



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

ADVERTISING TO THE GENERAL PUBLIC

of medicinal products for human use

I. DEFINITION

II. PROCEDURES

Notification

Visa

III. COMMISSION FOR THE CONTROL OF ADVERTISING OF MEDICINAL PRODUCTS

IV. ADVERTISING VIA INTERNET

Website/web page

Banner

Google ads

I. DEFINITION

Advertising to the general public

- = Advertising addressed to the general public
- = Advertising addressed to other target groups than persons qualified to prescribe or deliver medicinal products

Among others: nurses,
physiotherapists,
pharmacy assistants

II. PROCEDURES

NOTIFICATION

all types of advertising other than radiophonic or televisual advertising

→ notification to the Minister
at least 30 days before diffusion

Ex: placard, poster, brochure, website, banner, ...

VISA

advertising on radio or television

→ visa granted by the Minister following advice of the Commission for the control of advertising of medicinal products

II. PROCEDURES

1. NOTIFICATION

- 1.1. Notification dossier
- 1.2. Renewal of a notification
- 1.3. Reminder advertising
- 1.4. Note

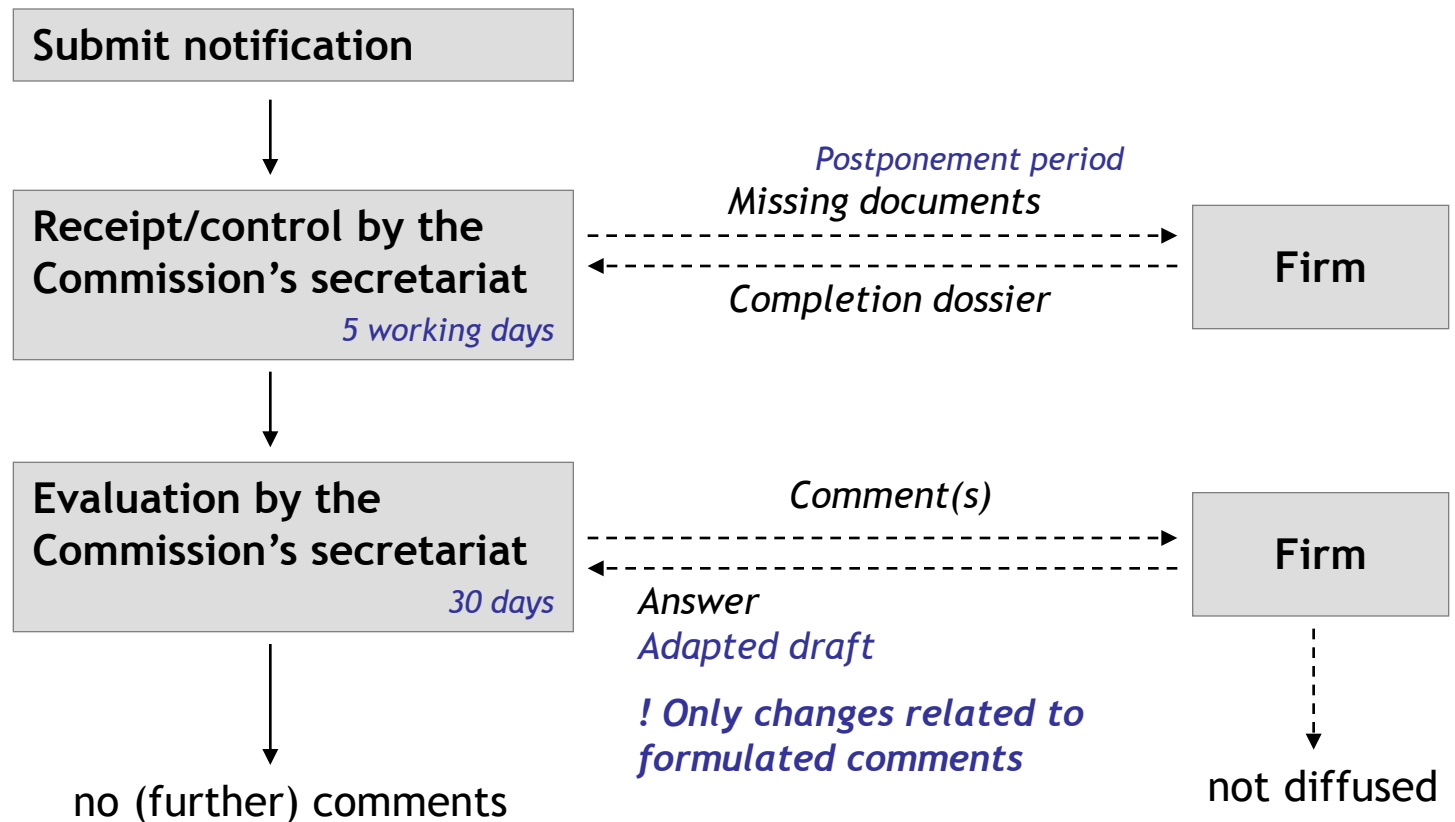
2. VISA

- 2.1. Visa application
- 2.2. Submission final version
- 2.3. Renewal of a visa
- 2.4. Reminder advertising
- 2.5. Note

II. PROCEDURES - 1. NOTIFICATION - 1.1. Notification dossier

1. NOTIFICATION

1.1. NOTIFICATION DOSSIER



II. PROCEDURES - 1. NOTIFICATION - 1.1. Notification dossier

Submission notification dossier

- addressed to the **Minister** by the **authorisation holder**
- by **registered letter** sent to the **FAMHP** for the attention of the **secretariat** of the **Commission** for the Control of advertising of medicinal products

Federal Agency for Medicines and Health Products

Secretariat of the Commission for the Control of advertising of medicinal products

Proper Use of Medicinal Products

Eurostation

Place Victor Horta 40/40

1060 Brussels

II. PROCEDURES - 1. NOTIFICATION - 1.1. Notification dossier

Content notification dossier

- cover letter signed by the **authorisation holder** and countersigned by the **person responsible for information**
- copy of the **authorisation certificate** (= MA or registration)
- mock-up of the **packaging**
- **draft of the advertising**
 - in both national languages (*if diffusion in french and dutch*)
 - clear (!) description of the advertising
(*medium (placard, display, ...), essential data, pictures, sizes, description model, ...*)
- envisaged **way of diffusion** (*via physicians, pharmacies, in magazines, ...*)
- essential elements for the control of the veracity of the advertising (SPC, Patient Information Leaflet, ...) **! Please check**
- proof of payment (2011: € 292,79)
(*Exception: free for medicinal products containing nicotine for the treatment of tobacco dependence*)

II. PROCEDURES - 1. NOTIFICATION - 1.1. Notification dossier

Payment:

preferably via provision

Form (Excel) can be downloaded from the website www.afmps.be / Human use / Proper use of medicine / Advertising / Advertising to the general public

REDEVANCE PUBLICITE	
Demandeur	Nom et forme pharmaceutique du médicament
À déduire du compte Firme:	Description / Référence publicité
Numéro d'autorisation:	
Preuve et motif du paiement:	
Montant:	
Code: 7	
Personne de contact de la firme: Nom:	
Tél.:	
Fax:	
E-mail:	
Si les questions sur la façon de compléter ce formulaire, adressez-vous au 'Bouillage', AFMPS info.medicines@fagg-afmps.be	Uniquement si questions sur l'état de votre compte, adressez-vous à la comptabilité, AFMPS fn@fagg-afmps.be
A remplir par l'Administration:	
N° de dossier:	
Gestionnaire:	
Référence: <i>A mentionner à côté du paiement</i>	

II. PROCEDURES - 1. NOTIFICATION - 1.1. Notification dossier

Evaluation of the notification dossier

1. The absence of a reaction within a **period of 30 days**, does not prevent the diffusion of the advertising.
→ *the deadline starts after receipt of the dossier*
(+ postponement if incomplete) and payment
2. Once notified and without further comment(s) from the secretariat of the Commission, **no changes** can be made to the notification.

Period of validity of a notification dossier

A notification is valid for 2 years.

II. PROCEDURES - 1. NOTIFICATION - 1.2. Renewal of a notification

1.2. RENEWAL OF A NOTIFICATION

- Notification is renewable
- No renewal of the notification is requested
confirm to the secretariat of the Commission on the expiry date
→ the dossier is closed definitively
- Application for renewal of notification
submit 3 months before the expiry date
(*expiry date = 2 years and 30 days after the receipt of the dossier*)

II. PROCEDURES - 1. NOTIFICATION - 1.2. Renewal of a notification

Content of the notification renewal dossier

- cover letter signed by the **authorisation holder** and countersigned by the **person responsible for information**
- **copy** of the advertising as diffused
(! *Identical to the initial notification dossier, no modifications*)
Exception: - 'new' (not relevant in case of renewal)
- modification lay-out packaging, ...)
- proof of **payment** (2011: € 146,40)
(*Exception: free for medicinal products containing nicotine for the treatment of tobacco dependence*)

II. PROCEDURES - 1. NOTIFICATION - 1.3. Reminder advertising

1.3. REMINDER ADVERTISING

- Submission **notification dossier**

- What **must** be mentioned:
name of medicinal product

- What **may** also be mentioned:
 - active ingredient
 - authorisation holder
 - logo authorisation holder

NOT: logo medicinal product, picture of the packaging, ...

II. PROCEDURES - 1. NOTIFICATION - 1.4. Note

1.4. NOTE

- Legally obligatory mentions: clearly legible
 - **legibility** = combination of:
 - **character size**
 - **type face** (italic, narrow, spacious, ...)
 - **contrast** between:
 - the **color** of the **text**
 - the **color** of the **background**
 - ! Draft of the legally obligatory mentions in real size*
 - **size** ~ way of diffusion
publication in magazine ↔ poster
 - **large placard** intended to put it on the floor:
→ legally obligatory mentions at the **top** or in the **middle**

II. PROCEDURES - 1. NOTIFICATION - 1.4. Note

- legally obligatory mentions on **bilingual advertising**:
both languages **clearly separated**
 - *preferably*: two separate blocks
 - *at least*: other language = new line

- **E-screens**
 - the legally obligatory mentions have to be visible on the screen during at least 6 seconds or in case the legally obligatory mentions are spread over multiple screens, during at least 3 seconds per screen
 - specify the duration of each screen
 - same recommendations as for TV-spots → Circular 441 of 2 March 2004

II. PROCEDURES - 1. NOTIFICATION - 1.4. Note

- legally obligatory mentions concerning several medicinal products
 - **structured**
 - **highlight the name of the medicinal products (e.g. bold)**

Example:

Medicinal product A (active ingredient A) is a medicinal product. Do not administer to children under 12 years. Medicinal product B (active ingredient B) is a medicinal product. Do not administer to children under 6 years. No prolonged use without medical advice. Read carefully the patient information leaflet. Ask the advice of your doctor or pharmacist. Marketing authorisation holder X.

Recommended!

Medicinal product A (active ingredient A) is a medicinal product. Do not administer to children under 12 years.

Medicinal product B (active ingredient B) is a medicinal product. Do not administer to children under 6 years.

No prolonged use without medical advice. Read carefully the patient information leaflet. Ask the advice of your doctor or pharmacist.

Marketing autorisation holder X.

II. PROCEDURES - 1. NOTIFICATION - 1.4. Note

- **Displays** can have a storage area at the **back**, on the condition that:
 - the medicinal product is only accessible to the **pharmacist**
 - the packaging is **not visible** for the **public**

- **Not admitted** (*non-usual communication mean*):
 - **real packaging**
 - = packaging as available on the market
 - ↔ is allowed:
 - flat image/photo
 - enlarged model (! at least 2 x the real size)
 - use of **lamps/lights**
 - **press kits**
 - systems that transform a common tool into an advertising
e.g.: placard around Bancontact
 - ...

II. PROCEDURES - 1. NOTIFICATION - 1.4. Note

- **Advertising medicinal product / non-medicinal product**
→ clearly separated!
E.g.: placard - publication in magazine
→ visual images clearly separated
E.g.: brochure
→ advertising of a medicinal product and a non-medicinal product *on the same page* of a brochure is not allowed
→ brochure should be designed in such a way that no confusion is possible
E.g.: website
→ clearly separated columns
ex: medicinal products, food supplements

- **Information on the back intended for pharmacist**
in accordance with advertising intended for healthcare professionals
→ ! *Legally obligatory mentions*

II. PROCEDURES - 1. NOTIFICATION - 1.4. Note

- **Notification: notified as a whole**
 - not allowed to use a part of the notification as advertising object
 - e.g.: brochure**
 - notified brochure
 - would like to use a particular page of this brochure for publication in a magazine
 - ⇒ submit a separate notification

- **Other photo/ image → other notification**
 - E.g.: placard in the sun/in the snow**
 - ⇒ separate notification

II. PROCEDURES - 2. VISA - 2.1. Visa application

2. VISA

2.1. VISA APPLICATION

Submission visa application

- addressed to the **Minister** by the **authorisation holder**
- by **registered letter** sent to the **FAMHP** for the attention of the **secretariat** of the **Commission** for the Control of advertising of medicinal products

Federal Agency for Medicines and Health Products

Secretariat of the Commission for the Control of advertising of medicinal products

Proper Use of Medicinal Products

Eurostation

Place Victor Horta 40/40

1060 Brussels

II. PROCEDURES - 2. VISA - 2.1. Visa application

Content dossier

- cover letter signed by the **authorisation holder** and countersigned by the person **responsible for information**
- copy of the **authorisation certificate** (= MA or registration)
- mock-up of the **packaging**
- **draft of the advertising**
 - in both national languages (*if diffusion in french and dutch*)
 - clear description of the advertising spot / scenario
(image / spoken text / written text / duration spot / duration of the legally obligatory mentions)
- envisaged **way of diffusion**: radio/TV
- essential elements for the control of the veracity of the advertising (SPC, Patient Information Leaflet, ...) **! Please check**
- proof of **payment** (2011: **€ 1463,96**) (preferably via provision)
(*Exception: free for medicinal products containing nicotine for the treatment of tobacco dependence*)

II. PROCEDURES - 2. VISA - 2.1. Visa application

Receipt/control of the visa application

day 0

- deadline starts after receipt of dossier and payment
- secretariat verifies if the dossier is complete
- if not: sent back to firm

5 working days

postponement deadline



Visa application submitted to the Commission

day 5

= day 0 + 5 working days + maybe postponement



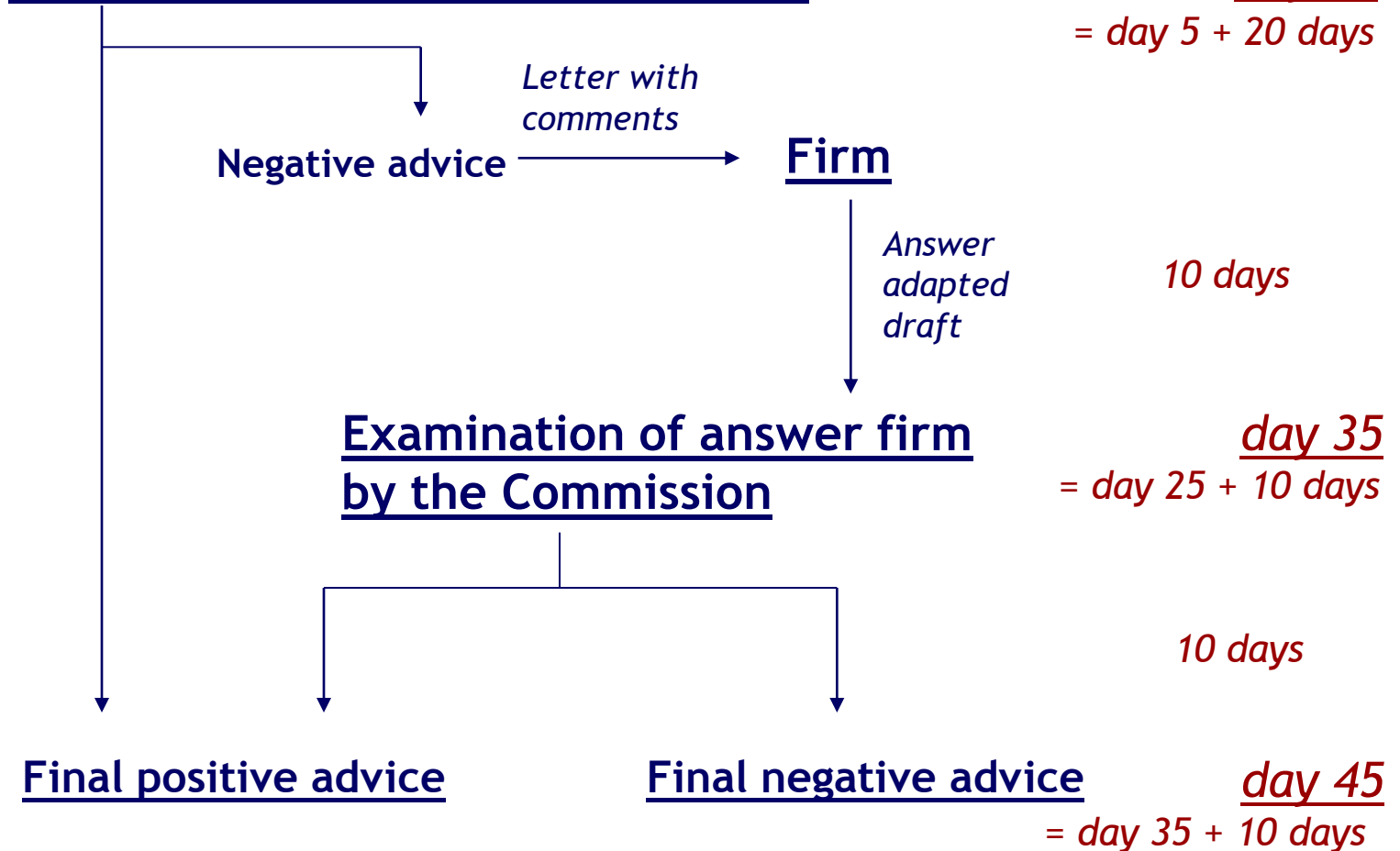
Justified advice of the Commission

day 25

= day 5 + 20 days

II. PROCEDURES - 2. VISA - 2.1. Visa application

Justified advice of the Commission



II. PROCEDURES - 2. VISA - 2.1. Visa application

Final positive advice
of the Commission

or

Final negative advice of
the Commission

day 45
= day 35 + 10 days



Minister



10 days

Visa granted

or

Visa refused

day 55
= day 45 + 10 days



Firm

II. PROCEDURES - 2. VISA - 2.1. Visa application

Note

1. The absence of a decision of the Minister on the visa application within a **period of 45 days** (*+ maybe 10 days postponement if comments are given*), after the submission of the complete dossier does not prevent the diffusion of this advertising.
 - *allowed without visa number*
 - *but article 9 §2 indent 4 and 5 of the law of 25 March 1964 on medicinal products*
2. Once approved **no modifications** may be made to the spot.

Visa period of validity

Visa is valid for two years.

II. PROCEDURES - 2. VISA - 2.2. Submission final version

2.2. SUBMISSION FINAL VERSION

2 possibilities:

- ➔ Final version is submitted at the same time as the visa application
- ➔ Final version is submitted after granting the visa

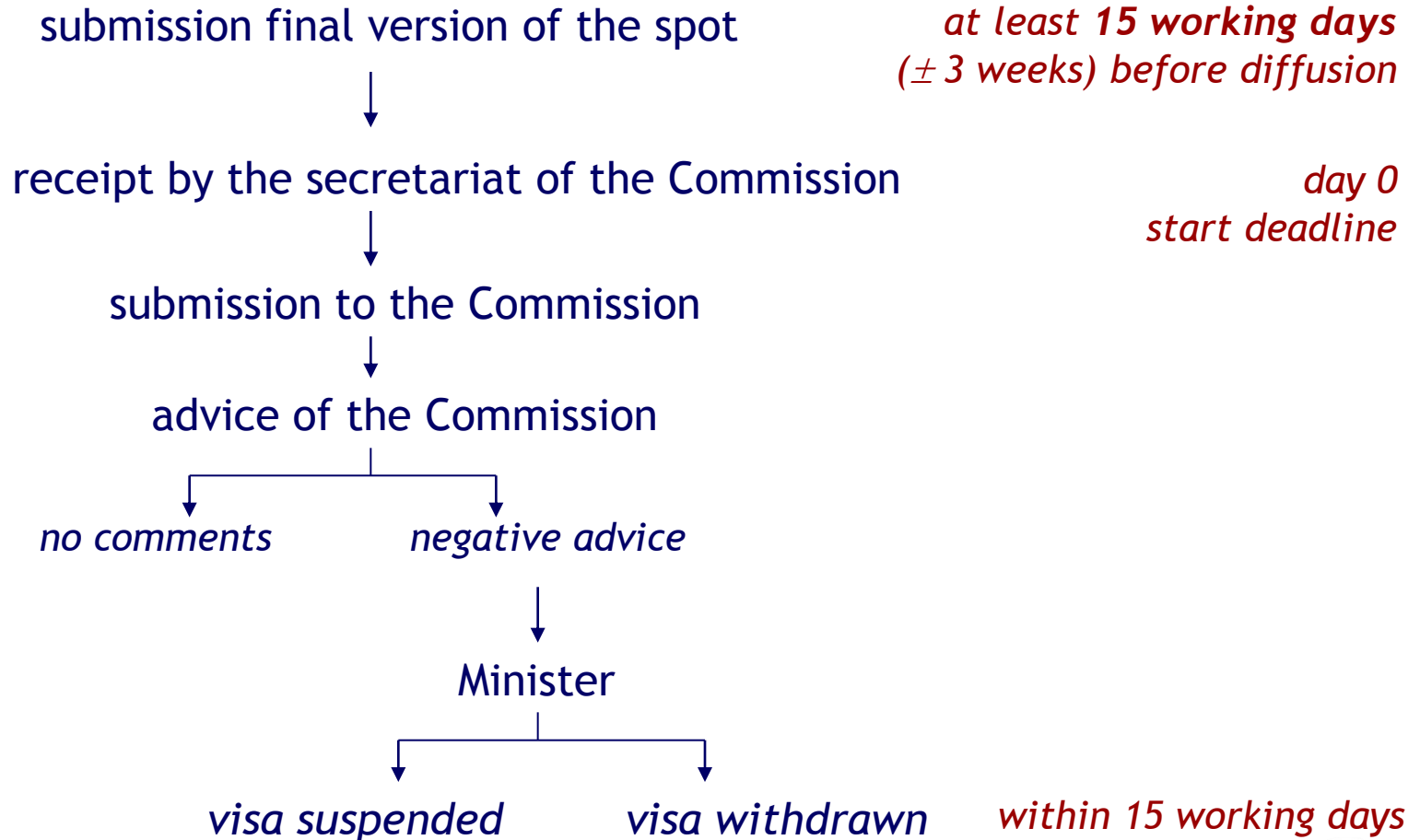
Final version submitted at the same time as the visa application

- final version of the spot is part of the evaluation by the Commission
- possible comments during visa application procedure
- visa only granted if final version has been approved

⇒ *Once visa is granted, the spot can be diffused on radio or TV.*

II. PROCEDURES - 2. VISA - 2.2. Submission final version

Final version submitted after granting the visa



II. PROCEDURES - 2. VISA - 2.2. *Submission final version*

Suspension or withdrawal of visa can only be cancelled by the Minister on the advice of the Commission for the Control of advertising of medicinal products

- advice to cancel the suspension of the visa
- advice to cancel the withdrawal of the visa

⇒ *Diffusion of the spot on radio or TV is only allowed after approval of the final version (at the earliest 15 working days after the submission of the final version).*

II. PROCEDURES - 2. VISA - 2.3. Renewal of a visa

2.3. RENEWAL OF A VISA

- Visa is renewable
- No renewal of the visa is requested
confirm to the secretariat of the Commission on the expiry date
→ the dossier is closed definitively
- Application for renewal of the visa
submit 3 months before the expiry date
(*expiry date is mentioned in the visa number*
E.g.: VN xxx/04-2013 → valid until end April 2013)

II. PROCEDURES - 2. VISA - 2.3. Renewal of a visa

Content of the visa renewal dossier

- cover letter signed by the **authorisation holder** and countersigned by the **person responsible for information**
- **copy** of the radio or TV spot as diffused
(! *Identical to the initially approved spot, no modifications*)
Exception: - 'new' (not relevant in case of renewal)
- modification lay-out packaging, ...)
- Proof of **payment** (2011: € 731,97)
(*Exception: free for medicinal products containing nicotine for the treatment of tobacco dependence*)

II. PROCEDURES - 2. VISA - 2.4. Reminder advertising

2.4. REMINDER ADVERTISING

- No submission visa application

The visa granted for the original advertising is also valid for the reminder advertising!

- What must be mentioned:

- name of the medicinal product
- visa number

- What may also be mentioned:

- active ingredient
- authorisation holder
- logo authorisation holder

NOT: logo medicinal product, packaging image, ...

II. PROCEDURES - 2. VISA - 2.5. Note

2.5. NOTE

Legally obligatory mentions in TV spots: clearly legible !

- final version: preferably on **DVD**
- in case of **spreading** the legally obligatory mentions over multiple screens: **logical splitting**

E.g.: contraindication completely on one screen

Not acceptable

Screen 1

This is a medicinal product. No prolonged use without medical advice. Do not administer

Screen 2

to children under 12 years. Read carefully the patient information leaflet. Firm X VN....

Acceptable

Screen 1

This is a medicinal product.
Do not administer to children under 12 years.

Screen 2

No prolonged use without medical advice. Read carefully the patient information leaflet. Firm X VN ...

II. PROCEDURES - 2. VISA - 2.5. Note

- Recommendations in Circular 441 of 2 March 2004

For a screen with a diagonal dimension of 45,5 cm

- The legally obligatory mentions are placed in a fixed **block** with a 50% grey colour, with a height of 16 mm, placed at 10 mm from the left, right and bottom edges of the screen.
- **The text:**
 - is centrally positioned in both height and width;
 - is printed in white letters, minuscule, typeface Helvetica Vet - 19 points, spacing – *depending of the programme* – “zero”, “automatic” or “standard”, line spacing 22;
 - does not contain more than two lines per screen (if necessary the legally obligatory mentions can be split up into multiple screens).
- If the **logo** proposed by pharma.be is used, this should be placed in the block in the form of a circle with a diameter of 14 mm, on a white background, placed at 1 mm from the right and/or left edge of the block.

The values of these technical standards should be adapted proportionally to the size of the reference screen.

The legally obligatory mentions have to be visible on the screen **during at least 6 seconds** or in case the legally obligatory mentions are spread over multiple screens, during at least 3 seconds per screen.

III. COMMISSION

COMMISSION FOR THE CONTROL OF ADVERTISING OF MEDICINAL PRODUCTS

MEMBERS

a) Chairman or supply chairman: magistrate or honorary magistrate

→ *appointed by the King*

royal decree of 18/9/2008

supply chairman - royal decree of 26/4/2009

b) *two members of law*

- Chief Executive Officer of the FAMHP or delegate
- Chairman of the Commission for Medicines or delegate

III. COMMISSION

c) *members appointed by the Minister (+ alternates)*

ministerial decree of 18/9/2008, amended by the ministerial decree of 8/9/2009

- two members of the Commission for Medicines or former members
- a representative of the “Collège Intermutualiste National”
- two physicians responsible for information
- two pharmacists responsible for information
- a representative of the medicines industry
- a representative of pharmacists
- a representative of general practitioners

→ appointed for a period of 3 years, mandate renewable

III. COMMISSION

ROLE

- examination of the visa applications
- advice to the Minister in case of sanctions for non-compliance with legislation concerning information and advertising for medicinal products
- advice on:
 - advertising practices that can distort the use of a medicinal product from that approved when granting the MA/registration
 - course of advertising or information campaigns
 - use of different media for promotional purposes

→ *The Commission deliberates validly if at least 7 members are present.*

III. COMMISSION

CALENDAR

The data of the next meetings of the Commission for the control of advertising of medicinal products are available on the website www.afmps.be / *Human use / Proper use of medicine / Advertising / Advertising to the general public.*

Commission de Contrôle de la publicité des médicaments	
<u>Dates des réunions</u>	
▪ <i>jeudi</i>	19 mai 2011
▪ <i>jeudi</i>	9 juin 2011
▪ <i>mardi</i>	28 juin 2011
▪ <i>mercredi</i>	20 juillet 2011
▪ <i>jeudi</i>	11 août 2011
▪ <i>jeudi</i>	1 septembre 2011

→ *Please introduce visa applications at least 10 days before the next meeting.*

IV. ADVERTISING VIA INTERNET

1. WEBSITE / WEB PAGE
2. BANNER
3. Google Ads

IV. ADVERTISING VIA INTERNET - 1. WEBSITE / WEB PAGE

1. WEBSITE / WEB PAGE

Notification - SCOPE

Notification must be submitted for web pages/websites which contain advertising for medicinal products directed to the general public

Notification is not acceptable in the following cases:

- website of a firm: other columns than those where advertising is made for medicinal products
- web pages only accessible for health care professionals (via password)
- websites: information campaigns
- ...

IV. ADVERTISING VIA INTERNET - 1. WEBSITE/WEB PAGE

Notification - 3 cases

1. one or more web pages for different sites
→ 1 notification per draft
2. entire website
→ 1 notification per medicinal product (range)
3. one or more web pages within a website
→ 1 notification per draft or medicinal product (range)

*Multiple notifications may be submitted together (one dossier).
Payment (€ 292,79 (2011)) for every notification.*

A medicinal product range = all medicinal products with:

- *the same name*
- *the same composition on active ingredients*
- *the same indication(s)*

IV. ADVERTISING VIA INTERNET - 1. WEBSITE/WEB PAGE

Notification - dossier content

See also II.Procedures - 1.1. Notification dossier

1. one or more web pages for different websites

→ draft advertising

2. complete website

→ - URL website

- web structure (SITE MAP)

- draft complete website

(text, images, at least one example of the layout)

! Paper version required

! TIP: - access to test version

- number the pages

3. one or more web pages within one site

→ - URL website

- web structure (SITE MAP)

- the way to the advertising with the content of each step on this way

- draft web page(s)

IV. ADVERTISING VIA INTERNET - 1. WEBSITE/WEB PAGE

Legally obligatory mentions

- on each web page
! on first screen - visible without scrolling

OR

- after every mention of the medicinal product

OR

- at least on every first page of a new chapter where the medicinal product is mentioned
! on the first screen - visible without scrolling

These data should be mentioned in such a way that they don't disappear automatically, but only after intervention of the user.

IV. ADVERTISING VIA INTERNET - 1. WEBSITE/WEB PAGE

! Highly recommended:

Legally obligatory mentions in a **fixed block** at the bottom of the screen.

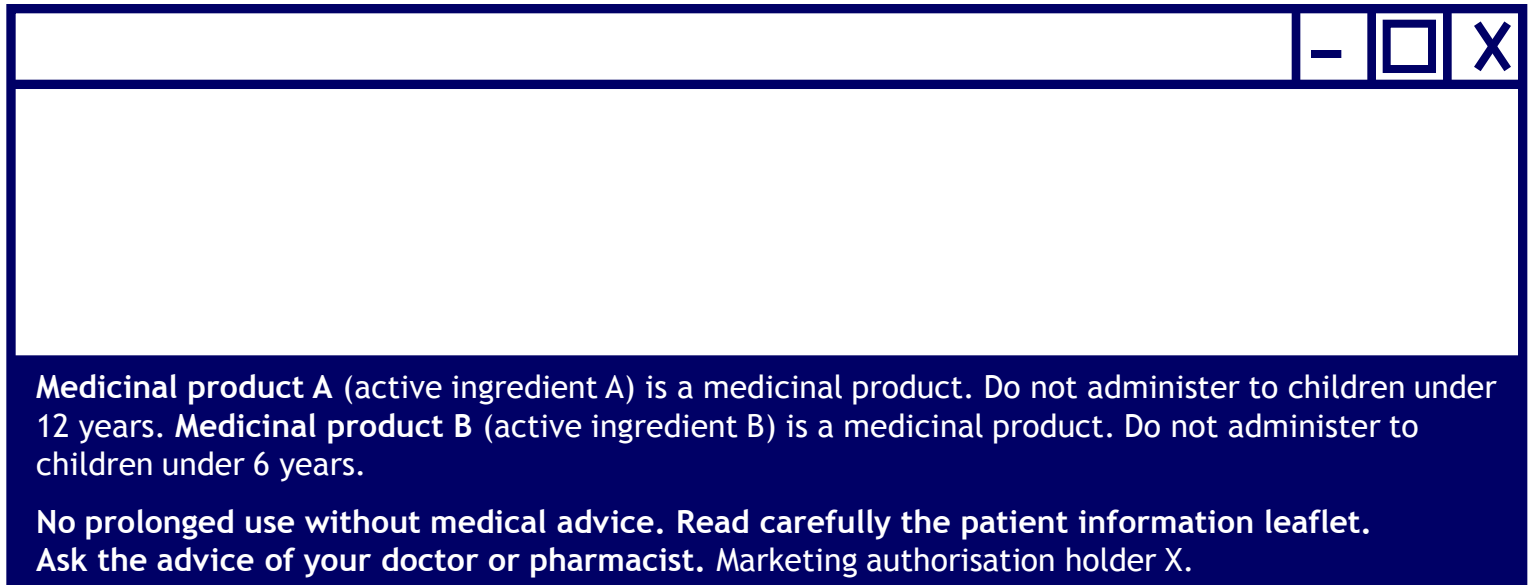
→ the block is still visible after scrolling

→ the complete text remains visible after reducing the screen

Legally obligatory mentions concerning **more than one medicinal product**

→ **structured**

→ **highlight** the name of the medicinal product (*e.g. in bold*)



The screenshot shows a browser window with a dark blue footer. The footer contains the following text:

Medicinal product A (active ingredient A) is a medicinal product. Do not administer to children under 12 years. Medicinal product B (active ingredient B) is a medicinal product. Do not administer to children under 6 years.

No prolonged use without medical advice. Read carefully the patient information leaflet. Ask the advice of your doctor or pharmacist. Marketing authorisation holder X.

IV. ADVERTISING VIA INTERNET - 1. WEBSITE/WEB PAGE

Note

- **Link**
Authorised:
 - website of official/recognised body
(*site with reliable, objective information*)
 - other notified website
Not authorised: website of (pharmaceutical) company
(*content not verifiable/changes regularly*)

- **URL website = www.medicinalproductname.be**
 - a. range of medicinal products containing only OTC medicinal products
→ ***authorised***
 - b. range of medicinal products containing OTC medicinal products and medicinal products on medical prescription
→ ***authorised on the condition that the content only refers to OTC medicinal products***
 - c. range of medicinal products containing only medicinal products on medical prescription
→ ***not authorised for a website accessible to the general public***

IV. ADVERTISING VIA INTERNET - 2. BANNER

2. BANNER

Notification - 2 cases

1. banner with advertising for medicinal product(s)

= one fixed image

or

= set of images which succeed one another

→ 1 notification per draft

2. banner without mention of a medicinal product (name /image)
with a link to a website

= banner is considered as part of the website ('gateway')

→ 1 notification per draft (+ link to website)

*! If the website is also directly accessible (via specific url, regardless of banner),
a separate notificaton dossier must be submitted.*

E.g.: website = notification 1

banner 1 + website = notification 2

banner 2 + website = notification 3

...

Payment (€ 292,79 (2011)) for each notification.

IV. ADVERTISING VIA INTERNET - 2. BANNER

Notification - dossier content

See also ook II.Procedures - 1.1. Notification dossier

1. banner with advertising for medicinal product(s)

- draft advertising (! real size)
- dimensions
- way of showing + duration

Important to specify:

- *image disappears after intervention of the user*
- *image disappears automatically after a certain time (... seconds)*
- *images follow each other automatically, each image visible for ... seconds.*

2. banner without mention of a medicinal product (name/ image) with a link to a website

- draft advertising (! real size)
- dimensions
- website where you arrive via the link
(with reference to the relevant notification)

IV. ADVERTISING VIA INTERNET - 2. BANNER

Legally obligatory mentions

- 1. banner with advertising for medicinal product(s)**
 - the legally obligatory mentions have to be visible on the screen during at least 6 seconds or in case the legally obligatory mentions are spread over multiple screens, during at least 3 seconds per screen
- 2. banner without mention of a medicinal product (name/ image) with a link to a website**
 - legally obligatory mentions don't have to be mentioned on the banner (banner = 'gateway' to the website)
 - legally obligatory mentions have to be mentioned on the first web page (first screen) of the website where you arrive after clicking

IV. ADVERTISING VIA INTERNET - 3. Google ads

3. Google ads

Google ad = considered as an access to a web page/website

Notification - dossier content

See also II.Procedures - 1.1. Notification dossier

- search terms (to use in the Google search)
- text that you see after insertion of each search term
- website/specific web page where you arrive via the link
(with reference to the relevant notification)

*Several Google advertisements can be submitted as one notification
(one payment € 292,79 (2011)).*

IV. ADVERTISING VIA INTERNET - 3. Google ads

Legally obligatory mentions

- legally obligatory mentions don't have to be mentioned in the Google ad (Google ad = 'gateway' to the web page/website)
- legally obligatory mentions have to be mentioned on the first web page (first screen) of the web page/website where you arrive after clicking