COMMENT RESPONSE DOCUMENT (CRD) TO NOTICE OF PROPOSED AMENDMENT (NPA) 2008-17C

for an Agency Opinion on a Commission Regulation establishing the Implementing Rules for the medical certification of pilots

and

a draft Decision of the Executive Director of the European Aviation Safety Agency on Acceptable Means of Compliance and Guidance Material on the medical certification of pilots

"Implementing Rules for Pilot Licensing - Medical Certification"

CRD a. 1 – Explanatory Note A

I. General

1. The purpose of the Notice of Proposed Amendment (NPA) 2008-17, dated 3 June 2008, was to develop an Opinion on the Implementing Rules for the licensing and medical certification of pilots and a Decision on the related Acceptable Means of Compliance (AMC) and Guidance Material (GM). The scope of this rulemaking activity was outlined in the Terms of Reference (ToR) FCL.001 and was described in detail in the NPA.

2. NPA 2008-17 was divided into 3 separate documents:

   - NPA 2008-17a contained the Explanatory Note to the NPA, with detailed explanatory memorandums for both Part-FCL and Part-Medical, as well as cross-reference tables between JAR-FCL 1, 2 and 3 and the proposals presented in the NPA.
   - NPA 2008-17b contained draft proposals for Implementing Rules (IR) and related AMC and GM for the licensing of pilots (Part-FCL).
   - **NPA** 2008-17c contained draft proposals for IR and related AMC and GM for the medical certification of pilots (Part-MED).

II. Consultation on NPA 2008-17

3. NPA 2008-17 was published on the website (http://www.easa.europa.eu) on 5 June 2008.

   The consultation period of the NPA was extended in accordance with Article 6(6) of the Rulemaking Procedure[1], at the request of stakeholders, to ensure an overlap of the consultation periods of the first extension NPAs[2]. By the closing date of 28 February 2009, the European Aviation Safety Agency ('the Agency') had received 11.197 comments from over 800 commentators, including National Aviation Authorities, professional organisations, private companies and individual persons.

4. In addition, the Regulatory Impact Assessment for Part-FCL was published at the end of October 2008, as NPA 2008-22f, and was open for consultation until 15 April 2009.

5. Due to the amount of comments received, and in accordance with the work programme established by the Agency in agreement with the European Commission and the Management Board, it was decided that the Comment Response Document (CRD) for NPA 2008-17 would be divided and published in phases. Accordingly, the present CRD only focuses on NPA 2008-17c (Part-Medical). An overview of the comments received, as well as of the changes made to the text of the NPA as a result, is included in Annex II to this Explanatory Note.

6. The CRD for NPA 2008-17b (Part-FCL) was published on 9 April 2010. As for the comments received on NPA 2008-17a (the Explanatory Note) a full CRD will not be published, even though the Agency has reviewed and taken into account all the comments. The comments included in NPA 2007-17a were largely a repetition of more

[1] EASA Management Board Decision 08-2007, amending and replacing the Rulemaking Procedure, adopted at the Management Board meeting 03-2007 of 13 June 2007 (http://www.easa.eu.int/ws_prod/g/management-board-decisions-and-minutes.php).

[2] More specifically, NPA 2008-22 on Authority and Organisation Requirements, and NPA 2009-02 on Implementing Rules for Air Operations of EU Operators (http://www.easa.eu.int/ws_prod/r/r_archives.php).

detailed comments that were also made to NPA 2008-17b and c, and it was therefore not considered necessary to provide a full CRD in this case.

7. As for the comments received on NPA 2008-22f (the Part-FCL RIA), it was also decided not to publish a full CRD, even though the comments received were taken into account when reviewing the comments on Part-FCL.

III. Publication of the CRD

8. The provisions for the medical fitness for pilots (NPA 2008-17c) and for cabin crew (NPA 2009-02e) are now combined in this CRD as they will be for the Opinion and Decision Part Medical. However, it has to be noted that the comment period for NPA 2008-17c closed considerably earlier than the one on NPA 2009-02e, and the comments were treated differently because the working procedures changed in the meantime. All further details on NPA 2009-02e are described in the Explanatory Note B, published as document CRD a.2.

9. All comments received on NPA 2008-17c have been acknowledged and incorporated into part c of this CRD with the responses of the Agency.

10. In reviewing and replying to the comments and making the necessary changes to the text of the NPA, the Agency was supported by the Review Group FCL.001[3]. This group was created in accordance with the Rulemaking Procedure and, for the review of the comments on NPA-FCL 2008-17c included the Chair Person of the Subgroup Medical to the FCL.001 core drafting group, as well as other experts from the Agency, National Aviation Authorities and industry, who had not been involved in the initial drafting phase.

11. The work on the review of comments to NPA 2008-17c was framed by the common approach to the extension of EU competences agreed between the Agency, the European Commission and the Management Board of the Agency. This common approach established not only a detailed prioritisation of the work to be developed by the Agency, but also high level principles that would preside over the review of the comments. Among these were the adherence to ICAO Standards and Recommended practices, EU law and adopted Joint Aviation Requirements (JARs); the necessary due consideration to safety and regulatory principles and to the current distribution of text between hard and soft law, as well as to constraints such as changes stemming from the Basic Regulation and from Joint Aviation Authorities (JAA) NPAs which had reached consensus; the need to create proportionate requirements; and, finally, the requirement to pay special attention to the clarity, legal certainty and enforceability of the proposed regulatory text.

12. In responding to comments, a standard terminology has been applied to attest the Agency's acceptance of the comment. This terminology is as follows:

- **Accepted** – The comment is agreed by the Agency and any proposed amendment is wholly transferred to the revised text.
- **Partially Accepted** – Either the comment is only agreed in part by the Agency, or the comment is agreed by the Agency but any proposed amendment is partially transferred to the revised text.

[3] The composition of the Medical Subgroup to the FCL.001 review group can be found on the Agency's website (http://www.easa.europa.eu/ws_prod/r/r_crd.php).

- **Noted** – The comment is acknowledged by the Agency but no change to the existing text is considered necessary.
- **Not Accepted** – The comment or proposed amendment is not shared by the Agency.

13. In some cases, due to the number of comments received and taking into account the existence of repeated comments, the Agency has also used **Noted** to reply to repeated comments. In this case, reference is made to the comment where the Agency has included a detailed answer.

14. The resulting text, highlighting the changes as compared to the text proposed in the NPA, is published as part b of this CRD.

15. Parts b (resulting text) and c (replies to comments) will not be published in the Comment Response Tool, but only on the Agency's website, due to the size of the documents concerned. More details on the different documents, which are part of this CRD, can be found in Annex I to this Explanatory Note.

16. The Agency's Opinion will be issued at least two months after the publication of this CRD to allow for any possible reactions of stakeholders regarding possible misunderstandings of the comments received and answers provided.

17. Such reactions should be received by the Agency not later than **by 23 August 2010** and should be submitted using the Comment-Response Tool at http://hub.easa.europa.eu/crt/. When submitting their reactions, stakeholders are kindly invited to clearly identify the issue and, if relevant, the article/paragraph in question.

Annex I to the Explanatory Note

CRD documents

Original document	***CRD #***	***Content***
N/A	**CRD a**	**Explanatory Note**
NPA 2008-17c	CRD a.1	Explanatory Note A
NPA 2009-02e	CRD a.2	Explanatory Note B
NPA 2008-17c	**CRD b**	**Resulting text**
NPA 2009-02e	CRD b.1	Cover Regulation
	CRD b.2	Part-MED
	CRD b.3	AMC/GM to Part-MED
NPA 2008-17c	**CRD c**	**Comments and Responses**
	CRD c.1	Comments and Responses to Subparts A, B, C, D
	CRD c.2	Comments and Responses to AMCs
NPA 2009-02e	CRD c.3	Comments on Cabin Crew medical fitness
	CRD. c.4	Comment Response Summary Table (CRST)
n/a	information	Application and Examination forms for medical certificates LAPL

Annex II to the Explanatory Note A

Explanatory memorandum on the review of comments on NPA 2008-17c and the resulting text

A. General analysis of comments received

1. By the closing date of the consultation period of NPA 2008-17, the European Aviation Safety Agency ('the Agency') had received 11.197 comments from over 800 commentators, including National Aviation Authorities, professional organisations, private companies and individual persons. These comments were distributed as follows:

   - 714 comments on NPA 2008-17a (Explanatory Note),
   - 8.107 comments on NPA 2008-17b (Part-FCL),
   - 2.376 comments on NPA 2008-17c (Part-MED).

Comments received on NPA 2008-17a — Explanatory Note

2. A total of 714 comments were received on NPA 2008-17a. The majority of these comments focused on the same issues that were commented upon in NPA 2008-17c, with a large amount of them being repetitions of comments also provided in NPA 2008-17c. For that reason, they will not be specifically mentioned here.

3. Some of them were, however, original comments, specifically those on transition measures. NPA 2008-17 did not contain detailed proposals on transition measures for the new pilot licensing rules. However, the Agency highlighted some principles that it intended to apply in the definition of its proposals for those measures and specifically asked stakeholders to provide feedback on those principles. 52 comments were received on this issue, and they have been taken into account in the definition of the proposals that can be found in the draft Cover Regulation that is published in part b.1 of this CRD.

Comments received on NPA 2008-17c — Part-Medical

4. The following tables show the distribution of comments received on NPA 2008-17c. As can be seen from Table 1, more comments where made on Implementing Rules than on Acceptable Means of Compliance.

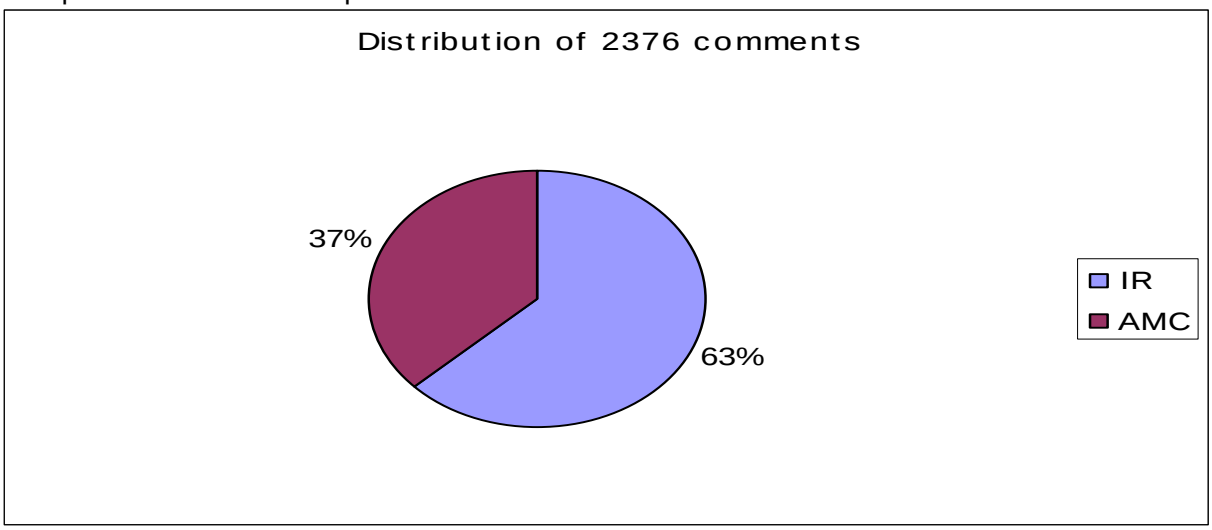

Table 1: All comments and the distribution to IRs and AMCs

5. Table 2 shows the distribution of comments that were received on IRs, where Subpart A received the largest number of comments. This Subpart deals with the general requirements, including those addressing the new Light Aircraft Pilot Licence (LAPL). Subpart B relates to technical medical requirements for all classes of medical certificates and Subpart C contains the rules for aero-medical examiners (AME). Subpart D addresses the General Medical Practitioner who may issue medical certificates for the LAPL, if permitted under national law.

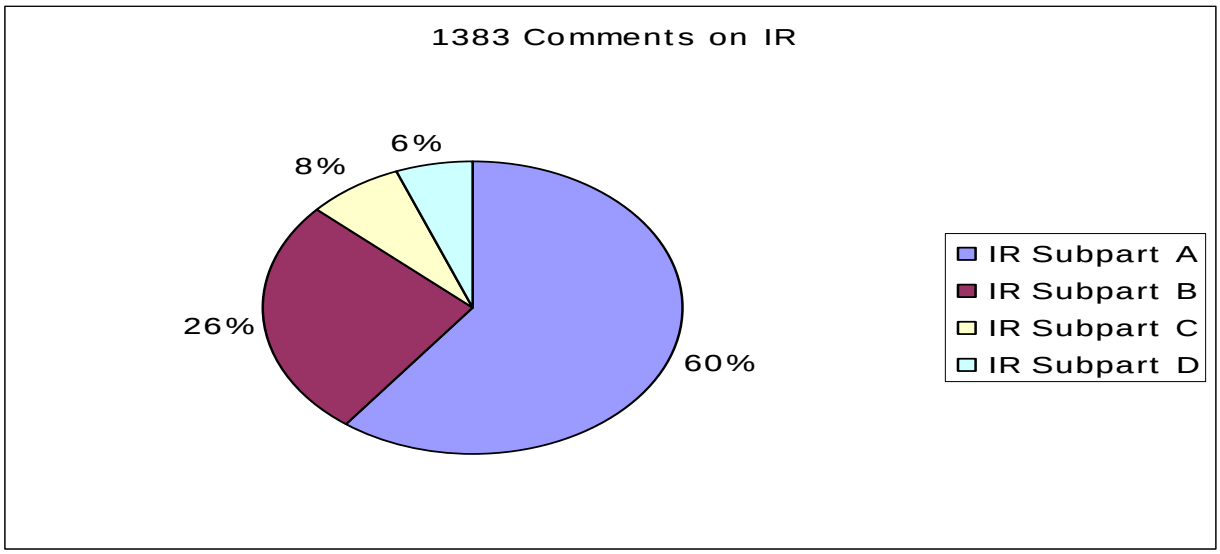

Table 2: Comments on IR and distribution between the Subparts

6. Regarding the comments received on the AMCs to Part-Medical, Table 3 shows that the majority of comments were addressed to the AMCs to Subpart B. There are three sections in the AMC to this Subpart, all dealing with detailed medical provisions: AMC 1 to Subpart B is for commercial pilots (class 1), AMC 2 to Subpart B for private pilots (class 2), and AMC to MED.B.090 for the new LAPL medical certificates.

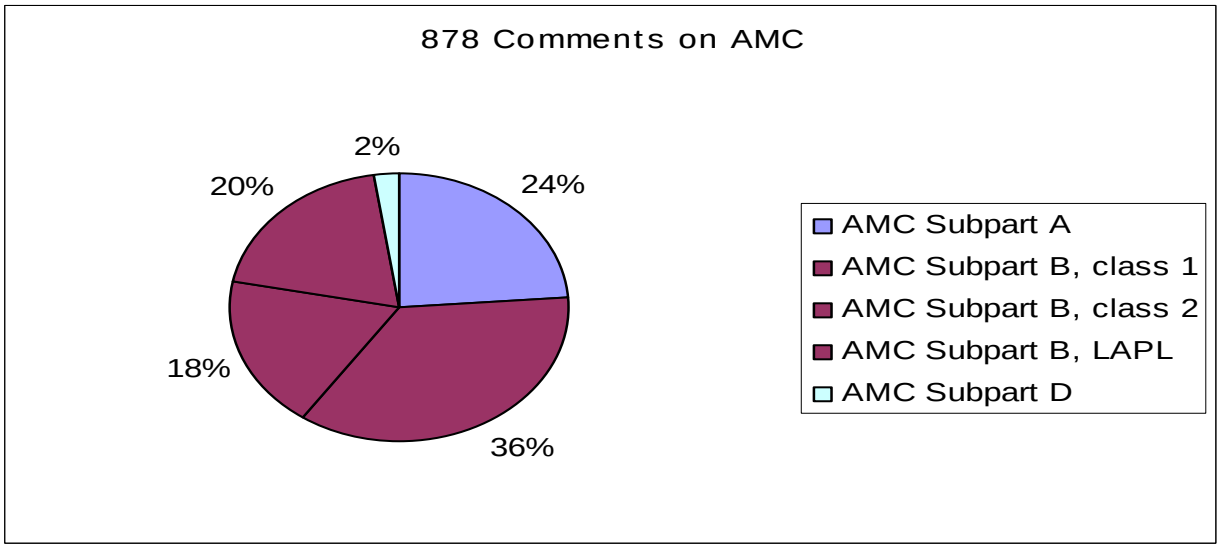

Table 3: Comments on AMC and distribution between Subparts

7. Table 4 shows that many comments were placed on the Title Page of the NPA and slightly more than half of 949 comments received on the Implementing Rules in Subpart A are on 4 out of 14 paragraphs in this Subpart. Most of these comments address the medical certificate for the new Light Aircraft Pilot Licence and will be detailed later on. No other paragraphs in the IRs reached 100 comments.

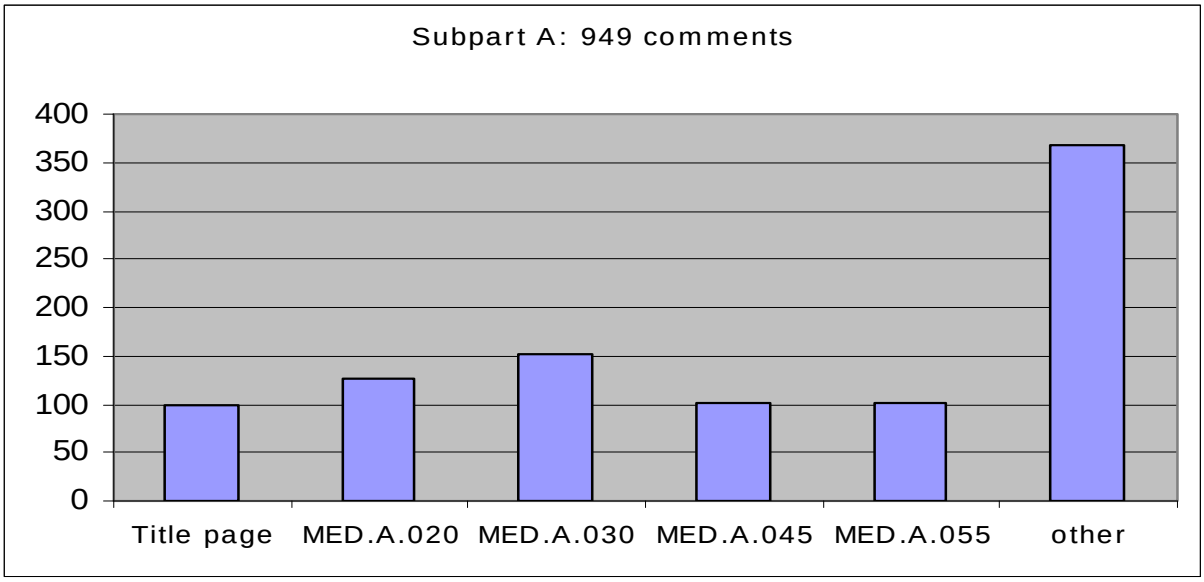

Table 4: Paragraphs on IRs having received more than 100 comments

8. Of course, not all of these comments represented individual or original views. Out of 2376 comments received on NPA 2008-17c, only 5 were identified as duplicates by the Comment-Response Tool — meaning that the same comment made by the same user had been introduced several times in different segments of the NPA. The tool unfortunately cannot identify cases where the same comment was introduced by different users. However, even a cursory reading of part c of the CRD will show that this happened very frequently. In almost every segment were comments that were consistently repeated by groups of stakeholders. This happened in all categories: National Aviation Authorities, professional organisations, private companies and even individual persons.

9. Therefore, the conclusions extracted from an analysis of the number of comments received have to be considered in the light of this reality. It also needs to be understood that when assessing the comments, the primary factor considered by the Agency was the quality and pertinence of those comments, as well as the justifications provided. The number of comments received was useful in identifying the concerns of stakeholders, but it was not — as the Agency indicated several times to stakeholders — a decisive factor when evaluating the changes to be made to the initial proposals as a result of the consultation.

B. Description of comments received and resulting text

10. The Agency carefully reviewed and replied to the comments received on NPA 2008-17c. Based on this, changes were made to the initial draft text of Part-Medical and related AMCs. The following paragraphs highlight the most significant changes and explain the reasons behind the resulting text published in part b of this CRD.

Cover Regulation

11. NPA 2008-17 did not contain draft proposals for a pilot licensing Cover Regulation, for the reasons that were detailed in the Explanatory Note to NPA 2008-17a. However, the Explanatory Note described the intentions of the Agency regarding the possible transition measures for Part-FCL. Based on the comments received on the Explanatory Note, the Agency has prepared a draft Cover Regulation, which has been published with the resulting text in part b.1 of the CRD Part-FCL. It has now been amended and is re-published in part b.1 in this CRD Part-MED to include transition measures for the applicability of Part-MED and remains otherwise unchanged.

12. The Cover Regulation defines the general applicability of Part-FCL and its other Annexes and proposes transition measures for the applicability of Part-FCL. However, it needs to be noted that the definition of a maximum applicability date for the Implementing Rules for pilot licensing in Article 70 of the Basic Regulation has limited not only the periods available for transition, but also the type of possible transition measures. Indeed, since the Basic Regulation establishes that the Implementing Rules for pilot licensing shall be applicable no later than 8 April 2012, any transition measures going beyond that date need to be opt-outs[4].

Part-MED and related AMC and GM

13. The rule text of Subarts A and B of NPA-2008c and the corresponding AMCs contain implementing rules and acceptable means of compliance for the ICAO compliant licences for commercial and private pilots as well as those for the new light aircraft pilot licence. However, it seems more convenient to deal with ICAO compliant and LAPL provisions separately in this Explanatory Note in order to provide a consistent overview. Therefore, the following paragraphs 14–45 will deal with General Requirements and specific medical provisions for ICAO compliant medical certificates, followed by the description of comments and resulting changes for the LAPL medical certificate starting in paragraph 46.

Subpart A — General

14. **MED.001** — Competent Authority. Comments on the paragraph indicated that it was not very well understood. Editorial changes have been made to clarify the content.

15. **MED.A.005** — Scope. This paragraph has been amended to include medical fitness of cabin crew in Part-MED. The corresponding IRs and AMCs have been added as Subpart E to Part-MED and the Explanatory Note B, published under a.2, further details the medical provisions for cabin crew.

16. **MED.A.010** — Definitions. Comments to this paragraph asked for changes in the definitions of ‘colour safe’, ‘refractive error’ and ‘eye specialist’. The first definition is ICAO compliant and was not changed for that reason. The definition of ‘refractive error’ was kept as it is scientifically correct and the same as in JAR-FCL 3. The definition ‘eye specialist’ was contested by Ophthalmologist Organisations saying that it is not for the Agency to define medical professional specialities. The Agency was of the opinion that a

[4] An opt-out is a type of transition measure that leaves to the Member States the choice to postpone the implementation date of a certain provision up to a certain time limit defined by law.

definition is needed because it is not possible to require all eye examinations to be done by ophthalmologists as they are not easily available in all Member States. The definition is there to ensure that other specialists performing the examinations are properly trained to recognise pathologies to be referred to an ophthalmologist. One definition on 'accredited medical opinion' was added and the wording was taken from ICAO Annex 1.

17. **MED.A.015** on medical confidentiality received comments asking for further and more detailed implementing rules and AMCs considering the fact that medical data are very sensible and data protection has to have a very high priority. The Agency agrees with this statement but considered that protection of medical data is already regulated under Community law and that MED.A.015 therefore does not need to be amended.

18. **MED.A.020** on medical certification received several comments from National Aviation Authorities (NAA) asking to add a minimum age for a candidate to apply for a medical certificate. These comments were not accepted because it would be an addition to the present JARs, and a minimum age to apply for a medical certificate is not mentioned in ICAO Annex 1.

19. **MED.A.030** — Competence for the issuance, revalidation and renewal of medical certificates. This paragraph defines that medical certificates shall be issued by AMEs, AeMCs and GMPs only. Numerous NAAs sent comments requesting changes to this paragraph to provide the Aero-medical Section (AMS) of an NAA with the possibility to issue medical certificates as is the case under JAR-FCL 3. When drafting the NPA, the Agency concluded from Article 7 of the Basic Regulation that NAAs will not issue medical certificates because they are not mentioned therein. For this reason also the term 'Aero-medical Section' has not been included in the NPA and it was replaced by 'licensing authority' following the wording in ICAO Annex 1. The comments indicated that the text in the Basic Regulation is that an AeMC, AME or GMP may issue the medical certificate which would leave room for the NAA/licensing authority to do that as well, whereas the implementing rule states that the AeMC, AME or GMP shall issue the medical certificate which would exclude the NAA from doing so. The position of the Agency is that the Basic Regulation specifically mentions the Organisation/persons who may issue the medical certificate but agreed that under some circumstances the licensing authority would need to have the possibility to do so as well. The paragraph was amended to say that the licensing authority may issue the medical certificate in cases where an applicant was referred to it by an AME or AeMC for a decision on medical fitness as indicated in Subpart B, and for administrative reasons, for example to correct a medical certificate that was issued incorrectly.

20. **MED.A.035** — Application for a medical certificate. Comments on this paragraph requested a common form in Europe for this application as was the case under JAR-FCL 3. The corresponding form from JAR-FCL 3, as well as the examination form, will be re-introduced without significant changes as an AMC in the Authority Requirements.

21. **MED.A.045** — Limitations to medical certificates. This paragraph was amended significantly. The original intention of the Agency was to leave the decision on medical fitness to AeMCs and AMEs also for applicants who do not fully meet the requirements, but who could be assessed as fit with a limitation as stated in the Basic Regulation (see paragraph 19 above). However, already in the drafting phase of the NPA, NAAs warned that some AMEs may not have sufficient experience to take that decision in difficult cases and that consistent and standardised decisions can only be taken by the AMS of the NAAs. Also, some NAAs never authorised AMEs to assess commercial pilots and to issue class 1 medical certificates. They either issued the medical certificates in the AMS or gave this privilege only to AeMCs that were also limited in numbers. It will therefore take time for these NAAs to have sufficiently trained AMEs for class 1 assessments. In addition, referral to the AMS was the key factor under the JAR system for the assessment of medical fitness in the cases mentioned above. MED.A.045 was amended for class 1 medical assessments and decisions on fitness of commercial pilots that were taken by the

AMS under JAR-FCL 3 will be taken by the licensing authority under Part MED. However, applicants for class 2 medical certificates will not be referred to the authority as in JAR-FCL 3, but the decision will be taken in consultation with the licensing authority. This in order to give the licensing authority sufficient flexibility to delegate this decision to AMEs or AeMCs.

22. Notwithstanding the above, it has to be mentioned that one AeMC, supported by AMEs, individual pilots, the Ministry of Transport and several local Government Authorities of the NAA concerned, proposed not to involve the licensing authority in cases where the decision on medical fitness of a pilot cannot be taken by an AME according to Subpart B. The proposal is to refer these pilots to an AeMC where the decision on fitness would be taken and the medical certificate issued with limitations as necessary. The copy of the medical certificate should then be sent to the licensing authority and the medical file should remain either with the AME or the AeMC. The reasons behind these comments are good experience with this system which is presently implemented in that Member State, less bureaucracy, faster decisions and full compliance with national data protection rules. Another argument is that, in general, it is highly unusual for a medical doctor to take a far reaching decision on a person he/she never saw. These comments were not accepted in the light of JAR-FCL 3, ICAO Annex 1 and the way of handling this issue in other parts of the world, e.g. the FAA, TCAA, CASA and others.

23. On the same paragraph, the list of limitations to a medical certificate, with the exception of the operational multi-pilot limitation (OML) for class 1 and the operational safety pilot limitation (OSL) for class 2, was deleted from the IR and added to the AMC to go back the way the limitations were placed in JAR-FCL 3. The OML wording was taken over from JAR-FCL 3 where only one pilot with an OML limitation is allowed to be rostered in a multi crew environment. This raised a significant number of comments arguing that the risk that both pilots would suffer an incapacitation on the same flight, and therefore jeopardise safety, was highly improbable, whereas the proposed rule made rostering difficult for Operators. Although the Agency understands these comments they were not accepted, and the text in the CRD remained as presently in JAR-FCL 3.

24. **MED.A.050** — Obligations of the AeMC, AME and GMP. One of their obligations is to send the medical records of an applicant to the licensing authority after the aero-medical examination has been performed and the assessment made. One NAA is of the opinion that this is against data protection rules while others state that keeping one complete medical file of a pilot in the licensing authority is a question of safety, arguing that the medical history is the key factor to assess medical fitness. This was also the process in JAR-FCL 3 and the rule was not changed.

25. The same paragraph, subparagraph (e) requires the AeMC, AME or GMP to submit all aero-medical records and reports to the competent authority on its request for oversight purposes. This raised concerns regarding data protection and the paragraph was amended to specify that the files have to be sent to the medical assessor of the competent authority.

26. **MED.A.065** — Suspension and revocation of medical certificates. One NAA expressed doubts whether a medical certificate issued by an AeMC, AME or GMP can be suspended or revoked by the authority as long as the AME, AeMC or GMP does not work on behalf of the authority. The Agency is of the opinion that in cases where a medical certificate has been issued in violation of defined rules established in MED.A.060, the licensing authority has the basis to suspend or revoke that certificate.

Subpart B, AMC 1 and AMC 2 to Subpart B — Requirements for Medical Certificates

27. **MED.B.001** — contains the basic medical requirements for all classes of medical certificates. Comments were made to point out that the guidance material on incapacitation risk that was in JAR-FCL 3 has not been carried over to Part Medical (so-

called 1%-rule). The Agency agrees that this material on the aero-medical safety risk should be included again in the Guidance Material of Part-MED. However, the text that was in JAR-FCL 3 dates back to the 1990s, is outdated and needs a complete revision. In addition, many comments on the LAPL stated that the acceptable risk of an incapacitation should not be the same as was the case in JAR-FCL 3 but should be different depending on the activity. Proposed numbers were 1% incapacitation risk for commercial pilots, 2% for private pilots and for LAPL holders, and 20% for LAPL holders with a limitation to no passengers (OPL). This seems to be a simplified way to use statistical values because it has also to be stated in which relation the percentage is given (number of flight hours, age and condition of the pilot, activity involved, etc.). The Guidance Material from JAR-FCL 3 was not re-introduced in this CRD but new guidance on the incapacitation risk will be developed during a new rulemaking task and will be added as Guidance Material.

28. **MED.B.005 through MED.B.085** and the corresponding AMC 1 (class 1) and AMC 2 (class 2) to Subpart B address the specific requirements for class 1 and class 2 medical certificates. This Explanatory Note highlights only the most important changes that were made to NPA 2008-17c following the comments received. The highest number of comments was placed on MED.B.005 (Cardiology) and MED.065 (Visual System).

29. The main difference between NPA 2008-17c and JAR-FCL 3 was that the requirements for class 2 medical certificates were aligned with ICAO class 2 SARPs. Comments show that this move has been well received by almost all stakeholders.

30. A number of comments from Aero-medical Sections of NAAs and pilot organisations expressed concern about specific medical requirements placed in implementing rules as they cannot be changed quickly following new medical knowledge. Commentators also requested some significant changes to some medical provisions that were transferred from JAR-FCL 3 with the reasoning that medical science did advance since the last revision of JAR-FCL 3 and that this should be reflected in Part-MED.

31. The Agency was of the opinion that the distribution between hard law and soft law is equilibrated, also taking into account that the Appendices of JAR-FCL 3 — that are considered to be binding — are now in AMCs. On the other hand, some comments proposing rule changes based on medical evidence were accepted and are outlined in detail below. Comments on medical provisions that were not accepted were either highly controversial between different stakeholder groups, or were considered to need more consideration before they could be introduced. In these cases the provisions of JAR-FCL 3 were kept in the resulting text.

32. A general change in Subpart B, compared to the version published in NPA 2008-17c, is that all paragraphs have been reviewed to determine which pilots presenting with medical conditions have to be assessed by the licensing authority (for class 1), or in consultation with the licensing authority (class 2) to be in line with the changes made to MED.A.045 that were explained in paragraph 21 above. The intention was to accept the comments that requested to go back to JAR-FCL 3.

33. Some specialists (mainly cardiologists, ophthalmologists and psychologists) and some AMEs asked for additional rules, or rules that are more stringent than the ones published in JAR-FCL 3. These comments were not accepted with reference to the agreement to only change current regulations for compelling reasons and to follow the principle to draft rules that are proportionate to the privileges of the licence.

34. A significant number of comments was made asking for a register to hold information on commercial pilots who were assessed as unfit to fly, for AMEs in all Member States, for approved AME training courses and for an European Medical Appeal Board in EASA where pilots who were assessed as medically unfit by their licensing authority could appeal. The reason given for this appeal board was that licensing authorities may have different opinions in some individual cases and that uniform assessments should be ensured. The

Agency explained that the Basic Regulation presently does not contain provisions to give this mandate to EASA.

35. **MED.B.005** — Cardiology. One significant change is in MED.B.005 concerning systemic anticoagulation that was not acceptable for any fit assessment for commercial or private pilots under JAR-FCL 3. The NPA text was changed to the effect that applicants who need systemic anticoagulation may be assessed as fit under certain conditions and with limitations imposed by, or in consultation with the licensing authority.

36. **MED.B.020** — Metabolic and Endocrine Systems. The main issue here are applicants with diabetes mellitus who require insulin. These pilots are assessed as unfit under JAR-FCL 3 and insulin is also not accepted under ICAO 6.3.2.16 (class 1) and 6.4.2.16 (class 2). However, ICAO offers guidance on a fit assessment for these pilots with type 2 diabetes who require insulin. The Agency considered that it would be too early to change the rule in this respect but it should be taken up, if required by stakeholders, in the next rulemaking task on medical fitness.

37. **MED.B.055** — Psychology. Only 44 comments (IRs and AMCs combined) were received on this paragraph; however, they were well explained and need to be discussed here. Psychologist organisations and one NAA commented that the rules in this paragraph were considerably reduced as compared to JAR-FCL 3. This comment was accepted and the text of Appendix 17 in JAR-FCL 3 was brought back in the AMC to MED.B.055, while one subparagraph was added to the implementing rule saying that the psychologist shall send a report of his/her assessment to the licensing authority or the AeMC/AME as appropriate. However, another important issue from psychologist organisations was to require psychological examinations of pilots independently of the AME assessment. This was not accepted as there is no basis neither in JAR-FCL 3 nor in ICAO.

38. Further comments to the paragraph on psychology mentioned that the psychological assessment of a pilot should be done by ‘a psychologist “acceptable to the authority”’, which is the wording in JAR-FCL 3 but was not transferred to NPA 2008-17c. This comment was not accepted in order not to restrict access to psychologists and because, on a general basis, the wording ‘acceptable to the authority’ leads to different rules in Member States while common law is to be created. The comments also included the argument that pilots should only be assessed by aviation psychologists with accreditation from one psychologist organisation. However, the Agency considered that this accreditation is highly valuable but, as far as it could be assessed, not a speciality that is officially applicable in all Member States. The comment was therefore not accepted.

39. **MED.B.065** — Visual System. There is one significant change in this CRD compared to JAR-FCL 3: One change follows comments from stakeholders and applies to all applicants for a class 1 medical certificate at initial examination and revalidation, where all limits concerning refractive error for myopia as well as limits concerning anisometropia and astigmatism were abolished provided that the visual requirements can be met with glasses or contact lenses.

40. The second issue on the visual requirements is hyperopia above +5 dioptres, which is the upper limit for a fit assessment for class 1 medical certificates. This condition entails unfitness according to JAR-FCL 3 and received a significant number of comments requesting to abolish it. Although deleting the limits for myopia was accepted, this was not the case for hyperopia. The argument of commentators who were asking to abolish the limit was that refractive errors should not be of importance as long as they can be corrected with glasses or contact lenses. However, commentators opposing this change said that other pathologies of a highly hyperopic eye could lead to e.g. diplopia in situations where a pilot is tired and this could be against safety of the flight. Discussions in the Review Group on this issue did not lead to a satisfactory solution. As this resulted to be a case of doubt, the Agency kept the JAR-FCL 3 limits but is still prepared to revise

the CRD as long as consistency can be ensured for initial and revalidation assessments as well as for applicants with a high hyperopia before refractive surgery.

41. **MED.B.070** — Colour Vision. A new test for colour vision is proposed to be included as being acceptable for a medical assessment for class 1 and class 2. This test has been developed by a university and seems to give good results. Taking into account that new cockpit displays use more colours than was previously the case and pilots have to be able to distinguish these colours correctly, the Agency is of the opinion that any new test needs an independent evaluation before it can be accepted for an aero-medical assessment on colour vision.

Subpart C and new AMC to Subpart C

42. **MED.C.005** — Application. Among other issues, this paragraph deals with how an AME can apply alternative AMCs and it has been amended to say that the AME cannot apply alternative AMCs other than those agreed with the competent authority beforehand. It has to be noted that further changes to this paragraph may apply following changes to the Authority Requirements.

43. **MED.C.010** — Requirements for the issue of an AME certificate, **MED.C.015** — Requirements for the extension of privileges, and **MED.C.020** — Training courses in aviation medicine. The Agency accepted the comments to re-introduce the expressions 'basic training course' and 'advanced training course' from JAR-FCL 3 as well as the syllabi for these courses in the newly developed corresponding AMCs. However, the hours prescribed for the different subjects in JAR-FCL 3 were not included. This was done because the syllabi were developed when starting work on JAR-FCL 3 and need to be reviewed in a new rulemaking task. The hours on the individual subjects may be reconsidered at that stage, but the introduction of competency-based training for AMEs may be the preferred option following the ICAO approach to training in general.

44. There were well-founded comments urging the Agency to approve all training courses for AMEs, instead of the approval by the competent authorities as foreseen in **MED.B.020**. The reason for the comments is to ensure that AMEs can attend a training course in any Member State and that the certificate issued by the training supplier is accepted in all Member States. However, the Agency does not see a legal basis in the Basic Regulation to approve training courses for AMEs within Member States and is of the opinion that the approval by the competent authority of one Member State does render the corresponding certificate of completion valid in all Member States. The comments for approval of AME training courses by the Agency were therefore not accepted.

45. **MED.C.030** — Validity of AME certificate. Following comments of NAAs and discussions in the Review Group, the validity of AME certificates that was to be indefinite in the NPA 2008-17c was restricted to a validity period of 3 years as is under JAR-FCL 3. The refresher training that is required in MED.C.030 has been further determined in Guidance Material that has been added to this paragraph using the material that is available in the guidance material in JAR-FCL 3.

Medical Certificate for LAPL

46. The provisions for the LAPL medical certificate received very diverse comments from individual pilots, several European and national pilot organisations, as well as from AMEs, AeMCs, one European AME organisation, and National Authorities. The main reason for the amount of comments is the fact that licences and medical certificates for gliders, balloons and some national private pilot licences are presently regulated very differently on a national basis. The second reason is that the opinions of pilots and their organisations are very different from those of AMEs and their organisations which, in turn, differ from the view of National Authorities. Another reason for the high number of comments is that many are duplicates and some have been entered more than 15 times.

A high percentage of comments was not specific to individual paragraphs but repeated either support or rejection of the proposed provisions for medical certificates for the LAPL and of the possibility for the GMP to issue them.

47. The comments from pilots and pilot organisations from one Member State were mainly to say that their system should continue unchanged in the European environment. This includes a self-declaration on medical facts by the pilot and the GMP signing that he/she cross-checked the medical history. However, the Agency is of the opinion that the GMP, when acting as AME, makes an aero-medical fit assessment and signs a medical certificate which is needed for all pilots.

48. After review of the comments and discussions with the Review Group and various stakeholders, the Agency decided to withdraw the 'Leisure Pilot's Licence Medical Report' and the AMC to MED.B.090 containing the specific medical provisions, which has consequently been redrafted together with the Review Group. Another significant change was made to the validity period of the initial medical certificate. The main reason was that, considering the Basic Regulation, it is not possible to make a split between glider pilots and pilots who fly non-complex motor-powered aircraft with a maximum take-off weight of 2000 kg. For many commentators, the privileges of a licence to fly the latter category of aeroplanes with 4 passengers seem to be incompatible with a medical certificate issued on the basis of a driving licence standard. The detailed explanation for the revised approach is provided below.

Subpart A and AMC to Subpart A.040

49. As can be seen from Table 2 above, 4 out of 14 paragraphs in Subpart A received more than 100 comments, mainly on the medical certificate for the LAPL. The comments made on the Explanatory Note to NPA 2008-17c and on the title page are included in this summary, as well as 152 comments on AMC to MED.A.040, containing the medical questionnaire for the medical assessment with embedded provisions to be complied with.

50. **MED.A.030** — Competence for the issue, revalidation and renewal of medical certificates. The possibility to have the medical certificate issued by their GMP is widely supported by pilots and pilot organisations while some NAAs, AeMCs and AMEs have reservations. Pilots also urge the European legislator not to restrict this privilege to GMPs of Member States where this activity is permitted under national law, but to provide a legal basis to accept the GMP to act as AME for LAPL in all Member States. However, this request is not in line with Basic Regulation.

51. Many pilots and organisations commented in support of the GMP to issue the medical certificates for the LAPL. General practitioners presently issue medical certificates for national licences in one Member State and comments were made that it would be preferable to keep the national licences if the present system cannot continue exactly as it is today. The new rules as presented in the NPA were considered as being too complicated to ensure that the medical certificate will remain affordable.

52. Some National Aviation Authorities commented that oversight of GMPs, and with this monitoring the correctness of medical certificates, will be difficult as a GMP does not have to have a certificate but will act under a self-declaration. The fact that this medical certificate permits pilots to fly aircraft up to 2 tons max t/o weight and they may carry up to 4 passengers is seen as a safety issue.

53. After considering all comments received on the competence of the GMP to issue medical certificates and taking into account Article 7 of the Basic Regulation, only editorial text changes were made to MED.A.030.

54. **MED.A.035** — Application for a medical certificate. The application form in JAR-FCL 3 has been re-introduced for applications for class 1 and class 2 medical certificates and

should also be used for the application for a medical certificate for the LAPL. The form is to be completed by the pilots providing the facts on their medical history. The Agency and the Review Group considered the questions on this form are uncomplicated to complete and adequate to gain sufficient knowledge on the applicant's medical history to enable the AeMC, AME or GMP to make an aero-medical assessment after a clinical examination that should be proportionate to the privileges of the licence. The application and examination forms (see paragraph 59 below) will be in an AMC in the Authority Requirements to be published later this year. However, to provide clarity on the application and examination forms they are also published for information with this CRD.

55. **MED.A.040** — Requirements for the issue, revalidation and renewal of medical certificates. Pilots commented on this paragraph, opposed the idea of having a medical examination for the LAPL and requested to rely on the medical history instead. The arguments were not against an examination for a medical assessment but expressed concern about the financial consequences.

56. However, AMEs as well as some NAAs commented that a medical certificate issued on the basis of the applicant's medical history and a driving licence standard, as is the case in the proposed AMC to MED.A.040, is not sufficiently safe considering the fact that flying includes the third dimension and altitude can have an adverse effect on persons with certain medical conditions. They also commented that in some countries the GMP will not be able to get the full medical history of the applicant for data protection reasons. This may happen because there are countries where a person does not have to have his/her GMP but has the freedom of choice as to which GMP to consult and which data to release or not.

57. Some NAAs and AMEs insisted that all pilots should have an ICAO compliant class 2 medical certificate; however others agreed that the LAPL medical certificate, issued after assessing the applicant's history on the basis of driving licence provisions, could be appropriate for pilots flying gliders and aircraft with a take-off mass significantly lower than 2000 kg, and, in the case of non-complex motor-powered aircraft, holding a licence that is restricted in terms of airspace, route, no passengers carried and distance from the airfield.

58. **MED.A.040** remains unchanged in this CRD for the following reason: Annex III, 4.a.1, of the Basic Regulation requires that medical fitness is to be assessed based on aero-medical best practice. After evaluating the comments received, as well as the discussions in the Review Group and with various stakeholders, the Agency concluded that best aero-medical practice includes a basic medical examination as appropriate for the LAPL medical certificate.

59. **AMC to MED.A.40** contained the medical provisions for the LAPL that were embedded in the proposed 'Leisure Pilot's Licence Medical Report'. 152 comments were received on this paragraph and the opinions were diverse. The common denominator was that the form was considered as being too complicated and this comment was made from all concerned parties, namely AMEs, pilots and organisations. After discussions in the Review Group, other stakeholders and NAAs, the Agency decided to withdraw the form and replace it by an examination form that has the same format as the one for class 1 and class 2 aero-medical examinations. The difference is that a considerable number of fields where examination results for ICAO compliant medical certificates are to be entered have been greyed out as not applicable for the LAPL medical certificate. This was done to reduce the complexity of the examinations and to keep the proportionality principle with regard to the privileges of the licence. The examination form will be published with the Authority Requirements later this year but is also published with this CRD for clarity and information.

60. **MED.A.055** — Validity, revalidation and renewal of medical certificates. The NPA proposed to limit the initial period of validity of the medical certificate to age 45 of the

pilot. This was considered as a safety issue by AMEs and NAAs as it could cover a period of almost 30 years. Medical conditions that are not compatible with the safe exercise of a pilot licence, specifically for the higher end of the LAPL, could develop during this period of time and comments asked for a defined and overseeable period of validity. Discussions on this issue resulted in amending this paragraph to restrict the validity periods to 5 years until age 50, 2 years to age 70 and 1 year thereafter. Considering the comments as well as the original proposal of a longer period of validity, a rule was added to MED.090 on the medical requirements for the LAPL, to say that the AME or GMP can reduce the medical examination with due regard to the evaluation of the medical history in applicants under age 50.

Subpart B and AMC to Subpart B

61. **MED.B.090** — Medical examination of applicants for LAPL medical certificates. This paragraph received the highest number of comments (176) on one single paragraph in this NPA and, as with all comments on the LAPL medical certificate, the comments were diverse. The majority of commentators said that medical examinations and tests are not needed for the LAPL, and on the other hand commentators asked for more — and more detailed — requirements to determine medical fitness of these pilots. Again, there are comments saying that the original proposal would be acceptable if the rules were for glider and balloon pilots only. As explained in paragraph 9 of this CRD, pure numbers of comments were not the key factor when evaluating them. The Agency is aware of the concerns of pilots, mainly from one Member State, who fear that any examination will make the medical certificate considerably more expensive than it is today. However, according to the Basic Regulation, all pilots have to demonstrate medical fitness and shall be assessed based on aero-medical best practice. Many commentators said that at least a basic clinical examination is needed for this assessment.

62. **MED.B.090** was revised together with the Review Group, the main difference being that up to age 50 the aero-medical examination can be reduced with due regard to the applicant's history. The examinations now include a clinical examination while the tests for vision and hearing have been reworded to provide a higher flexibility on how this is done.

63. **AMC to MED.B.090** — This text mainly concerns AMEs or AeMCs as it defines the criteria along which a LAPL holder can be assessed as fit if the GMP considers that he/she cannot take the decision. The paragraph has been redrafted after the review of comments and consultation with the Review Group. The main reason was that the published text contained many paragraphs that were commented with valid arguments as not being sufficiently mature for a medical assessment of pilots. The main issues of concern were cardiology (e.g. aortic aneurysm, heart attack), psychiatry (e.g. alcohol use/misuse), and neurology (e.g. epilepsy), but also others. As this AMC was completely revised, the comments on this paragraph have not been answered individually in the CRT.

64. Compared to the medical provisions in AMC 2 to Subpart B (class 2), the provisions for the LAPL are more flexible and the aero-medical assessment depends, whenever possible, rather on an assessment whether the pilot can perform his/her duties safely than on strictly medical criteria that entail unfitness. The AMEs should also base their assessment of the fitness of an applicant on the privileges of their licence (e.g. glider vs SEP) and should not conclude that an applicant is unfit to fly before having considered an OPL limitation (see MED.A.045).

65. With rare exceptions (e.g. blood pressure, visual acuity), AMC to MED.B.090 does not contain numerical limits that would result in an unfit assessment if these limits are not met by the pilot.

66. The revised AMC to MED.B.90 is also supposed to provide the GMP with guidance on the question in which cases they should refer a pilot to an AME.

Subpart D

67. **MED.D.001** — Requirements for the General Medical Practitioner. The comments received on this paragraph range from stakeholders who do not see any reason to put any requirements on the GMP to those who argue that medical fitness of a pilot can only be determined by an AME. However, there are also comments saying that the GMP does not determine fitness of a pilot but that they cross-check the medical history of an applicant and sign that, to their knowledge, there is nothing in the medical history that would prevent a pilot from flying safely. As already mentioned before, some comments also say that in some Member States the GMP may not be in a position to know whether or not he/she has the full medical history of an applicant because of the medical system in that Member State.

68. Fit assessment: The Agency is of the opinion that a GMP who acts as an AME is assessing the pilot as fit to fly, or, if this is not possible, refers him/her to an AeMC or AME.

69. For the reason given above, the GMP should have some basic knowledge in aviation medicine and following the corresponding comments the paragraph has been amended to say so. However, it was left open to what extent the GMP has to gain knowledge in aviation medicine and how to acquire it. The reason for this is that the GMP can only act as AME if permitted under national law and the competent authority in the Member State concerned should provide guidance to the GMPs on the knowledge he/she has to have. The Agency is prepared to add an AMC to the knowledge requirement in MED.D.001 to maintain uniform application of the rules, once a significant number of Member States accept the GMP to act as AME for the issuance of medical certificates for LAPL holders.

70. The concern that the GMP may not be in a position to have sufficient knowledge of an applicant's history has been taken into account by adding on subparagraph to MED.D.001 saying that GMPs shall only act as AMEs if exercising their activity in a Member State where the health system grants them access to the full medical history of patients.