

Rationale for a proposal for a change of the actual Draft of the acceptable means of compliance (AMC) Part-MED of EASA - 07.01.2017

Topic: Anticoagulation

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The actual draft of AMC Part-MED contains several requirements which are either not compatible with actual cardiological practice or which are just unpractical. Furthermore we have made a new analysis about the risks of anticoagulation and have drawn the conclusion that - in contrast to the actual valid AMC Part-MED (15.12.2011) - it is justified to eliminate the restriction of OSL for the class 2-Medical if several conditions are fulfilled (see below).

In November 2010 René Maire presented the paper „ANTICOAGULATION AND FITNESS TO FLY“ at the ECAM-congress in Athens. After the congress René Maire und Severin Muff made a document which was a summary of the content of that presentation (see annex 1). This document contains a literature review concerning the risk of anticoagulation with vitamin K-antagonists. The conclusion was that pilots under anticoagulation with vitamin K-antagonists can be declared fit to fly with OML/OSL-restriction if certain criteria are fulfilled, and this conclusion was put further as a proposal to EASA. And the proposal has been accepted by EASA, thus you find the appropriate text in the actual valid version of AMC Part-MED.

Reconsidering the data of the literature which we cited in the document mentioned above (annex 1), you can even conclude, that the annual risk of bleeding with vitamin K-antagonists is generally < 2%, if certain criteria are fulfilled (see below). Let's assume that we accept an annual risk of 2% for sudden incapacitation for pilots with a class 2-Medical, then a subset of pilots with anticoagulation can be declared fit to fly without restriction. Since a few years a new class of anticoagulation drugs has become standard for anticoagulation for many indications. They were initially called new oral anticoagulants = NOAC. The term NOAC is still widely used, today it can be translated as Non vitamin K- oral anticoagulants. Instead of NOAC, you find also the term DOAC (direct oral anticoagulants). These drugs are well established and are recommended in many international guidelines like in those of the ESC (European Society of Cardiology). The wide application of NOAC is based on numerous papers which have shown, that the use of NOAC is not-inferior compared to vitamin K-antagonists in respect of prevention of thromboembolic events and of bleeding complications (being even better in some of these NOAC drugs). This is valid for all four classes of NOAC, which are actually on the market. Because this is very well known, there is no need for us to enumerate all important NOAC-papers and data concerning thromboembolic events and bleeding complications in this document. The conclusion is that the statement for vitamin K-antagonists concerning the annual risk for sudden incapacitation, given above, is also valid for NOAC.

The risk for an adverse medical event in patients being under anticoagulation is related to the underlying medical disease, which demands an anticoagulation, and to the risk of bleeding defined by the presence of specific „risk factors“. These „risk factors“ are found in scores like the HAS-BLED-score and similar scores. You can estimate the given bleeding risk in these scores. In case of vitamin K-antagonists the ratio of INR is important, therefore we have the condition of an observation period of six months with INR-checking etc. within the regulations. In case of NOAC we have the condition of an observation period of three months.

Concerning the definition of fitness to fly for pilots under anticoagulation, each case has to be analysed according to its individual risk. This is a premise. In order to transform the different scenarios of pilots with anticoagulation into regulations it is justified to make the following conclusions:

- 1) If the underlying medical disease has a high risk and/or the risk of bleeding is high, the pilot is unfit to fly (for the class 1- as well as for the class 2-Medical).
- 2) If the underlying medical disease has a low risk and/or the risk of bleeding is low, the pilot is fit to fly with the restriction of OML for the class 1-Medical, and he is fit to fly without restriction for the class 2-Medical.
- 3) If the underlying medical disease has an intermediate risk and/or the risk of bleeding is intermediate, the decision has really to be made on an individual basis. Probably the pilot will be unfit for the class 1-Medical, and he might be fit to fly with the restriction of OSL or OPL for the class 2-Medical.

These conclusions 1) to 3) are valid for vitamin K-antagonists as well as for NOAC.

In the actual draft of AMC Part-MED there are especially two wordings which are not compatible with medical practice:

- 1) The one concerns anticoagulation with pilots having a mechanical valve prosthesis. Those patients are anticoagulated only with vitamin K-antagonists, and it is forbidden to give NOAC in these cases according to international guidelines (it would be a medical malpractice). Thus, it does not make sense to mention NOAC in this context.
- 2) The other strange wording contains the following: „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.“ This scenario seems to imitate the regulation about pilots with a LAPL-Medical using insulin. This concept of checking the INR before flight and showing the result once to the AME leads to a laborious administrative work which does not make sense. If we accept that the risk using vitamin K-antagonists is low if certain conditions are fulfilled (see above), then we must not distinguish any more the requirements in respect of vitamin K-antagonists and of NOAC, and thus, the requirements can be written in a simpler and more concise way.

Annexes:

- 1) Document „Anticoagulation and Fitness to fly“ (Summary of the presentation at the ECAM-congress Athens 11/2010)
- 2) Document with wording of the text within AMC Part-MED which should be changed: „Proposal for a change of the actual Draft of the acceptable means of compliance (AMC) Part-MED of EASA“