Labelling of medicinal products

I. Introduction

In 2004, revision of the European law on medicinal products, better known as 'Review 2001', was completed. Directive 2001/83/EC was thus adapted by Directive 2004/27/EC. Implementation ensued and in Belgium, the revision of the Law on medicinal products of 25 March 1964 and the corresponding implementing decree, the Royal Decree on Human and Veterinary Medicinal Products of 14 December 2006 are currently in force.

Labelling includes the outer packaging and the immediate packaging. It is also possible that there may only be the immediate packaging.
Labelling must be drafted in such a way that the critical information necessary in order to use a medicinal product correctly and safely is clearly legible, easily accessible and comprehensible.
The information presented on the packaging must be approved by the FAMHP. The information must therefore correspond to the marketing authorisation (MA), the summary of product characteristics (SPC) and the package leaflet, and must always be provided in the three national languages.

The information mentioned is important but the manner in which it is expressed is also important. This is why the mock-up must also be approved by the FAMHP. A mock-up is a two-dimensional draft design, in colour and employing the final font and character size, which gives a clear image of the three-dimensional presentation of the packaging.
Given that the FAMHP receives numerous questions relating to labelling and the mock-ups, this document is intended to provide explanations concerning the labelling requirements.

II. Legislation and policy documents relating to labelling

- Law on medicinal products of 25 March 1964:
  - Article 1: definitions
  - Article 6 §1*quinquies*, paragraph 5: general provision permitting the King to set the conditions that must be met by the outer packaging as well as the immediate packaging.
  - Article 6*septies*, paragraph 1: indication that the text on the outer/immediate packaging must be drafted in the three national languages.
  - Article 6*septies*, paragraph 6: indication of the name of the medicinal product in Braille.
  - Article 6*septies*, paragraph 7: possibility of exemptions (derogations).

- Royal Decree on Human and Veterinary Medicinal Products of 14 December 2006
  - Article 53: list of the data that must appear on the outer packaging, as well as on the immediate packaging where there is no outer packaging.
  - Article 54: list of the data that must appear on the immediate packaging.
  - Article 56: additional data for the packaging of medicinal products registered according to the central procedure, as well as the possibility of signs and pictograms.
  - Article 57: additional data for radionuclides
  - Article 58: additional data for plasma derivatives of human origin.

- Homeopathic medicinal products: Royal Decree on the registration of medicines of 3 July 1969, CHAPTER III. - (Provisions relating to the registration of homeopathic medicinal products.) <RD 1999-06-23/41, Article 10, 024; Entry into force: 03-09-1999>, Article 28*bis*.

- QRD template. (link: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&mid=WC0b01ac0580022c59)
- Guideline on the excipients in the label and the package leaflet of medicinal products for human use (Link: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001683.jsp&mid=WC0b01ac05808c01f6)
- A Guideline on the readability of the label and package leaflet of medicinal products for human use", hereinafter referred to as the "Guideline on readability". (link: http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf)
- Guidance concerning Braille requirements for labelling and the package leaflet. (link: http://ec.europa.eu/health/files/pharmacos/docs/doc2005/04_05/braille_text20050411_en.pdf)
- QRD recommendations on the expression of strength in the name of centrally authorised human medicinal products (as stated in section 1 of SPC, and in the name section of labelling and PL) (Link: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/01/WC500056428.pdf)
- Notice to Applicants volume 2C. Guideline on the packaging information of medicinal products for human use authorised by the union (Link: http://ec.europa.eu/health/files/eudralex/vol-2/c/bluebox_06_2013_en.pdf http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/CMDh_258_2012_Rev09_2016_03_clean.pdf
- Note for Guidance on the Declaration of Storage Conditions A) in the product information of medicinal products, and B) for active substances. (link: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003468.pdf)
- Exemptions document: a document drafted by the FAMHP concerning the acceptable exemptions. (link: http://www.fagg-afmps.be/sites/default/files/content/POST/MAH/90-fr-derogations_fr.pdf
- Document National guideline for the denomination of medicines for human use. (Link: http://www.fagg-afmps.be/sites/default/files/downloads/guideline%20dénominations%20FR%20highlighted%20april%202013.doc)

III. QRD template

This template was drafted by the European-level working group Quality Review of Documents (QRD). This document explains how the various fields indicated in the legislation should be completed. It is used as the basic reference document for the packaging of medicinal products. See below for a point-by-point explanation of the various items to be indicated.

When there is a harmonised labelling, this has to be strictly followed: exemptions are only permitted in a limited number of cases. For more on this topic, see the Exemptions document.
The QRD template only contains information on what must be mentioned on the packaging.

Particulars that must appear on the outer packaging and on the immediate packaging:

1. Name of the medicinal product

The name is defined as follows in the Law of 25 March 1964:

'the name, which may be an invented name, not to be confused with the common name, or a common or scientific name combined with a brand or the name of the marketing authorisation/permit holder;'

The Royal Decree of 14 December 2006 provides that: '*the name of the medicinal product, followed by its dosage and its pharmaceutical form and, where applicable, mention of the patient (infants or adults); when the medicinal product contains up to three active substances, the international non-proprietary name (INN) or, if this does not exist, the usual common name;*'

The name is one of the distinctive characteristics of a pharmaceutical product and shall be found alongside such characteristics as the dosage and the pharmaceutical form. The name shall be indicated in the same way as in the Summary of Product Characteristics/the package leaflet.
'Name' should be understood to mean:

- an invented name;
- the INN plus the name of the marketing authorisation holder.

The rules concerning naming are explained in the document “National guidelines on the denomination of medicinal products for human use”.
As has already been indicated, the chosen name above must then be followed on the packaging by the dosage, the pharmaceutical form and the active substance. If a pharmaceutical product is intended to be used exclusively by a particular age group, this age group may be indicated (for example: newborn, infants, adults) as part of this name. A grouping of distinctive characteristics thus appears on the packaging, to ensure that a product can always be uniquely identified.
The active substance(s) should ideally be expressed in the three national languages, in accordance with the INNs recommended by the World Health Organization (WHO) or, in the absence of an INN, in accordance with the usual common name accepted at authorisation. They may also be indicated only in Latin or in English.. For more information, see the Exemptions document.
The way in which the name, dosage, pharmaceutical form and active substance should be indicated on the packaging is explained in detail in the QRD template. One important requirement in this area is that the reference to the active substance must always correspond to the dosage expressed in the name or following the name. If the name of the product is made up of the general or scientific name and the name of the marketing authorisation holder, it is no longer compulsory to indicate the general or scientific name

of the active substance again immediately adjacent (below or to one side) to the name on the packaging. Note: the complete name of the active substance must appear within the name. (see also the Exemptions document).
We would also draw attention to the fact that the description of the pharmaceutical form must always correspond to the recommendations in the Standard Terms published by the Council of Europe.

It should also be emphasised that the aforementioned information may be presented in a number of lines and if necessary in various font sizes, provided that the reader perceives it as one integrated text. 'One integrated text', means that this information must appear on the same side and no other text may appear between the components making up the name of the medicinal product, namely the (invented) name, dosage, pharmaceutical form and active substances.

2. Statement of Active substance

The Royal Decree of 14 December 2006 provides that: *'the qualitative and quantitative composition in active substances by dosage units or, according to the form of administration, for a certain weight or volume, using the common names.'*

Concerning indication of the composition, the rule is that this must be seen in combination with the name, the dosage and the pharmaceutical form, as has already been indicated above.

The composition must be expressed in the three national languages, in accordance with the INN recommended by the World Health Organization (WHO) or, in the absence of an INN, in accordance with the usual common name accepted at authorisation. Exceptions to the obligation to mention the composition in the three national languages are explained in the Exemptions document.

Just like the QRD European working group, the FAMHP also imposes the following requirements: for the immediate packaging and for the outer packaging, the qualitative and quantitative composition of the active substance(s) must be mentioned as follows:

- Per dose unit (thus per tablet, per 'puff' in the case of aerosols, etc.) or according to the form of administration for a particular volume or weight. The way in which the dosage should be expressed is indicated in the following document: QRD recommendations on the expression of strength in the name of centrally authorised human medicinal products (as stated in section 1 of SPC, and in the name section of labelling and PL). In certain cases, both the quantity per dose unit and the total quantity in the packaging should be indicated. The total quantity per total volume may be very important because of the safety aspects of injectable products.

- If the active substance is present in the product in the form of a salt, this must also be clearly indicated.

If more than one dosage is available for a given medicinal product, this dosage must then also always be expressed in the same way. For example: 250 mg, 500 mg, 750 mg, 1 000 mg and not 1 g. Wherever possible, commas should be avoided, for example, 250 mg rather than 0,250 g.

If the dosage is expressed in micrograms, this dosage unit must, for reasons of safety (confusion with milligrams), be written out in full. Exclusively in cases where this would cause practical problems, the abbreviation 'mcg' may be used for the dosage. Under no circumstances may the abbreviation 'µg' be used, given the high risk of the Greek 'mu' for 'microgram' being confused with the 'm' for 'milligram'. For more information see the European Commission document 'Guideline on readability'.

3. List of excipients

The Royal Decree of 14 December 2006 provides as follows: *'a list of excipients that have a well-known action or effect and which are described in the detailed guidelines published by the European Commission in 'The Rules governing medicinal products in the European Union', as laid down in the latest available version. However, if the product is injectable, or a topical or eye preparation, all excipients must be stated;'*

The European Commission has published a list of the excipients that must always be mentioned (see the 'Guideline on the excipients in the label and package leaflet of medicinal products for human use').

If a pharmaceutical product is intended for parenteral or topical use (i.e. not only medicinal products intended for external dermal use, but all medicinal products applied to the oral, nasal, rectal and vaginal mucosa), or is an eye preparation or is used for inhalation, all of the excipients must be indicated qualitatively.

The excipients should ideally be indicated in the three national languages. It is also possible to have the excipients only in English or Latin. For more on this topic, see the Exemptions document.

The entire composition may of course still be indicated on the label for each pharmaceutical product.

4. Pharmaceutical form and content

The Royal Decree of 14 December 2006 provides as follows: 'the pharmaceutical form and the content by weight, volume or dosage units'.

Pharmaceutical form has already been discussed in detail in relation to the name of the medicinal product.

The total content of the packaging must be indicated here, for example thirty tablets.

Where applicable, any devices included (and the number thereof), such as needles, disinfectant swabs, etc., must also be mentioned. It might also, for example, include the attachment system for a drip bag.
Given that it is important for professional groups to know what form of packaging they will be handling, it is recommended that information on this subject be included on the outer packaging and on the label. It should moreover be emphasised that such additional information relating to the form of packaging may obviously not be presented in a promotional manner.

5. Method of use and administration route(s)

The Royal Decree of 14 December 2006 provides as follows: *'the administration method and, if necessary, the administration route. A space must be provided to indicate the prescribed dose;'*

An indication emphasising that the package leaflet must always be consulted before use, must always be included: 'Read the package leaflet before use'.

It is generally necessary to indicate the administration route if this cannot be concluded from the pharmaceutical form. The description of the administration route must always be given as per the Standard Terms published by the Council of Europe. Generally accepted abbreviations, for example 'IV', are permitted. (see also the Exemptions document). Negative statements may not be used, for example: 'Not for intravenous use'.

This category also includes the technical indications for correct use of the medicinal product, for example: 'Do not chew', 'Shake before use'.

6. Special warning stating that the medicinal product must be kept out of the sight and reach of children

The Royal Decree of 14 December 2006 provides as follows: '*a special warning stating that the medicinal product must be kept out of the sight and reach of children*;'

The phrase 'Keep out of the sight and reach of children' must appear on the packaging.

7. Other special warning(s), if necessary

The Royal Decree of 14 December 2006 provides as follows: '*a special warning, if required for the medicinal product*;'

In particular cases, a special warning may be requested by the FAMHP.

8. Expiry date

The Royal Decree of 14 December 2006: '*clear indication of the expiry date (month/year)*.'

The date until which the product is considered good to be used must be clearly indicated. The month must be indicated with two figures or at least three letters and the year with four figures. Where only the month and the year are indicated, the expiry date shall be considered to be the last day of the month. See also Annex IV to the QRD template.
The shelf life after opening of the immediate packaging, or after dilution or reconstitution, must be indicated or there must be a referral to the package leaflet.

9. Special storage conditions

The Royal Decree of 14 December 2006 provides as follows: *'the special storage conditions, if appropriate*;'

See also Annex III to the QRD template. Note: these indications only apply if the stability tests submitted have been performed according to ICH standards.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products (if applicable)

The Royal Decree of 14 December 2006 provides as follows: *'where applicable, the particular precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, as well as reference to any collection system that may be implemented;'*

These indications must be mentioned in the case of substances presenting particular hazards, such as cytostatics or radiopharmaceuticals.

11. Name and address of the Marketing authorisation holder

The Royal Decree of 14 December 2006 provides as follows: *'the name or business name and permanent address or registered office of the marketing authorisation holder and, where applicable, the name or business name of the representative designated by the marketing authorisation holder.'*

The name of the holder, followed by their address, must appear on the packaging. Some examples of contact possibilities include: postal address, telephone number, fax number, email address.
Concerning the address (also the postal address), the rules are as follows: a post office box (plus the town) is not acceptable. This cannot be considered an address in the legal sense. The address must therefore comprise the street, house number and town. The country name must also be added if the marketing authorisation holder is not established in Belgium.
An Internet address is not permitted to appear. Concerning the telephone number, it should further be noted that this must be the general telephone number of the marketing authorisation holder. The indication of special telephone numbers, which do not redirect to the number of the marketing authorisation holder but transfer the caller to special patient information programmes or patient help programmes, is not permitted. The same applies to 0800 numbers, unless the caller is put directly in contact with the company or the local representative of the marketing authorisation holder, as indicated in field 6 of the package leaflet.

To be complete, it should be mentioned that it is quite permitted to indicate, in addition to the marketing authorisation holder, the business name of a representative designated by the marketing authorisation holder. This is only possible if this representative is also indicated in section 6 of the package leaflet as a local representative and this capacity of local representative is indicated on the packaging.

The name of the distributor may not be indicated in their capacity as distributor, because they assume no responsibility for the placement on the market of the product. An exception to this arises when the representative of the marketing authorisation holder, whose contact details are indicated as an 'alternative address for correspondence and information', is also the distributor. This representative can obviously be indicated by

name, albeit exclusively in the context of their role as 'representative for correspondence and information'. The role of representative for correspondence and information must therefore be clearly indicated before the name of this representative. It is not permitted to explicitly indicate the capacity of distributor, given that the term 'distributor' creates confusion regarding who is really responsible for placing the product on the market. In other words, whether or not this responsibility is included in the capacity of distributor.

12. Marketing authorisation number

The Royal Decree of 14 December 2006 provides as follows: *'the marketing authorisation number*'.

This is a unique number in the following format: the letters BE followed by six figures, for example: BE123456.

13. Batch number

The Royal Decree of 14 December 2006 states: '*the manufacturing batch number*'.

The batch number must be a characteristic combination of figures and/or letters that identifies a specific batch in accordance with the European GMP guideline. See also Annex IV to the QRD template.

14. General classification for supply

The supply status of a medicinal product is established by the FAMHP and must appear on the packaging. (blue box item: http://www.hma.eu/91.html).

In the case of prescription-only medicinal products, the following should be indicated: 'prescription medicinal product' or 'on medical prescription'.
For a non-prescription medicinal product, the following should be indicated: 'Medicinal product not subject to medical prescription' or 'Not subject to medical prescription' or 'Non-prescription'.
The following may also need to be indicated: 'Medicinal product available on written request' or 'on written request', in accordance with the order of the *regent*.

15. Instructions for use

The Royal Decree of 14 December 2006 provides that: *'the indication of uses for medicinal products not subject to medical prescription*.'

In the case of medicinal products not subject to medical prescription or medicinal products available on written request, the following should be indicated:

- indication(s) (if no reference is made to the pharmacotherapeutical group, then all of the indications must be indicated). The indication must be in a uniform format (for example no parts in bold or italic);
- dosage, contraindications and warnings. If the packaging is too small, there must be at least one referral to the package leaflet;
- for certain medicinal products, general information and warnings concerning overdose may be required.

16. Information in Braille

The name of the medicinal product must also be indicated in Braille on the outer packaging. From a practical point of view, it is acceptable to add the dosage and pharmaceutical form only when multiple dosages and/or pharmaceutical forms of the medicinal product are available. When the dosage is expressed in micrograms, it is sufficient to indicate 'mcg' in Braille. If there is no outer packaging, the Braille must appear on the immediate packaging. Some exceptions are noted in the Exemptions document. In Belgium, 'Louis Braille' script is used. Concerning the size of the Braille characters, Marburg Medium is strongly recommended.

17.Unique Identifier – 2D Barcodes

2D Barcodes may be included incorporating the unique identifier.

18. Unique Identifier – Human readable Data

The product code, serial number or any other number used for identification and/or national reimbursement of the medicinal product, that is present in the 2D Barcode must also appear in this section.

19. Specific requirements or in other words blue box requirements

These requirements are as follows and may be consulted on the CMDh website: www.hma.eu/91.html .

- Reimbursement category
- Supply status, see section 14, above, 'General classification for supply'. The main narcotic and psychotropic medicinal products subject to a prescription associated with a special regulation must have a code number. This code must appear on the outer packaging or, in the absence of any secondary packaging, on the immediate packaging.
- Identification: for all medicinal products, a national code (potentially presented in the form of a barcode) is accepted. In the case of reimbursed medicinal products (with the exception of oxygen bottles and medicinal products restricted to hospital use), a unique barcode must be present. This barcode must be printed in black on a white background. A non-detachable label with the barcodes is also acceptable.
- Pictograms in the case of medicinal products for external use.
  In the case of a medicinal product for external use, it is strongly recommended that the outer packaging and, if possible, the immediate packaging, be marked with an orange rectangle with the following inscription: '*Uitwendig gebruik/Usage externe/Ausserliche anwendung*' ('external use'). The same applies to the tactile warning sign in relief. This warning sign is an equilateral triangle with sides of 18 mm (+/- 0.2 mm). The width of the side is 1.7 mm (+/-0.2 mm). Around 2 mm above the triangle, there is a point of diameter 1.7 mm (+/- 0.2 mm). All of these elements must have a relief (height) of 0.25 mm to 0.5 mm. A reduced format is provided for small packages: side of 9 mm (+/- 1 mm), width of 1 mm (+/- 0.2 mm). The height remains unchanged. The brand shall in principle be applied at a maximum height of 50 mm from the bottom of the packaging. On small packages, however, it may be placed anywhere.

Minimum particulars to appear on blisters or strips packaging

1. Name of the medicinal product

This point has already been discussed in detail earlier in this document. Here too, the rule is that the (invented) name is followed by the dosage and the pharmaceutical form, and that the active substance(s) must be indicated. In certain cases, exemptions are possible. For more on this topic, see the Exemptions document.

2. Name of the marketing authorisation holder

This point has already been discussed in detail earlier in this document. Note: only the (commercial) name of the marketing authorisation holder should be indicated here and not that of the local representative designated by the marketing authorisation holder.
An exemption is possible in the case of small packaging, provided that the full name of the marketing authorisation holder is already included in the name of the medicinal product. For more information, see the Exemptions document.

3. Expiry date

This point has already been discussed in detail earlier in this document.

4. Batch number

This point has already been discussed in detail earlier in this document.

5. Other

This is for other information necessary in order to use and administer the product correctly. Certain information necessary in order to use and administer the product correctly may be indicated on blister packaging. For example: calendar indications.

6. Specific requirements or, in other words, blue box requirements

This point has already been discussed in detail earlier in this document.

Minimum particulars that should appear on small immediate packaging units

Small packaging is defined as follows (see also the Exemptions document):
bottles (of tablets), vials (for injection) bottles and ampoules *with* a content of up to 100 ml; tubes *with* a content of up to 50 ml or 50g; pouches and patches with a surface area of up to 36 cm^2.

1. Name of the medicinal product and administration route(s)

This point has already been discussed in detail earlier in this document. Here too, the rule is that the (invented) name is followed by the dosage and the pharmaceutical form, and that the active substance(s) must be indicated. The administration route(s) must also be indicated here. The information relating to the administration route(s) has also been discussed earlier in this document. In certain cases, exemptions are possible. For more on this topic, see the Exemptions document.

2. Administration method

This category includes the technical indications for correct use of the medicinal product. For example: 'Do not chew' 'Shake before use', etc.
If not all of this can be indicated on the packaging, there must be a referral to the notice: 'Read the package leaflet before use'.

3. Expiry date

This point has already been discussed in detail earlier in this document.

4. Batch number

This point has already been discussed in detail earlier in this document.

5. Content by weight, by volume or by unit

Information relating to the content may be found in the point entitled 'pharmaceutical form and content'.

6. Other

If space permits, any other information necessary for the proper use and correct administration of the medicinal product may be indicated here. For example: storage conditions.

7. Specific requirements or, in other words, blue box requirements

This point has already been discussed in detail earlier in this document.

IV. Mock-up

As already indicated above, the QRD template only covers what needs to be indicated on the packaging.
But the way in which the elements are indicated on the packaging is also important (font size, use of colours, lay-out, etc.). The guidelines on the best way of indicating this are available in *The Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use*. Reference is made below to the Guideline on Readability.

'Mock-up', means: a two-dimensional draft design, an exact reproduction of the packaging as it will be placed on the market. Namely: a draft design in the final colour, with the final font, the final character size and the final lay-out, which gives a clear image of the three-dimensional presentation of the packaging. The dimensions of the packaging (or the label) and the size of the characters in the *mock-up* shall be indicated.
You are requested to submit the smallest packaging (marketed) so that it is possible to evaluate the *worst case scenario*.
If the smallest packaging size is not marketed, the next size may be submitted under a *commitment* (PAC).
On existing *mock-ups*, *sticky notes* with the modifications to be made are only permitted if a correct readability assessment is still possible (i.e. limited modifications).

Readability

As indicated in the Guideline on readability, the font size of the packaging text must be at least, or equivalent to 9 points, -Times New Roman - not narrowed. Smaller character sizes will be evaluated on a case-by-case basis, with regard to readability. On blister and strip packaging, it is permitted to indicate certain data (for example batch number, expiry date, etc.) using embossed instead of printed text.
Avoiding the use of repeated mentions improves readability. If, for example, referral to the package leaflet is necessary in more than one section, it is sufficient for the words 'Read the package leaflet before use' to appear only once on the mock-up.

- Readability - technique

In order to facilitate readability, requirements have been imposed and advice is given in section A of the Guideline on readability, concerning the type and size font, use of colours, syntax, paper format and paper quality.

- Sufficient distinction

In order to avoid any confusion or medication errors, it is necessary that the packaging of the various pharmaceutical forms and dosages, as well as that of other products from the same marketing authorisation holder or potentially also from other marketing authorisation holders, may be clearly distinguished from one another. The use of different colours to distinguish between different dosages is highly recommended.

- Exemption from using the three national languages

Exemption from using the three national languages shall only be granted in very particular cases and is still limited to the immediate packaging of radiopharmaceutical products. See also the Exemptions document.

Logos, signs and pictograms

The Royal Decree of 14 December 2006 provides as follows: '*The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in Articles 53 and 55, paragraph 1, and other information compatible with the SPC which is useful to the patient, to the exclusion of any element of a promotional nature.'*

This article permits the inclusion of signs or pictograms (intended to make explicit the data that must be compulsorily included based on Articles 53 and 55), as well as other data.
The label may not include any data, logo, sign or pictogram that:

- is contrary to the SPC text that has been approved by the FAMHP;
- concerns information promoting the use of the product.

Signs, illustrations or pictograms may only be used for the purposes of clarification and cannot replace the compulsory text.
If logos, illustrations, signs and pictograms are added, this must have a clear added value.
Whether or not the signs, illustrations or pictograms are accepted, the definitions, principles and control criteria below shall be respected.

- **Definitions**

- Signs and pictograms: this means standardised symbols and simple, stylised illustrations used to express information or an indication in an unequivocal manner.
- Logo: this means the recognisable sign or distinctive mark of a particular legal person (for example the marketing authorisation holder), with a fixed design.
- Illustrations: this means all graphical illustrations other than logos or signs/pictograms.

- **Principles**

When evaluating packaging, the packaging is evaluated as a whole, in order to see whether the total composition is still clear and coherent.
Although it is often said that "a picture is worth a thousand words", graphical information also has its limits. Illustrations on packaging must therefore always be evaluated according to the (corresponding) explanations, which give information on the package leaflet or the labelling.

Signs, pictograms or other illustrations may only be used for the purposes of clarification and may not replace the compulsory text. Should an agreement be reached concerning standardisation of the pictograms, the marketing authorisation holders will be obliged always to use these pictograms. The marketing authorisation holder may also voluntarily put logos or other illustrations on the packaging, provided that this meets the control criteria below.
The graphical elements for the marketing authorisation holders are also important in distinguishing one product from another.

- **Control criteria**

Should the marketing authorisation holder want to place signs, pictograms, logos, illustrations or other data next to the compulsory information texts on the packaging of a medicinal product, these must meet the following general criteria:

- *they are not contrary to the approved SPC text or to the text on the packaging of the medicinal product:*

The SPC text with the corresponding package leaflet constitutes the basis for all communication relating to the medicinal product and therefore also for the information that is provided via the packaging. The aim is not however to repeat the SPC text verbatim. The compulsory wording on the packaging must be derived from the SPC text but formulated in a way that is easy for the user to understand.

- *they comply with the Guideline on readability:*

The choice of colours and the clarity of graphical elements may not have a negative impact on the readability of the compulsory wording on the packaging.
Concerning their dimensions, the graphical elements may not dominate and must, in terms of the choice of colours/clarity, be subordinate to the minimum compulsory text. They must therefore not distract the user's attention away from the compulsory text.

- *they are not untruthful:*

It is obviously not permitted to suggest via the packaging that the product has properties that it does not possess, such as a wider range of indications for the medicinal product, or exaggeration of its efficiency.

- *they do not cause confusion:*

The purpose, among others, of the signs, pictograms and other illustrations, is to clarify the textual information on the packaging of a medicinal product.
If too much visual imagery is present on the packaging, the explanatory purpose is lost.
This would also apply in cases where an illustration would have to be so complicated that it would not be understood by the average consumer.
Therefore, the aim is, for example, to standardise the pictograms illustrating particular precautions, so that everyone understands a given pictogram in the same way.
Clear and correct pictograms could themselves also lead to confusion in certain cases, for example where combined. This must be avoided.
The product must always remain identifiable as a medicinal product and an illustration may not lead to misunderstandings concerning the nature of the product (for example, it being mistaken for sweets).

- *they are not contrary to the norms of good taste and decency:*

During the design phase, due regard should be given to the fact that the illustrations may not evoke any undesirable association (offensive, racist, discriminatory, sexist, pornographic, blasphemous, etc.) in the minds of users (or some of them).

- *they are not presented in a promotional manner:*

Any form of information relating to a product may contribute to a user's preference for that product and therefore appear promotional at a certain level. The choice of graphical form may also be a determining factor in the product's perceived attractiveness. However, the purpose of the illustration(s) must be to provide visual information intended to clarify the compulsory text.
This is why the FAMHP chooses in principle not to authorise any photographs on packaging (except to illustrate the pharmaceutical form).

- *they contribute to the health information.*

The information present on packaging is intended to promote correct use of the medicinal product by the user. In a single case, subject to clear reasons being given, a

written text may be supported by graphical elements and thus contribute to the health information.

Note: The addition of a pictogram is examined and evaluated internally.

Some specific remarks relating to illustrations

Certain illustrations are difficult to standardise and it is not generally deemed desirable by the marketing authorisation holders to do so, as images are a determining factor for the identity of the company or the product.

Without more precise specific conditions, the following illustrations (graphical elements) are in principle permitted: abstract (stylised) layout elements such as lines, arcs, circles and background colours, without any other meaning and provided that the readability of the textual information is not compromised. Priority should be given to sober graphical elements. Exuberant loops or excessive use of graphical elements such as flowers should be avoided.

In precise terms, the following illustrations are permitted:

- Pharmaceutical form (potentially a photograph):

with such an illustration, there may be no confusion regarding the pharmaceutical form. There must be no ambiguity regarding the pharmaceutical form in question (attention in the case of solutions, suspensions, etc.). Furthermore, the illustration of the pharmaceutical form must correspond exactly to its actual form and appearance; this means that if there is a break line, this must also appear in the illustration.

- Particular administration devices:

such an illustration may be permitted, provided that the illustration is subordinate to the compulsory elements on the packaging.

- Designation of the target group:

an illustration indicating the target group is exclusively permitted if the medicinal product is only intended for a single target group. This especially applies to the indication of children as the target group . Here, particular attention should be given to indication of the age category. The illustration may not in any way suggest another age category than that for which the product is intended. Therefore, the age category must be explicitly indicated next to or within the illustration.

A toy is not explicit enough to designate children as the target group, so it is therefore neither functional nor acceptable. Furthermore, this may lead children to misunderstand the nature of the product and attract them to it in an undesirable manner.

- administration/ treatment site:

this concerns a stylised illustration indicating the part of the body in which the affliction to be treated is present and to which the medicinal product may also be administered; for example, an ear on a medicinal product for earache, a nose on a nasal decongestant, or a foot on a medicinal product for athlete's foot. This is obviously only permitted if the medicinal product can only be administered to a single site.

- Illustration of the indication:

Illustration of the indication will only be possible in some cases and exclusively if it covers all of the registered indications. This prevents an illustration that does not cover all of the registered indications for the product from appearing on the packaging. This will therefore mostly be the case for products for which there is only one indication. It is in this case alone that visual information is sufficient and confusion avoided. Hence why it is

not, for example, permitted to illustrate only a headache or only a backache on an analgesic that is also registered for other conditions.
This image must correspond to the indication, but must also be particularly well thought out and clear (a person coughing can therefore not be mistaken, for example, for a person vomiting).
The illustration may not in any way give the impression that the medicinal product may also be used for indications for which it has not been registered. This could for example be the case if, in addition to a stomach, an œsophagus was also illustrated on a product that was only registered for stomach aches and not for acid refluxes.
Finally, the illustration should in principle be a stylised reproduction of the indication.

Use of trademarks, the symbols ® and TM, the indication '*Marque de*' ('Brand of'), etc.

The use of trademarks, the symbols ® and TM or the indication 'Brand of', etc., is not accepted. These are promotional in nature and are considered of no use to the patient. Exception to this rule: cases where failing to indicate a trademark would mean breach of contract. The same principle applies to licence contracts between different companies and also to copyright indications (in accordance with the Q&A Pre-authorisation guidance [question 3.1.5] on the EMA website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000167.jsp&mid=WC0b01ac0580b18196#section4).

Use of logos

The only logos permitted on packaging are exclusively those of the marketing authorisation holder of the medicinal product in question and their representative for correspondence and information (local representative). If the logo of the local representative is used, it must be placed next to the text on the local representative. The logo of the local representative is only permitted if the logo of the marketing authorisation holder is also present. This precludes any possible confusion and ambiguity concerning the marketing authorisation holder.
Concerning the logos, there can be no question of any indications that might be interpreted as promotion of the product, for example: 'MAH (Marketing Authorisation Holder) X – for better health', is not permitted.
The logo may only contain objective, truthful and non-promotional information.
These logos may only be indicated if there is sufficient space and may not have a negative impact upon the readability of the compulsory information.

QR Codes

The QR code may be added under Article 56 of the Royal Decree of 14 December 2006: *'The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in Articles 53 and 55, paragraph 1, and other information compatible with the SPC which is useful to the patient, to the exclusion of any element of a promotional nature.'.*
The QR code may be added to the packaging provided that it is subordinate to the information described in Articles 53 & 55 of the Royal Decree of 14 December 2006 and that it does not compromise readability. The QR code may not replace the information described in Articles 53 & 55 of the Royal Decree of 14 December 2006. This information must also be available on text form.

For the positive list of acceptable content, please refer to the CMDh template documenttemplate (link: http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/01_General_Info/CMDh_313_2014_Rev04_2016_04_clean.pdf).
QR codes incorporating the batch number, expiry date, BE number, codes for traceability or quality control (CNK, GTIN, etc.) may be added during an ongoing procedure with an impact on the mock-ups. The content of the QR code must be described in the file.
For all other content, case-by-case evaluation will need to be made through submission of a variation or notification.

V. Some particular points

Packaging for more than one country

Packaging for more than one country is acceptable subject to the following conditions:

- all data must also be indicated in the three national languages
- there is a common name (and a common marketing authorisation holder in the event that the name = INN + MAH);
- the classification for supply is identical
- the readability must remain clear

Labelling of ready-made medicinal products

The FAMHP is aware that marketing authorisation holders sometimes wish to place (very) large packaging on the market. This packaging (the specifications of which should simply be set out in the authorisation file) are not intended to be dispensed (by the pharmacist) directly to a patient, but are intended to serve as stock that the pharmacist can use to provide the desired quantity to a number of patients. The labelling of (very large) packaging will therefore need to meet the normal requirements of (immediate) packaging. In the case of the indication of the product name in Braille, an exemption may be obtained. For more on this topic, see the Exemptions document.

Labelling of radiopharmaceutical medicinal products

In addition to what has already been indicated above in the QRD template field, the following must also be mentioned on the packaging of radiopharmaceutical medicinal products:

- the name or chemical symbol of the radionuclide;
- the name of the batch releaser;
- the international symbol for radioactivity.

As already mentioned above, the exemption may be obtained for the immediate packaging (and the lead outer surface) of radiopharmaceutical medicinal products to

permit the data on the immediate packaging to be indicated only in English. Other exemptions are also possible, see also the Exemptions document.

Labelling of combined packaging

Combined packaging contains two or more active substances in (more than) one distinct form of administration.
The aim of combined packaging is to improve patient medication compliance.
Examples: a box with one alendronate tablet and six pouches of effervescent calcium/vit. D granules, a box with one risedronate tablet and six calcium carbonate tablets.
Concerning the denomination rules for combined packaging, see the document National guidelines on the denomination for medicinal products for human use.

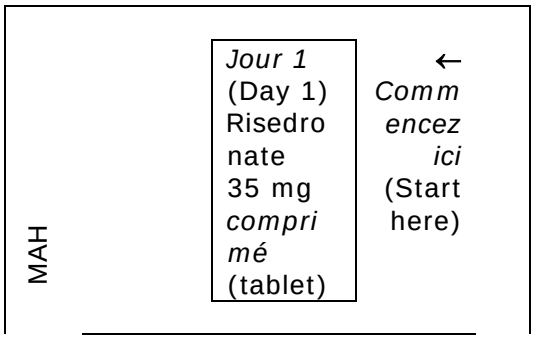
For the outer packaging and intermediate packaging (weekly unit):

A combinatieverpakking van X en Y	A boîte combinée de X et Y	A Kombinationspackung (combined box) von X und Y (X and Y)

A = name of the combined packaging
X and Y = individual names of the component products

However, if the various forms of administration are packaged in the same single blister, there is no individual packaging for X and Y, and therefore no individual denomination is attributed to X or Y. The immediate packaging must however unequivocally indicate from which active substance each tablet is made.

Example:



Lot n (Batch n)

Jour 2 (Day 2) *Calcium 500 mg Vitamine D 880 IU comprimé effervescent* (effervescent tablet)	*Jour 3* (Day 3) *Calcium 500 mg Vitamine D* 880 IU *comprimé effervescent* (effervescent tablet)	*Jour* 4 (Day 4) *Calcium 500 mg Vitamine D 880 IU comprimé effervescent* (effervescent tablet)

Jour 5 (Day 4) *Calcium 500 mg Vitamine D 880 IU comprimé effervescent* (effervescent tablet)	*Jour* 6 (Day 6) *Calcium 500 mg Vitamine D 880 IU comprimé effervescent* (effervescent tablet)	*Jour* 7 (Day 4) *Calcium 500 mg Vitamine D 880 IU comprimé effervescent* (effervescent tablet)

Exp.

NAME A

Batch numbers:
The batch number xxx is indicated on the individual packaging of X.
The batch number yyy is indicated on the individual packaging of Y.
Both (xxx and yyy) are indicated on the outer packaging of the combined packaging.

However, if the various forms of administration are packaged in the same single blister, there is no individual packaging for X and Y, and therefore no individual denomination is attributed to X or Y.

Marketing authorisation number:
The combined packaging receives its own authorisation number.
If there is intermediate packaging (weekly unit), this must receive the same authorisation number as the combined packaging.

Labelling of plant based medicinal products

In the case of plant-based medicinal products, the following document may also be relevant concerning the packaging:

- Guideline on declaration of herbal substances and herbal preparations1 in herbal medicinal products/Traditional herbal medicinal products (Annex 1) (Link: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003272.pdf)

The following points apply specifically to plant-based medicinal products:

- Concerning the name of the medicinal product: for plant-based medicinal products, the dosage should not be systematically included in the name. The particularities associated with the expression of active substances for plant-based medicines may be found in the Guideline on declaration of herbal substances and herbal preparations[1] in herbal medicinal products[2]/Traditional herbal medicinal products (Annex 1).
- In the case of registration as a traditional plant-based medicinal product, the registration number is defined as follows: BE-TU 123456.

Labelling of homeopathic medicinal products

- Homeopathic medicinal product must be indicated in the labelling.

- The authorisation number in accordance with Article 16 is defined as follows: HO-BE123456.

- In the case of homeopathic medicinal products registered according to the simplified procedure (Article 14), the following indications must compulsorily appear on the label:

1) In the case of homeopathic medicinal products for human use, in addition to the indication 'Homeopathic medicinal product registered according to the special simplified procedure':

a) the scientific and/or usual common name of the stock(s) followed by the degree of dilution, using the symbols from the pharmacopoeia used in accordance with paragraph 1;
b) the name and address of the party responsible for placement on the market and, where applicable, the manufacturer;
c) the administration method and, if necessary, the administration route;
d) the expiry date, clearly (month, year);
e) the pharmaceutical form;
f) the volume of the sales model;
g) the particular storage precautions, if appropriate;
h) the special warning, if required for the medicinal product;
i) the manufacturing batch number;
j) the registration number;
k) a warning advising the user to consult a doctor if symptoms persist.

2) In the case of homeopathic medicinal products for veterinary use, in addition to the indication 'Homeopathic medicinal product for veterinary use registered according to the special simplified procedure' and indication of the target species, the wording mentioned in points a) to j) of 1) should also appear.

3) Small immediate packaging on which it is impossible to mention the indications provided for in 1) must, in addition to the indications 'Homeopathic medicinal product registered according to the special simplified procedure' or 'Homeopathic medicinal product for veterinary use registered according to the special simplified procedure', bear at least the following information:

- the name of the medicinal product and, if necessary, the dosage and the administration route;
- the administration method;
- the expiry date;
- the manufacturing batch number;
- the content in weight, in volume or in units.

- The registration number according to Article 14 is defined as follows:

- For a unitary component without indication: HO-BE-UH123456
- For a complex without indication: HO-BE-CH123456

Labelling of parallel imported medicinal products

The requirements relating to labelling in principle apply in their totality to medicinal products imported parallelly. The following points apply in a specific manner:

- The packaging must indicate not only the name in Belgium but also the name of the medicinal product as it exists in the country of origin. The name of the country of origin, preceded by the indication 'Original name in the country of origin'. Given that only the name in Belgium may appear on the immediate packaging, it may be useful in this regard to add a sticky label bearing the original name to the immediate packaging. In the case of blister packaging, this label may not hide the formulation of the tablets.
- The packaging must clearly mention the name and address of the importer (= parallel importation authorisation holder), preceded by the indication 'Imported by'.
- The packaging must mention the name and address of the manufacturer responsible for releasing the batch, preceded by the words 'Manufacturer of the imported medicinal product'.
- The packaging must mention the name and address of the foreign marketing authorisation holder for the imported medicinal product, preceded by the words 'marketing authorisation holder for the imported medicinal product'.

The outer packaging of the medicinal product for parallel import must indicate the same data as that indicated on the packaging of the reference medicinal product in the three national languages.
If the immediate packaging of the reference medicinal product includes data relating to the use of the medicinal product, the immediate packaging of the medicinal product for parallel import must also indicate this data in the three national languages. If the

imported medicinal product employs calendar card packaging, the days of the week must therefore also be indicated in the three national languages.

If the blister packs are cut, it must be ensured that no information is cut off.
The batch number that should be indicated on the label and packaging of the medicinal product for parallel import is the batch number allocated by the manufacturer in the member state of origin.