ARTICLE

The Complete Guide to **Article 10a Compliance and Mastery**

By AKRA TEAM

10a

EU MDR & IVDR insider

Inaugural Issue - **January 2025**

January 2025

UPDATE

Welcome to the Inaugural Issue of EU MDR & IVDR Insider, January Update by Bassil Akra, PhD

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Recording of the Article 10a Webinar including *full transcript and slides*

Q&A

Top 10 Questions Submitted by the Audience During the Article 10a Webinar

UPCOMING

EU Orphan Devices: Regulatory Pathway and Clinical Evidence Requirements - Register Now

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UPDATE

Welcome to the Inaugural Issue of EU MDR & IVDR Insider

By Bassil Akra, PhD

This month, the spotlight is on Article 10a, a critical regulatory requirement effective January 10th, 2025. At its core, Article 10a aims to safeguard the European healthcare system by ensuring proactive communication about device supply interruptions or discontinuations.

But beyond compliance, there is a significant strategic opportunity for manufacturers to demonstrate leadership in regulatory readiness and patient safety.

As Erik Vollebregt said during the webinar:

> *This provision isn't just about compliance—it's an opportunity for manufacturers to showcase their commitment to healthcare system continuity, gaining trust and positioning themselves competitively.*

What's Happening with EU MDR and IVDR?

December 2024 brought some key developments shaping the regulatory landscape:

European Commission
Launch of Public Consultation and Call for Evidence for EU Medical Devices Evaluation (December 12, 2024): The European Commission initiated a public consultation to gather feedback on the performance of the medical device regulations and seek input from stakeholders to inform future policy decisions.

MDCG
Manufacturer Information Form on Interruption or Discontinuation of Supply (MDCG 2024-16) (December 6, 2024): The MDCG released guidance to assist manufacturers in notifying authorities about interruptions or discontinuations in the supply of certain medical devices and in vitro diagnostic devices, aiming to ensure transparency and maintain device availability.

MedTech Europe
Post-EPSCO Statement on MDR/IVDR Reforms (December 4, 2024): Following the Health Council (EPSCO) meeting on December 3, 2024, MedTech Europe emphasized the urgent need for reforms in the MDR and IVDR frameworks.

Looking Ahead

The European Parliament is expected to debate MDR revisions in the coming months, focusing on balancing innovation and patient safety. These discussions could reshape the regulatory landscape and provide much-needed relief for manufacturers navigating CE marking challenges.

Bassil Akra

PS Don't miss the **EU Orphan Devices** webinar on January 21st

FEATURE

What You Need to Know about Article 10a

By Lawrence Yeh

To mitigate risks to public health because of medical device shortages, the MDR and IVDR now requires additional requirements in a soon-to-be infamous “Article 10a.” Here is what you need to know about it, and what you need to have done yesterday, to comply with the amended regulations.

What is the scope of Article 10a?

Article 10a applies to all devices under the MDR / IVDR, except custom-made devices, which have been placed on the Union market; this includes legacy devices. There are 2 scenarios in which manufacturers need to assess the need to inform certain stakeholders:

1. There is a temporary inability or unwillingness on the manufacturer’s part to place a device on the market (60+ days as a guideline but not a strict rule) AND this supply interruption could result in serious harm to patients or public health, or…
2. The manufacturer will permanently stop placing a device on the market AND this discontinuation could result in serious harm to patients or public health.

The overall picture

At a high level, Article 10a essentially creates a communication chain, where each stakeholder must inform the next stakeholder of anticipated (that is, reasonably foreseeable) product interruptions or discontinuations.

Not all interruptions or discontinuations – specifically those that could result in serious harm (or even just risk of serious harm) to patients or public health.

The manufacturer of devices placed on the union market informs the competent authority of their Member State where the manufacturer is located. There is a form for this, MDCG 2024-16. If the manufacturer is outside the EU, then it is the competent authority where the authorised representative is located. The competent authority then informs other impacted competent authorities and the European Commission.

Depending on how the manufacturer places the devices on the market, the manufacturer directly informs the health institutions and healthcare professionals to whom they supply devices, or the manufacturer informs the importers and distributors, who then pass on the message to the downstream health institutions and healthcare professionals.

Why this is happening

> In essence, it is a mechanism allowing the member states to identify product shortages.

That was the intention of the lawmakers, knowing that they have regulatory bottlenecks, to somehow become aware of device shortages early enough to be able to react. They don’t need to know all product shortages, only some, so let’s talk about the scope and other details on LinkedIn for more insights on all things related to medical devices!

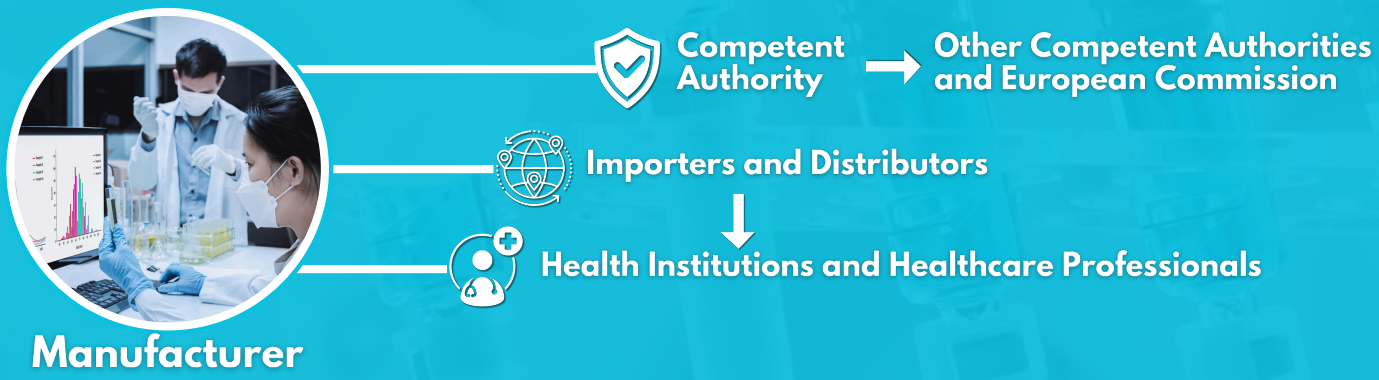

Figure: Communication Pathways Under Article 10a

Identifying a supply interruption or discontinuation

At least 6 months prior to an anticipated supply interruption or discontinuation, manufacturers are now required to submit the MDCG 2024-16 form. The manufacturer needs to consider situations including - but not limited to - a regulatory, supply chain, or manufacturing issue. In more tangible terms, this would include situations such as not having a valid certificate, deciding to not pursue certification anymore, the emergence of device performance issues, encountering difficulties in obtaining components necessary for manufacturing, or financially driven decisions to suspend or discontinue product lines.

The manufacturer also needs to identify reasons why this may present a risk of serious harm, such as the device being a life-sustaining or life-saving device or accessory, or a device intended for a vulnerable population, such as paediatric or geriatric patients, and whether or not the lack of the device on the market would prevent patients from accessing treatment.

There are allowances in the amended regulation for exceptional circumstances, which are unforeseen situations where the manufacturer is unable to anticipate or confirm a supply interruption or discontinuation.

Example scenarios include a natural disaster, a sudden inability to obtain raw materials or components, or economic or financial circumstances. In these cases, the manufacturer must simply inform the stakeholders without undue delay.

I'm overwhelmed, what do I do now?

Time is of the essence! If you do not have the resources to meet this requirement, effective as of January 10th, 2025, book a meeting! We can help you:

- Understand the triggers, taking into account your device portfolio and operational structure
- Enable proactive mechanisms in your QMS for 6+ month forecasting
- Ensure stakeholder communication and follow-ups and customer identification is possible
- Revise your written QMS procedures and economic operator agreements (a common area of weakness, and an area of focus for auditors!)

And as always, you can follow us (@AkraTeam) on LinkedIn for more insights on all things related to medical devices!

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RESOURCES

Official Sources

Regulation (EU) 2024/1860
The amendment to the MDR and IVDR which introduces Article 10a among other changes.

MDCG 2024-16
The form that manufacturers can use to submit information regarding the supply interruption or discontinuation to the competent authority.

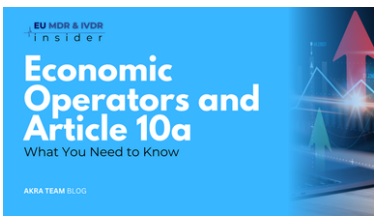
MDCG 2024-16 Annex
A useful table that manufacturers can use to list the devices in question.

Q&A document revision 1 (EC)
Provides more information and can be found alongside the MDCG documents on the EC Commission website.

Advice from Our Blog

Legacy Device Manufacturers and Article 10a: A Practical Guide
Legacy device manufacturers face new obligations under Article 10a of the EU MDR and IVDR. Compliance is critical to avoid regulatory pitfalls—this guide breaks down the requirements and how to navigate them effectively. Read more>>

Quality Management Systems and Article 10a: Ensuring Compliance
Article 10a under the EU MDR and IVDR requires manufacturers to update their quality management systems (QMS) to manage risks and ensure compliance. Learn how Article 10a impacts QMS and the steps you need to take. Read more>>



Economic Operators and Article 10a: What You Need to Know
Article 10a introduces significant responsibilities for economic operators, including importers, distributors, and authorized representatives. Understand how these roles impact the supply chain and how to comply. Read more>>

What Notified Bodies Need to Know About Article 10a
Notified bodies face new responsibilities in assessing compliance under Article 10a of the EU MDR and IVDR. Discover the key requirements and how NBs can support manufacturers while safeguarding public health. Read more>>

DECISION TREE

Does Article 10a Apply?

1 **Is the device custom-made?**

YES →
Article 10a does not apply

NO →
Proceed to the next question.

2 **Is there a temporary (>60 days) or permanent supply interruption or discontinuation?**

NO →
Article 10a does not apply

YES →
Proceed to the next question.

3 **Could the interruption result in serious harm or risk to patients or public health?**

NO →
Article 10a does not apply

YES →
Proceed to the next question.

4 **Is there a suitable successor device or alternative product?**

YES →
Mitigate risks; Article 10a may not apply

NO →
Article 10a applies

WORKSHEET

Article 10a Compliance Assessment

1 Device Identification

Device Name: _____

Device Class: _____

Intended Use: _____

Vulnerable Populations Affected: _____

2 Supply Interruption or Discontinuation Details

Nature of Interruption:

- Temporary (Expected Duration: _____)
- Permanent
- Anticipated Start Date: _____

Reason for Interruption (Check all that apply):

- ☐ Regulatory (e.g., certificate withdrawal)
- ☐ Supply Chain (e.g., raw material shortage)
- ☐ Manufacturing (e.g., performance issues)
- ☐ Business/Marketing Decisions
- ☐ Exceptional Circumstances (e.g., natural disaster)

3 Risk Assessment

Could the interruption lead to serious harm or risk to patients or public health?

- ☐ Yes
- ☐ No

Is there a suitable alternative device or successor product?

- ☐ Yes (Specify: _____)
- ☐ No

4 Notifications and Communication

Have you notified the competent authority?

- ☐ Yes
- ☐ No

Have you informed directly affected economic operators (importers, distributors)?

- ☐ Yes
- ☐ No

Have healthcare institutions and professionals been notified?

- ☐ Yes
- ☐ No

5 Documentation

Manufacturer Information Form Completed:

- ☐ Yes
- ☐ No

QMS Procedures Updated for Article 10a:

- ☐ Yes
- ☐ No

Supporting Documentation for Notifications:

- ☐ Yes
- ☐ No

6 Additional Considerations

Available Stockpile for Bridging Supply?

- ☐ Yes (Duration Covered: _____)
- ☐ No

Consulted Stakeholders for Risk Assessment:

- ☐ Yes
- ☐ No

WEBINAR

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Erik Vollebregt
Partner
Axon Lawyers

Lawrence Yeh
Senior Consultant
AKRA TEAM

Recording Slides Transcript

Introductions and Housekeeping (00:00 - 05:00)
Webinar on Article 10a requirements effective January 10, 2025
Speakers: Bassil Akra, Erik Vollebregt, Lawrence Yeh

Article 10a Overview (05:01 - 15:00)

- Applies to all MDR and IVDR devices, except custom-made devices
- Requires communication of anticipated product interruptions or discontinuations
- Focuses on cases that could result in serious harm to patients or public health
- Manufacturer must inform competent authority, importers, distributors, health institutions, and healthcare professionals
- Manufacturer Information Form (MDCG 2024-16) standardizes reporting

Implementation Challenges (15:01 - 30:00)

- Manufacturers need to identify triggers for supply interruptions
- Six-month advance notice required, except in exceptional circumstances
- Challenges in predicting and communicating business decisions
- Potential competitive risks in early disclosure of supply issues
- Importance of updating agreements with economic operators

Legal and Business Considerations (30:01 - 45:00)

- Risk of legal consequences from early disclosure (e.g., anticipatory breach)
- Confidentiality concerns with information shared with authorities
- Potential for Freedom of Information requests to reveal strategic information
- Need for careful communication to avoid market rumors
- Importance of evaluating device criticality in healthcare system

Health System Impact (45:01 - 55:00)

- Focus on devices critical to healthcare system continuity
- Consideration of market share and ability of competitors to meet demand
- Post-market surveillance obligation to monitor competitive landscape
- Notified bodies expected to assess Article 10a implementation in audits
- Importance of documented evidence in quality management system

Risk Assessment and Stock Management (55:01 - 01:01:23)

- Need for risk assessment considering multiple factors (e.g., market share, training requirements)
- Consideration of bridging stock in risk assessment
- No explicit requirement to maintain six months of stock
- Importance of having a procedure in place ASAP

Q&A

Top 10 Questions Submitted by the Audience During the Article 10a Webinar

1. Is Article 10a applicable to legacy devices that are not transitioning to MDR?
2. What is considered a “serious harm” under Article 10a?
3. Do manufacturers need to notify stakeholders about interruptions if alternative devices are available?
4. Should manufacturers maintain a list of devices exempt from Article 10a reporting?
5. How should manufacturers handle “exceptional circumstances” such as sudden supply chain disruptions?
6. What is the role of notified bodies in assessing compliance with Article 10a?
7. What information should be included in notifications to economic operators and competent authorities?
8. Does Article 10a require manufacturers to stockpile devices?
9. What are the practical challenges for smaller manufacturers in complying with Article 10a?
10. Are manufacturers responsible for informing healthcare institutions directly?

To review the detailed answers, including insights from Erik Vollebregt and other experts, please visit our blog.

UPCOMING

EU Orphan Devices

Understanding the Regulatory Pathway and Clinical Evidence Requirements

Join us for an expert-led webinar exploring the unique regulatory landscape for orphan medical devices in the EU.

- Learn the criteria for qualifying as an orphan device.
- Discover strategies to accelerate notified body approvals for new and legacy products.
- Review the latest MDCG guidance on clinical evidence requirements.
- Gain insights into clinical data strategies for orphan device submissions.
- Get an up-to-date overview of key considerations for bringing orphan devices to market.
- Understand how to include niche indications into current product labeling.

Stay informed about the evolving regulatory framework and its impact on device development strategy.

Subject Matter Experts

Matthias Fink
Senior Clinical Consultant
AKRA TEAM

Richard Holborow
Global Head Clinical Compliance
British Standards Institute

Nebojsa Serafimovic
Assessor, Clinical Investigations
BASG/AGES

When: January 21, 2025*
Time: 4 pm CET / 10 am ET
Where: Online (Zoom)

REGISTER NOW

*Recording will be made available to all registrants.

EU MDR & IVDR Insider

Welcome to the inaugural issue of *EU MDR & IVDR Insider*, the new free monthly publication from AKRA TEAM.

Each issue is packed with expert insights, actionable analysis, and resources from top industry leaders, it's your ultimate guide to staying ahead in regulatory excellence.

Subscribe for Free

About AKRA TEAM

We are a diverse team of high-level expert consultants dedicated to assisting stakeholders in all steps towards bringing medical devices, in-vitro diagnostics, and combination products to market.

Our experience and knowledge are applied to ensure timely product launches in full compliance with complex legal and regulatory requirements.

Bassil Akra, PhD

Chief Executive Officer
AKRA TEAM GmbH

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