Proposal for a change of the actual Draft of the acceptable means of compliance (AMC) Part-MED of EASA

Topic: Anticoagulation

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The rationale for this proposal is written in a separate document, called:

Rationale for a proposal for a change of the actual Draft of the acceptable means of compliance (AMC) Part-MED of EASA, ...

... the annex 1 being part of that document.

Actual draft of AMC Part-MED:

> Section 2/ Specific requirements for class 1 medical certificates AMC1 MED.B.010 Cardiovascular system/ (f) Valvular surgery/ (3~~-4~~):
>
> 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. In cases of anticoagulation medication not requiring INR monitoring, a fit assessment with an OML may be considered after review by the licencing authority after a stabilisation period of 3 months.

Our proposal:

> Where anticoagulation is needed after valvular surgery, a fit assessment with an OML may be considered if the haemorrhagic risk is acceptable 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.
>
> *Thus, to eliminate the lower part of the section.*

Actual draft of AMC Part-MED:

Section 3/ Specific requirements for class 2 medical certificates AMC2 MED.B.010 Cardiovascular system/ (f) Valvular surgery/ (2):

Where anticoagulation is needed after valvular surgery, a fit assessment with an ORL ~~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 sugery performed. Applicants who measure their INR on a ‚near patient' testing system within 12 hours prior to flight and only exercise the privileges of their licence(s) if the INR is within the target range, may be assessed as fit without the above-mentioned limitation. The INR results should be recorded and the results should be reviewed at each aero-medical assessment. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit without the above-mentioned limitation in consultation with the licensing authority after a stabilisation period of 3 months.

Our proposal:

Where anticoagulation is needed after valvular surgery, a fit assessment may be considered after cardiological 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 sugery performed.

Thus, to eliminate the lower part of the section.

Actual draft of AMC Part-MED:

Section 2/ Specific requirements for class 1 medical certificates AMC1 MED.B.010 Cardiovascular system/ (g) Thromboembolic disorders:

Applicants with arterial or venous thrombosis ... ... undergo a re-assessment by the licensing authority (*text over 9 lines*).

Our proposal:

There is no need of a change of this section with the exception to put in the word *deep*:

„Applicants with arterial or deep venous thrombosis or pulmonary embolism should ....“

Actual draft of AMC Part-MED:

> Section 3/ Specific requirements for class 2 medical certificates AMC2 MED.B.010 Cardiovascular system/ (g) Thromboembolic disorders:
>
> Applicants with ~~A~~arterial or venous thrombosis or pulmonary embolism should be assessed as unfit. ~~are disqualifying whilst anticoagulation is being used as treatment. After 6 months of stable anticoagulation as prophylaxis, a~~ A fit assessment with an ORL ~~OSL or OPL limitation~~ may be considered after a period of stable anticoagulation as prophylaxis ~~after review~~ in consultation with the licensing authority. 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 and the haemorrhagic risk is acceptable. Applicants who measure their INR on a ‚near patient' testing system within 12 hours prior to flight and only exercise the privileges of their licence(s) if the INR is within the target range, may be assessed as fit without the above-mentioned limitation. The INR results should be recorded and the results should be reviewed at each aero-medical assessment. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit without the above-mentioned limitation in consultation with the licensing authority after a stabilisation period of 3 months. Applicants with ~~P~~pulmonary ~~embolus~~ embolism should ~~require~~ also undergo a cardiological ~~full~~ evaluation. Following cessation of anticoagulant therapy for any indication, applicants should undergo a re-assessment in consultation with the licensing authority.

Our proposal:

> Applicants with arterial or deep venous thrombosis or pulmonary embolism should be assessed as unfit. A fit assessment may be considered after a period of stable anticoagulation as prophylaxis in consultation with the licensing authority. 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 and the haemorrhagic risk is acceptable. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit in consultation with the licensing authority after a stabilisation period of 3 months. Applicants with pulmonary embolism should also undergo a cardiological evaluation. Following cessation of anticoagulant therapy for any indication, applicants should undergo a re-assessment in consultation with the licensing authority.
>
> *Thus, to eliminate the middle part of the section.*

Actual draft of AMC Part-MED:

Section 2/ Specific requirements for class 1 medical certificates AMC1 MED.B.010 Cardiovascular system/ (l) Rhythm and conduction disturbances/ (3):

Where anticoagulation is needed for a rhythm disturbance, a fit assessment with an OML may be considered if the haemorrhagic risk is acceptable and the anti-coagulation 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. In cases of anticoagulation medication not requiring INR monitoring, a fit assessment with an OML may be considered after review by the licensing authority after a stabilisation period of 3 months.

Our proposal:

There is no need of a change of this section.

Actual draft of AMC Part-MED:

Section 3/ Specific requirements for class 2 medical certificates AMC2 MED.B.010 Cardiovascular system/ (l) Rhythm and conduction disturbances/ (2):

Where anticoagulation is needed for a rhythm disturbance, a fit assessment with an ORL may be considered, if the haemorrhagic risk is acceptable and the anti-coagulation 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. Applicants who measure their INR on a ‘near patient’ testing system within 12 hours prior to flight and only exercise the privileges of their licence(s) if the INR is within the target range may be assessed as fit wit-hout the above-mentioned limitation. The INR results should be recorded and the results should be reviewed at each aero-medical assessment. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit without the above-mentioned limitation in consultation with the licensing authority after a stabilisation period of 3 months.

Our proposal:

Where anticoagulation is needed for a rhythm disturbance, a fit assessment may be considered, if the haemorrhagic risk is acceptable 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. Applicants taking anticoagulation medication not requiring INR monitoring, anticoagulation should be considered stable after a stabilisation period of 3 mon-ths.

Thus, to eliminate the middle part of the section.

Actual draft of AMC Part-MED:

Section 2/ Specific requirements for class 1 medical certificates AMC1 MED.B.010 Cardiovascular system/ (l) Rhythm and conduction disturbances/ (4) Supraventricular arrhythmias/ (i) Atrial fibrillation/flutter/ (B):

For revalidation, applicants may be assessed as fit if cardiological evaluation is satisfactory and the stroke risk is sufficiently low. A fit assessment with an OML may be considered after a period of stable anticoagulation as prophylaxis, after review by the licensing authority. 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. In cases of anticoagulation medication not requiring INR monitoring, a fit assessment with an OML may be considered after review by the licensing authority after a stabilisation period of 3 months.

Our proposal:

There is no need of a change of this section.

Actual draft of AMC Part-MED:

Section 3/ Specific requirements for class 2 medical certificates AMC2 MED.B.010 Cardiovascular system/ (l) Rhythm and conduction disturbances/ (4) Supraventricular arrhythmias/ (ii):

Applicants with atrial fibrillation/flutter may be assessed as fit if cardiological evaluation is satisfactory and the stroke risk is sufficiently low. Where anticoagulation is needed, a fit assessment with an ORL may be considered after a period of stable anticoagulation as prophylaxis, in consultation with the licensing authority. 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. Applicants who measure their INR on a ‘near patient’ testing system within 12 hours prior to flight and only exercise the privileges of their licence(s) if the INR is within the target range may be assessed as fit without the above-mentioned limitation. The INR results should be recorded and the results should be reviewed at each aero-medical assessment. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit without the above-mentioned limitation in consultation with the licensing authority after a stabilisation period of 3 months.

Our proposal:

Applicants with atrial fibrillation/flutter may be assessed as fit if cardiological evaluation is satisfactory and the stroke risk is sufficiently low. Where anticoagulation is needed, a fit assessment may be considered after a period of stable anticoa-

gulation as prophylaxis, in consultation with the licensing authority. 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. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit in consultation with the licensing authority after a stabilisation period of 3 months.

Thus, to eliminate the middle part of the section.

Actual draft of AMC Part-MED:

GM3MED.B.010 Cardiovascularsystem ANTICOAGULATION:

Applicants and licence holders taking anticoagulant medication which requires monitoring with INR testing, should measure their INR on a 'near patient' testing system within 12 hours prior to flight and the privileges of the applicable licence(s) should only be exercised if the INR is within the target range. The INR result should be recorded and the results should be reviewed at each aeromedical assessment.

Our proposal:

To eliminate completely this whole section.

Actual draft of AMC Part-MED:

Section 2/ Specific requirements for class 1 medical certificates AMC1 MED.B.030 Haematology/ (g) ~~Thrombo-embolic disorders~~ Thromboembolic disorders:

(1) Applicants with a thrombotic disorder require investigation. A fit assessment ~~with a multi-pilot limitation~~ may be considered ~~if there is no history of significant clotting episodes~~ when the applicant is asymptomatic and there is only minimal risk of secondary complication or recurrence.

(2) If anticoagulation is used as treatment, refer to AMC1 MED.B.010(g).

(3~~2~~) An Applicants with arterial embolus ~~is disqualifying~~ should be assessed as unfit. A fit assessment may be considered once recovery is complete, the applicant is asymptomatic, and there is only minimal risk of secondary complication or recurrence.

Our proposal:

There is no need of a change of this section.

Actual draft of AMC Part-MED:

> Section 3/ Specific requirements for class 2 medical certificates AMC2 MED.B.030 Haematology/ (f) ~~Thrombo-embolic disorders~~ Thromboembolic disorders:
>
> Applicants with a thrombotic disorder may be assessed as fit if there is ~~no~~ minimal likelihood of significant clotting episodes. If anticoagulation is used as treatment, refer to AMC2 MED.B.010(g).

Our proposal:

> There is no need of a change of this section.

Concerning the specific requirements for LAPL medical certificates, the text in the draft version AMC Part-MED in relation with anticoagulation should be corrected by following the proposed changes for Class 2-Medical (see above).

Concerning the aero-medical requirements of cabin crew, the text in the draft version AMC Part-MED in relation with anticoagulation must not be changed.

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