Federal **A**gency for **M**edicines and **H**ealth **P**roducts
(FAMHP)

Bras-Meeting

SAMPLES LEGISLATION

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1.Legal context

- The Directive 2001/83/EC of the European Parliament and of the Council of 6/11/2001 on the Community Code relating to Medicinal Products For Human Use (O.J.L-311 28/11/2004) article 86,96.

- The Law on the medicinal products of 25.03.1964 (B.O.J. 17.04.1964) - revised dd. 01.05.2006 (B.O.J. 16.05.2006) article 6ter, 12.

- The Royal Decree establishing the conditions under which the delivery of drugs for human use in the form of samples may be effected of the 11/01/1993 (B.O.J. 12.05.1995) – revised dd. 26.04.2007 (B.O.J. 18.05.2007) article 1,2,3,4,7 and 8.

2. To who may be distributed sample of medicinal product?

- Prohibition to supply samples of a medicinal product to any member of the public for promotional purposes.

  Supply via publication or by mail, for example with magazine, is unacceptable.

- A sample may only be supplied on an exceptional basis only to a person qualified to prescribe medicinal products

3.What medical product can be distributed as a sample?

- Medicinal product that has a marketing authorization in Belgium
- Medicinal product commercialized in Belgium
- The sample shall be no larger than the smallest presentation available for sale in Belgium or a smaller packaging described in the marketing authorization.
- No narcotic
- No psychotropic
- No medicine for oral use containing isotretinoin

4.Which are the conditions for distribution of samples (1)?

- The prescribers must provide *a written, dated and signed request*.

- The request mentions :
  - the name and the of the medicinal product
  - the number of conditionings
  - the name , first name and adress of the prescriber
  - the registration number of the prescriber at the Order

- These prescriber requests must be kept by the responsible of information for 10 years.

4.Which are the conditions for distribution of samples (2)?

- Each prescriber can receive at most **8** samples per year of a medicinal product.
- The samples must be appropriately labelled in line with the requirements of Article 96 of Directive 2001/83/EC and be marked “free medical sample – not for sale” (or similar).
- This labelling must be apparent, easily readable, indelible, permanent.
- Every sample shall be accompanied by a copy of the approved Summary of Product Characteristics.

5.Obligation of the Marketing Autorisation Holder (1):

- The MAH must have an adequate system of control and accountability.
- The responsible for information has the responsibility of the system of control.
- This system of control indicates, among others, for each medicinal product and prescriber, the name and lot number of samples delivered to the prescriber with his name and address.
- This listing needs to be kept by the MAH 10 years.

5.Obligation of the Marketing Autorisation Holder (2):

- The responsible for information must submit to the FAMHP by March 1 of each calendar year a listing with the following information:

- name, dosage, pharmaceutical form and size of the packaging of the medicinal product given as a sample
- the total number of samples given by medicinal product
- the Anatomical Therapeutic Chemical classification (ATC) code.

6. Important Information:

- The delivery arrangements for these medicinal products must be validated to ensure the medicinal product will be transported expeditiously under controlled GDP conditions.

- The distribution of the samples usually involves storage and delivery in a representative's vehicle that has no provision for maintaining any correct storage conditions. Temperatures in a car boot in summer can reach 50°C or go below 0°C in winter. Procedures need to be in place to ensure that samples are stored and distributed in accordance with the labelled storage requirements at all times.

6. Important Information:

- The only reason for which sales representatives may hold samples is for the purpose of product presentation. In this regard procedures must be in place to ensure accountability for any stock of samples.