EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

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. Cmax, C_{max}	Acronyms must be written in their standard form; e.g. C_{max}
Abbreviations and acronyms	Not always understood, particularly in package leaflet. Different languages have different approaches, so the acronyms are in the language of the translation or are derived from the English; e.g. ECT, COPD.	Non-standard abbreviations and acronyms should be avoided and the term written out in full. In cases where this is not possible, the acronym should be at least written out and introduced in brackets at its first occurrence. See also the most frequently used non-standard abbreviations published on this Website, "Tables of non-standard abbreviations"

Rev.15: Changes since the last revision:

- Modification of conditions for combined leaflet request
- 'Units: SI base units' – litre update
- 'Units: micrograms' update for BG
- 'Use of EN/Latin Translation of INNs in Product information Annexes' update for BG & SK

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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.
Conditional	The translation of "should" causes problems in Romance languages and Croatian where its literal translations actually mean "it would be preferable" or "it is recommended".	Romance languages and Croatian should 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 advisable that the word "should" is avoided wherever possible in the English original text. E.g. "Pregnant women should not breast-feed" could be phrased as "Pregnant women must not breast-feed"; "X should be taken with food" could be phrased as "X is to be taken with food".
Consistency	Inconsistencies of 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.
Food and drink	Applicants sometimes choose examples of food to be taken with a medicinal product without considering whether such food is available in all Member States; e.g. apple sauce, cranberry juice.	For general food the applicant should choose examples of food to take with a medicine based on their availability and cultural acceptability in all MS. 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."
Foreign terms	Foreign and particularly Latin terms appear frequently in product literature.	Foreign terms must be written in italics; e.g. *in vivo, in vitro, Helicobacter pylori.* In Greek documents foreign terms appear in their original spelling, i.e. Roman characters.
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?	Council Directive 2001/83/EC art.62 states that "*the package leaflet may include...*" "*...other information compatible with the SmPC which is useful for health education, to the exclusion of any element of a promotional nature*." 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. 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. 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. 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).
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.
Invented name: excessive use	Excessive use of the invented name and unnecessary repetition in SmPC and package leaflet.	Avoid unnecessary repetition in the product information (SmPC, label and package leaflet). INN or pronouns should be used whenever possible in the SmPC. In the package leaflet, the term "this medicine" should be used.
Invented name: format	Format of the invented name and use throughout text. 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. It 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	Different languages use different number separators (a comma or a dot) to distinguish between thousands and decimals. Style of number must correspond to language used.	For decimals: EN: dot (e.g. 12.50 ml) All other languages: comma (e.g. 12,50 ml) For thousand: EN: 1,000.00 DA, DE, EL, ES, IT, NL, PT, SL: 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
Package leaflet: combined printed package leaflets.	Are combined printed package leaflets acceptable? Are there any safety issues: i.e. are they clear for the patient?	A combined printed package leaflet (PL) can only be acceptable if **all the** following **3** conditions are met: • 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. 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.
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 in the 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 "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)".

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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. 10ºC, 10 ºC, 10º C	No space between the º symbol and the indicator of scale used; e.g. 10ºC, 10·ºC (= *non-breaking space (ctrl/shift/space)*)
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.	Preferred style is figure and unit or symbols separated by a non-breaking space; e.g. 100 ml; > 10; etc. (= *non-breaking space (ctrl/shift/space)*)
Units: SI base units - litre	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). As this directive allows litre to be written either "l" or "L".	Recommendations from Member States should be followed: 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"** HR, PL: **"l" or "L"**

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"Unit dose" pack sizes	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.	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". *e.g. "Aluminium/PVC" Please find below the term "perforated unit dose blisters" translated in all official languages plus Icelandic and Norwegian. BG : перфориран еднодозов блистер CS: perforovaný blistr jednodávkový DA: perforeret enkeltdosisblister DE: perforierter□Blister zur Abgabe von Einzeldosen EN: perforated unit dose blisters ES: blister precortado unidosis ET: üheannuseline perforeeritud blisterpakend FI: yksittäispakattu läpipainopakkaus FR: plaquette thermoformée pour délivrance à l'unité EL: διάτρητο blister, μονάδων δόσης HR: perforirani blister djeljiv na jedinične doze HU: adagonként perforált buborékfólia IT: blister divisibile per dose unitaria IS: rifgataðar stakskammtaþynnur LT: perforuoti vienadoziai blisteriai (for veterinary products) LV: perforēti blisteri ar vienu devu kontūrligzdā NL: geperforeerde eenheidsblisterverpakking NO: perforert endoseblister PL: blister perforowany podzielny na dawki pojedyncze PT: blisters destacáveis para dose unitária RO: blister perforat pentru eliberarea unei unităţi dozate SK: blister s perforáciou, umožňujúci oddelenie jednotlivej dávky SL: perforiranem pretisnem omotu za enkratni odmerek SV: perforerat endosblister

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Units: micrograms	Use of the abbreviation for micrograms in the product information.	Issue addressed in the European Commission's Readability Guideline concerning the labelling and Package leaflet: *Section B Recommendations for Labelling* *2 Strength and Total Content:* *"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."* **SmPC** In the SmPC, it is acceptable to use the abbreviation for microgram recognised by each Member State throughout the text of the document, except 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 and Package Leaflet** Micrograms always spelt out in full. **Small Immediate Labelling** Except for FRANCE where micrograms is to always be spelt out in full on small 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: **"mcg"** FR* (BE packs), IT: **"µg or mcg"** * Belgium would accept an abbreviation for the French language. However, in the French language Annexes (Annex IIIA) adopted by the CHMP, micrograms should be spelt out in full.

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Use of EN/Latin Translation of INNs in Product Information Annexes	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. As no official translated pharmacopoeia is available in the national languages of some of the EU Member States it is often unclear whether the Latin, English or the national language version of the INN can be used on the outer/inner packaging. 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 Baltic States.	For the purpose of allowing combined labelling material in case of space constraints for some of the Member States, the English or Latin version of the INN will be acceptable as follows:- The national language version of the INN must be used throughout the SmPC and package leaflet together with the EN/Latin name in brackets after the description of the actual substance in section 2 of the SmPC & at the beginning (top introductory part) of the package leaflet. - The approved Annex IIIA will only include the EN/Latin INN in the language versions where this has been allowed. - Such requests will have to be discussed and agreed with the Agency/QRD secretariat prior to implementation in the product information annexes/printed material. AT: EN BE: Latin or EN BG: BG or EN***** CS: Latin DA: DA or EN or Latin DE: EN EL: EN ES: EN or ES* ET: Latin FI: Latin FR: Human products: FR Veterinary products: Latin HR: EN or Latin or HR**** HU: EN or Latin IE: EN IS: Latin or EN IT: Latin LT: Latin LV: Latin or EN MT: EN NL: EN NO: NO or Latin or EN** PL: Human products: Latin Veterinary products: PL or EN PT: PT RO: Latin SK: SK or EN or Latin****** SL: Latin SV: SV or Latin*** *EN for multilingual labels, ES for other labels ** EN for multilingual labels, NO or Latin in Nordic labels *** Latin for multilingual labels, SV for other **** EN or Latin for multilingual labels, HR for Croatian labels ***** EN for multilingual labels in case of space limitation, BG for other ****** SK in SmPC, PL and labels, EN or Latin for multilingual labels in case of space limitation