Placing on the market and making available of IVDs and medical devices during the transition periods of the IVD Regulation and MD Regulation

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Questions / Content:

In this document, MedTech Europe wishes to highlight the transitional provisions which exist to help industry to smoothly transition devices from the Directives to the Regulations.

A correct understanding of the concept of 'placing on the market' can play a pivotal role when planning the transition of *in vitro* diagnostic medical devices (IVD) and medical devices (MD) from the current regime to the Regulations (EU) 746/2017 ("the IVDR") and (EU) 745/2017 ("the MDR"). How supply and stock are foreseen to be placed on the market impacts on the obligations of the manufacturer according to the Regulations.
Wherever the text of the Regulations may lead to different interpretations, reference is made to relevant MDCG guidance documents which give an interpretation of the text.

Q1. At what point is a product considered to be 'placed on the market', 'put into service' or 'made available on the market'?

These concepts are defined by the IVDR and MDR:

MDR Article 2

(28) **'placing on the market' means the first making available of a device, other than an investigational device, on the Union market**[1]

IVDR Article 2

(21) **'placing on the market' means the first making available of a device, other than a device for performance study, on the Union market**

MDR Article 2

(27) **'making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge**

IVDR Article 2

(20) **'making available on the market' means any supply of a device, other than a device for performance study, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge**

MDR Article 2

(29) **'putting into service' means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose**

IVDR Article 2

(22) **'putting into service' means the stage at which a device, other than a device for performance study, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose**

The 'Blue Guide' on the implementation of EU product rules (2016) provides complementary information to the above definitions (in particular see Section 2.3).

Some important implications which may be noted are the following:

- The concept of placing on the market **refers to each individual product**, not to a type of product, nor whether it was manufactured as an individual unit (by serial number) or in series (by batch/lot number). (See Blue Guide 2.2)

[1] The 'Union market' refers to all Member States of the European Union. Through the Agreement on the European Economic Area., a product is not only placed on the Union market, but also on the EEA market (i.e. the national markets of the Member States and Iceland, Liechtenstein and Norway). For more information, see Section 2.8 of the 'Blue Guide' on the implementation of EU products rules 2016. Blue Guide 2.8.2.1.Basic elements of the Agreement on the European Economic Area: The Agreement on the European Economic Area, in force since 1 January 1994, covers all Union harmonisation legislation to which this Guide is applicable. Thus, Union harmonisation legislation covered by this Guide also applies to the so-called EEA EFTA States: Iceland, Liechtenstein and Norway.
For existing Mutual Recognition Agreements and Customs Agreements with countries outside of the Union, please check their current status.
Note that an updated version of the Blue Guide will be made available by the Commission soon. It will include additional guidelines on the definition of placing on the market, in particular as regards online sales.

- (Individual) products made available on the market must **comply with the applicable Union harmonisation legislation[2] at the moment of placing on the market**. (See Blue Guide 2.3)
- Devices which are **manufactured and used within health institutions** shall be considered as having been put into service (IVDR/MDR Art. 5)
- Devices which are not placed on the market but used in the context of a commercial activity for the **provision of diagnostic or therapeutic service offered by means of information society services (distance sales)**, are considered to be put into service (IVDR/MDR Art. 6)
- **Devices for performance study (IVDR), investigational devices (MDR), and devices for performance evaluation (IVDD)** are not considered to be placed on the market or put into service. See IVDD Art 1(2.i) / IVDR / MDR

The placing on the market is the most decisive point in time concerning the application of the Union harmonised legislation. Placing on the market is the act when the product is released from manufacturing phase and enters the distribution phase in the EU. It requires an offer or an agreement (written or verbal) between two or more legal or natural persons for the transfer of ownership, possession or any other property right concerning the product in question after the stage of manufacture has taken place). This transfer could be for payment or free of charge. It does not require the physical handover of the product. (See: 2.3 Placing on the market chapter of the Blue Guide - 2016)

Depending on company procedures and supply chain structures, the moment of placing on the market will vary. It requires an offer or an agreement (written or verbal) between two or more legal or natural persons. Activities like 'release to inventory' of a product with the intention to distribute it in the EU, or a documented transfer of physical or legal ownership of the product from the manufacturer to another legal entity in the EU, may be considered adequate to satisfy the definition of 'placed on the market'. However, note that simply placing the device in the warehouse of the manufacturer is not considered as being 'placed on the market', as then the products have not yet entered the distribution phase in the EU unless e.g., the manufacturer is storing the products for another economic operator. The same applies to products in transit in the EU, as they are not supplied for distribution, consumption or use in the EU.[3]

As regards online sales though, the European Commission has indicated that products are considered to be made available on the market if the offer is targeted at end users in the Union. Such products should comply with EU product rules when they are offered for sale online. This applies also for products available through online sellers based outside of the EU. In this case, physical fulfilment to end-users in the EU of a product ordered from an online seller based outside the EU (including by a fulfilment service provider regardless of whether it is based in or outside the EU) gives irrefutable confirmation that a product is placed on the EU market. (Blue Guide Section 2.3.)

As processes may vary from company to company, the interpretation of when the device is placed in the market is left to the individual company to decide.

[2] Both the Directives and the new Regulations are examples of 'Union harmonisation legislation' as are other applicable legislation, e.g. RoHS Directive 2011/65/EU, Electromagnetic Compatibility Directive 2004/108/EC and Radio Equipment Directive 2014/53/EU, etc.
[3] Section 2.3, eighth dot of the Blue Guide. A list of cases when the product is not considered to be placed on the market can be found in the Blue Guide Section 2.3.

Q2. What are the two main transitional provisions of the IVDR and MDR?

There are two main transitional provisions to be aware of: the so-called 'grace period' and the so-called 'sell-off provision'.

'Grace period'

The 'grace period' starts after the relevant date of application and ends on 27 May 2024.

The IVDR and MDR transitional provisions (IVDR Article 110(3) and MDR Article 120(3)) allow legacy devices to be placed on the market or put into service after the date of application of the Regulations (see definition below).[4] However, the validity of such certificates cannot go beyond 26 May 2024. Note that such legacy devices need to respect additional conditions, i.e. there must be **no significant changes[5] in their design and intended purpose compared to the scope of their directive certificate, they must continue to comply with the applicable Directive,** and they must also **apply and replace the corresponding requirements in that Directive with those of the applicable Regulation relating to post-market surveillance, market surveillance, vigilance, and registration of economic operators and of devices by the mandatory dates specified by the Commission[6].**

'Sell-off provision'

The IVDR and MDR transitional provisions (IVDR Article 110(4) and MDR Article 120(4)) allow that the following devices which comply with the relevant Directive may continue to be made available or put into service until 26 May 2025, if they are:

1) **'Older than legacy devices' / 'Old' devices**[7]: devices placed on the market according to the medical devices directives or the in vitro diagnostic medical devices directive before the date of application of the MDR and IVDR or placed on the market before the directives entered into force (regardless, if they have a Notified Body certificate or not i.e. self-certified); or
2) **'Legacy devices'**[8] should be understood as devices, which, in accordance with Article 120(3) MDR and Article 110(3) IVDR, are placed on the market after MDR or IVDR dates of application respectively and until 26 May 2024, or until the relevant certificate becomes void, if certain conditions are fulfilled.

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[4] For the IVD sector, only few and specific devices (IVDD Annex II List A and B; and self-tests) have a Notified Body certificate under the IVDD and therefore may qualify for the IVDR transitional grace period. This means that 26 May 2022 is a 'hard stop' for most IVDs.

[5] See MDCG Guidance 2020-3 on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD. There is no corresponding MDCG guidance for the IVD sector available; it may be helpful to consult MedTech Europe position paper, Significant Changes According to IVDR Article 110(3)

[6] Application of the corresponding MDR requirements cover:

- Registration of economic operators and of devices (Art. 31 MDR and Art. 29 MDR)
- Post market surveillance (PMS) (Art. 83 - 86, 92 MDR including Annex III but without the PMS having to be an integral part of the QMS)
- Market surveillance (Art. 93 – 100 MDR, but device standards to be met = Directives)
- Vigilance (Art 87-92 MDR)

Application of the corresponding IVDR requirements cover:

- Registration of economic operators and of devices (Art. 28 IVDR and Art. 26 IVDR)
- Post market surveillance (PMS) (Art. 78-81, 87 IVDR including Annex III but without the PMS having to be an integral part of the QMS)
- Market surveillance (Art. 88 – 95 IVDR, but device standards to be met = Directives)
- Vigilance (Art. 82-87 IVDR)

Source: CAMD FAQs – IVDR Transitional provisions & CAMD FAQs – MDR Transitional provisions (Jan 2018)

[7] See definition in MDCG 2021-13 Rev. 1

[8] See definition in MDCG 2021-13 Rev. 1

- devices which are class I devices under Directive 93/42/EEC, for which a declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a notified body;
- devices covered by a valid certificate issued in accordance with Directives 90/385/EEC or 93/42/EEC prior to 26 May 2021;
- devices covered by a valid certificate issued in accordance with Directive 98/79/EC prior to 26 May 2022.defined here as, legally placed on the market *after* the date of application of the relevant Regulation under a valid Directive certificate (which must have been issued by a Notified Body prior the date of application) and which maximum validity is limited by the regulations to the 26 May 2024). Legacy devices also include Class I devices under the (AI)MDD, which need to undergo NB assessment according to the MDR. See MDR 120(3).

See Visual 1 below for explanation on 'older than legacy devices' and 'legacy devices'.

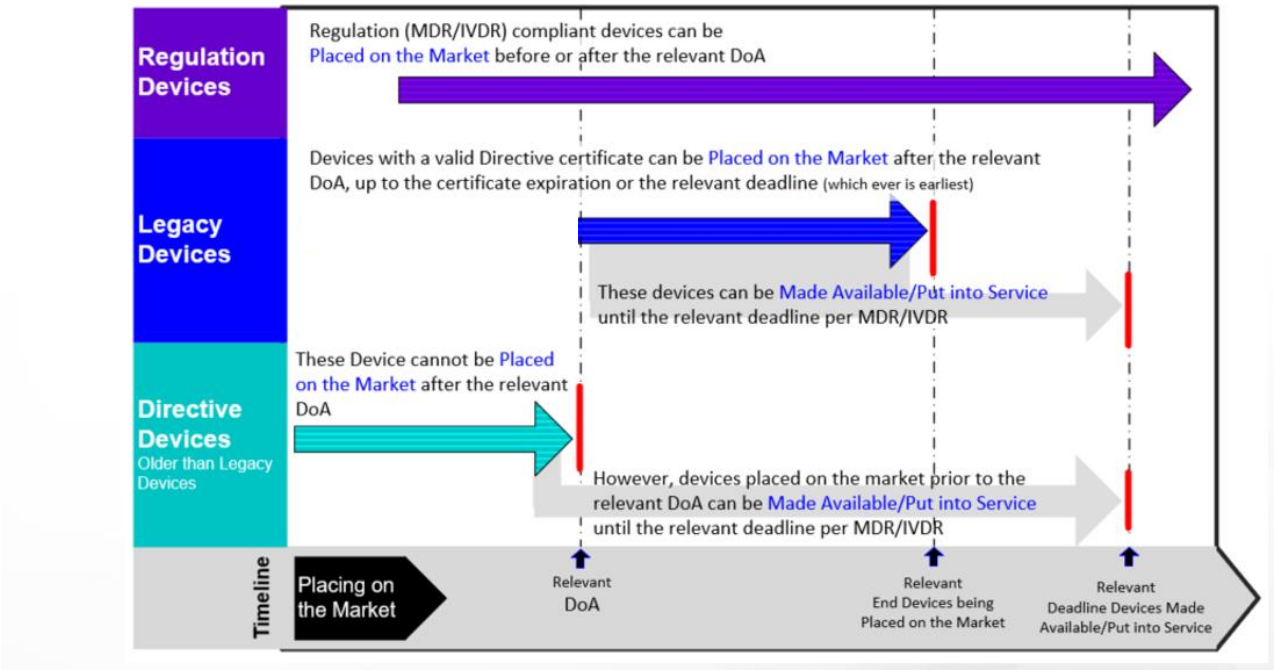
Q3. What is the implication of the 'placing on the market' concept for the transition from the Directives to the Regulations?

For IVDD/MDD/AIMDD devices which are placed on the market *before* the IVDR/MDR date of application ('older than legacy devices' under 1 above, titled as "sell-off provision"), there is no obligation for these devices to comply with requirements of the Regulations .. This does not preclude that Member States can continue to develop guidance in the remit of the Directives in areas of registration and Vigilance. [9]
This will be the case, for example, for devices transferred by an EU manufacturer to an EU distributor before the IVDR/MDR date of application.

For legacy devices, the transitional provisions apply according to IVDR Article 110(3) and MDR Article 120(3) for the 'grace period' following the date of application for each Regulation. When placed on the market, these devices will need to comply with the requirements of the Directives and additionally, with requirements of the relevant Regulation relating to post-market surveillance, vigilance, and maintaining the registration of economic operators and of devices.

The legal obligation connected to 'legacy devices' arise from the fact that they are to be placed on the market after Date of Application of the respective Regulation. These rules are not taking into account if the device will be upgraded to the requirements of the Regulations or not (if they will be discontinued after the expiration of the Directive certificate.)
See: https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_5_legacy_devices_registration_eudamed_en.pdf
[9] MDCG 2019-5 Registration of legacy devices in EUDAMED (Apr 2019)

Visual 1 – explaining the 'grace period' for legacy devices and the 'sell-off provision' applicable both for Legacy* and Older than legacy devices



Relevant DoA: 26 May 2021 for MDR and 26 May 2022 for IVDR
Relevant End Devices being place on the market (end of validity of Directive certificates): 26 May 2024 both under MDR and IVDR
Relevant Deadline devices made available/put into service: 27 May 2025 both under MDR and IVDR

** Corrigenda to the MDR (published on 27 December 2019), enlarged the scope of the "grace period" to include devices which were Class I self-certified under the Medical Devices Directive (MDD) and which need to undergo conformity assessment with a Notified Body to comply with the MDR. For more detail see Note 1 below.*

An example: Medical Devices with valid MDD/AIMDD certificates which are in the stock of a distributor warehouse in the Union after the MDR Date of Application and are therefore placed on the market, may be made available to another distributor or transferred to the user and therefore put into service by that distributor until 26 May 2025.

Stockpiling

Companies have the possibility to manufacture devices and transfer them to a distributor (and therefore placed on the market) based on their estimated demand, until the expiry of the corresponding IVDD/MDD/AIMDD certificates. The distributors may sell off such devices (i.e., make them available on the market or put them into service) until 26 May 2025. This may be more convenient for devices with a longer shelf-life, e.g. some IVD instrumentation or MD equipment. Should a company decide to do this, it may be helpful for them to consider where they will need to make explicit use in combination claims which will cover both older and newer instrumentation or equipment versions (i.e. under the relevant directive and regulation) with devices which have a shorter lifetime such as reagents or consumables.

Other considerations:

- Where the device is being made available in parallel under the relevant directive and regulation, the manufacturer would need a way to track which devices fall under which legislation. This could be done in different ways, depending on the company philosophy, strategy and procedures which are in place to allow traceability.
- While the final date where these devices may continue to be made available or put into service is 26 May 2025, nothing in the Regulations affects second-hand sales by the final user. Once the device has reached the user and therefore has been put into service (this includes devices in renting, on loan, in consignment), the Regulations do not harmonise rules relating to the further making available of the device which has already been put into service (see IVDR/MDR preamble 3).

Notes

1. Medical devices which do not require certification under the Directives (class A IVDs and MDs that were Class I self-certified under the MDD and do not depend on the availability of MDR-designated Notified Bodies in order to comply with the MDR) must comply with IVDR or MDR from the applicable Date of Application, in order to be lawfully placed on the market (there is no 'grace period' for these; the 'sell-off provision' can still be used). The corrigenda to the MDR (published on 27 December 2019), has enlarged the scope of the 'grace period' to include devices which were Class I self-certified under the Medical Devices Directive (MDD) and which need to undergo conformity assessment with a Notified Body to comply with the MDR.
2. For Procedure packs (both Article 12 MDD and Article 22 MDR) see: MedTech Europe Q&A
3. Please note that the dates of application for the MDR and for the IVDR are different. 26 May 2021 is the date of application of the MDR. 26 May 2022 is the date of application of the IVDR.
4. The 'Blue Guide' is one of the main reference documents published by the European Commission, explaining how to implement the legislation based on the New Approach, now covered by the New Legislative Framework. This Guide is intended to contribute to a better understanding of EU product rules and to their more uniform and coherent application across different sectors and throughout the single market. In cases where the IVDR or MDR lay down more specific rules than the Blue Guide, those more specific rules take precedence. Another core reference document published by the European Commission is the Interpretative document of the Commission Services on the "Placing on the market of medical devices"[10]. See Annex II for more detail.

Glossary

- IVDR: *In vitro* Diagnostics Medical Device Regulation (EU) 2017/746
- MDR: Medical Device Regulation (EU) 2017/745
- AIMDD: Directive 90/385/EEC on Active Implantable Medical Devices
- IVDD: Directive 98/79/EEC on *In vitro* diagnostic medical devices
- MDD: Directive 93/42/EEC concerning Medical Devices
- IVDD/MDD/AIMDD certificates: certificates in accordance with Directive 98/79/EEC, Directive 93/42/EEC and Directive 90/385/EEC
- DoA: date of application (of the applicable regulation)

[10] While this interpretive document was prepared for the Directives, the concepts may be helpful also for the MDR/IVDR.

References

- The 'Blue Guide' on the implementation of EU product rules 2016, OJ of 26 July 2016, C272
- Interpretative document of the Commission Services on the "Placing on the market of medical devices" (16 December 2010)
- *In vitro* Diagnostics Medical Device Regulation (EU) 2017/746
- Medical Device Regulation (EU) 2017/745
- Directive 98/79/EEC on *In vitro* diagnostic medical devices
- Directive 90/385/EEC on Active Implantable Medical Devices
- Directive 93/42/EEC concerning Medical Devices

*For EU legislation please see latest consolidated version. For MedTech Europe documents, in case any links are broken, please consult the latest version under the *Industrial Policies E-Library*.

About MedTech Europe

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The *In Vitro* Diagnostic Medical Devices Regulation and Medical Devices Regulation contain several provisions that are capable of being given more than one interpretation. In the preparation of this series of Questions and Answers, MedTech Europe has used its best efforts to ensure that the opinions and advice expressed are sound. However, the Association makes no assertion that those opinions and advice are correct and it accepts no legal responsibility for them. Specific legal advice should be sought before acting on any of the topics covered. MedTech Europe reserves the right to change or amend this document at any time without notice in order to keep the information up to date. Members are reminded that, while competent authorities and notified bodies may be helpful in providing views as to the meaning of the IVD Regulation and MD Regulation, it is ultimately for the courts to interpret legislation.

Annex I – Summary table of transitional provisions

After the date of application of the respective Regulation, can a device	Device self-certified under Directive (does not hold a CE Certification issued by a Notified Body)	Device holds a valid CE Certificate issued by a Notified Body under Directive
benefit from the grace period and from the sell-off period?	It cannot benefit from grace period (for MDR only, there is exception for devices which will require Notified Body involvement under the MDR – see Corrigenda to MDR Art 120(3) e.g. reusable surgical instruments. These CAN benefit from the grace period). It can benefit from sell-off period if it was placed on the market before the date of application.	It can benefit from grace period. It can benefit from sell-off period regardless if it was placed on the market before or after the date of application
be manufactured and placed on the EU market by manufacturers?	No. No new products of the device can be manufactured and placed on the EU market unless they bear the CE-marking under the relevant Regulation. If the product has already been manufactured BEFORE the date of application, it may benefit from the sell-off period if it has been placed on the market before the date of application of the respective Regulation which is a legal or physical transfer of ownership (the product is released from manufacturing phase to distribution phase).	Yes. If the device has a still valid notified body certificate under the respective Directive, then new product can continue to be manufactured and placed on the market (under certain conditions[11]) after the date of application of the respective Regulation up to the validity of their certificates or the 26 May 2024, whichever the earliest.
continue to be made available and put into service?	Yes. If the product has already been manufactured and placed on the market BEFORE the date of application of the respective Regulation, it can continue to be	Yes. The product that is manufactured and placed on the market before or after the date of application of the respective Regulation, it can continue to be

[11] MDR Article 120.3; IVDR Article 110.3

	distributed until it expires or latest until the end of the sell-off period, until 26 May 2025.	distributed until the end of the sell-off period, until 26 May 2025.
can customers continue to use their inventory?	Yes.	Yes.

Annex II – Helpful excerpts from EU level guidance

1. The **'Blue Guide' on the implementation of EU product rules (2016)** provides the following considerations to support the concept of 'placing on the market' (section 2.3 of the 2016 version of the Blue Guide):

- The manufacturer and the importer are the only economic operators who place products on the market – they do this by offering a product to a distributor or an end-user for the first time.
- Any subsequent operation, for instance, from a distributor to distributor or from a distributor to an end-user is defined as making available.
- The concept of placing on the market refers to each individual product/unit and not to a 'type' of product or other product range. This is the case regardless of whether that individual product was manufactured as an individual unit or as part of a series. Consequently, even though certain individual items from a product model or type may have been placed on the market before the Date of Application of the MDR/ IVDR, other individual units of the same model or type, which are placed on the market after the Date of Application, must comply with the MDR/IVDR.
- Placing a product on the market requires an offer or an agreement (written or verbal) between two or more legal or natural persons for the transfer of ownership, possession or any other property right concerning the product in question. This transfer could be for payment or free of charge. It does not require the physical handover of the product, but it does require that the stage of manufacture has already taken place. Commercial activity is understood as providing goods in a business-related context.
- **Placing on the market** is considered **not** to take place where a product is:
  1. manufactured for one's own use,
  2. bought by a consumer in a non-EU country while physically present in that country and brought by the consumer into the EU for the personal use of that person,
  3. transferred from the manufacturer in a non-EU country to an authorised representative in the EU whom the manufacturer has engaged to ensure that the product complies with the EU harmonisation legislation,
  4. introduced from a non-EU country in the EU customs territory in transit, placed in free zones, warehouses, temporary storage or other special customs procedures (temporary admission or inward processing),
  5. manufactured in an EU Member State with a view to exporting it to a non-EU country (this includes components supplied to a manufacturer for incorporation into a final product to be exported into a non-EU country),
  6. transferred for testing or validating pre-production units considered still in the stage of manufacture,
  7. displayed or operated under controlled conditions at trade fairs, exhibitions or demonstrations, or

8. in the stocks of the manufacturer (or the authorised representative established in the EU) or the importer, where the product is not yet made available, that is, when it is not being offeredfor distribution, consumption or use, unless otherwise provided for in the applicable EU legislation.

- The placing on the market is the most decisive point in time concerning the application of the EU legislation. When made available on the market, **products must be in compliance with the EU legislation applicable at the time of placing on the market**. Accordingly, new individual products manufactured in the EU and all individual products imported from non-EU countries — whether new or used — must meet the provisions of the applicable EU legislation when placed on the market, i.e. when made available for the first time on the EU market. **MDD/AIMDD/IVDD-compliant products, once they have been placed on the market before the MDR/IVDR Date of Application, may subsequently be made available along the delivery chain independently from the new legal requirements after the Date of Application of the MDR/IVDR, until 27 May 2025 at the latest.**

More details about offered for sale by an online operator can be found in the 'Blue Guide' under section 2.3.

2. The Interpretative Document of the Commission Services of 16 December 2010 on the "Placing on the market of medical devices" lists the following considerations in view of the Directives, but may nevertheless be worthy of consideration in the context of the MDR/IVDR:

- "(10) The Blue Guide states that the placing on the market takes place when the product is **transferred** from the stage of manufacture with the intention of distribution or use on the Community market..."
- "(11) The transfer can consist in **a physical hand-over and/or be based on a legal transaction**. It can relate to the ownership, the possession or any other right transferred from the manufacturer to a distributor or to the end user. A transfer of a product is considered to have taken place, e.g., when it is **sold, leased, given as a gift, rent out or hired**. Where a manufacture operates an own distinct distribution chain, the transfer can also occur to that distribution chain" provided that the distributor is a legally independent entity – see the definition of distributor
- "(12) According to the "Blue Guide", placing on the market is considered **not** to take place where a product, amongst others, is
  - in the stocks of the manufacturer, or the authorised representative established in the Community, where the product is not yet made available, unless otherwise provided for in the applicable directives
  - not (yet) granted release for free circulation by customs, or has been placed under another customs procedure (for example transit, warehousing or temporary importation), or is in a free zone"
- "(14) In certain circumstances, a device which physically is still in the manufacturer's warehouse can be considered as placed on the market. For example, this may be the case where **the ownership or another right of a certain product has already been transferred to either a distributor or the end user,** but the product is still stored by the manufacturer on their behalf."