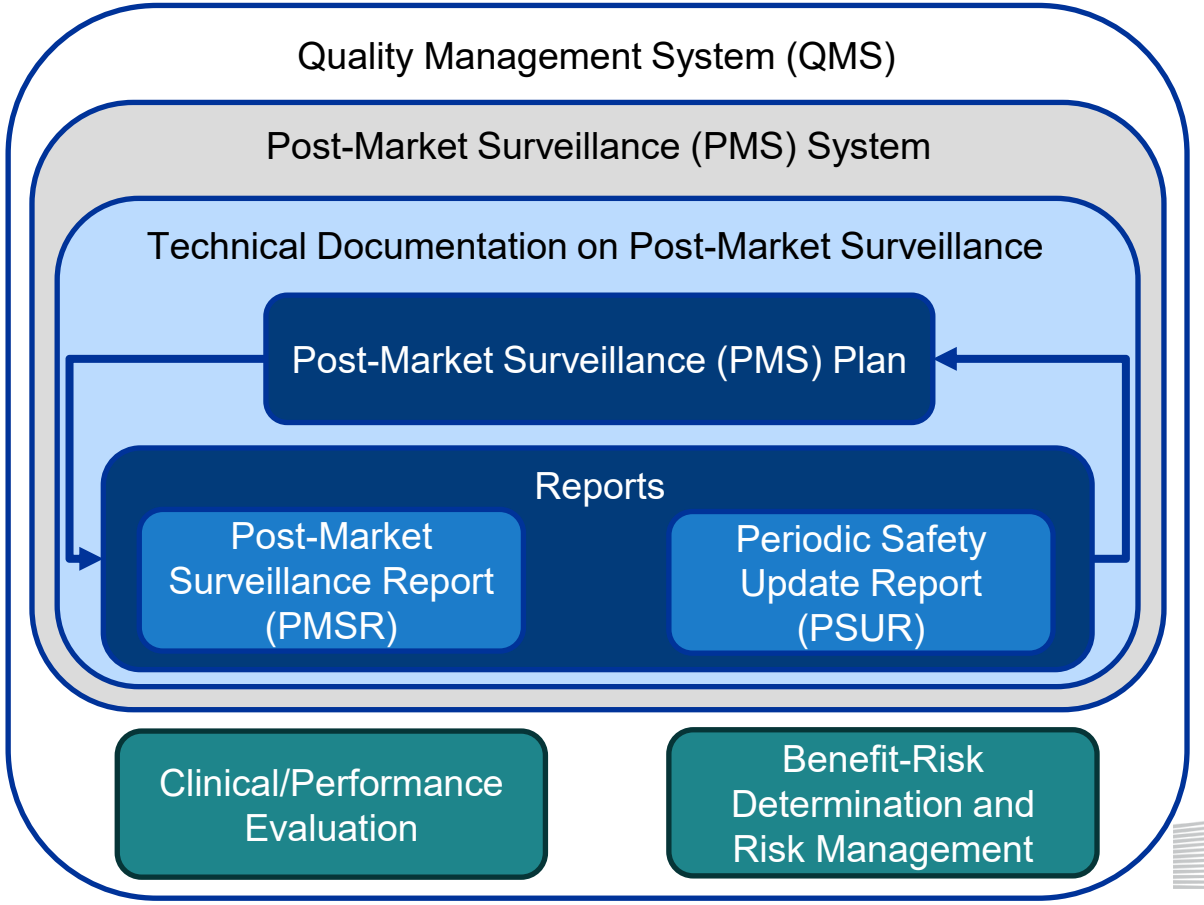
Article 2(60) MDR/ 2(63) IVDR

Manufacturer



Insulin pump
(with software component)

CE xxxx



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Adapted from Figure 1 in MDCG 2025-10 Guidance on post-market surveillance of medical devices and in vitro diagnostic medical devices. December 2025.

Post-Market Surveillance and Vigilance Reporting

Table of Contents

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Reports	Proposed changes
• Periodic Safety Update Reports (PSURs)	• Scope, frequency and evaluation
• Post-Market Surveillance Reports (PMSRs)	• None
• Serious incident reports	• Timelines
• Trend reports	• Scope
• Corrective and Preventive Actions (CAPAs)	• Scope
• Field Safety Corrective Actions (FSCAs)	• None

"whilst the increase in reporting reflects an increased capacity to detect and potentially manage emerging safety risks, it remains challenging to assess whether any evolution observed reflects changes in device safety or only on reportability"[1]

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[1] Evaluation findings in effectiveness for post-market surveillance and vigilance from the Targeted Evaluation.

Legal reference: Chapter VII, Article 86 MDR/ 81 IVDR

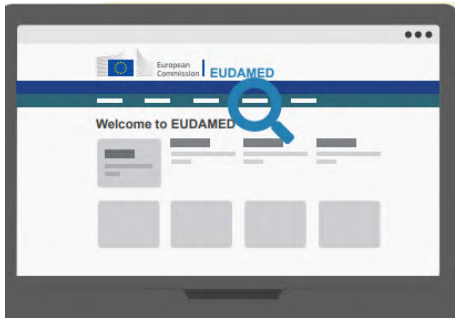
Periodic Safety Update Report (PSUR)

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The PSUR **summarises** the results and conclusions of the **analysis** of the post-market surveillance **data gathered** as a result of the Post-Market Surveillance Plan[1].

Minimum content:

a) the conclusions of the benefit-risk determination;
b) the main findings of the Post-Market Clinical Follow-up (PMCF); and
c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.



PSURs which have been linked to actions taken by a notified body[2]:

- 2022: 14
- 2023: 1
- 2024: 1

[1] MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 (MDR). December 2022.
[2] Data from the targeted national competent authority survey as part of the Targeted Evaluation.

Legal reference: Chapter VII, Article 86 MDR/ 81 IVDR

Periodic Safety Update Report (PSUR)

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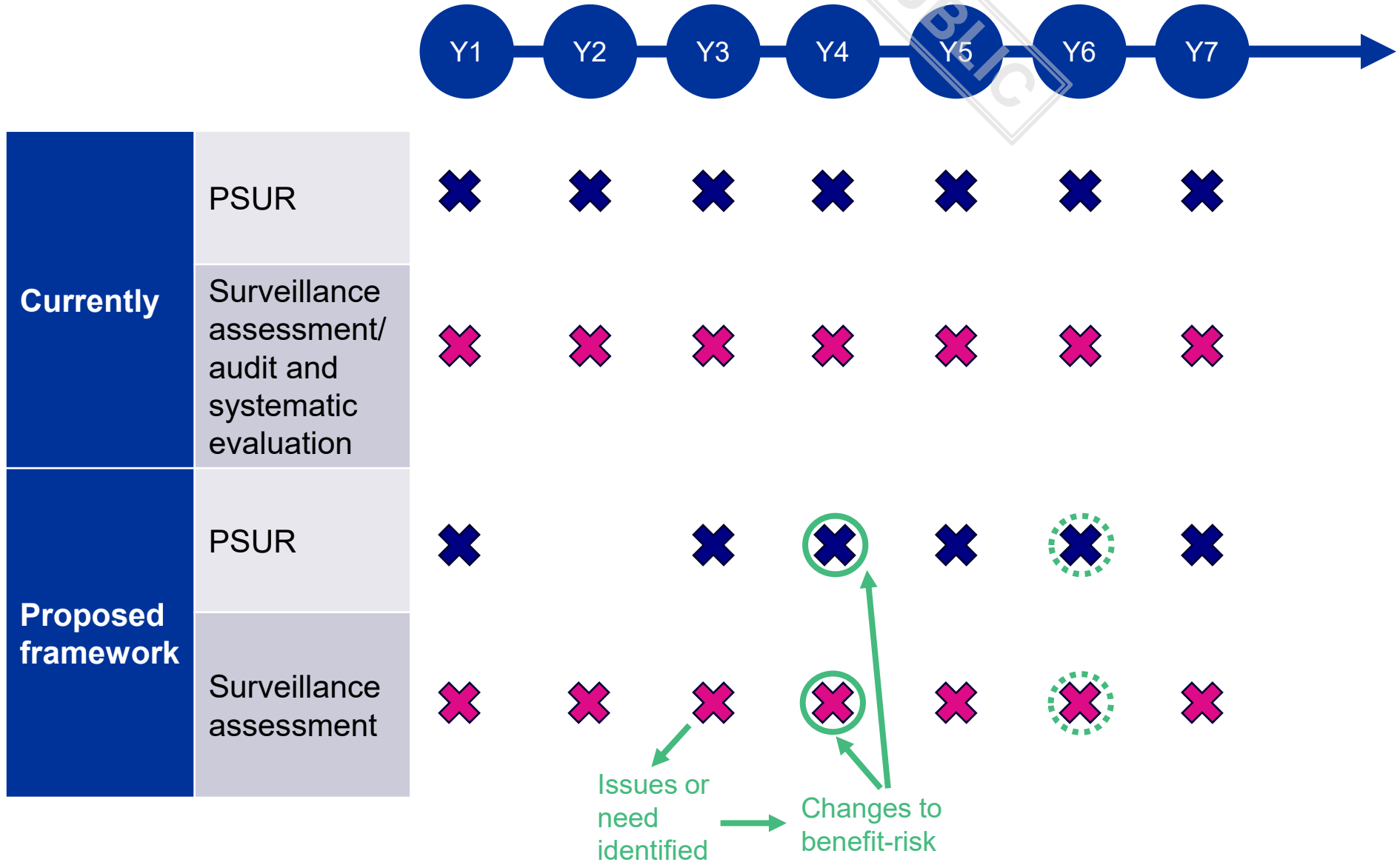
Topic	Risk class	Currently	Proposed changes
Frequency	Class IIb & III MDs Class C & D IVDs	Annually	First year and every two thereafter or when significant change
	Class IIa MDs	Every two years	When necessary
Evaluation			

Note: custom-made devices and well-established technology devices are removed in the proposed changes.

Legal reference: Chapter VII, Article 86 MDR/ 81 IVDR

Periodic Safety Update Report (PSUR)

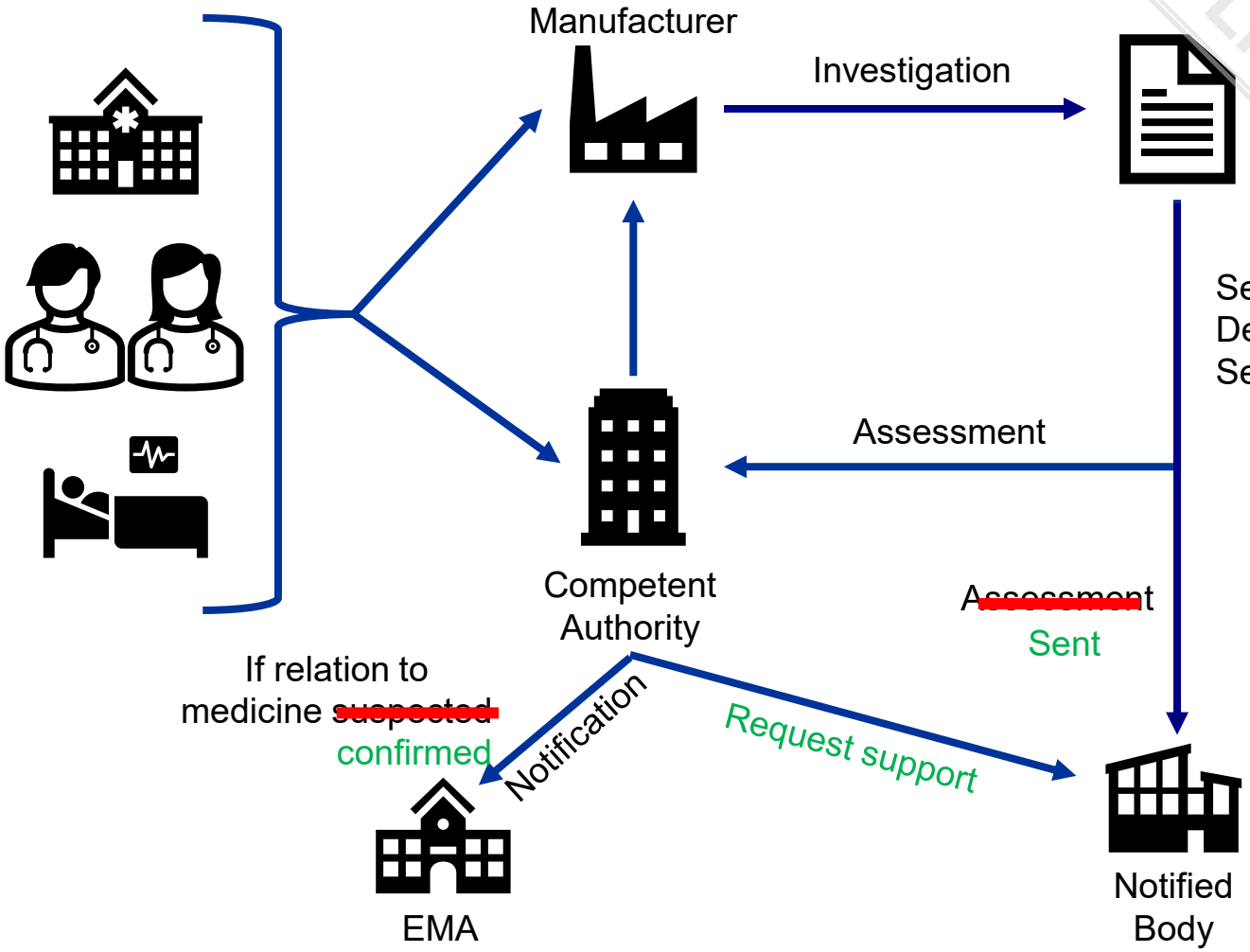
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Legal reference: Chapter VII, Article 87 MDR/ 82 IVDR

Vigilance Reporting

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Serious public health threat	2 days
Death	10 days
Serious deterioration	~~15 days~~ 30 days

~150,000
serious incidents reported in the EEA in 2024[1]

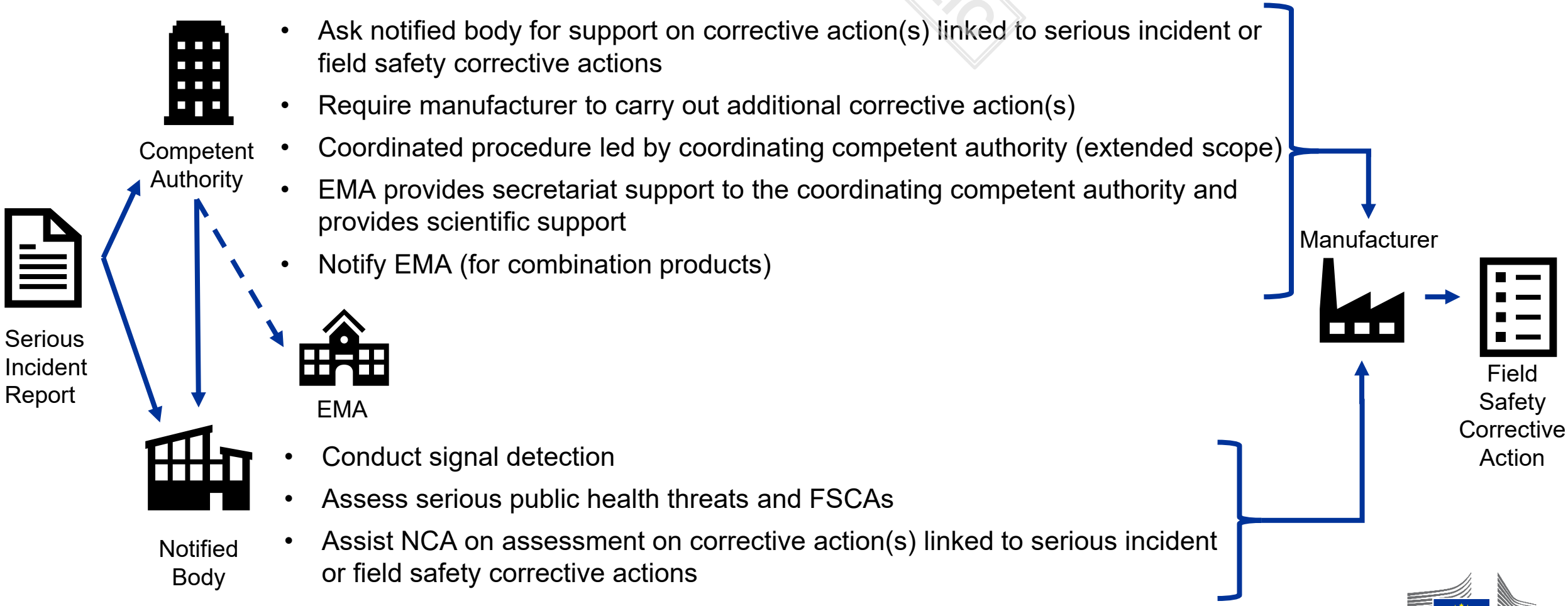
13.5%
of manufacturers had submitted at least one report in the previous 3 years that, after further analysis, demonstrated not to fulfil the vigilance reporting requirements

[1] Data from the targeted national competent authority survey as part of the Targeted Evaluation.
[2] Data from the public consultation as part of the Targeted Evaluation.

Legal reference: Chapter VII, Article 89 MDR/ 84 IVDR

Analysis of Vigilance Reports

PUBLIC



- Ask notified body for support on corrective action(s) linked to serious incident or field safety corrective actions
- Require manufacturer to carry out additional corrective action(s)
- Coordinated procedure led by coordinating competent authority (extended scope)
- EMA provides secretariat support to the coordinating competent authority and provides scientific support
- Notify EMA (for combination products)

- Conduct signal detection
- Assess serious public health threats and FSCAs
- Assist NCA on assessment on corrective action(s) linked to serious incident or field safety corrective actions

Trend Reporting

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MDR:

Manufacturers shall report […] any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 8 of Annex I ~~**and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits**~~.

IVDR:

Manufacturers shall report by means of the electronic system referred to in Article 87 any statistically significant increase in the frequency or severity of incidents that are not serious incidents that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 8 of Annex I ~~**and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons**~~ or of any significant increase in expected erroneous results established in comparison to the stated performance of the device as referred to in points (a) and (b) of Section 9.1 of Annex I and specified in the technical documentation and product information.

e.g. redness (erythema), itching, skin swelling, bruising, skin dryness, bleeding at insertion site

Cybersecurity Reporting

PUBLIC

- **Actively exploited vulnerabilities** (Art. 3(42) CRA):
  - *'vulnerability'* means a **weakness**, **susceptibility** or **flaw** of a **product** with digital elements that can be exploited by a cyber threat;
  - *'actively exploited vulnerability'* means a vulnerability for which there is reliable evidence that a **malicious actor** has exploited it in a system without permission of the **system** owner.

- **Severe incidents** (Art. 14(5) CRA):

  an incident having an impact on the security of the product with digital elements shall be considered to be severe where:

  a) it **negatively affects** or is capable of negatively affecting the **ability** of a product with digital elements **to protect** the availability, authenticity, integrity or confidentiality of sensitive or important **data** or **functions**; or

  b) it has led or is capable of leading to the **introduction** or **execution** of **malicious code** in a product with digital elements or in the network and information systems of a user of the product with digital elements.

		MDR/IVDR	
		Incident	**Serious Incident**
CRA	**Actively Exploited Vulnerability**	Third-person accessing technical logs from insulin pump without affecting device functionality	Third-person connecting to insulin pump and controlling dosage
	Severe Incident	Third-person extracting personal data from insulin pump	Third-person connecting to insulin pump and changing the dosage algorithm code

All reported in Eudamed and sent to the relevant responsible authority(ies);



Generation and documentation of evidence

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Legal reference: Chapter VI, Article 61 MDR

Clinical Evaluation & Clinical Evidence

PUBLIC

- Manufacturers shall plan, conduct and document a **clinical evaluation** to:
  - confirm the safety and performance of the device under normal conditions;
  - evaluate any undesirable side-effects;
  - evaluate the acceptability of the risk-benefit ratio.
- For this, manufacturers shall specify and justify the appropriate level of **clinical evidence** in view of:
  - device characteristics;
  - intended purpose.
- Clinical evidence is based on sufficient amount and quality **clinical data** and **clinical evaluation results**.

Currently		Proposed changes
• Documentation on clinical evaluation is updated yearly (Art. 61(11) MDR).	=	• Documentation on clinical evaluation is updated when relevant (proposed Art. 61(11) MDR).
• Annex XIV implementing acts for divergences in interpretation and practical application (Art. 61(13) MDR).		• Annex XIV implementing acts for divergences in interpretation and practical application (Art. 61(13) MDR).
		• Annex XIV delegated acts to adapt to scientific and technical progress and for international convergence (proposed Art. 61(14) MDR).
		• Removal of separate PMCF evaluation report.

Clinical Data

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Current wording	Proposed wording
'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from the following:	
clinical investigation(s) of the device concerned,	clinical investigations of the device concerned or of a device for which equivalence to the device concerned can be demonstrated,
clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,	other studies published in scientific literature on the device concerned or of a device for which equivalence to the device concerned can be demonstrated,
reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,	other clinical experience published in peer-reviewed scientific literature with the device concerned or a device for which equivalence to the device concerned can be demonstrated,
clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up.	clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up.

Note: the definition of 'clinical evidence' in Article 2(51) MDR has not changed.

Equivalence

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A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence:

- **Technical**: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements;
- **Biological**: the device uses the same or similar materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;
- **Clinical**: the device is used for the same or similar clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

Note: the definition of ‘clinical evidence’ in Article 2(51) MDR has not changed.

Non-Clinical Data

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Without prejudice to paragraph 4, where the ~~**demonstration of conformity with general**~~ **confirmation of** safety and performance ~~**requirements**~~ based on clinical data is not deemed appropriate, adequate justification ~~**for any such exception**~~ shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer **and the data available for the generic device group**. In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance 93 requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing, **in vitro**, **ex vivo**, **in silico testing**, **computational modeling or simulation** and pre-clinical evaluation, to be adequate.

Note: these non-clinical testing methods have also been included in the proposed Annex II, MDR.

Legal reference: Chapter VI, Article 61(1) & (10) MDR

Use of Non-Clinical Data

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Current wording

Article 61(1): […] That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

Article 61(10): Without prejudice to paragraph 4, where the **demonstration of conformity with general** safety and performance **requirements** based on clinical data is not deemed appropriate, adequate justification for **any such exception** shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer. In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing, and pre-clinical evaluation, to be adequate.

e.g. spinal anaesthesia needle, scalpel

Proposed wording

Article 61(1): That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose, **taking into consideration paragraph 10**.

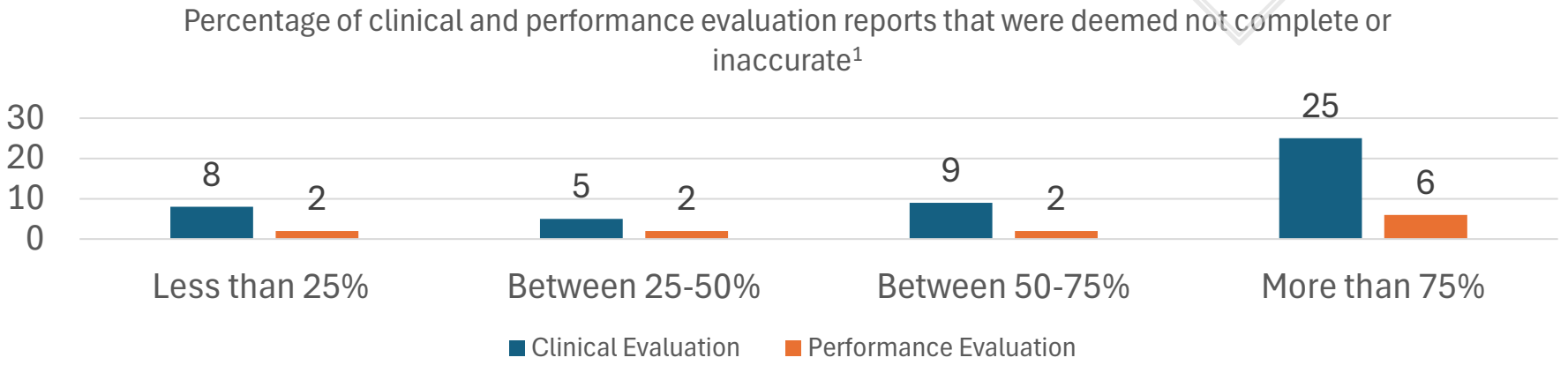
Article 61(10): Without prejudice to paragraph 4, where the **confirmation of** safety and performance based on clinical data is not deemed appropriate, adequate justification shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer **and the data available for the generic device group**. In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing, **in vitro, ex vivo, in silico testing, computational modeling or simulation** and pre-clinical evaluation, to be adequate.

Legal reference: Chapter VI, Article 61(2)

Voluntary Consultation to Expert Panels

PUBLIC

Review of the manufacturer's intended clinical development strategy or proposals for clinical investigation.



29

Advices from the expert panels[2]

Currently

- Voluntary by the manufacturer
- For class III and IIb active implantable devices
- Consideration only by the manufacturer
  - Clinical Evaluation Report (CER)

Proposed changes

- Voluntary by the manufacturer
- For class III and IIb devices, and class C and D IVDs
- Consideration by manufacturer and notified body
  - Clinical Evaluation Report (CER)
  - Clinical Evaluation Assessment Report (CEAR)
- Justify when advice not followed

[1] Data from the targeted notified body survey as part of the Targeted Evaluation.

[2] Pilot on the Advice from the Expert Panels to Manufacturers of High-Risk Medical Devices. Interim report.

Legal reference: Chapter VI, Article 61(4), (5) and (6) MDR

Mandatory Clinical Investigations

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Currently

- Class III devices
- Implantable devices
- Exemptions:
  - Legacy devices
  - WET
  - Equivalent devices with contract giving full access to technical documentation

For which there is sufficient clinical evidence

Proposed changes

- Class III devices
- Class IIb implantable devices
- Exemptions:
  - Legacy devices
  - WET
  - Equivalent devices

For which there is sufficient clinical evidence

In practice

- Class IIa implantable devices no longer require mandatory clinical investigations. → The majority of Class IIa implantable devices are in dentistry.
- A manufacturer may rely on the clinical evaluation of an equivalent device provided it was performed in compliance of the MDR and there is clear evidence for the notified body.
- However, clinical investigations must still be conducted if the clinical evaluation does not contain sufficient clinical evidence.

Clinical Investigations

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Currently		Proposed changes
• To demonstrate conformity *(Art. 62 MDR/ 57&58 IVDR)* a) Intended purpose and performance b) Clinical benefits c) Clinical safety, undesirable side-effects, and risk-benefit	=	• To demonstrate conformity *(Art. 62 MDR/ 57&58 IVDR)* a) Intended purpose and performance b) Clinical benefits c) Clinical safety, undesirable side-effects, and risk-benefit
• Post-Market Clinical(/Performance) Follow-up (PMCF/PMPF) *(Art. 74 MDR/ 70 IVDR)*	=	• Post-Market Clinical(/Performance) Follow-up (PMCF/PMPF) *(Art. 74 MDR/ 70 IVDR)*
• Others *(Art. 82 MDR)*		
• Special populations *(Art. 64 MDR, 65 MDR, 66 MDR, 68 MDR/ 64 IVDR)* • Direct benefit for the individual subjects		• Special populations *(Art. 64 MDR, 65 MDR, 66 MDR, 68 MDR/ 64 IVDR)* • Direct benefit for the individual subjects *or* • Benefit for the patient population

Legal reference: Chapter VI, Articles 79a MDR/ 75a IVDR

Combined Studies

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'combined study' means a clinical trial[1] of one or more medicinal products, combined with a performance study of one or more *in vitro* diagnostic medical devices, and/or with a clinical investigation of one or more devices;

Medicine Clinical Trial + Medical Device Clinical Investigation + *In Vitro* Diagnostic Performance Study

Currently

- Application for clinical trial under CTR
- Application for clinical investigation under MDR
- Application for performance study under IVDR

Proposed changes

- Single application under Article 14c CTR (as proposed in the Biotech Act[2])

[1] As defined in Article 2(2), point (2), of Regulation (EU) No 536/2014 (Clinical Trials Regulation, CTR).
[2] Proposal for a Regulation to establish measures to strengthen the Union's biotechnology and biomanufacturing sectors (European Biotech Act).

Legal reference: Article 32 MDR

Summary of Safety and Clinical Performance (SSCP)

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"The SSCP is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of the medical device.

The SSCP is not intended to:

- *give general advice on the diagnosis or treatment of particular medical conditions, nor*
- *replace the instructions for use (IFU) as the main document that will be provided to ensure the safe use of a particular device, nor*
- *replace the mandatory information on implant cards or in any other mandatory documents."*[1]

Currently

- Implantable and class III devices
  (custom-made and investigational devices exempted)
- For intended user and patient, if relevant
- Validated by the notified body during conformity assessment
- Uploaded to Eudamed by the notified body

Proposed changes

- Class IIb implantable and class III devices
  (custom-made, investigational and WET exempted)
- For intended user only
- No separate validation but reviewed by notified body during conformity assessment
- Uploaded to Eudamed by the manufacturer

[1] MDCG 2019-9 Rev. 1 Summary of safety and clinical performance: A guide for manufacturers and notified bodies. March 2022.

Annex II MDR

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- Clarification that technical documentation includes the clinical evaluation plan, and that the PMCF is already included in the clinical evaluation plan/report (Section 6.1(c) and (d), Annex II, MDR).

- Update *'tissues or cells of human origin'* to *'substances of human origin'* (Section 6.2(b), Annex II, MDR).

- Clarification of documentation requirements for integral MD-IVD devices (Section 6.2(h), Annex II, MDR).

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