Below (in bold/red and highlighted in gray) is the contribution of the Military Medical Service of the Italian Air Force to the EASA Notice of Proposed Amendment (NPA) 2013-2015

(Update of part –MED annex IV to Commission regulation(EU) No 1178/2011 and Update of Acceptable Means of Compliance and Guidance Material to Part –MED - ED decision 2011/015/R)

Pag 29

MED.B.001 Limitations to medical certificates

(a) Limitations to class 1 and class 2 medical certificates

(1) If the applicant does not fully comply with the requirements for the relevant class of medical certificate but is considered to be not likely to jeopardise flight safety, the AeMC or AME shall:

(i) in the case of applicants for a class 1 medical certificate, refer the decision on fitness of the applicant to the licensing authority as indicated in this Subpart. **The licensing authority can delegate an AMC for this function** ;

Pag 30

(d) Operational limitation codes

(1) Operational multi-pilot limitation (OML – Class 1 only)

(i) When the holder of a CPL, ATPL or MPL does not fully meet the requirements for a class 1 medical certificate and has been referred to the licensing authority, it shall be assessed whether the medical certificate may be issued with an OML 'valid only as or with qualified co-pilot'. This assessment shall be performed by the licensing authority.

(ii) The holder of a medical certificate with an OML shall only operate an aircraft in multi-pilot operations when the other pilot is fully qualified on the relevant type of aircraft, is not subject to an OML and has not attained the age of 60 years. (iii) The OML for class 1 medical certificates may shall only be initially imposed and only be removed by the licensing authority.

(iii) The OML for class 1 medical certificates may shall only be initially imposed and only be removed by the licensing authority. **The licensing authority can delegate an AMC for this function**.

Pag 31

MED.B.010 Cardiovascular System

(a) Examination

(1) A standard 12-lead resting electrocardiogram (ECG) and report shall be completed on clinical indication, and:

(i) for a class 1 medical certificate, at the initial examination for the first issue of a medical certificate, then every 5 years until age 30, every 2 years until age 40, annually until age 50, and at all revalidation or renewal examinations thereafter;

(ii) for a class 2 medical certificate, **at the initial examination, then every five years until age 50 , and every two years thereafter.**

Pag 36

MED.B.030 Haematology

(a) Applicants shall not possess any haematological disease which is likely to interfere with the safe exercise of the privileges of the applicable licence(s).
(b) (ab) For class 1 and class 2 medical certificates, **haemochrome** shall be tested at each examination for the issue of a medical certificate

Pag 38

MED.B.055 Psychiatry and MED.B.060 Psychology

Only for the first examination of the first class applicants it is proposed an integrated psychodiagnostic approach* including : psychiatric interview and a battery of personality and efficiency tests.

(*)subtle, still important, psychological disturbances may not arise during a general medical visit and the reliability of the anamnestic report may be, even without specific intention, relatively low due to existing psychological problems)

Pag 38-39

MED.B.065 Neurology

(a) Applicants shall have no established medical history or clinical diagnosis of any neurological condition which is likely to interfere with the safe exercise of the privileges of the applicable licence(s). (ab) Applicants with an established history or clinical diagnosis of:

(1) epilepsy;

(2) recurring episodes of disturbance of consciousness of uncertain cause

shall be assessed as unfit.

Applicants with an established history or clinical diagnosis of:

(1) epilepsy without recurrence after age 5;

(2) epilepsy without recurrence and off all treatment for more than 10 years;

(3) epileptiform EEG abnormalities and focal slow waves;

(4) progressive or non-progressive disease of the nervous system;

(5 a single episode of disturbance of consciousness of uncertain cause;

(6) loss of consciousness after head injury;

(7) penetrating brain injury;

(8) spinal or peripheral nerve injury;

(9) disorders of the nervous system due to vascular deficiencies including haemorrhagic and ischaemic events;

(10) recurring crises of migraine with aura

shall undergo further evaluation before a fit assessment can may be considered. Applicants for a class 1 medical certificate shall be referred to the licensing authority. Fitness of class 2 applicants shall be assessed in consultation with the licensing authority.

Pag 56

(5) CCL Wear contact lenses that correct for defective vision Correction for defective distant vision: whilst exercising the privileges of the licence, the holder of a medical certificate should wear contact lenses that correct for defective distant vision, as examined and approved by the AeMC or AME. A spare set of similarly correcting **contact lenses** *shall be readily available for immediate use whilst exercising the privileges of the applicable licence.

(*) in case of CCL limitation spectacles are unuseful

Pag 58-59

(e) Cardiac valvular abnormalities

(1) Applicants with previously unrecognised cardiac murmurs should undergo evaluation by a cardiologist and assessment by the licensing authority. If considered significant, further investigation should include at least 2D Doppler echocardiography or equivalent imaging.

(2) Applicants with minor cardiac valvular abnormalities may be assessed as fit by the licensing authority. Applicants with significant abnormality of any of the heart valves should be assessed as unfit.

(3) Aortic valve disease

(i) Applicants with a bicuspid aortic valve may be assessed as fit if no other cardiac or aortic abnormality is demonstrated. Follow-up with echocardiography, as necessary, should be determined by the licensing authority.

(ii) Applicants with aortic stenosis may be assessed as fit provided the left ventricular function is intact and the mean pressure gradient is less than 20 mmHg. Applicants with an aortic valve orifice of more than 1 cm2 and a mean pressure gradient above 20 mmHg, but not greater than **40***mmHg, may be assessed as fit with an OML*.(*see indicator for severe aortic stenosis in ACC/AHA 2006 guidelines for the management of patients with valvular heart disease; ESC guidelines indicate 50 mmHg)* Follow-up with 2D Doppler echocardiography, as necessary, should be determined by the licensing authority in all cases. Alternative measurement techniques with equivalent ranges may be used. Regular evaluation by a cardiologist should be considered. Applicants with a history of systemic embolism or significant dilatation of the thoracic aorta should be assessed as unfit.

Pag 60

Where anticoagulation is needed after valvular surgery, a fit assessment with an OML multi-pilot limitation may be considered after review by the licensing authority, if the haemorrhagic risk is acceptable. The review should show that and the anticoagulation is stable. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. The INR target range should be determined by the type of surgery performed. **Where association between anticoagulation and platelet antiaggregation therapy is needed after surgery, applicants must be assessed as unfit.**

Pag 63

(4) Supraventricular arrhythmias

Applicants with significant disturbance of supraventricular rhythm, including sinoatrial dysfunction, whether intermittent or established, should be assessed as unfit. A fit assessment may be considered by the licensing authority if cardiological evaluation is satisfactory.

(i) Atrial fibrillation/flutter

(A) For initial applicants, a fit assessment should be limited to those with a single episode of arrhythmia which is considered by the licensing authority to be unlikely to recur.

(B) For revalidation, **applicants with previous episodes of atrial fibrillation /flutter or with permanent atrial fibrillation may be assessed as fit if cardiological evaluation is satisfactory. The use of new anticoagulants (direct thrombin inhibitors, direct factor Xa inhibitor) is not disqualifying. An OML should be considered.**

(ii) Applicants with asymptomatic sinus pauses up to 2.5 seconds on resting electrocardiography may be assessed as fit if exercise electrocardiography, echocardiography and 24-hour ambulatory ECG are satisfactory. (iii) Applicants with Ssymptomatic sino-atrial disease should be disqualifying assessed as unfit.

Pag 64

(9) Pacemaker

((it is necessary to have more accurate description and guidelines related to all the ICDs (intracardiac Devices)currently available))

Applicants with a subendocardial pacemaker should be assessed as unfit. A fit assessment with an OML may be considered at revalidation by the licensing authority no sooner than 3 months after insertion and should require provided:

(i) there is no other disqualifying condition;

(ii) a bipolar lead system, programmed in bipolar mode without automatic mode change of the device has been used;

(iii) that the applicant is not pacemaker dependeant;.

(iv) that the applicant has a regular follow-up, including a pacemaker check

(10) QT prolongation

…….

(11) Brugada pattern

Applicant with type 1 form, coved upward ST segment elevation with a J wave amplitude > 0.2 mV followed by an inverted T wave in V1 and V2 (the Brugada sign), is unfit.

Applicant with types 2 (saddle back) and 3(coved or a saddle back pattern with less than 2 mm J-point elevation and less than 1 mm ST elevation) may be assessed as fit if administration of class Ia, Ic and III anti-arrhythmic drugs does not induce a type 1, he has not a history of syncope or a family history of sudden death. An electrophysiological study could be indicated to select high risk subjects. An OML and/or observation may be necessary.

Pag 74

b) Comprehensive eye examination

A comprehensive eye examination by an eye specialist is required at the initial examination. All abnormal and doubtful cases should be referred to an ophthalmologist. The examination should include:

(1) history;

(2) visual acuities - near, intermediate and distant vision (uncorrected and with best optical correction if needed);

(3) examination of the external eye, anatomy, media (slit lamp) and fundoscopy;

(4) ocular motility;

(5) binocular vision;

(67) visual fields

(78) tonometry on clinical indication; and (89) objective refraction: hyperopic initial applicants with a hyperopia of more than +2 dioptres and under the age of 25 should undergo objective refraction in cycloplegia.; (9) assessment of contrast **sensitivity**; and (106) colour vision;.

Pag 75

(iiiiv) anisometropia not exceeding **3.0 dioptres** *subject to satisfactory ophthalmic evaluation and provided that optimal correction has been considered and no significant pathology is demonstrated.

(*)no functional consequences on binocular vision

Pag 76

(i) Eye surgery

The assessment after eye surgery should include an ophthalmological examination.

(1) After refractive surgery, a fit assessment may be considered, provided that:

(i) **in case of hypermetropia** pre-operative refraction was not greater than did not exceed +5.0 dioptres;

(ii) post-operative stability of refraction has been achieved (of less than 0.75 dioptres variation diurnally) has been achieved

***Pag* 77**

AMC1 MED.B.080 Otorhinolaryngology (ENT)

- **A tympanometry or equivalent should be performed at the initial examination and when clinically indicated.**
- **an active pathological process, acute or chronic, or any sequela of surgery* or trauma *of the internal or middle ear"**

(*) After ear surgery: at least a three months healing period should be [required] before approval. In cases involving a potential, but not obvious risk of a perilymphatic leak (stapes surgery, including type III tympanoplasties, and intra-operative observations of an otic capsule weakness) [a multi-pilot limitation may be required for two years].

- **sinus and/or tubal dysfunctions**

Pag 80

(e) Cardiac valvular abnormalities (1) Applicants with previously unrecognised cardiac murmurs require should undergo further cardiological evaluation.

(2) Applicants with minor cardiac valvular abnormalities may be assessed as fit.

(3) Aortic valve disease

(i) Applicants with a bicuspid aortic valve may be assessed as fit if no other cardiac or aortic abnormality is demonstrated. Follow-up with echocardiography, as necessary, should be determined in consultation with the licensing authority.

(ii) Applicants with aortic stenosis may be assessed as fit provided the left ventricular function is intact and the mean pressure gradient is less than 20 mmHg. Applicants with an aortic valve orifice of more than 1 cm2 and a mean pressure gradient above 20 mmHg, but not greater than **40*** mmHg, may be assessed as fit with an OS.*(*see indicator for severe aortic stenosis in ACC/AHA 2006 guidelines for the management of patients with valvular heart disease; ESC guidelines indicate 50 mmHg)* . Follow-up with 2D Doppler echocardiography, as necessary, should be determined in consultation with the licensing authority in all

cases. Alternative measurement techniques with equivalent ranges may be used. Regular cardiological evaluation should be considered. Applicants with a history of systemic embolism or significant dilatation of the thoracic aorta should be assessed as unfit.

(iii) Applicants with trivial aortic regurgitation may be assessed as fit. A greater degree of aortic regurgitation should require an OML limitation. There should be no demonstrable abnormality of the ascending aorta on 2D Doppler echocardiography. Follow-up, as necessary, should be determined in consultation with the licensing authority.

Pag 81

(iii) Applicants with trivial aortic regurgitation may be assessed as fit. A greater degree of aortic regurgitation should require an **OSL** limitation. There should be no demonstrable abnormality of the ascending aorta on 2D Doppler echocardiography. Follow-up, as necessary, should be determined in consultation with the licensing authority.

(f) Valvular surgery

(1) Applicants who have undergone cardiac valve replacement or repair may be assessed as fit without limitations subject to satisfactory post-operative cardiological evaluation and if post-operative cardiac function and investigations are satisfactory and no anticoagulants are needed.

(2) Where anticoagulation is needed after valvular surgery, a fit assessment with an OSL or OPL limitation may be considered after cardiological review evaluation if the haemorrhagic risk is acceptable. The review should show that the anticoagulation is stable. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. The INR target range should be determined by the type of surgery performed. **Where association between anticoagulation and platelet antiaggregation therapy is needed after surgery, applicants must be assessed as unfit.**

Pag 83

(l) Rhythm and conduction disturbances

Any significant rhythm or conduction disturbance should require cardiological evaluation and an appropriate follow-up before a fit assessment may be considered. An OSL or OPL limitation should be considered as appropriate.

(1) Ablation

A fit assessment may be considered following successful catheter ablation subject to satisfactory cardiological review undertaken at a minimum of 2 months after the ablation.

(2) Supraventricular arrhythmias

(i) Applicants with significant disturbance of supraventricular rhythm, including sinoatrial dysfunction, whether intermittent or established, may be assessed as fit if cardiological evaluation is satisfactory.

(ii) Applicants **with previous episodes** of atrial fibrillation/flutter **or with permanent atrial fibrillation** may be assessed as fit if cardiological evaluation is satisfactory. **The use of new anticoagulants (direct thrombin inhibitors, direct factor Xa inhibitor) is not disqualifying. An OSL should be considered.**

(iii) Applicants with asymptomatic sinus pauses up to 2.5 seconds on resting electrocardiography may be assessed as fit if cardiological evaluation is satisfactory.

(7) Pacemaker

((it is necessary to have more accurate description and guidelines related to all ICDs (intracardiac devices)currently available))

Applicants with a subendocardial pacemaker may should be assessed as unfit. A fit assessment may be considered no sooner than 3 months after insertion provided:

(i) there is no other disqualifying condition;

(ii) a bipolar lead system is used, programmed in bipolar mode without automatic mode change of the device has been used;

(iii) that the applicant is not pacemaker dependeant;

(iv) that the applicant has a regular follow-up, including a pacemaker check.

A paragraph on QT Prolungation should be added to class 2

QT PROLONGATION

Applicants with the prolongation of the QT interval on the ECG associated with symptoms should be assessed as unfit. Asymptomatic applicants require cardiological evaluation for a fit assessment and an OSL may be required.

Brugada pattern

Applicant with type 1 form, coved upward ST segment elevation with a J wave amplitude > 0.2 mV followed by an inverted T wave in V1 and V2 (the Brugada sign), is unfit.

Applicant with types 2 (saddle back) and 3(coved or a saddle back pattern with less than 2 mm J-point elevation and less than 1 mm ST elevation) may be assessed as fit if administration of class Ia, Ic and III anti-arrhythmic drugs does not induce a type 1, he has not a history of syncope or a family history of sudden death. An electrophysiological study could be indicated to select high risk subjects. An OSL and/or observation may be necessary.

Pag 102

AMC11 MED.B.095 Psychiatry

a) Applicants with a mental or behavioural disorder due to alcohol or other psychoactive substance use or misuse, with or without dependency, should be assessed as unfit.

The above mentioned sentence should be replaced by the following:

Applicants with:

a) a mental or behavioural disorder due to alcohol or other psychoactive substance use or misuse, with or without dependency;

b) a report of, or an identified recent use (1) of some illegal drugs (2);

should be assessed as unfit.

(1) self-report use, report of use from Civil/Police authorities; identified with medical-legal procedures;

(2) as established by national authorities

Drug Test should be performed for the first examination for the issue of a class 1 medical certificate.

dc) Psychotropic substances

Applicants who use or abuse of psychotropic substances likely to affect flight safety should be assessed as unfit is disqualifying. If a stable maintenance psychotropic medication is confirmed, a fit assessment with an appropriate limitation may be considered. If stability on maintenance psychoactive medication is confirmed, a fit assessment with an operational limitation, as appropriate may be considered. If the dosage of the medication is changed, a further period of unfit assessment should be required.

The above mentioned sentence should be replaced by the following:

Applicants who use or abuse psychotropic substances (dietary or pharmacological) likely to affect flight safety should be assessed as unfit. Applicants with a documented therapeutic need of psychotropic substances should undergo psychiatric evaluation and show satisfactory results in neurocognitive testing. If clinical stability on maintenance a treatment with psychoactive medication is confirmed as appropriate, a fit assessment with the most appropriate operational limitation may be considered. If the dosage of the medication is changed an evaluation by a psychiatric specialist is required and a period of unfit assessment could be considered.

FINAL PROPOSAL : to include in the Regulation, as a practical memo, the following table summarizing the minimal periodic requirements (see last page)

Medical Certificate: Minimum Periodic Requirements

LICENCE	class 1- cpl, atpl	class 2 – ppl
haemochrome	**every examination**	**every examination**
ecg	initial then under 30yrs: 5 yearly 30-39: 2 yearly 40-49: annually 50 and over: every revalidation/renewal	**initial then** **under 50 yrs: 5 yearly** 50 and over: 2
audiogram	initial then under 40: 5 yearly after 40: 2 yearly	initial then under 40: 5 yearly after 40: 2 yearly
extended otorhinolaryngology	initial	if indicated
extended ophthalmology	initial, then according to easa part-med	if indicated
metabolic profile (cholesterol, triglyderide, glucose, uric ac.)	**initial then at age 40** **after 40: 2 yearly**	**initial then at age 40** **after 40: 2 yearly**
blood test (transaminases, gamma gt, ldh, creatinine)	**initial and then every two years**	**initial and then every five years**
pulmonary function test	initial, then if indicated	if indicated
psychiatric and neurological evaluation	**initial, then if indicated**	**if indicated**
drug test	**initial, then if indicated**	**if indicated**
urinanalysis	every examination	every examination
note: any test may be required at any time if clinically indicated		