29 February 2024
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Human Medicines Division

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 the package leaflet. The approach varies across languages, so acronyms/abbreviations may be either in the language of the translation	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 must 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 the Agency's website: Table of non-standard abbreviations.

***Rev.23 Changes since last revision:** Inclusion of new guidance for 'INN: display on packaging when product name is MAH+INN' and 'Package leaflet: ATMPs with orphan designation, not intended to be delivered directly to patients'. Revised guidance for 'Abbreviations and acronyms', 'E-numbers', 'Number separators (DK)', 'Strength: sodium chloride solution', 'Use of English or Latin (FI, IT and SE requirements)' and 'Wallet packs: particulars on blisters sealed inside a wallet'. The use of 'must' vs 'should' has been revised throughout to avoid confusion between 'obligation' and 'recommendation'.

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	or derived from English, e.g. ECT, COPD.	The use of abbreviations and acronyms is particularly discouraged in the package leaflet as they tend to impair readability.
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 must 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	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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	emphasise in the labelling the special handling prior to administration of the product.	
Conditional	The translation of "should" causes problems in several EU languages, 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 must 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).

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Desiccant	For medicinal products packaged with a desiccant there is a risk to accidently mistake the desiccant for a tablet and ingest it. Although the SmPC and package leaflet include information about the desiccant, this is not consistently reflected in the labelling.	The foil of blister packs containing a desiccant must 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.
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?	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) 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).
Direct speech	What style should be used when writing the SmPC and the package leaflet?	The *Guideline on the readability of the labelling and package leaflet of medicinal products for human use* provides that an active style rather than passive should be used when writing the package leaflet. There is no similar legal provision for the SmPC, however considering that the audience of this document is much wider, the SmPC should be written using an indirect style or the passive voice. Direct speech should only be used in section 6 of the SmPC for instructions about shelf-life, storage, handling and disposal. It is also possible to use direct speech inside tables (e.g. dose recommendations) to minimise space constraints.

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Drug	Can the term 'drug' be used in the product information annexes?	As laid down in the Compilation of QRD Decisions on the use of terms, the term 'drug' must not be used in the product information annexes because it entails a risk of misinterpretation and mistranslation, i.e. in most Member States the term has connotations of narcotics or illicit drugs. The term 'drug' though can be used in the product information annexes when it is part of a standard set of terms (e.g. 'adverse drug reaction', 'drug interaction', 'drug elimination', etc.).
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.	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."
E-numbers	How to reflect E-numbers of excipients in the product information annexes.	The excipients of a medicinal product and their corresponding E-numbers* must be reflected in the product information annexes, i.e. section 6.1 of the SmPC and section 6 of the package leaflet, according to the provisions of the Excipients Guideline: https://health.ec.europa.eu/document/download/4f42a7d7-ec4e-4d37-8917-8c9d0df91830_en?filename=guidelines_excipients_march2018_en.pdf. The inclusion of E-numbers is however not restricted to the ones listed in the Excipients Guideline, and it is encouraged to include them in the PI annexes with the aim to facilitate the production of the labelling items in case of space constraints. Only in case of space constraints on the labelling, the E-number alone could be used provided it is added in brackets next to the full name of the excipient, both in section 6.1 of the SmPC and section 6 of the package leaflet. A statement such as "See leaflet for further information" should be printed at least once on the labelling. * E-numbers are published in the Commission Regulation (EU) No 1130/2011: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583858070210&uri=CELEX:32011R1130.

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Foreign terms	Foreign terms, particularly in Latin, 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.
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 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.
INN: display on packaging when product name is MAH+INN	How and where should the INN be displayed on the packaging when the	If the name of the product is expressed as INN + MAH, the active substance must be displayed at least once on the front panel. The active substance may also be displayed on the side panels if space permits. However, if the active substance differs from the INN (e.g., due to active moiety vs. salt/hydrate or because of the INN translation), the active substance should be repeated on every panel.

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	product name is composed of MAH+INN?	
INN: inclusion in blisters and unit dose blisters	When the name of the medicinal product is made of INN + MAH name, is there a need to repeat the INN in the blister?	In blisters and unit dose blisters, the INN may be omitted on the printed materials* only when space is a major issue and the name of the medicinal product is made of INN + MAH name. Applicants should ensure that there is little variation in the INN name in different languages before agreeing its omission with the Agency. * The INN should be included in grey-shading in Annex IIIA.
INN: spelling	How the INN should be spelled throughout the Product Information annexes, i.e. lower case or upper case.	The INN must always be spelled in lower case throughout the product information annexes when not at the beginning of a sentence. In particular, in section 1 of Annex IIIA and at the header of the package leaflet the INN must also be written in lower case. 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.
INN: translation	What are the national requirements for translation of the 'international non-proprietary name (INN)' or 'common name' when included in the name of the medicinal product?	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. AT: German 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. Examples: - ibuprofen (NL, EN), ibuprofène (FR), Ibuprofen (DE): any of these INN forms can be accepted in the name since it is very similar between NL, FR, DE and EN. - 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. HR: Croatian. English when justified in the interest of market supply (e.g. multilingual packs). HU: Hungarian. English on a case-by-case basis. 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. IT: Italian. When no Italian translation is available the English versions are accepted. LT: Lithuanian or English at applicant's discretion. LV: English

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		BG: Bulgarian CZ: Czech or English at applicant's discretion. CY: English DE: German DA: 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. EE: English EL: English FI: Finnish or English at applicant's discretion. FR: French	MT: English NL: Dutch 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.). PL: Polish, English or Latin. PT: Portuguese RO: Romanian SK: English SL: Slovene ES: Spanish 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.).
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 annexes 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.	

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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 must 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 must 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.
Multilingual packaging: impact on Annex IIIA	How to include text in Annex IIIA when there are differences between English and other languages that are part of a multilingual pack, e.g. abbreviations or short terms may be accepted for multilingual packs.	When the applicant agrees with the Agency that short terms and/or abbreviations can be used on multilingual packs, this will be reflected in Annex IIIA in the language(s) concerned, i.e. the term as per the adopted English PI will be written in normal text, followed by the agreed short term/abbreviation in grey-shading. For example: **English PI** **MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS** **VIAL** **1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION** Product 25 mg/ml concentrate for solution for infusion active substance Intravenous use **Dutch PI (part of BE multilingual pack)** **GEGEVENS DIE IN IEDER GEVAL OP PRIMAIRE KLEINVERPAKKINGEN MOETEN WORDEN VERMELD** **FLACON**

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		1. NAAM VAN HET GENEESMIDDEL EN DE TOEDIENINGSWEG(EN) Product 25 mg/ml concentraat voor oplossing voor infusie steriel concentraat wekzame stof Intraveneus gebruik i.v.
Notations in ATMPs strength	How should the strength for ATMPs with large numbers of units be expressed?	When the strength of a medicinal product includes large numbers of units such as viable CAR-T cells or vector genomes, scientific notation should be used to express the strength. The use of the term 'million' should be avoided as this will lead to translation and potential readability issues in the labelling. E.g. 1.2×10^{6} – 6×10^{8} cells dispersion for infusion 10^{6} plaque forming units (PFU)/mL solution for injection 5×10^{12} vector genomes/mL concentrate and solvent for solution for injection
Number separators	Different languages use different number separators (a space, a comma or a dot) to distinguish between thousands and decimals. The style of number separator used in the product information annexes must correspond to the language used in the relevant Member State. This is applicable to all figures appearing in the product information annexes in Microsoft Word and Pdf format, as well as the corresponding printed materials.	For decimals: EN*, MT: dot (e.g. 12.50 mg) All other languages: comma (e.g. 12,50 mg) The figures after the dot or the comma must be written without any space (e.g. 0.5678 or 0,5678). For thousand and larger numbers: DK, EL, IS, NL: dot (e.g. 1.000 mg) BG, CS, DE, EN, ES, FI, FR, IT, LT, LV, MT, NO, PL, RO, SK, SV: space** (e.g. 1 000 mg) ET, HU, HR, PT, SL: no space for 4-digit figures (i.e. 1000-9999) and space** for larger figures (e.g. 10 000) ISO 80000-1 provides that numbers consisting of long sequences of digits can be made more readable by separating them into groups, preferably groups of three digits separated by a space, i.e. one thousand would be written as 1 000 and one million as 1 000 000. Such groups of digits should never be separated by a comma or a point, as these are reserved for use as the decimal sign. *IE packs: The use of commas instead of dots can be accepted on multilingual immediate and outer packaging, where absolutely necessary and where no risk of confusion exists. Prior agreement with the HPRA should be sought to ensure compliance with this requirement and to prevent delays in assessment. Otherwise, the above EN requirements apply.

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		**non-breaking space (*ctrl/shift/space*) in Microsoft Word files. A deviation from the requirements listed above might be possible to facilitate multilingual packaging, however this would need to be agreed with the relevant competent authorities on a case-by-case basis. Very specific cases in which writing the strength with a space (as part of the name of the medicinal product) can lead to potential medication errors need to be brought to the attention of the QRD Group for discussion.
Open date	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.	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:_____'). Some products may need a more detailed time specification (e.g. 'hh:mm') due to the very short shelf life.
Overfill in injection devices - standard statements	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 assumption that a wrong dose could be given to the patient resulting in under-dosing.	The below statements aim to address these concerns and apply to all injection devices/pre-filled pens used by patients or caregivers. Two options are available: Option 1: In case the use of the residual solution in the device is not allowed and the remaining quantity must be discarded: *SmPC section 4.2 (end of 'Method of administration')* 'Before using the {device}, the instructions for use must be read carefully.' *SmPC section 6.6* '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}.' *Package leaflet section 3*

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		'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. Option 2: In case the use of the residual solution in the device is allowed: *SmPC section 6.6* '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}.' *Package leaflet section 3* '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.
Over-labelling	Is the over-labelling concept (use of stickers to replace imprinting on the outer/intermediate packaging) acceptable?	As a general rule over-labelling is not acceptable for the following reasons: • 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. 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.

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Package leaflet: ATMPs with orphan designation not intended to be delivered directly to patients	Is it possible to market an ATMP with orphan designation that is administered by healthcare professionals in a hospital setting (i.e. will never be stored at home) with the printed package leaflet only in English?	It is acknowledged that it can be difficult to include a printed package leaflet in each national language inside the pack of ATMPs with orphan designation due to the low number of patients treated across different Member States. For companies that are not able to comply with the requirement of including a package leaflet in each national language inside the carton of an ATMP used by healthcare professionals in a hospital setting, the following recommendation from the Member States can be followed: • AT, BE, BG, CY, CZ, DK, ET, EE, EL, ES, ET, FR, HR, HU, LT, NL, PL, PT, RO, SE, SI and SK* would accept an English printed package leaflet included inside the outer carton provided that a printed package leaflet in their national language(s) is distributed along with the supply of the medicinal product by the MAH. The MAH shall engage with the National Competent Authorities to discuss the provision of package leaflet(s) in the respective national language(s) of the MSs concerned. • IE and MT would accept an English printed package leaflet included inside the outer carton. • IS, FI, IT and NO would accept an English printed package leaflet included inside the outer carton and would not require the printed package leaflet in their national language(s) as long as an electronic version of the package leaflet in their national language(s) is available online. • For DE the MAH should contact the NCA directly (request will be assessed on a case-by-case basis). * The MAH should always contact SIDC (section of inspection) directly prior to placing the product on the market in Slovakia in order to formally finalise the exemptions. Applicants are also reminded that the obligation to provide translations of the product information annexes in all EEA languages, as per the standard post-opinion linguistic procedure, is not waived.
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 can only be acceptable if **all the** following **3** conditions are met: • posology in the SmPC foresees at least 2 dosages (e.g. titration phase, dose adjustment based on clinical response or for special populations); • package leaflets are completely identical, except for the few strength-specific details; and • a combined package leaflet must not create any risk of confusion or misuse for the patient or user. Applicants must submit the request for a combined package leaflet three weeks in advance of a QRD Plenary meeting, together with a justification/rationale, as part of the application for a new Marketing Authorisation, a Line Extension, a Renewal, a Variation or an Article 61.3 Notification. The request must also be sent directly to the QRD Secretariat (qrd@ema.europa.eu). A decision on the request will be taken on a case-by-case basis and communicated to the applicant shortly after the QRD Plenary meeting.

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Peel-off labels for traceability purposes	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.).	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). 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. The peel-off part of the label always displays, at least, the invented name, the batch number and the expiry date. The following points should be considered by applicants when including a peel-off label for traceability purposes: 1. It is recommended that the peel-of 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.
'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?	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: • there is no legal basis for such documents; • all information intended to patients must 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?	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 must be

Issues	Connected problems	QRD Suggestions
		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. 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. 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: • 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).
Sodium/potassium: information in the PI when content is below threshold	Declaration of sodium/potassium in the product information annexes when the content is **below** the threshold set in the Annex to the Excipients guideline (i.e. 1mmol).	SmPC section 2: no need to declare sodium/potassium, neither qualitatively nor quantitatively, if this is below the threshold set in the Excipients Guideline. This principle will be equally applied to all excipients. Irrespective of whether any excipients are declared quantitatively in this section, the standard statement "For the full list of excipients, see section 6.1" must always be included if the product contains excipients. SmPC section 4.4: the sodium/potassium-free statement provided in the annex to the Excipients Guideline must always be included at the end of the section. Annex IIIA: no need to declare sodium/potassium if the quantity is below the threshold set in the Excipients Guideline, provided the product is not topical, ocular or parenteral. This principle will be equally applied to all excipients. Package leaflet: the sodium/potassium-free statement provided in the annex to the Excipients Guideline should always be included in the section "X contains {name the excipients}". When sodium/potassium is found in trace amounts due to its use for pH adjustment, it must not be declared in section 2 of the SmPC and Annex IIIA, and the sodium/potassium-free statement must be included in section 4.4 of the SmPC and section 2 of the package leaflet.

Issues	Connected problems	QRD Suggestions
Sodium/potassium: information in the PI when content may vary	Declaration of sodium/potassium in the product information annexes when the content **may vary** depending on the posology.	SmPC section 2: the content of sodium/potassium must be declared, both qualitatively and quantitatively, when any of the possible doses leads to a content above the threshold set in the Excipients Guideline. This principle will be equally applied to all excipients. SmPC section 4.4: in case some of the recommended doses cannot be considered sodium/potassium-free, the relevant warning must be included, e.g. "This medicinal product contains X mg sodium per <dosage unit>, equivalent to Y% of the WHO recommended maximum daily intake of 2 g sodium for an adult." Annex IIIA: sodium/potassium must be declared qualitatively in section 3, followed by a statement such as "See leaflet for further information". Package leaflet: the relevant sodium/potassium warning provided in the annex to the Excipients Guideline must be included in the section "X contains {name the excipients}", e.g. "This medicine contains x mg sodium (main component of cooking/table salt) in each <dosage unit> <unit volume>. This is equivalent to y% of the recommended maximum daily dietary intake of sodium for an adult.".
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><or><infusion>" Label for the vial of solvent: "sodium chloride 9 mg/mL <solution for> <injection><or><infusion>"
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)*".

Issues	Connected problems	QRD Suggestions
Symbols: Non-Unicode	The use of non-Unicode symbols (e.g. for "µ" or "≤") in product information can lead to their conversion to incorrect symbols when published in HTML format. This has the potential for confusion.	Only Unicode symbols must be used in submitted product information annexes. It should be ensured that non-Unicode symbols are replaced in existing product information annexes, e.g. Unicode symbols can be added by using "insert symbol" in Word processors. Examples of non-Unicode symbols are those from the "Symbols" font in Microsoft Word.
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 must 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.

Issues	Connected problems	QRD Suggestions
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. "28×1 tablets". In the SmPC and package leaflet the pack size must be stated as e.g. "28×1 tablets in <material*> perforated unit dose blisters". *e.g. "Aluminium/PVC" Please find below the term "perforated unit dose blisters" translated in all EEA languages: BG : перфориран блистер с единични дози CS: perforovaný jednodávkový blistr DA: perforeret enkeltdosisblister DE: perforierte Einzeldosis-Blisterpackung EN: perforated unit dose blisters ES: blíster precortado unidosis ET: üksikannuseline blister FI: yksittäispakattu läpipainopakkaus FR: plaquette prédécoupée unitaire EL: διάτρητο blister, μονάδων δόσης HR: perforirani blister s jediničnim dozama HU: adagonként perforált buborékfólia IT: blister divisibile per dose unitaria IS: rifgataðar stakskammtaþynnur LT: perforuotos dalomosios lizdinės plokštelės LV: perforēti dozējamu vienību blisteri MT: folji mtaqqba ta' doża waħda NL: geperforeerde eenheidsblisterverpakking NO: perforert endoseblisterpakning PL: blister perforowany podzielny na dawki pojedyncze PT: blisters destacáveis para dose unitária RO: blister perforat cu doze unitare SK: perforovaný blister s jednotlivými dávkami SL: perforiran deljiv pretisni omot s posameznimi odmerki SV: perforerat endosblister

Issues	Connected problems	QRD Suggestions
Units: degrees	Degrees are expressed in different styles; e.g. 10ºC, 10 ºC, 10º C	There should be a non-breaking space (*ctrl/shift/space*) between the figure and the º symbol, and no space between the º symbol and the indicator of scale used; e.g. 10 ºC
Units: general format	Space between figure and unit is missing; e.g. 100mg. Spaces occurring within numbers or between figures and mathematical symbols might break and lead to confusion.	There should be a non-breaking space (*ctrl/shift/space*) between the figure and the unit or symbol, e.g. 100 mg, > 10, etc.

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 must 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) IE packs: **"mcg"** or **"µg"** • **Package Leaflet** Micrograms always spelt out in full. * Belgium accepts the use of the abbreviation "mcg" on the trilingual outer carton (printed materials), in case of space limitations. ** Belgium accepts the use of the abbreviation "mcg" on the trilingual small immediate labelling (printed materials). 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.

Issues	Connected problems	QRD Suggestions
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). This directive allows litre to be written either "l" or "L".	Recommendations from Member States must be followed: FR, IT: **"L"** BG, CS, DA, DE, ES, ET, FI, HU, IS, LT, LV, NL, NO, PT, RO, SK, SL, SV: **"l"** BE, EL, EN, HR, MT, PL: **"l" or "L"** With the aim of displaying the strength only once on multilingual packs, the use of either "l" or "L" is accepted. In order to minimise the potential for medication errors, it is recommended to use "L" in upper case whenever the unit is preceded by the figure 1. The recommendations above apply to all units of volume (i.e. 'mL' or 'ml', 'dL' or 'dl', etc.), and consistency must be ensured across the product information annexes.
Use of EN or 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 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.	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. The tables are **only** applicable to outer and inner labelling of multilingual packaging. With regard to the approved Annexes, please note the following: • The approved Annex IIIA must only include the EN or Latin INN as per the concerned Member State requirement. EN or Latin INN must **only** be included **in the language versions** where this has been allowed. • The EN or Latin INN must 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. **For Human medicinal products** AT: EN BE: EN or Latin BG: EN* FI: EN or Latin FR: not accepted HR: EN or Latin MT: EN NL: EN NO: EN or Latin

Issues	Connected problems	QRD Suggestions		
	The problem occurs in particular in cases of combined labelling material for more than one Member State and can potentially affect the availability of centrally authorised medicines, especially in the market of small Member States; e.g. the Nordic States.	CS: EN or Latin DA: EN or Latin DE: EN EL: EN ES: EN ET: Latin * EN for immediate packaging only **For Veterinary medicinal products** AT: EN BE: EN or Latin BG: EN or Latin CS: Latin DA: EN or Latin DE: not accepted (pharmaceuticals) EN or Latin (biologicals) EL: EN ES: EN ET: Latin	HU: EN or Latin IE: EN IS: EN or Latin IT: EN or Latin LT: Latin LV: Latin or EN FI: EN or Latin FR: not accepted HR: EN or Latin HU: EN or Latin IE: EN IS: EN or Latin IT: EN or Latin LT: EN or Latin LV: EN or Latin	PL: Latin PT: EN RO: EN or Latin SK: EN or Latin SL: EN or Latin SV: EN or Latin MT: EN or Latin NL: EN NO: EN or Latin PL: EN or Latin PT: not accepted RO: Latin SK: EN or Latin SL: EN or Latin SV: EN or Latin

Issues	Connected problems	QRD Suggestions
Wallet packs: particulars on blisters sealed inside a wallet	A blister sealed inside a wallet should in principle display the minimum particulars for blisters as per the QRD template. However, more and more requests for exemption from printing all required particulars are received whenever a blister is supplied to patients inside a wallet.	After reviewing a considerable number of requests for exemption from printing all particulars on blisters sealed inside a wallet, the QRD Group concluded that the minimum particulars that must be printed on such blisters are: name of the medicinal product, strength, INN, EXP and Lot. The INN can be printed in English only, provided the spelling does not differ much across languages, in order to address space constraints or to have a unique blister for all markets. If an applicant still wishes to deviate from this requirement, a request must be submitted to qrd@ema.europa.eu for discussion at one of the QRD Plenary meetings. The request should be provided three weeks in advance of a QRD Plenary meeting together with a detailed justification and a few samples of the proposed pack.
With or without needle guard	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.	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.