Svenska Läkaresällskapet

2012-03-15

Swedish Standards Institute

118 80 Stockholm

Remiss SIS9547 Aesthetics Surgery Services

Svenska Läkaresällskapet (SLS) är en politiskt och fackligt obunden organisation, som arbetar för förbättrad hälsa och sjukvård med patientens bästa för ögonen.

Efter synpunkter från sektionen Anestesti och intensivvård, sektionen för Dermatologi och Venereologi samt svenska infektionsläkareföreningen vill SLS avge följande yttrande. Se bifogade svarsblanketter från samtliga.

För Svenska Läkaresällskapet

Stockholm den 15 mars 2012

Peter Friberg
Ordförande

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SIS/TK 553, Aesthetic Surgery Services
Svar på SIS-remiss 9547
avseende prEN 16372

Senaste svarsdatum **2012-03-22**

Uppgifter om svarslämnaren

☒ Företag/Organisation/Myndighet ☐ Enskild person

Företag/Organisation/Myndighet: Svenska Läkaresällskapet, SFAI

Handläggare (namn, telefon): Anna Borgström, 08-440 88 92

Datum: 2012-03-09

Remissvar

- ☐ Avstår
- ☐ Tillstyrker utan kommentarer
- ☒ Tillstyrker med kommentarer
- ☐ Avstyrker med motivering
- ☐ Har erfarenhet inom det område förslaget täcker
- ☐ Har tillämpat förslaget
- ☐ Ej berörd
- ☐ Kommentarer till föreslagen svensk titel

Datum

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	6.2.5		te	Restriction of risk assessment to an abbreviated ASA class scale is potentially severely misleading due to the shortcomings of the ASA class definitions. An example is the restriction to systemic disease. A patient with a localised disease process in the upper airway may be relatively unaffected under normal conditions, it is not a systemic disease, but the patient could be subjected to substantial risk during sedation or general anaesthesia. Also, abbreviation of the ASA class scale is unnecessary and confusing.	The potential impact of the patients medical conditions on the risk associated with the procedure should be assessed in relation to the type and severity of the condition, the nature of the procedure, the required type of anaesthesia, and available resources.	
	3.3	c		The reference to “CME accredited scientific events” is not used in Sweden and consequently disqualifies such national activities.	c) attend at least two scientific events, endorsed by a national or international society, per year relevant to aesthetic medical procedures.	

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BE	Title Introduction Scope Services Practitioners Definition Procedures Content			1.**<u>The title</u>**"Aesthetic SURGERY services" even in this 3rd version , be it final version, still does NOT at all cover the contents; many delegates objected in vain that ALL the NON-surgical aesthetic treatments were included but nothing has been changed ,this is totally incorrect , misleading and not logic ! and is a major issue. 2.**<u>The introduction (line 1-2)</u>** states explicitely that the draft concerns aesthetic SURGERY and it is stated that the major part of the text is about SURGERY facilities (without a clear distinction between minor and major procedures). Consequently, it is obvious that this is a draft concerning surgery only. 3.**<u>The scope</u>** however includes ALL NON surgical aesthetic **services(**line 2); this conflicts clearly with the title and the introduction. 4. The scope includes also ALL aesthetic (**NON surgeon**)practitioners. This also conflicts with the title and the content. 5. A definition of aesthetic surgery is given whereas a definition of aesthetic medicine is lacking. 6. Aesthetic MEDICAL procedures seem to be a part of the described aesthetic SURGICAL services. Conclusion: Medical procedures and surgical procedures are usually distinguished from each other, but this is not done in this draft. This is a good draft for aesthetic surgery services by surgeons working in surgery facilities .	**This document cannot be called a draft for aesthetic medical services by non surgeons performing office procedures or minor to intermediate procedures.**	

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				This draft however does not reflect: 1. the fact that nowadays **most** aesthetic treatments are **non-surgical or minor /intermediate** surgical procedures 2. the fact that these procedures by large **majority** are performed by **non surgeons** 3. the fact that surgical and medical (be it minor invasive) procedures are different from each other but complementary to each other.		
BE	UEMS CLAUSE	6.3		"Not all UEMS syllabi have specified all procedures ....; for these specialities those procedures falling in the anatomical region specific of specialist's competence are to be selected...." Aesthetic medical practitioners are mentioned but have no existant UEMS syllabus. Therefore this draft shall at least include: 1/ a stringent recommendation to the UEMS to elaborate a syllabus for aesthetic medicine . 2/ a transition period for practizing aesthetic doctors with proven experience for the period that a UEMS syllabus is lacking. In any case: 3/ UEMS membership shall not be used to exclude practitioners from practising , because this membership is neither a sufficient nor a legally necessary criterion for a competence to perform aesthetic procedures. 4/ CEN recommendations shall not be used as an administrative instrument to discriminate collegues from other disciplines.	It is the CEN's duty to make a firm and urgent recommendation to the official authorities to reorganize the aesthetic competences **before** standardization shall be done. **Medical and surgical** aesthetic education and training , being the most important factor in quality management,(6.2.1)have to be reviewed thouroughly to keep step with the evolution in aesthetic procedures. A recommendation to recognize aesthetic medicine shall be made. A recommendation to create an UEMS syllabus for aesthetic medical doctors shall be made. A recommendation to adapt the UEMS syllabi for all the concerned specialists shall be made too. **If no agreement can be found satisfying all the stakeholders, CEN 's recommendation shall be to organize an independant international examination for ALL practitioners.**	
BE		2.2		2.1 defines aesthetic **surgery** 2.2 defines aesthetic medical procedure	2.2 shall give a definition of aesthetic **medicine**	
BE		3.2		"A practitioner undertaking category2 and/or 3 procedures shall have had aesthetic surgical training as	1.Define or delete "aesthetic **surgical** training"	

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				part of the syllabus." Keep in mind that category 2 procedures are intermediate or minor invasive procedures under local anaesthesia; Many of these procedures were invented or adjusted by **non surgeons** that adapted them for use in **non surgical** facilities.	2. delete category2	
BE		4.12.e/d		"Practitioners/clinics performing aesthetic medical procedures under category 2 or category 3 shall ensure that there is appropriate anaesthetic cover in the case of emergencies.".... According to the common medical, surgical and dental standards **,covering by an anaesthesist and critical care facilities are not required for category 2 procedures** (intermediate or minor invasive procedures under local anaesthesia). There is no proven need to require these arrangements.	Delete: category 2; .	
BE		4.12.d		...critical care facilities..."	Add only ....for major procedures.	
BE		4.13.a		"Practitioner/clinics or if applicable the anaesthesiologist shall ensure that there is appropriate qualified anaesthetic cover."	Add ....for major procedures.	
BE		5.1.6		"The following requirements apply only for facilities in which aesthetic medical procedures under category 2 and/or category 3 are performed. " **Facilities and their devices are classified according to the name of the procedures and not according to the way this procedure is done**. 1/Category 2 procedures can be done using tumescent or local anesthesia in an intermediate facility and these procedures have **proven to be much safer** than general anaesthesia or IV anaesthesia with sedation. 2/Anaesthesia personnel is neither required , nor accustomed to administer tumescent anaesthesia. 3/category 2 procedures are defined as intermediate or minor invasive procedures under local anaesthesia, NOT general anesthesia. 4/**according to 6.2.1 ; The most important factor is**	-DELETE category 2;	

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				the practitioner. In other words: the most important factor is the way the procedure is done. **5/ Facilities and their devices shall be classified according to the risk of the procedure; logically this is the extent and depth of the invasive treatment; minor and major invasive treatments shall be distinguished.**		
BE		5.Facilities General requirements		Many of these **general** requirements are requirements for major surgery and are **oversized** for office procedures or small to intermediate procedures without any proven justification.	Adapt requirements: Delete: - facility safety manual (5.1.4.f) -written protocol for security emergencies..(5.1.4.r) -written protocol for cardiopulm. resuscitation(5.1.4.s) -a separate Surgical Log (5.1.4.u) -hygiene standards for treatment rooms (5.1.5);are in fact those of an operating room -anaesthesia device (5.1.6) only applies to category 3 procedures; delete category 2.....	
BE		Table 2		Rhinoplasty is classified in category III facility ; This is an example of the **surgeons' classification** that omits the existence of a medical rhinoplasty in a category I facility. Rhinoplasty however can be surgical or medical and this sets different requirements for the required facilities. Ref: Alessio Redaelli ,Frédéric Braccini :*Medical rhinoplasty, basic principles and clinical practice*.Officina Editoriale Oltrarno S.r.l., Firenze, 2010.	Add Medical Rhinoplasty, category I facility	
BE		Table 1-2		**Localized** deep peelings (phenol ...)l peels have NO systemic toxicity. Ref:Deprez Philippe*: Textbook of Chemical Peels,*	Add : Localized deep peelings (phenol...) , in table 1, facility I	

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				Superficial, Medium and Deep Peels in Cosmetic Practice, Informa UK Ltd, 2007		
BE		Table 2		Depth of peeling is dependent on the competence of the practitioner and not dependent of the product . Maximum depth is skin depth. Sterility is no problem Toxicity or safety is operator dependent ,not facility dependant.	Deep peels (phenol or other) under local anesthesia ,in table 1, facility I-II	
BE		Table 1		"Radiofrequency for skin tightening, facility category II" 1/What's the logic for adding a technology of a bloodless kind of treatment in a facility type II ? 2/ Radiofrequency as a cutting or coagulating tool is safer than an ordinary thermic cauter or an electrocoagulator that is commonly used in facility I. 3/**All technologies and instruments shall be available to all practitioners for minor procedures**; **Typical "surgical" instruments like scalpels and needles are likewise accepted for use in the office. These technologies are dependent on the competence of the practitioner, not on the facilities**. 4/ Radiofrequency as an office –procedure: Ref: Sorin Eremia: *"Office –Based Cosmetic Procedures and Techniques",* Cambridge University Press, 2010	Facility category I	
BE		Table 2		"Free fat grafting facial**, facility III"** "Liposuction face , **facility II"** 1/Suction or filling making a difference in type of facility: this is illogic. 2/ facial and hand autologous fat transfer can be done In minor facilities: Ref: Sorin Eremia: *"Office –Based Cosmetic Procedures and Techniques",* Cambridge University Press, 2010	free fat grafting **face-hands-body** ,**Facility II**	
BE		Table 2		"Body liposuction facility III" "Liposuction face, facility II"	**Minor** (<3000ml) liposuction, **facility II** **Major** (>5000ml) liposuction**, facility III**	

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				"Liposuction upper limbs,facility III" "Liposuction lower limbs, facility III"		
BE		Table 2		"Free fat grafting facial,facility III" "Free fat grafting body,facility III"	**Minor** *(<50ml*) free fat grafting, **facility II** **Major** (>80ml) free fat grafting, **facility III**	
BE		Table 2		*"Laser skin resurfacing (full resurfacing), facility III"* *"Dermabrasion mechanical, facility II"* *1/A safer technology for a same (anatomical) result requires a facility III ? This is* ***illlogic. !*** ***2/ This is a discrimination in the use of a modern technology for those not working in a facility type III.*** *3/Lasers as an* ***office procedure****: Ref: Sorin Eremia: "Office –Based Cosmetic Procedures and Techniques", Cambridge University Press, 2010*	Laser skin resurfacing (full resurfacing) **, facility I- II**	
BE		Table 2		Rhytidectomy, facility III	**Minor** rhytidectomy,**facility II** **Major** rhytidectomy,**facility III**	
BE		Table 2		Implants, facility III Specify; fillers can be seen as(liquid) implants		
BE	5.2.2 Whole draft			Aesthetic medical doctors participating in this draft had no other opportunity than **acting merely as an observer** because all the decisions were forced by a overwhelming **voting majority** of plastic surgeons. **The standard clearly can NOT be called a VOLUNTARY standard for aesthetic medical doctors and the participation of the aesthetic medical doctors in the draft shall NOT be interpreted as:** 1/ their recognition of the authority/competence of the CEN regarding medical standardization/regulation. 2/ their agreement with the resolutions But shall be interpreted as a continuing struggle against an administrative kind of discrimination in accessing aesthetic procedures.	This draft can **NOT** be a definitive one . This draft does not include the non surgeons and shall not exclude them from aesthetic medical treatments. Surgical standards are different from those for minor invasive procedures and office procedures. Anaesthesia personel and equipment cannot be called mandatory for intermediate procedures that are performed under local anesthesia and that have proven to be more safe and effective than general anaesthesia. Equipment, facility and other technical standards for **COSMETIC** treatments do **NOT** need to be different from those for **NON-COSMETIC** treatments.	

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				1/It must be admitted that most new aesthetic treatments originated from other specialities than surgery and that aesthetic medicine is to be recognized; 2/It must be admitted that competence is more important than oversized facilities and that this is even more important for non-surgical or minor surgical procedures. Scientific literature and patients favour non-surgical and minor surgical procedures over major surgical procedures and they favour out patient procedures and local anesthesia over clinical procedures and general anaesthesia.. Moreover aesthetic treatments are non mandatory and are preferably minor and low risk procedures on healthy persons. There is **NO proven benefit for oversizing the facilities and the regulations**. For minor and intermediate surgical interventions there is **NO proven benefit to favor surgeons over non-surgeons.**		
BE		4.3.k		"The patient's consent shall be performed in the patient's native language".	Add: ' or an international language both parties agrees'	
BE		4.7.e		"In case of late aesthetic/functional concerns the patient shall have the right to consult his/her practitioner. The patient remains responsible to make appropriate arrangements. "	Delete. This is not about the patients duties.	
BE		4.8		"..only the **speciality** (annex B) in which the practitioner is qualified shall be used." **This seems to be a discrimination** because: "medical doctors " are not listed as specialists in annex B	Aesthetic medicine is a speciality	
BE		Annex B		"Other practitioners provided that aesthetic medical procedures are in the national syllabus" **This seems to be a discrimination for the" medical doctors" because this argument is also valid for specialists** (not all procedures being in their national syllabus). This requirement is however not mentioned for the specialists.	National syllabi of **ALL** practitioners have to be updated. **The actual titulation does not reflect the competence for all the new aesthetic procedures.**	

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BE		Annex B		"Medical doctors, if they meet the requirements specified in this European standard..." **This seems to be a discrimination for the" medical doctors" because this argument is also valid for specialists**	**ALL** the practitioners have to meet the requirements	
BE		Annex B		All the medical practitioners, that can give prove of an existing practice of a specific aesthetic technique for more than 3 years, shall be authorised to continue to practice this technique.	Add as a **transitional measure**: practitioners with an existing aesthetic practice for more than 3 years are included.	
BE		6.1, category 2		Liposuction face and minor liposuction of the body have the same risks and require the same facilities....	Add :minor liposuction of the body	
BE		6.3		Procedures that do not yet exist at this time shall be classified as ..... Only existing procedures can be regulated !	Delete!	

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		5.1.5		Bloodbourne infections can be transmitted via the use of multidose vials of saline for intravenous use.	Add sentence: n) Mulidose vials conataining saline for intravenous use should not be used in order to avoid bloodbourne infections.	