



15 June 2019
EMA/25090/2002 rev.19*
Scientific & Regulatory Management

Compilation of QRD decisions on stylistic matters in product information

Issues	Connected problems	QRD Suggestions
Abbreviations	Subscript and superscript are sometimes not used correctly in acronyms; e.g. C _{max} , C ^{max}	Acronyms must be written in their standard form; e.g. C _{max}
Abbreviations and acronyms	Not always understood, particularly in the package leaflet. The approach varies across languages, so acronyms/abbreviations may be either in the language of the translation or derived from English; e.g. ECT, COPD.	Non-standard abbreviations and acronyms should be avoided and the term should be written out in full. In cases where this is not possible, at its first occurrence the term should be spelled out in full followed by the acronym/abbreviation in brackets. The acronym/abbreviation can then be used thereafter. See also the most frequently used non-standard abbreviations published on this Website, "Table of non-standard abbreviations".

***Rev.19 Changes since the last revision:** Inclusion of new guidance for 'Braille: unit as part of the name', and 'Overfill in injection devices – standard statements'.



Issues	Connected problems	QRD Suggestions
Antiretrovirals: reference and translations	Different practices across Member States on whether it is acceptable to have the English full term followed by the English abbreviation; e.g. protease inhibitors (PIs), or whether the full term and/or the abbreviation should be translated.	EL, FR, HU, LT, IS, RO: full term and the abbreviation in national language. BG, CS, DA, DE, ES, ET, FI, HR, IT, LV, MT, NL, NO, PL, PT, SL, SK, SV: full term in national language. English abbreviation is acceptable.
Braille: 'unit' as part of the strength	When the text in Braille includes the strength, should the unit accompany the figure (e.g. 100 mg)?	The "Guideline on the readability of the labelling and package leaflet of medicinal products for human use" states that for medicinal products authorised only in one single strength, it is acceptable that only the invented name in Braille is stated on the package. However, in cases where the strength is to be reflected in Braille (i.e. medicinal products authorised in more than one strength), the unit should always be included.
Capsules	When the pharmaceutical form is a capsule, either "hard" or "soft", how is this meant to be stated in the product information annexes?	In the EDQM Standard Terms, capsules are referred to as "capsule, hard", "capsule, soft", "chewable capsule, soft", etc. However, this is only for indexing and sorting purposes and the logical word order must be used throughout the product information annexes; i.e. Tradename X mg soft capsules, Tradename X mg hard capsules, Tradename X mg soft chewable capsules, etc. The same applies when stating the pharmaceutical form in section 3 of the SmPC and section 4 of the labelling; i.e. Soft capsule, Hard capsule, Soft chewable capsule, etc.
Concentrate	When the pharmaceutical form is a concentrate, e.g. 'Powder for concentrate for solution for infusion' or 'concentrate for solution for infusion', it is recommended to emphasise in the labelling the special handling prior to administration of the product.	On the outer carton it is recommended to give prominence to the term 'concentrate'. A statement reflecting critical steps prior to administration of the product should also be included (section 5 of Annex IIIA). For instance, in case the pharmaceutical form is "concentrate for solution for infusion" the following statements could be added, taking into account space availability: e.g. "For intravenous use after dilution", "For dilution", "Dilute before use". In case of other pharmaceutical forms such as "Powder for concentrate for solution for infusion" the reconstitution and dilution steps should be accurately reflected depending on the space available, e.g. "For intravenous use after reconstitution and dilution".

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Conditional	The translation of "should" causes problems in Romance languages, Czech, Slovak, Hungarian and Croatian where its literal translations actually mean "it would be preferable" or "it is recommended".	Each language has to make use of the form that best conveys the meaning equivalent to "must" where instructions to the patient or to the doctor are given. However, in order to offer a more precise indication on the mandatory nature of the advice it is recommended that the word "should" is avoided, wherever possible, in the English original text. E.g. "X should be taken with food" could be phrased as "X must be taken with food" or "X is to be taken with food".
Consistency	Inconsistencies in style are often found in product information; e.g. punctuation, symbols, spacing, redaction style, etc.	Once a particular style or house style has been selected it must be used consistently throughout the text.
Container	When the pharmaceutical form is combined with the container, how and where can the container be mentioned in the product information annexes?	The container should be included in section 1 of the SmPC, labelling and package leaflet regardless of the number of presentations available. The examples provided in the EDQM guidance should be strictly followed. E.g. Tradename 150 mg solution for injection in pre-filled syringe Tradename 150 mg solution for injection in pre-filled pen In section 3 of the SmPC and section 4 of the labelling only the pharmaceutical form (e.g. solution for injection) is to be included. The only exception to this rule will be those cases where the container has a tradename and this is to be included in section 3 (see issue "device" below).
Desiccant	For medicinal products packaged with a desiccant there is a risk to accidentally mistake the desiccant for a tablet and ingest it. Although the SmPC and package leaflet include information about the	The foil of blister packs containing a desiccant should be clearly labelled to show which blister pocket contains the desiccant. When space permits, a reference on the outer carton is also recommended, e.g. "Do not swallow the desiccant". For bottles containing a desiccant, a similar statement should also be considered provided there is available space.

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	desiccant, this is not consistently reflected in the labelling.	
Device	If the medicinal product is provided in a device that has a tradename, how and where can this be mentioned in the product information annexes?	<p>Except in the cases where the name of the device is part of the invented name approved by the NRG, the name of the device cannot be part of the name of the medicinal product, and it can therefore NOT be mentioned in section 1 of the SmPC, labelling and package leaflet. It can only be included in brackets in section 3 of the SmPC and section 4 of the labelling. E.g. solution for injection in pre-filled pen (device Tradename)</p> <p>If the short term for the pharmaceutical form is to be used on the labelling, then it needs to be included in brackets as well; e.g. solution for injection (injection) in pre-filled pen (device Tradename).</p>
Food and drink	When choosing examples of food to be taken with a medicinal product, it should be considered whether such food is available in all Member States; e.g. apple sauce, cranberry juice.	<p>For general food, the applicant should choose examples of food to take with a medicine based on their availability and cultural acceptability in all Member States. Special meals should be described in a generic way. In the package leaflet, if necessary, the following wording may be added: "Your doctor or pharmacist will advise you on what meal to take."</p>
Foreign terms	Foreign terms, particularly in Latin, appear frequently in product literature.	<p>Foreign terms must be written in italics; e.g. <i>in vivo</i>, <i>in vitro</i>, <i>Helicobacter pylori</i>. In Greek documents foreign terms appear in their original spelling, i.e. Roman characters.</p>
Gender	The patient or the physician is often referred to as "he".	"He/she" should be used if no other neutral gender locution is possible. Patients can be referred to as "he" or as "she" when the medicinal product is exclusively for use by males or females.

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Health information	Can general information on health or disease be included in the package leaflet in certain justified cases?	<p>Council Directive 2001/83/EC art.62 states that “<i>the package leaflet may include...</i>” “<i>...other information compatible with the SmPC which is useful for health education, to the exclusion of any element of a promotional nature.</i>”</p> <p>Information on the disease should normally be limited to a patient-friendly description of the sections “indications” and “pharmacotherapeutic group” of the SmPC, under their respective headings.</p> <p>Any additional concise information on the disease (e.g. symptoms and signs of the disease, general precautions and appropriate treatment or other measures to take) could be included in section 1 or at the end of the package leaflet, for health education purposes.</p> <p>This information would usually relate to complex or chronic illnesses (e.g. diabetes, osteoporosis). Its inclusion has to be justified by the applicant, and will be assessed on a case-by-case basis.</p> <p>If references to patient organisations are included in the package leaflet, such organisations must be mentioned for all EU Member States (equal access to information for patients).</p>
Imperial measures	Surfaces or other measurements are sometimes expressed in imperial measures in the package leaflet; e.g. “one sachet contains enough cream to cover an area of 20 cm ² (approx. 3 square inches)”.	Imperial measures (e.g. inches) can be included, where appropriate (e.g. if the product in question might be used by elderly patients), in brackets after the metric measures in the English text. These imperial measures must not appear in the translations in other languages.
INN: spelling	How the INN should be spelled throughout the Product Information annexes, i.e. lower case or upper case.	<p>The INN should always be spelled in lower case throughout the PI annexes when not at the beginning of a sentence.</p> <p>In particular, in section 1 of Annex IIIA and at the header of the package leaflet the INN should also be written in lower case.</p> <p>This is applicable to all EU languages with the exception of German, whose grammatical rules make it necessary for the INN to be always spelled with a capital initial.</p>
INN: translation	What are the national requirements for translation of the ‘international	The following list contains national guidance on how to present the international non-proprietary name (INN) in section 1 of the SmPC of medicinal products authorised through the centralised procedure during the post-opinion translation exercise, i.e. when the name of the medicinal product is constructed using the INN or common name followed by the name of the marketing authorisation holder (MAH) or a trademark.

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	<p>non-proprietary name (INN) or 'common name' when included in the name of the medicinal product?</p>	<p>AT: German</p> <p>BE: The INN can be expressed in English or in one of the national languages (NL, FR or DE), at applicant's discretion. English may not be accepted if the INN/common name in English is too different from any of the national languages (FR/NL/DE). If the INN is too different between the national languages, the translations in all national languages have to be included in the name.</p> <p>Examples:</p> <p>- ibuprofen (NL, DE, EN), ibuprofène (FR) : any of these INN forms can be accepted in the name since it is very similar between NL, FR, DE and EN.</p> <p>Potassium iodide (EN), Iodure de potassium (FR), Kaliumjodide (NL) and Kaliumjodid (DE) are too different from each other, and should therefore be translated into the 3 national languages.</p> <p>BG: Bulgarian</p> <p>CZ: Czech or English at applicant's discretion.</p> <p>CY: English</p> <p>DE: German</p> <p>DK: Danish translation of the name should be used, particularly when the English term is very different from the national one e.g. if the name includes "potassium" or "sodium". The English language form of the INN may be used when common Nordic packs are requested and if no safety issues are foreseen.</p> <p>HR: Croatian. English when justified in the interest of market supply (e.g. multilingual packs).</p> <p>HU: Hungarian. English on a case by case basis.</p> <p>IS: The INN should be written in English unless the English term is very different from the national version, for example, if the name includes potassium or sodium.</p> <p>IT: Italian. When no Italian translation is available the English versions are accepted.</p> <p>LT: Lithuanian or English at applicant's discretion.</p> <p>LV: English</p> <p>MT: English</p> <p>NL: Dutch</p> <p>NO: Norwegian or English at applicant's discretion. However, the Norwegian version of the INN may be required if the English term is very different from the Norwegian term (e.g. if the name includes "potassium" or "sodium", etc.).</p> <p>PO: Polish or English.</p> <p>PT: Portuguese</p> <p>RO: Romanian</p>

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		<p>EE: English SK: English</p> <p>EL: English SL: Slovene</p> <p>FI: Finnish or English at applicant's discretion. ES: Spanish</p> <p>FR: French SE: Swedish or English at applicant's discretion. However, the Swedish version of the INN may be required if the English term is very different from the Swedish term (e.g. if the name includes "potassium" or "sodium", etc.).</p>
Invented name: excessive use	Excessive use of the invented name and unnecessary repetition in SmPC and package leaflet.	Unnecessary repetition of the invented name in the product information (SmPC, label and package leaflet) must be avoided. The INN, pronouns or alternative terms (e.g. 'treatment') should be used whenever possible in the SmPC; in particular, the INN should be used when reference is made to the properties of the active substance. In the package leaflet, the term "this medicine" should be used.
Invented name: format	Format of the invented name and use throughout text; e.g. if the registered trade name is written in uppercase, must it be written as such throughout the text of the product information and in the EPAR? What style can be used (maximum font size, bold, underlined, colour etc.)?	The invented name should be used throughout the product information in a consistent format (either upper or lower case) whichever is the choice of the applicant/MAH. However, in order to increase the readability of the product information it is recommended that the invented name is written as "Inventedname", i.e. the first letter in upper case and the rest as lower case letters. In case the name is registered as 'camel case' (e.g. InventedName), this would also be acceptable. In addition, it should be noted that the invented name should be written in the same font and font size as surrounding text (i.e. Times New Roman, size 11) and must not be highlighted in any way.

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Number separators	<p>Different languages use different number separators (a comma or a dot) to distinguish between thousands and decimals.</p> <p>Style of number separator must correspond to the language used.</p>	<p>For decimals: EN, MT: dot (e.g. 12.50 ml) All other languages: comma (e.g. 12,50 ml)</p> <p>For thousand: EN, MT: 1,000.00 DA, DE, EL, ES, IT, NL, PT, SL (and BE packs): 1.000,00 CS, FI, LV, PL, SK, SV: 1 000,00* or 1000,00 ET, HR, HU, RO: 1000,00 BG, LT, FR: 1 000,00* HU, HR: 1000,00 but 10 000* *non-breaking space (<i>ctrl/shift/space</i>)</p>
Open date	<p>A reference to the in-use shelf life is included in the labelling, when medicinal products have short expiry date after first opening. A space to write down the open date is not consistently included in the labelling.</p>	<p>For medicinal products with short expiry date after first opening, the applicant is advised to include a statement referring to the date when the product is opened (e.g. 'Open date: _____') in the labelling. If space permits, a statement referring to the date when the product is discarded may also be included (e.g. 'Discard date : _____').</p> <p>Some products may need a more detailed time specification (e.g. 'hh:mm') due to the very short shelf life.</p>
Overfill in injection devices - standard statements	<p>After the use of certain pre-filled pens, some solution still remains after all doses available in the pen (as per the information provided to the patients in the package leaflet and the instructions for use) have been administered. This was found to be confusing, in particular due to the</p>	<p>The below statements aim to address these concerns and apply to all injection devices/pre-filled pens used by patients or caregivers.</p> <p>Two options are available:</p> <p><u>Option 1:</u></p> <p>In case the use of the residual solution in the device is not allowed and the remaining quantity must be discarded:</p> <p><u><i>SmPC section 4.2 (end of 'Method of administration')</i></u></p> <p>'Before using the {device}, the instructions for use must be read carefully.'</p>

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	<p>assumption that a wrong dose could be given to the patient resulting in under-dosing.</p>	<p><u>SmPC section 6.6</u></p> <p>'A small amount of <active substance><solution><suspension><emulsion> may remain in the {device} after all doses have been correctly given. Patients should be instructed not to try to use the remaining <active substance><solution><suspension><emulsion>, but to properly discard the {device}.'</p> <p><u>Package leaflet section 3</u></p> <p>'A small amount of medicine may remain in the {device} after all doses have been correctly given. Do not try to use any remaining medicine. After administration of the last dose, the {device} must be properly discarded.</p> <p><u>Option 2:</u></p> <p>In case the use of the residual solution in the device is allowed:</p> <p><u>SmPC section 6.6</u></p> <p>'A small amount of <active substance><solution><suspension><emulsion> will remain in the {device} after all doses have been correctly given. Patients should be instructed to follow the instructions for use of the {device}.'</p> <p><u>Package leaflet section 3</u></p> <p>'A small amount of medicine will remain in the {device} after all doses have been correctly given. <Inject><use> the amount left in your {device}, and then use a new {device} to give the rest of your dose, or get a new {device} and <inject><use> the full dose.</p>
<p>Over-labelling</p>	<p>Is the over-labelling concept (use of stickers to replace imprinting on the outer/intermediate packaging) acceptable?</p>	<p>As a general rule over-labelling is not acceptable for the following reasons:</p> <ul style="list-style-type: none"> • readability may be impaired; as reflected in article 56 of Directive 2001/83/EC "the particulars referred to in article 54, 55 and 62 shall be easily legible, clearly comprehensible and indelible"; • possible loss of information (the sticker can become loose); and • source of confusion with an increased risk of having the wrong information on the pack. <p>Over-labelling could only be accepted in exceptional situations. This would only be warranted if competent authorities consider it necessary to safeguard public health, such as situations of shortage supply of the product, and it should be discussed with the relevant competent authorities.</p>

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<p>Package leaflet: combined printed package leaflets</p>	<p>Are combined printed package leaflets acceptable? Are there any safety issues: i.e. are they clear for the patient?</p>	<p>A combined printed package leaflet (PL) can only be acceptable if all the following 3 conditions are met:</p> <ul style="list-style-type: none"> • posology in the SmPC/PL foresees at least 2 dosages (e.g. titration phase, dose adjustment based on clinical response or for special populations); • PLs are completely identical, except for the few strength-specific details; and • a combined PL must not create any risk of confusion or misuse for the patient or user. <p>The applicant must submit their request for a combined PL in advance, together with a justification/rationale. A decision will be taken on a case-by-case basis.</p>
<p>Peel-off labels for traceability purposes</p>	<p>There is a lack of specific guidance with regard to requirements (location, and content) for peel-off labels included for traceability purposes (e.g. plasma-derived medicinal products, vaccines, etc.).</p>	<p>The use of peel-off labels for traceability purposes is common practice for single dose vials and pre-filled syringes labels for certain products (e.g. vaccines, plasma-derived medicinal products).</p> <p>In general, these labels are composed of two parts, one part which remains affixed to the vial/syringe and another part that can be peeled-off and affixed onto the patient record.</p> <p>The peel-off part of the label always displays, at least, the invented name, the batch number and the expiry date.</p> <p>The following points should be considered by applicants when including a peel-off label for traceability purposes:</p> <ol style="list-style-type: none"> 1. It is recommended that the peel-off labels are preferably affixed directly onto the primary packaging (e.g. vial, syringe). If this is not feasible, applicants are required to submit a justification to the QRD secretariat and discuss alternative solutions. 2. The adhesive should be functional throughout the life cycle of the product (e.g. during storage in a refrigerator or in a freezer). 3. When including a peel-off label, the overall readability of the statutory information displayed on the fixed part of the label should not be affected by the inclusion of the peel-off part. 4. The information provided in the peel-off label should always remain available on the fixed part of the label once the peel-off part is detached.

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'Quick starter/reference guide', 'FAQs', etc	Is the inclusion of a separate document in the pack (e.g. quick starter /reference guide, FAQs, etc.) summarising or complementing the package leaflet acceptable?	<p>As a general rule, separate documents summarising or complementing the package leaflet and providing patients with only key messages are not acceptable for the following reasons:</p> <ul style="list-style-type: none"> • there is no legal basis for such documents; • all information intended to patients should be included into the package leaflet and a summary of the latter is not allowed; and • there is a high risk that patients will only read the quick guide, hence missing important information provided in the package leaflet.
SmPC: combined SmPCs	Are combined SmPCs acceptable? During the evaluation procedure? After opinion? In which cases?	<p>The use of combined SmPCs for different strengths of the same pharmaceutical form is encouraged (for evaluation and after the adoption of the opinion for all languages) when the SmPCs are completely identical, except for the few strength-specific details (i.e. if the indications are different for the different strengths, the SmPCs cannot be combined). In case of combined terms, only the primary pharmaceutical form should be considered, e.g. solution for injection in a vial and solution for injection in a pre-filled syringe can be combined. No justification will be required, provided the above conditions are met.</p> <p>For different strengths not meeting the criteria above (e.g. if the indications are different for the different strengths), applicants may present SmPCs for different strengths in one document for the evaluation process only, clearly indicating with titles the strength or presentation to which alternative text elements refer.</p> <p>However, a separate SmPC per strength and per pharmaceutical form, containing all pack-sizes related to the strength and pharmaceutical form concerned will have to be provided as follows:</p> <ul style="list-style-type: none"> - English language version: immediately after adoption of the opinion. - All other language versions: at the latest 25 days after adoption of the opinion (i.e. at the latest after incorporation of Member States comments).

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Strength: sodium chloride solution	"0.9% w/v sodium chloride solution", "9 mg/ml sodium chloride solution" or "sodium chloride 9 mg/ml (0.9%) solution". Practices differ across Member States.	Reference in SmPC and package leaflet: "sodium chloride 9 mg/ml (0.9%) solution for injection" Label for the vial of solvent: "sodium chloride 9 mg/ml <solution for> injection"
Strength: expression of strength in the name of medicinal product in the form of powders for reconstitution prior to parenteral administration	Can the strength in the name of medicinal product in the form of powders for reconstitution be expressed as the total quantity or as the concentration of the active substance?	For further guidance on how to express the strength in the name of human medicinal products, please refer to the " <i>QRD recommendations on the expression of strength in the name of centrally authorised human medicinal products (as stated in section 1 of SmPC, and in the name section of labelling and package leaflet)</i> ".
Trade marks/ brand names of materials/devices/ special meals	Use of trademarks and brand names of medicinal products, materials or devices in product information.	The common name or a generic description of the material, device or special meal should be used. When it is important for the correct use that only one specific device, etc. (with a specific trademark) is used, then that specific trademark should be mentioned, together with a patient-friendly general description in the package leaflet, if necessary.
Units: degrees	Degrees are expressed in different styles; e.g. 10°C, 10 °C, 10° C	There should be a non-breaking space (<i>ctrl/shift/space</i>) between the figure and the ° symbol, and no space between the ° symbol and the indicator of scale used; e.g. 10 °C
Units: general format	Space between figure and unit is missing; e.g. 100ml. Spaces occurring within numbers or between figures and mathematical symbols might break and lead to confusion.	There should be a non-breaking space (<i>ctrl/shift/space</i>) between the figure and the unit or symbol, e.g. 100 ml, > 10, etc.

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<p>Units: SI base units - litre</p>	<p>International Standard base units have been introduced in the European Union with Council Directive 80/181/EEC of 20.12.79 (O.J. L 39 of 15.2.80). This directive allows litre to be written either "l" or "L".</p>	<p>Recommendations from Member States should be followed:</p> <p>EN, FR, IT, MT: "L" BG, CS, DA, DE, EL, ES, ET, FI, HU, IS, LT, LV, NL, NO, PT, RO, SK, SL, SV: "l" BE*, HR, PL: "l" or "L"</p> <p>* With the aim of displaying the strength only once on the BE trilingual pack, Belgium accepts the use of either "l" or "L".</p> <p>In order to minimise the potential for medication errors, in English it is recommended to use "L" in upper case whenever the unit is preceded by the figure 1.</p> <p>The same recommendations above apply to all units of volume (i.e. 'mL' or 'ml', 'dL' or 'dl', etc.) and consistency should be ensured across the product information annexes.</p>

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<p>“Unit dose” pack sizes</p>	<p>The term “unit dose” is intended to differentiate a perforated blister, which is presented to facilitate single tablet administration, from the standard tablet blister presentation.</p>	<p>On the outer carton, the pack size must be stated in section 4 as e.g. “28 x 1 tablets”. In the SmPC and package leaflet the pack size must be stated as e.g. “28 x 1 tablets in <material*> perforated unit dose blisters”.</p> <p>*e.g. “Aluminium/PVC”</p> <p>Please find below the term “perforated unit dose blisters” translated in all EEA languages.</p>	<p>BG : перфориран блистер с единични дози</p> <p>IS: rifgataðar stakskammtaþynnur</p> <p>CS: perforovaný jednodávkový blistr</p> <p>LT: perforuotos dalomosios lizdinės plokštelės</p> <p>DA: perforeret enkelt dosisblister</p> <p>LV: perforēti dozējamu vienību blisteri</p> <p>DE: perforierte Blisterpackung zur Abgabe von Einzeldosen</p> <p>NL: geperforeerde eenheidsblisterverpakking</p> <p>EN: perforated unit dose blisters</p> <p>NO: perforert endoseblisterpakning</p> <p>ES: blíster precortado unidosis</p> <p>PL: blister perforowany podzielny na dawki pojedyncze</p> <p>ET: üksikannuseline blister</p> <p>PT: blisters destacáveis para dose unitária</p> <p>FI: yksittäispakattu läpipainopakkaus</p> <p>RO: blister perforat pentru eliberarea unei unități dozate</p> <p>FR: plaquette prédécoupée unitaire</p> <p>SK: perforovaný blister s jednotlivými dávkami</p> <p>EL: διάτρητο blister, μονάδων δόσης</p> <p>SL: perforiranem pretisnem omotu za enkratni odmerek</p> <p>HR: perforirani blister s jediničnim dozama</p> <p>HU: adagonként perforált buborékfólia</p> <p>SV: perforerat endosblister</p> <p>IT: blister divisibile per dose unitaria</p>

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<p>Units: micrograms</p>	<p>Use of the abbreviation for micrograms in the product information.</p>	<p>Issue addressed in the European Commission’s Readability Guideline concerning the labelling and package leaflet:</p> <p><i>Section B Recommendations for Labelling</i> <i>2 Strength and Total Content:</i> <i>“For safety reasons it is important that micrograms is spelt out in full and not abbreviated. However, in certain instances where this poses a practical problem which cannot be solved by using a smaller type size then abbreviated forms may be used, if justified and if there are no safety concerns.”</i></p> <ul style="list-style-type: none"> • SmPC In the SmPC, it is acceptable to use the abbreviation for microgram recognised by each Member State throughout the text of the document, <u>except</u> in the name of the medicinal product in section 1 of the SmPC, where it should be spelled out in full to ensure consistency with the name on the label and the package leaflet. • Outer Carton Micrograms always spelt out in full*. • Small Immediate Labelling In case of space limitations and, on a case-by-case basis, different abbreviations for ‘micrograms’ can be used as follows: BG, CS, DE, EL, ES, ET, HR, HU, IS, IT, LT, LV, MT, PL, PT, RO, SK, SL, SV: “µg” IS: “µg or míkróg” DA, FI, NO: “mikrog” SV: “µg or mikrog” EN, NL, BE packs (FR/NL/DE)**: “mcg” IT: “µg or mcg” FR: “microgrammes” (France does NOT accept the use of the abbreviation) • Package Leaflet Micrograms <u>always</u> spelt out in full. <p>* Belgium accepts the use of the abbreviation “mcg” on the trilingual outer carton (<u>printed materials</u>), in case of space limitations. ** Belgium accepts the use of the abbreviation “mcg” on the trilingual small immediate labelling (<u>printed materials</u>). However in the language annexes (Annex IIIA), “micrograms” should be spelt out in full in the French language and the abbreviation “µg” should be used in the German language.</p>

Issues	Connected problems	QRD Suggestions																											
<p>Use of EN or Latin Translation of INNs in Product Information Annexes</p>	<p>Often the amount of legally required information to be included in the labelling components of Annex IIIA can cause significant difficulties for the production of multilingual labels, especially when there are space constraints.</p> <p>As no official translated pharmacopoeia is available in the national languages of some of the EU Member States it is often unclear whether Latin, English or the national language version of the INN can be used on the outer/inner packaging.</p> <p>The problem occurs in particular in cases of combined labelling material for more than one MS and can potentially affect the availability of centrally authorised medicines, especially in the market of small Member States; e.g. the Nordic States.</p>	<p>The readability of multilingual labelling can be impaired due to space limitation on the packaging. To overcome these difficulties and to improve the readability of multilingual labelling, the use of English or Latin INNs will be allowed by some Members States as per tables below.</p> <p>The tables are only applicable to outer and inner labelling of <u>multilingual packaging</u>.</p> <p>With regard to the approved Annexes, please note the following:</p> <ul style="list-style-type: none"> • The approved Annex IIIA should only include the EN or Latin INN as per the concerned Member State requirement. EN or Latin INN should only be included in the language versions where this has been allowed. • The EN or Latin INN should be included in brackets after the description of the active substance in section 2 of the SmPC and at the beginning (top introductory part) of the package leaflet. The national language version of the INN must then be used throughout the rest of the SmPC and package leaflet. <p>For Human medicinal products</p> <table border="0"> <tr> <td>AT: EN</td> <td>FI: Latin</td> <td>MT: EN</td> </tr> <tr> <td>BE: Latin or EN</td> <td>FR: not accepted</td> <td>NL: EN</td> </tr> <tr> <td>BG: EN*</td> <td>HR: EN or Latin</td> <td>NO: Latin or EN</td> </tr> <tr> <td>CS: Latin</td> <td>HU: EN or Latin</td> <td>PL: Latin</td> </tr> <tr> <td>DA: EN or Latin</td> <td>IE: EN</td> <td>PT: EN</td> </tr> <tr> <td>DE: EN</td> <td>IS: Latin or EN</td> <td>RO: Latin</td> </tr> <tr> <td>EL: EN</td> <td>IT: Latin</td> <td>SK: EN or Latin</td> </tr> <tr> <td>ES: EN</td> <td>LT: Latin</td> <td>SL: Latin</td> </tr> <tr> <td>ET: Latin</td> <td>LV: Latin or EN</td> <td>SV: Latin</td> </tr> </table> <p>* EN for immediate packaging only</p>	AT: EN	FI: Latin	MT: EN	BE: Latin or EN	FR: not accepted	NL: EN	BG: EN*	HR: EN or Latin	NO: Latin or EN	CS: Latin	HU: EN or Latin	PL: Latin	DA: EN or Latin	IE: EN	PT: EN	DE: EN	IS: Latin or EN	RO: Latin	EL: EN	IT: Latin	SK: EN or Latin	ES: EN	LT: Latin	SL: Latin	ET: Latin	LV: Latin or EN	SV: Latin
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Issues	Connected problems	QRD Suggestions	
		<p>For Veterinary medicinal products</p> <p>AT: EN</p> <p>BE: Latin or EN</p> <p>BG: EN or Latin</p> <p>CS: Latin</p> <p>DK: Latin or EN</p> <p>DE: not accepted (pharmaceuticals) EN or Latin (biologicals)</p> <p>EL: EN</p> <p>ES: EN</p> <p>ET: Latin</p>	<p>FI: Latin</p> <p>FR: not accepted</p> <p>HR: EN or Latin</p> <p>HU: Latin or EN</p> <p>IE: EN</p> <p>IS: Latin or EN</p> <p>IT: Latin or EN</p> <p>LT: Latin or EN</p> <p>LV: Latin or EN</p> <p>MT: EN or Latin</p> <p>NL: EN</p> <p>NO: Latin or EN</p> <p>PL: EN or Latin</p> <p>PT: not accepted</p> <p>RO: Latin</p> <p>SK: EN or Latin</p> <p>SL: Latin or EN</p> <p>SV: Latin</p>
<p>With or without needle guard</p>	<p>The way information is presented in the leaflet of medicinal products with presentations containing syringes with or without needle guard (leading to different instructions for use) has not always been consistent.</p>	<p>For medicinal products with presentations containing syringes with or without needle guard, the applicant is advised to have one single leaflet with 2 sets of instructions for use (IFU). One of the IFU set should be grey-shaded to show that only the relevant one will be printed.</p>	