ÖSTERREICHISCHE ÄRZTEKAMMER Körperschaft öffentlichen Rechts – Mitglied der World Medical Association

Draft opinion and decision of the European Aviation Safety Agency for the licensing and medical certification of pilots

Position of the Austrian Medical Chamber

February 10,2009 IB/Rö

The Austrian Medical Chamber would like to comment on the "NOTICE OF PROPOSED AMENDMENT (NPA) NO 200817C DRAFT OPINION OF THE EUROPEAN AVIATION SAFETY AGENCY, FOR A COMMISSION REGULATION establishing the implementing rules for the licensing and medical certification of pilots and DRAFT DECISION OF THE EXECUTIVE DIRECTOR OF THE EUROPEAN AVIATION SAFETY AGENCY on acceptable means of compliance and guidance material on the licensing and medical certification of pilots "Implementing Rules for Pilot Licensing" C. Part-Medical".

The following definition can be found after the title MED.A.010 on page 3 of the draft document: 'Eye specialist' means an ophthalmologist or a vision care specialist qualified in optometry and trained to recognise pathological conditions".

On page 44, in point 1.2. and point 2, as well as on page 45, in point 4, in the last paragraph, it is stipulated that all abnormal and doubtful cases should be referred to an ophthalmologist. This implies e contrario that all other cases could be examined by a less qualified optometrist.

The serious concerns we raise against these regulations are of legal and of medical nature:

1. Legal concerns

The **principle of subsidiarity** as defined in the EC Treaty strictly confines European legislators in the field of health care. **Art 152 par. 5 of the EC Treaty** sets forth:

(5) Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care..."

This implies that the Member States are responsible for defining for each health profession which kind of health services they are allowed to provide. European legislation fully respects this competence inherent to Member States (cp. for instance Article 21 par. 1 of Directive 2005/36/EC on the recognition of professional qualifications, according to which professional recognition of health professionals engaged in medical activities in another Member State is subject to the legislation of the host Member State, and not to the one of the country of origin). Art 15 par. 2 (d) of Directive 2006/123/EC on services in the internal market gives Member States the right to reserve access to service activities in question to particular providers by virtue of the specific nature of the activity.

The present EASA draft document sets forth a **Definition of "eye specialist"**, which subsequently will lead to the fact that the professionals covered by this definition will be authorized to perform the comprehensive eye examination and the routine eye examinations prescribed for pilots in all Member States. This regulation is contrary to the system outlined earlier and massively interferes in the competence of the Member States.

The Austrian Medical Chamber holds the opinion that due to the principle of subsidiarity and the national legislative competence in health care it is inadmissible to transform such regulation into a European standard. Cancelling of this both inadmissible and redundant European definition would lead to the fact that the Member States would continue to be competent for defining the providers authorized to perform eye examinations, without downgrading the quality of European standards. For this reason, we urgently request you to plead for the cancellation of this definition in the EASA draft document.

2. Medical concerns

The medical concerns we have against the proposed definition of an "eye specialist", as well as against the statement presumed on pages 44-45 that eye examinations are to be performed by eye specialists in normal cases, are at least as grave as our legal ones:

If the draft was implemented in its present form, this would lead to the fact that opticians, regardless of any additional training, would be authorized to perform the required medical eye examinations and to assess pathological ophthalmological anomalies. This means that they would carry out a differentiated diagnosis and give medical expertise. An **optometrist**, who is able to perform examinations in a technically correct manner, **does not have the comprehensive medical background knowledge of a medical doctor**, required in order to judge and assess the data with regard to other physical parameters. The **examination of eye functions**, **including vision**, **is only one of the elements** of a serious ophthalmological expertise. The examination with regard to ocular pathologies (such as diabetes, hypertension, ceratoconus, reduced colour vision, cataract, glaucoma, post-operative conditions etc.) is as important as and **the general assessment of the patient**.

In Austria, ophthalmic optics is a trade according to Art 94 par. 2 of the Austrian Trade Regulations. According to Art 98 of the Austrian Trade Regulations, the professional portfolio of optometrists covers the adjustment and dispensing of corrective glasses including the determination of eye glasses, as well as retail trade of contact lenses. No further competences and no further training curricula are foreseen for the profession of optometrists. For this reason, the diagnosing of pathological conditions by optometrists would mean a violation of the Trade Regulations in Austria.

In the medical certification required for pilots, the examination and detection of possible pathological conditions clearly outweighs the assessment of purely "optometric" data, such as visual fitness. The examination of patients for exploring possible physical and mental diseases or disorders, disabilities or abnormalities and malformations, of pathological nature, constitutes a medical activity according to the Austrian law (Art 2 par. 2 line 1, Austrian Medical Act), which is reserved to medical doctors for reasons of patient safety according to Art 3 par. 2, Austrian Medical Act. This means that the performance of such activities by optometrists would conflict with the Austrian Medical Act.

Obviously, the EASA, too, is aware of the fact that comprehensive specialist training is required for assessing abnormal and doubtful cases. It is with good cause that it is stipulated explicitly in AMC A - MED.B.065, VISUAL SYSTEM class 1 medical certificates, that all abnormal and doubtful cases should be referred to an ophthalmologist, i.e. a medical specialist. This makes it even less comprehensive how the EASA would medically justify the regulation of the optometrists' right to perform ophthalmological certificates in the entire EU.

The Austrian Medical Chamber is convinced that European minimum solutions are out of place, when it comes to aviation safety, where a great number of human lives are at stake. In times where airplanes transport up to 900 passengers in increasingly crowded flight traffic, it is of greatest importance that pilots have unobjectionable sight. Therefore, from the medical point of view, we consider it as absolutely imperative that the ophthalmological and optometric fitness of pilots is assessed by fully qualified specialists.

These considerations lead us to urge the introduction of high standards at EU level for the medical certification of pilots. If harmonization cannot be achieved at a high quality level, there should be at least the possibility for individual Member States to foresee higher quality standards in their national legislation. Therefore, we reiterate our urgent request to plead for an amendment of the present draft document, in order to guarantee that Member States have the possibility to foresee in their national legislation that pilots are examined and licensed according to the highest medical standards.

Tha Austrian Medical Chamber proposes the following amendments to the draft:

- 1. Cancellation of the definition of "eye specialist" on page 3 in MED.A.010
- 2. Amendment of the wording on page 44 et sqq., 1.2., 2. and 4., into: "Where national legislation allows the visual examination and review to be undertaken by eye specialists other than ophthalmologists, at least all abnormal and doubtful cases should be referred to an ophthalmologist".

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