TEAM NB

Inquiry report on languages and IFU supply

	A	B	CZ	D	DK	F	FIN	HUN	I	IRL	L	N	NL	S	UK
1. Actual language requirement for label, instruction for use (IFU) and screen information.															
1.1. Is there a general language requirement for the above in your national medical devices legislation (or other applicable legislation)?	Yes	Yes	Yes	Yes	Yes	Yes 43.		Yes	No, there isn't		Yes 39.	Yes 12.	Yes	Yes 15.	46.
1.2. What is/are the required language/s?	German	French, Dutch or German 22.	Czech language	German	Danish	French		Hungarian	25.		French, German or Lëtzeburg	Norwegian	Dutch	Swedish	English only practical language
1.3. Are there alternative languages? Which?	No	Yes 23.	Yes	No	No	No		No	/		No	/	No	No	/
1.4. Are there exemptions from these language requirements?	No	Yes 24.	No	Yes 3.	21.	No		No	/		Yes	13.	Not in the law	Yes	/
1.4.1. For certain devices/device groups? Which?	/	/	No	/	No	/		/	26.		No	/	/	Yes 16.	/
1.4.2. For certain user groups (e.g. professional use)? Which?	/	/	No	4.	No	/		/	27.		40.	/	/	No	/
1.4.3. For certain scenarios of use (e.g. in high-tech research hospitals)? Which?	/	/	No	/	No	/		/	28.		No	/	/	No	/
1.4.4. Which language requirements apply to these exemptions?	/	/	No	5.	No	/		/	29.		English	/	/	17.	/
1.5. Is some change of the above expected in the near or middle future?	/	No	Yes 1.	6.	No	/		No	30.		41.	/	No	No	No
2. Provision of IFU by different media and different means of supply															
2.1. Is provision of IFU by different media (e. g. on CD-ROM, on built-in screen) acceptable in your national medical devices regulation?	No	Yes	Yes 2.	7.	No official interpretation	45.		No any provision	31.		42.	14.	36.	18.	47.
2.2. Which different media are acceptable?	/	Electronic	CD-ROM	/	/	/		No any provision	CD ROM		/	/	/	/	/
2.2.1. For certain devices/device groups only?	/	/	/	8.	/	/		/	32.		/	/	/	/	/
2.2.2. For certain user groups only?	/	/	/	/	/	/		/	As above		/	/	/	/	/
2.2.3. For certain scenarios of use only?	/	/	/	/	/	/		No any provision	As above		/	/	/	/	/
2.2.4. Are there requirements for paper IFU as a backup on demand?	/	/	No	/	/	/		/	33.		/	/	/	/	/
2.2.5. Are there requirements that user must confirm he can read the IFU on different media?	/	/	/	/	/	/		/	No		/	/	/	/	/
2.3. Are different means of supply of IFU (e. g. per email or via the internet) acceptable in your national medical devices legislation?	No	Yes	/	9.	No	/		/	No		/	/	37.	19.	/

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2.4. Which means of supply are acceptable?	No regulation	Internet	/	/	None	/		/	34.		/	/	In general on paper	/	/
2.4.1. For certain devices/device groups only?	/	/	/	10.	/	/		/	/		/	/	38.	/	/
2.4.2. For certain user groups only?	/	/	/	/	/	/		/	/		/	/	/	/	/
2.4.3. For certain scenarios of use only?	/	/	/	/	/	/		/	/		/	/	/	/	/
2.4.4. Are there requirements for traditional delivery of IFU as a backup on demand?	/	/	No	/	/	/		/	No		/	/	/	/	/
2.4.5. Are there requirements that user must confirm he can receive the IFU via different means of supply?	/	/	/	/	/	/		/	No		/	/	/	/	/
2.5. Is some change of the above expected in the near or middle future?	/	No	No	11.	No	/		No	35.		/	/	No	20.	48.

1. depending on implementation of the MDD review
2. as a parallel version, IFU has to be published
3. in justified cases
4. If other language can be easily understood by the user
5. Warnings must be in German or in the language of the user
6. Only if changes are made in MDD/AIMD/IVD
7. No (requirements identical to EU directives)
8. For IVD devices, acc. to MEDDEV 2.14/3
9. No (requirements identical to EU directives)
10. For IVD devices, acc. to MEDDEV 2.14/3

11. Only if changes are made in AIMD/MDD/IVD
12. Information in annex I, article 13 has to be in Norwegian after 01 October 2007
13. Devices for clinical investigation are exempted. If the patient is the user, they must still be in Norwegian.'If safe and correct use can be other language may be but this must be applied for and the rules will be interpreted strictly.
14. This is not at all specified in the regulations, but EN 980:2003 and EN 1041:1998 are recommended used.
15. (for the information required to be provided by the manufacturer as stated in the Essential requirements of each Directive)
(Stated in LVFS 2001:5 4§ for AIMD 90/385 EEG
Stated in LVFS 2001:7 4§ for IVD 98/79/EG
Stated in LVFS 2003:11 4§ for MDD 93/42/EEC)
16. The competent authority “Läkemedelsverket” can, if they receive a justified application, make an exemption from the language requirement for a specific product in cases where the use of the product will protect human life and health. That is where there is no other alternative on the market that fulfills the requirements. The exemption is limited in time, number of products and is for use at a specific hospital or similar.
17. Not stated. But in our opinion English would be accepted.
18. No other provisions are stated in the regulations.
19. No other provisions are stated in the regulations.
20. Not unless there is a decision on EU level

21. The Danish Medicines Agency can in special situations deviate from the Danish language requirement.
(DGM are not familiar with any case).
22. Depending on local area
23, others EC languages accepted by the NB
24. case by case with signed agreement fo the parties.
25. All languages of the country where the product has to be used
26. No exemption are allowed
27. No exemption are allowed
28. No exemption are allowed
29. No exemption are allowed
30. There are some questions on the table of competent authorised, but probably no alternative languages will be allowed

31. Yes, but the same are to be useful for the final users; this is a common informal position, there is not any formal regulation
32. Yes, only for that devices that are intend to be utilised within a computer
33. Yes, some times may be
34. No one, except as in point 2.2
35. May be, but at the moment, the situation is in a stand still situation
36. The law does not specify the IFU needs to be on paper. But this has in practice been assumed. One trial has been run to allow electronic labelling. Currently under evaluation.
37. No, the IFU needs to be provided in the package
38. For low risk products that can be used without IFU, no IFU is needed
39. Article 4 point 4 of " Règlement Grand-Ducal du 11 août 1996 relatif aux dispositifs médicaux"
40. English is allowed in case of devices intended exclusively for professional use.

41. No to our current knowledge.
42. No specific requirements or guidelines. The transposition in the law of Luxembourg is equivalent to the requirements of Annex I subclause 13.1 of the MDD.
43 Code de la Santé Publique article R-5211-20 and R-5221-14.
44. May be related to screen information (information not confirmed)
45. There is no provision related to this possibility in the Code de la Santé Publique
46. Legally No but it must be in a language unstandable to the user. However in practice it would always be in English
47. Official position as per current directive. However in practice electronic media where this would always be acceptable to the user (because using a screen) acceptable
48. No apart from new directive