

# Federal agency for medicines and health products

BRAS

Advertising for medicines addressed to the public

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## Legal basis

European Directive 2001/83 / EC - title VIII  
articles 86 to 100, amended in 2004

-> Belgian legislation

- Article 9 of the Law of 25th March 1964 + modifications
- RD of 7th April 1995 on information and advertising for medicinal products for human use



## History

Belgium: pioneer in controlling medicinal advertising

**RD of 9th July 1984** on information and advertising for medicines

-> **RD of 7th April 1995** (human medicines) to meet the requirements of Directive 92/28 / EEC on the advertising for medicines for human use.

+ Modifications to meet the requirements of Directive 2001/83 / EC



## Advertising?

Any form of door-to-door selling, information, canvassing aiming to promote the prescription, the delivery, the supply, the sale or the consumption of medicines.

BUM -> controlling advertising targeted at the public



# General provisions on medicinal advertising

## Advertising

- must comply with the data accepted when granting the marketing authorization
- should be controllable
- should encourage the rational use of medicines by presenting them objectively without exaggerating their properties
- must not be misleading



# Media, advertising mediums or means that are prohibited

- Signs on the roadside
- Illuminated signs
- Verbal recommendations in public
- E-mails
- Phone calls
- SMS text messages
- Direct Mail
- Publications targeted at children
- Promotional competitions
- Objects intended for purposes other than to communicate information
- Practices such as 'satisfied or refunded'



# Special provisions for advertising targeted at the public

Especially

- Advertising allowed only for free delivery medicines
- No direct delivery of samples to the public by companies
- No suggestion of an effect equal to or greater than that of another treatment
- No advertising for the attention of children
- No reference to scientists, health professionals, famous people who recommend the medicine
- No pictures, drawings, undermining the sobriety required for advertising medicines
- No other motivation than curing or preventing disease
- Obviously advertising character



# READABILITY

- Name of the active substance
- Recommendations:
  - "Read carefully the patient information leaflet"
  - "This is a medicine, no prolonged use without medical advice"
  - Essential information for the proper use of the medicine





## Prior control

Advertisements aimed at the public  
(not radio or television advertisements)

-> Prior notification

- Assessment within 30 days: monitoring that the advertising complies with the legislation.
- In the absence of remarks within the prescribed period, the advertisement can be broadcast

75% of advertising is the subject of comments



## Points to pay attention to

- If the packaging (3D) is used to make the advertising -> it should be enlarged: twice the size of the real packaging
- ! Readability of legal information (full sized version in the dossier) – circular 407
  - Size of letters
  - Italics not recommended
  - Contrast
  - Well-structured text
  - Remove superfluous words and repetitions
  - Avoid splitting words over two lines
  - The separation of a sentence on two screens should be avoided.
  - Sufficient spacing between words and lines



## Points to pay attention to (continued)

- Legal mentions should be readable from where the advertising is read
- The advertising medium should be mentioned in the dossier
- Website: Exact URL
- Project (mock-up) with the pictures/ actually used
- Display: colour printing with real dimensions if possible. Photos + description and measurements of the materials
- During the procedure, changes only to the items that have been the subject of remarks
- Coherence between different languages
- "New" if the first marketing <year 1 or else specify
- Storyboard for screens: duration of the appearance of the legal mentions



## Radio and television advertising

### PRIOR VISA REQUIRED

- Visa issued by the Minister of Health on the advice of the Commission for the control of medicinal product advertising
- Valid 2 years, renewable
  
- The dossiers should be introduced at least one week before the meeting (circular 612) . The meeting dates are published on our [website](#) (page advertising).



## Radio and television advertising

- Legally obligatory mentions in TV spots: clearly readable
- In case of spreading the legally obligatory mentions over multiple screens: logical splitting (e.g.: contraindication completely on one screen)
- Recommendations in circular 441



# Radio and television advertising

## New recommendations

- « **Proposed in** » **medicines**: sobriety of advertisements and compliance to the SPC and PIL data
- **Readability** and **audibility** of legal mentions: clearly expressed to be assimilated by the public
- “**No prolonged use without medical advice**”: to clarify whether short (x days)
- **Advertisement for several medicines in a TV spot**:  
YES if same gamut, same active ingredient(s), same indications and pharmacological properties  
NO if different target groups
- **Medicines against pain and fever**:  
Symptoms such as pain and fever in flu or cooling: YES  
Flu or cooling: NO
- **No reference to a website** and therefore not URL in a advertising TV or radio



## Conclusion

Important role of the person  
responsible for  
pharmaceutical information



A large, stylized graphic of an eye is centered in the background. The eye is composed of several overlapping shapes: a grey arc at the top, a blue arc at the bottom, and a central blue circle with a white pupil. The overall effect is a soft, abstract representation of an eye.

Your medicines and health products,  
our concern