Defences for Health Institutions in case of Substantial Modification of AI Medical Devices under the rPLD

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Article 11(1)(c) rPLD: The 'Later Risk' Defence

- Article 11(1)(c) rPLD provides an exemption from liability where:
- "[I]t is probable that the defectiveness that caused the damage did not exist at the time the product was placed on the market, put into service or, in the case of a distributor, made available on the market, or that that defectiveness came into being after that moment."
- For health institutions that have substantially modified an AI medical device, this defence is particularly relevant. If the defectiveness arose after the modification, the institution may argue that it should not be liable for defects it did not create.

Article 11(2) rPLD significantly restricts this defence:

- By way of derogation from paragraph 1, point (c), an economic operator shall not be exempted from liability where the defectiveness of a product is due to any of the following, provided that it is within the manufacturer's control: (a) a related service; (b) software, including software updates or upgrades; (c) a lack of software updates or upgrades necessary to maintain safety; (d) a substantial modification of the product.
- This provision is critical for health institutions. If the defectiveness is due to software or a substantial modification—precisely the activities in which health institutions engage—the 'later risk' defence is unavailable.

Recital 50: The Temporal Dimension

- Recital 50 rPLD explains the temporal aspect of liability:
- "The moment of placing on the market or putting into service is normally the moment when a product leaves the control of the manufacturer... Manufacturers should therefore be exempted from liability where they prove that it is probable that the defectiveness that caused the damage did not exist when they placed the product on the market or put it into service or that the defectiveness came into being after that moment. However, since digital technologies allow manufacturers to exercise control beyond the moment of placing the product on the market or putting it into service, manufacturers should remain liable for defectiveness that comes into being after that moment as a result of software or related services within their control."

Article 11(1)(e) rPLD: The Development Risk Defence

- Article 11(1)(e) rPLD provides an exemption where:
- "[T]he objective state of scientific and technical knowledge at the time the product was placed on the market or put into service or during the period in which the product was within the manufacturer's control was not such that the defectiveness could be discovered."
- For health institutions dealing with AI medical devices, this defence may be available if the defectiveness could not have been discovered given the state of scientific and technical knowledge at the relevant time. However, Parziale (2025) warns that this defence may create perverse incentives:

Doctrine views

"The manufacturer can avoid liability by demonstrating that the AI system was defective from the outset, but such a defect could not be discovered. This does not seem to fully incentivize the manufacturer to make sure that the AI-powered product is safe from the outset. Rather, it seems to convey an incentive not to study and test the product in a way that expands the objective state of the art, in order to have room to potentially rely on the development risk defense itself”

For health institutions, this defence may be available but should be invoked with caution, as it may undermine patient trust and institutional reputation.

Article 11(1)(g) rPLD: The Partial Modification Defence

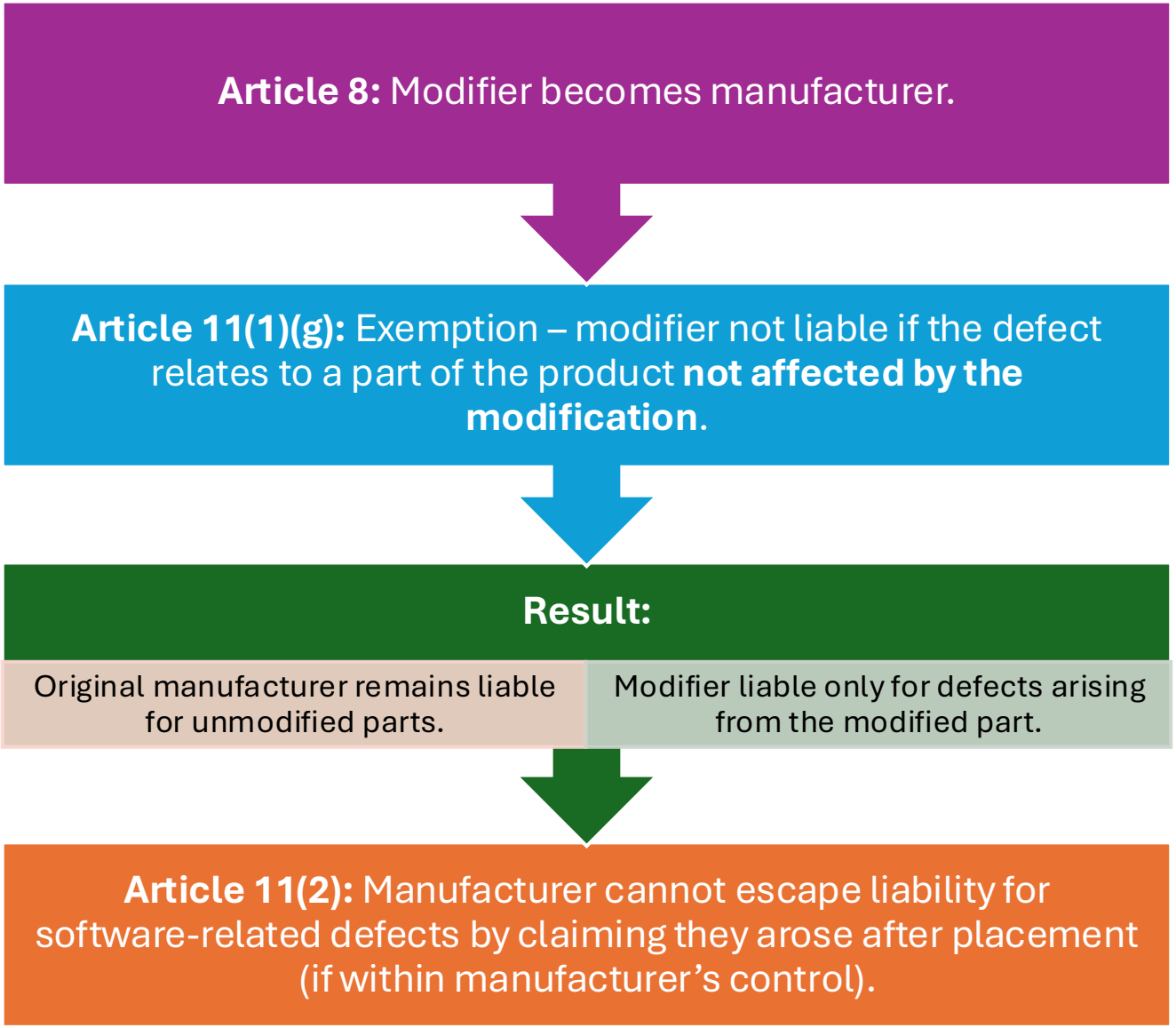
Article 11(1)(g) rPLD provides an exemption for substantial modifiers:

- "[I]n the case of a person that modifies a product as referred to in Article 8(2), that the defectiveness that caused the damage is related to a part of the product not affected by the modification."

This is a crucial defence for health institutions. If the defectiveness relates to a part of the AI medical device that was not affected by the substantial modification, the health institution may be exempt from liability. Recital 39 confirms this:

- "In the interests of a fair apportionment of risk in the circular economy, an economic operator that makes a substantial modification, other than the original manufacturer, should be exempted from liability if that economic operator can prove that the damage is related to a part of the product not affected by the modification."

Modular Liability – Joint Application of Articles 8 and 11



Article 13(2) rPLD: Contributory Fault

- Article 13(2) rPLD provides:
- "The liability of an economic operator may be reduced or disallowed where the damage is caused both by the defectiveness of the product and by the fault of the injured person or any person for whom the injured person is responsible."
- For health institutions, this defence may be relevant where the patient's own actions contributed to the damage. Recital 55 rPLD gives the example of a patient who "negligently failed to install updates or upgrades provided by the economic operator that would have mitigated or avoided the damage."