

Medical samples (Article 19)



Medical samples: What, Who, When, Why, How

WHAT (definitions)



A medical sample is a sample of Medicinal Product free of charge to persons qualified to prescribe or supply them.

Medical samples are allowed only for new Medicinal Product i.e. a product for which a new marketing authorisation has been granted.

WHO, WHEN & WHY



WHO: Persons qualified to prescribe or supply a Medicinal Product.



WHEN: Each recipient should receive, per year, not more than 4 Medical Samples for 2 years after the recipient first request.



WHY: To familiarise with new products and acquire experience in dealing with them.

HOW (key rules to follow)



No medical samples, except on an exceptional basis.



No inducement to recommend and/or prescribe, purchase, supply, sell or administer a Medicinal Product.



Samples given for the sole purpose of **treating patients**.



Medical Samples of a particular Medicinal Product given to an **HCP qualified to prescribe or supply it**.



HCP's requests must be written, signed and dated.



Member Companies must have **adequate systems of control and accountability** for the direct or indirect distribution of Medical Samples.



Each Medical Sample must be no larger than the smallest presentation of that particular Medicinal product in the relevant country.



Each Medical Sample must be marked "free medical sample – not for sale" and must be accompanied by a copy of the summary of product characteristics



Disclosure: the provisions of medical samples are excluded from the disclosure requirements.

Medical samples

Real Life Scenarios

Q1: What is the purpose of providing medical samples?

A: Medical samples may be provided to qualified HCPs to help them become familiar with a medicinal product and gain experience in dealing with it.

Q2: Can medical samples be provided to any Healthcare Professional?

A: No. Medical samples may only be provided to HCPs who are qualified to prescribe the medicinal product concerned, subject to applicable national requirements.

Q3: Can a pharmaceutical company provide unlimited quantities of medical samples?

A: No. Only a limited number of samples may be provided, in accordance with the EFPIA Code and applicable national rules.

Q4: Can a pharmaceutical company provide additional medical samples to an HCP who has already received the maximum number permitted under the EFPIA Code?

A: No. The EFPIA Code establishes the “4 × 2” standard, meaning that a maximum of four samples of a particular medicinal product may be provided to an HCP per year, for a period of two years following the first request. Once these limits have been reached, additional samples should not be provided, unless a specific exception applies under the Code and applicable national rules.

Q5: Can a pharmaceutical company provide medical samples of a medicinal product that has been authorised for several years but has recently received approval for a new indication?

A: No. The approval of a new indication does not automatically make an existing medicinal product a new product for the purposes of Article 19. The eligibility period for providing samples is linked to the medicinal product itself, rather than to each newly approved indication. Companies should therefore not restart the sampling period solely because a new indication has been authorised.

Q6: Can a pharmaceutical company provide medical samples to an HCP who requests them exclusively to treat patients who cannot afford the product?

A: No: Article 19 expressly prohibits providing medical samples for the sole purpose of treating patients, even when the intention is to help patients who cannot afford treatment. Medical samples must be provided exceptionally, with the objective of allowing prescribing HCPs to familiarise themselves with a medicinal product and gain experience in its use. Companies should consider other appropriate and legally compliant mechanisms for supporting patient access to treatment.

Curious to know more about medical samples?

Please refer to following link or connect with your Ethics & Compliance Officer:

[Chapter 3 \(article 19\), pages 26](#)

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