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

Responsible for Information and Publicity

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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 98, 1°.

- 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,9.

- The Royal Decree related to the information and advertising for human use medicinal products of the 07/04/1995 (B.O.J. 12.05.1995) – revised dd. 22.11.2006 (B.O.J. 08.01.2007) article 13,14 and 15.

2. Obligation of the Marketing Autorisation Holder:

- The Marketing Autorisation Holder must appoint a person responsible for information and publicity.
- He has to communicate his name to the authorities (he can be member of the company or a consultant).
- Any change must be notified to the authorities.
- When the responsible for information and publicity is absent (illness, vacation,…), his replacement must be notified to the autorities.
- Only one responsible for information and publicity by MAH.

3. Functions of the Responsible for Information and Publicity (1)

Some duties of the RIP:

- Verification of the compliance of the SPC, the leaflets and their translations

  → signs the "Declaration of Conformity" for registration of variations on a marketing authorisation

- Gives final approval on advertising projects

- Oversees the training of medicinal representatives to doctor or pharmacist, healthcare professionals.

3. Functions of the Responsible for Information and Publicity (2)

- Ensures compliances of regulations on « samples »

  (Royal Decree fixing the conditions in which the delivery of medicines for human use in the form of samples can be made of the 11.01.1993)
- Establishes an appropriate internal procedure for approving advertising and various promotional activities
- Responsible for the information provided by his company (ex.: questions from patients, professionals,…)
- Ensures compliance of regulations on « premiums or advantage »

  (Royal Decree of 7.04.1995, article 2 §2, article 13 §4, article 15 and law 25.04.1964 on medicines, article 10)

4. Granting of an agreement number as RIP (1)

The conditions to obtain an agreement number as RIP are:

- Be holder of a legal diploma of Pharmacist or Doctor.
- The EC nationals, holders of an equivalent diploma, can also be approved as RIP with a EU/EEA recognition of his professional title.

  The request for recognition EU/EEA professional title must be done by the Unit of International Mobility of Healthcare Professionals, FPS Public Health, Directorate General Primary Healthcare and Crisis Management, Victor Horta Place, 40 box 10, 1060 Brussels.
- Justification of an experience of at least one year in the field of the pharmaceutical information.

4. Granting of an agreement number as RIP (2)

The file to be introduced must contain the following documents:

1. A personal request
2. The Curriculum Vitae
3. A copy of his diploma of pharmacist or doctor
4. A justification of an experience of at least one year (date) in the field of the pharmaceutical information by the presentation of a descriptive certificate of the accomplished tasks.

   This certificate is delivered by the person (CEO) of the firm in which this experience was acquired or a RIP who has an agreement number since more than one year.

4. Granting of an agreement number as RIP (3)

If the conditions are fulfilled:

- An agreement number is communicated by post to the personal address of the applicant.
- The agreement is published in the Belgian Monitor(annual publication)

The agreement number is personal. It is not linked to a company.

A RIP can work for different companies.

The agreement number is valid during the career of the person except when this person is the object of a procedure of suspension or of withdrawal of his agreement.