EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 March 2011
EMA/57325/2011 rev. 8#
Patient Health Protection

Compilation of QRD decisions on use of terms

Term	Approved[1]	Preferred[2]	Acceptable in PL[3]	Not to be used[4]	Comments	Go to
acetylsalicylic acid	X				Depending on the case, refer to ASA in package leaflets (e.g. for interactions) as follows: "acetylsalicylic acid, <a substance present in many medicines used to relieve pain and lower fever> or <a substance present in many medicines used to prevent blood clotting> or <a substance present in many medicines used to relieve pain and lower fever, as well as to prevent blood clotting>".	For the translations of the ASA statements in the EU official languages, plus Icelandic and Norwegian, please click here
active ingredient				X		active substance
active substance	X					

#Changes since the last revision: Minor amendments throughout in order to improve the document and inclusion of the Croatian translation of the ASA statements

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Term	Approved[1]	Preferred[2]	Acceptable in PL[3]	Not to be used[4]	Comments	Go to
adolescents	X				Aged 12 years to 17 years (for the complete definition of ages, refer to *Note For Guidance On Clinical Investigation Of Medicinal Products in the Paediatric Population* - CPMP/ICH/2711/99).	
adverse effects				X		adverse events, adverse reactions
adverse reactions	X				To be used when there is a causal relationship with the use of the medicinal product.	adverse effects, adverse events
adverse events	X				To be used when it occurs during the use of the medicinal product but its causal relationship is not yet established. Note that adverse events without at least a suspected causal relationship should not be listed in the SmPC and the PL.	adverse effects, adverse reactions
aspirin				X		acetylsalicylic acid
breast-feeding mothers		X				lactating/nursing mothers
children	X				Aged 2 years to 11 (for the complete definition of ages, refer to *Note For Guidance On Clinical Investigation Of Medicinal Products in the Paediatric Population* - CPMP/ICH/2711/99).	
clinical studies	X				Correct term, if chosen it must be used consistently throughout, without alternating with "clinical trials".	clinical trials
clinical trials	X				Correct term, if chosen it must be used consistently throughout, without alternating with "clinical studies".	clinical studies
dextrose				X	It is not in a standard term in the European Pharmacopoeia.	glucose
dosage	X				The term “dose” is preferred.	dose, posology
dose		X			Preferred to “dosage”. To be used in the PL instead of "posology".	dosage, posology
drug				X	Only accepted as part of the term “adverse drug reaction”.	active substance, medicinal product, medicine

Term	Approved[1]	Preferred[2]	Acceptable in PL[3]	Not to be used[4]	Comments	Go to
drug substance				X		active substance
excipients	X				To be used in the SmPC. In the PL, "other ingredients" is also accepted.	other ingredients
expiration				X		expiry date
expiry date	X					
glucose	X				Standard term in the European Pharmacopoeia.	dextrose
HIV-				X		HIV negative
HIV+				X		HIV positive
HIV-associated	X				The term needs to be hyphenated by using a non-breaking hyphen, as a hyphen at the end of a line can be mistaken for a negative sign meaning HIV negative.	
HIV-infected	X				The term needs to be hyphenated by using a non-breaking hyphen, as a hyphen at the end of a line can be mistaken for a negative sign meaning HIV negative.	HIV positive
HIV negative	X					
HIV positive	X					
inactive ingredient				X		excipients, other ingredients
inactive substance				X		excipients, other ingredients
infants		X			Preferred term to include infants up to 23 months.	infants and toddlers
infants and toddlers	X				Aged 28 days to 23 months (for the complete definition of ages, refer to *Note For Guidance On Clinical Investigation Of Medicinal Products in the Paediatric Population* - CPMP/ICH/2711/99).	infants
intramuscular route				X		intramuscular use

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intramuscular use	X				Standard term in the European Pharmacopoeia. Abbreviation (IM) allowed only on small immediate labelling. The expression "into a muscle" is recommended in the PL.	
intravenous route				X		intravenous use
intravenous use	X				Standard term in the European Pharmacopoeia. Abbreviation (IV) allowed only on small immediate labelling. The expression "into a vein" is recommended in the PL.	
lactating mothers				X		breast-feeding mothers
medication				X		medicinal product, medicine
medicinal product	X				To be used in the SmPC. In the PL, "medicine" is to be used.	medicine
medicine			X			medicinal product
newborn babies			X			newborn infants
newborn infants	X				Aged 0-27 days (for the complete definition of ages, refer to *Note For Guidance On Clinical Investigation Of Medicinal Products in the Paediatric Population* - CPMP/ICH/2711/99).	newborn babies
nursing mothers				X		breast-feeding mothers
other ingredients			X		May be used in the PL. In the SmPC, "excipients" is to be used.	excipients
overdose	X					
overdosage				X		overdose
pack size	X					
posology	X				To be used in the SmPC. In the PL, "dose" is recommended.	dosage, dose
premature babies			X			preterm newborn infants
presentation				X	Ambiguous term, as it can mean either "pack size" or "pharmaceutical form".	pack size

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preterm newborn infants	X				≤36 weeks of gestation (refer to *Guideline on the Investigation of Medicinal Products in the Term and Preterm Neonate* - EMEA/536810/2008).	premature babies
radioactive medicinal product				X		radiopharmaceutical
radiopharmaceutical		X				
saline				X		sodium chloride solution
side effects			X		Only to be used in the PL and labelling.	adverse reactions
sodium chloride solution	X				Concentration to be specified, e.g. "sodium chloride 9 mg/ml (0.9%) solution for injection".	
subcutaneous route				X		subcutaneous use
subcutaneous use	X				Standard term in the European Pharmacopoeia. The expression "under the skin" is recommended in the PL.	
young children				X	For the complete definition of ages, refer to *Note For Guidance On Clinical Investigation Of Medicinal Products in the Paediatric Population* - CPMP/ICH/2711/99.	children, infants and toddlers

1 Terms used in legislation, guidelines and templates, or originating from other official sources.

2 Terms that cannot be traced to a specific source, however the QRD Group understands they constitute "good practice" and prefers them to another term of the same meaning.

3 Terms considered to be correctly used in Package Leaflets (which require "patient-friendly" terms). Such terms are accompanied by a "Go to" reference to the approved or preferred term.

4 Terms that the QRD Group deems unsuitable for use because of being misleading, unclear, obsolete or for other reasons. The "Go to" reference always leads to the approved term.