

JAA LICENSING SUBSECTORIAL TEAM (MEDICAL)



***** Draft Comment/Response
Document
NPA-FCL 3 – 21 (Medical)**

Version : LSST(M) proposal to LST

JAA SubSectorial Team on Medical Requirements, JAR-FCL 3

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Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
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General

030	ALPA, International	<p>The Air Line Pilots Association, International welcomes the chance to comment on this document. It is clear that a considerable amount of time was devoted into making this a more comprehensive, modern aeromedical certification outline. The section on tropical and travel medicine is particularly informative and well done. Notwithstanding our suggested changes, in general, ALPA is pleased with the outcome.</p> <p>We would be pleased to discuss our comments and suggestions in any further appropriate forums, as required.</p>		Noted
034	CIMP	<p>Generally, the new version of the cardiovascular sections (draft) is an improvement compared to the actual version. The topic "coronary artery disease" and the topic "arrhythmias" are better presented - with exceptions of those wordings, which we have criticized above (Comments 035 - 042).</p> <p>What has to be done as next step is a</p>		Noted

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		new version about the topic "aortic stenosis". This comment has already been made by Dr. R. Maire some years ago at the time when he was participating at the JAR-FCL-Medical-Subcommittee-Meetings.		

JAR-FCL 3.001

010	CJAA	see below	The mentioned paragraphs in JAR-FCL 3 are only copies of the relevant paragraphs in JAR-FCL 1 and of no relevance for aviation medicine. It has been proved to be difficult to keep these paragraphs in line with the actual amendments in JAR-FCL 1 thus creating inconsistent provisions in both documents.	Accepted
<p>JAR FCL 3.001 – Definitions and Abbreviations</p> <p>_____ (See IEM FCL 3.001)</p> <p>_____ Category (of aircraft):</p> <p>_____ Categorisation of aircraft according to specified basic characteristics, e.g. aeroplane, helicopter, glider, free balloon.</p> <p>_____ Conversion (of a licence):</p> <p>_____ The issue of a JAR FCL licence on the basis of a licence issued by a non-JAA State.</p> <p>_____ Co-pilot:</p> <p>_____ “Co pilot” means a pilot operating other than as pilot in command, an aircraft for which more than one pilot is required under the list of types of aeroplanes (see</p>				

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Appendix 1 to JAR-FCL 1.220) or the type certification of the aircraft, or the operational regulations under which the flight is conducted, but excluding a pilot who is on board the aircraft for the sole purpose of receiving flight instruction for a licence or rating.

Dual instruction time:
Flight time or instrument ground time during which a person is receiving flight instruction from a properly authorised instructor.

Flight time:
The total time from the moment that an aircraft first moves under its own or external power for the purpose of taking-off until the moment it comes to rest at the end of the flight.

Instrument time:
Instrument flight time or instrument ground time.

Instrument flight time:
Time during which a pilot is controlling an aircraft in flight solely by reference to instruments.

Instrument ground time:
Time during which a pilot is receiving instruction in simulated instrument flight in synthetic training devices (STDs).

Medical Institute:
A Medical Institute is an organisation consisting of clinical research and training facilities with a range of experts, including aeromedical specialists, available in the relevant area of aviation medicine to satisfy the technical need.

Multi-crew co-operation:
The functioning of the flight crew as a team of co-operating members led by the pilot-in-command.

Multi-pilot aeroplanes:
Aeroplanes certificated for operation with a minimum crew of at least two pilots.

Night:
The period between the end of evening civil twilight and the beginning of morning civil twilight, or such other period between sunset and sunrise as may be prescribed by the appropriate Authority.

Other training devices:
Training aids other than flight simulators, flight training devices or flight and navigation procedures trainers which provide means for training where a complete flight deck environment is not necessary.

Private pilot:
A pilot who holds a licence which prohibits the piloting of aircraft in operations for which remuneration is given.

Professional pilot:

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JARFCL 3.001 (continued)

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		<p>A pilot who holds a licence which permits the piloting of aircraft in operations for which remuneration is given.</p> <p>Proficiency checks: Demonstrations of skill to revalidate or renew ratings, and including such oral examination as the examiner may require.</p> <p>Rating: An entry in a licence stating special conditions, privileges or limitations pertaining to that licence.</p> <p>Renewal (of e.g. a rating or approval): The administrative action taken after a rating or approval has lapsed that renews the privileges of the rating or approval for a further specified period consequent upon the fulfilment of specified requirements.</p> <p>Revalidation (of e.g. a rating or approval): The administrative action taken within the period of validity of a rating or approval that allows the holder to continue to exercise the privileges of a rating or approval for a further specified period consequent upon the fulfilment of specified requirements.</p> <p>Route sector: A flight comprising take-off, departure, cruise of not less than 15 minutes, arrival, approach and landing phases.</p> <p>Single-pilot aeroplanes: Aeroplanes certificated for operation by one pilot.</p> <p>Skill tests: Skill tests are demonstrations of skill for licence or rating issue, including such oral examination as the examiner may require.</p> <p>Solo flight time: Flight time during which a student pilot is the sole occupant of an aircraft.</p> <p>Student pilot-in-command (SPIC): Flight time during which the flight instructor will only observe the student acting as pilot-in-command and shall not influence or control the flight of the aircraft.</p> <p>Touring Motor Glider (TMG): A motor glider having a certificate of airworthiness issued or accepted by a JAA Member State having an integrally mounted, non-retractable engine and a non-retractable propeller plus those listed in Appendix 1 to JAR-FCL 1.215. It shall be capable of taking off and climbing under its own power according to its flight manual.</p> <p>Type (of aircraft): All aircraft of the same basic design, including all modifications except those modifications which result in a change of handling, flight characteristics or flight crew complement.</p> <p>For abbreviations see IEM FCL 3.001</p>		
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[Amdt.1, 01.12.00; Amdt. 2, 01.06.02]

JAR-FCL 3.005

010	CJAA	see below	The mentioned paragraphs in JAR-FCL 3 are only copies of the relevant paragraphs in JAR-FCL 1 and of no relevance for aviation medicine. It has been proved to be difficult to keep these paragraphs in line with the actual amendments in JAR-FCL 1 thus creating inconsistent provisions in both documents.	Accepted
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~~JAR FCL 3.005 — Applicability~~

~~———— (See Appendix 1 to JAR FCL 1.005)~~

~~———— (See AMC FCL 1.005 & 1.015)~~

~~(a) — General~~

~~(1) — The requirements set out in JAR FCL shall apply to all arrangements made for training, testing and applications for the issue of licences, ratings, authorisations, approvals or certificates received by the Authority from 1 July 1999.~~

~~(2) — Whenever licences, ratings, authorisations, approvals or certificates are mentioned in JAR FCL, these are meant to be licences, ratings, authorisations, approvals or certificates issued in accordance with JAR FCL. In all other cases these documents are specified as e.g. ICAO or national licences.~~

~~(3) — Whenever a reference is made to JAA Member State for the purpose of mutual recognition of licences, ratings, authorisations, approvals or certificates, this means JAA full Member State.~~

~~(4) — All synthetic training devices mentioned in JAR FCL substituting an aircraft for training purposes are to be device qualified in accordance with JAR STD and user approved in accordance with JAR FCL by the Authority for the exercises to be conducted.~~

~~(5) — Whenever a reference is made to aeroplanes this does not include microlights as defined nationally, unless otherwise specified.~~

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JARFCL 3.005(b)(2) (continued)

JARFCL 3.010(a)(1) (continued)

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(6) A licence issued on the basis of training performed outside a JAA Member State, except training done according to JAR-FCL 1.055(a)(1), shall have an entry to limit the privileges to aircraft registered in the State of licence issue.

(7) Rating(s) issued on the basis of training performed outside a JAA Member State, except training performed according to JAR-FCL 1.055(a)(1), shall be limited to aircraft registered in the State of licence issue.

(b) *Transitional arrangements*

(1) Training commenced prior to 1 July 1999 according to national regulations will be acceptable for the issue of licences or ratings under national regulations provided that training and testing is completed before 30th June 2002 for the applicable licence or rating.

(2) Licences and ratings, authorisations, approvals or medical certificates issued in accordance with the national regulations of JAA Member States before 1 July 1999 or issued in accordance with paragraph (1) above, shall continue to be valid with the same privileges, ratings and limitations, if any, provided that after 1 January 2000 all requirements for revalidation or renewal of such licences or ratings, authorisations, approvals or medical certificates shall be in accordance with the requirements of JAR-FCL, except as specified in sub paragraph (4).

(3) Holders of a licence issued in accordance with the national regulations of a JAA Member State before 1 July 1999 or in accordance with (b)(1) above, may apply to the State of licence issue for the issue of the equivalent licence specified in JAR-FCL 1 (Aeroplane) which extends the privileges to other States as set out in JAR-FCL 3.015(a)(1). For the issue of such licences, the holder shall meet the requirements set out in Appendix 1 to JAR-FCL 1.005.

(4) Holders of a licence issued in accordance with the national regulations of a JAA Member State who do not fully meet the Section 1 requirements of JAR-FCL Part 3 (Medical) shall be permitted to continue to exercise the privileges of the national licence held.

(c) *Continuation of examiners holding national authorisations.* Examiners holding national authorisations prior to implementation date, may be authorised as JAR-FCL examiner provided that they have demonstrated a knowledge of JAR-FCL and JAR-OPS to the Authority. The authorisation will be for a maximum of 3 years. Thereafter re-authorisation will be subject to completion of the requirements set out in JAR-FCL 1.425(a) and (b).
[Amdt.1, 01.12.00; Amdt. 2, 01.06.02]

JAR-FCL 3.010

010	CJAA	see below	The mentioned paragraphs in JAR-FCL 3 are only copies of the relevant paragraphs in JAR-FCL 1 and of no relevance for aviation medicine. It has been proved to be	Accepted
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			difficult to keep these paragraphs in line with the actual amendments in JAR-FCL 1 thus creating inconsistent provisions in both documents.	
<p>JAR FCL 3.010— Basic authority to act as a flight crew member</p> <p>(a) — <i>Licence and rating</i></p> <p>(1) — A person shall not act as a flight crew member of a civil aeroplane registered in a JAA Member State unless that person holds a valid licence and rating complying with the requirements of JAR FCL and appropriate to the duties being performed, or an authorisation as set out in JAR FCL 1.085 and/or 1.230. The licence shall have been issued by:</p> <p>(i) — a JAA Member State; or</p> <p>(ii) — another ICAO Contracting State and rendered valid in accordance with JAR FCL 3.015(b) or (c).</p> <p>(2) — Pilots holding national motor gliders licences/ratings/authorisations are also permitted to operate touring motor gliders under national regulations.</p> <p>(3) — Pilots holding a restricted national private pilot’s licence are permitted, under national regulations to operate aeroplanes registered in the State of licence issue within that State’s airspace.</p> <p>(b) — <i>Exercise of privileges.</i> The holder of a licence, rating or authorisation shall not exercise privileges other than those granted by that licence, rating or authorisation.</p> <p>(c) — <i>Appeals, Enforcement</i></p> <p>(1) — A JAA Member State may at any time in accordance with its national procedures act on appeals, limit privileges, or suspend or revoke any licence, rating, authorisation, approval or certificate it has issued in accordance with the requirements of JAR FCL if it is established that an applicant or a licence holder has not met, or no longer meets, the requirements of JAR FCL or relevant national law of the State of licence issue.</p> <p>(2) — If a JAA Member State establishes that an applicant or licence holder of a JAR FCL licence issued by another JAA Member State has not met, or no longer meets, the requirements of JAR FCL or relevant national law of the State in which an aircraft is being flown, the JAA Member State shall inform the State of licence issue and the Licensing Division of the JAA Headquarters. In accordance with its national law, a JAA Member State may direct that in the interest of safety a n applicant or licence holder it has duly reported to the State of licence issue and the JAA for the above reason may not pilot aircraft registered in that State or pilot any aircraft in that State’s airspace.</p>				

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JARFCL 3.015(b)(3) (continued)

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JAR-FCL 3.015 (a) (2), (b), (c), (d)

010	CJAA	see below	The mentioned paragraphs in JAR-FCL 3 are only copies of the relevant paragraphs in JAR-FCL 1 and of no relevance for aviation medicine. It has been proved to be difficult to keep these paragraphs in line with the actual amendments in JAR-FCL 1 thus creating inconsistent provisions in both documents.	Accepted
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JAR-FCL 3.015 Acceptance of licences, ratings, authorisations, approvals or certificates

(See Appendix 1 to JAR-FCL 1.015)

(See AMC FCL 1.005 & 1.015)

(a) *Licences, ratings, authorisations, approvals or certificates issued by JAA Member States*

(1) Where a person, an organisation or a service has been licensed, issued with a rating, authorisation, approval or certificated by the Authority of a JAA Member State in accordance with the requirements of JAR-FCL and associated procedures, such licences, ratings, authorisations, approvals or certificates shall be accepted without formality by other JAA Member States.

(2) Training performed after 8 October 1996 and in accordance with all the requirements of JAR-FCL and associated procedures shall be accepted for the issuance of JAR-FCL licence and ratings, provided that licences in accordance with JAR-FCL shall not be issued until after 30 June 1999.

(b) *Licences issued by non-JAA States*

(1) A licence issued by a non-JAA State may be rendered valid at the discretion of the Authority of a JAA Member State for use on aircraft registered in that JAA Member State in accordance with Appendix 1 to JAR-FCL 1.015.

(2) Validation of a professional pilot's licence and a private pilot licence with instrument rating shall not exceed one year from the date of validation, provided that the basic licence remains valid. Any further validation for use on aircraft registered in any JAA Member State is subject to agreement by the JAA Member States and to any

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conditions seen fit within the JAA. The user of a licence validated by a JAA Member State shall comply with the requirements stated in JAR-FCL.

(3) The requirements stated in (1) and (2) above shall not apply where aircraft registered in a JAA Member State are leased to an operator in a non-JAA State, provided that the State of the operator has accepted for the period of lease the responsibility for the technical and/or operational supervision in accordance with JAR-OPS 1.165. The licences of the flight crews of the non-JAA State operator may be validated at the discretion of the Authority of the JAA Member State concerned, provided that the privileges of the flight crew licence validation are restricted for use during the lease period only on nominated aircraft in specified operations not involving a JAA operator, directly or indirectly, through a wet lease or other commercial arrangement.

(c) *Conversion of a licence issued by a non-JAA State.*

(1) A professional pilot licence and/or IR issued by a non-JAA State may be converted to a JAR-FCL licence provided that an arrangement exists between the JAA and the non-JAA State. This arrangement shall be established on the basis of reciprocity of licence acceptance and shall ensure that an equivalent level of safety exists between the training and testing requirements of the JAA and the non-JAA State. Any arrangement entered into will be reviewed periodically, as agreed by the non-JAA State and the JAA. A licence converted according to such an arrangement shall have an entry indicating the non-JAA State upon which the conversion is based. Other Member States shall not be obliged to accept any such licence.

(2) A private pilot licence issued by a non-JAA State may be converted to a JAR-FCL licence with single-pilot aeroplane class/type ratings by complying with the requirements shown in Appendix 2 to JAR-FCL 1.015.

[(d) When an Authority issues a licence which deviates from JAR-FCL, an endorsement shall be made on the licence, under item XIII.]
[Amdt. 2, 01.06.02; Amdt. 3, 01.06.03]

JAR-FCL 3.025 (a), (c)

010	CJAA	see below	The mentioned paragraphs in JAR-FCL 3 are only copies of the relevant paragraphs in JAR-FCL 1 and of no relevance for aviation medicine. It has been proved to be difficult to keep these paragraphs in line with the actual amendments in JAR-FCL 1 thus creating	Accepted
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JARFCL 3.025(c) (continued)

JARFCL 3.035 (continued)

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			inconsistent provisions in both documents.	
<p>JAR-FCL 3.025 Validity of licences and ratings</p> <p>(a) A licence holder shall not exercise the privileges granted by any licence or rating issued by a JAA Member State unless the holder maintains competency by meeting the relevant requirements of JAR-FCL.</p> <p>(b) The validity of the licence is determined by the validity of the ratings contained therein and the medical certificate.</p> <p>(c) The licence will be issued for a maximum period of 5 years. Within this period of 5 years the licence will be re-issued by the Authority:</p> <p>(1) after initial issue or renewal of a rating;</p> <p>(2) when paragraph XII in the licence is completed and no further spaces remain;</p> <p>(3) for any administrative reason;</p> <p>(4) at the discretion of the Authority when a rating is revalidated.</p> <p>Valid ratings will be transferred to the new licence document by the Authority.</p> <p>The licence holder shall apply to the Authority for the re-issue of the licence.</p> <p>The application shall include the necessary documentation.</p>				

JAR-FCL 3.065

009	CJAA	see below	The paragraph is a copy of the respective paragraph in JAR-FCL 1. The latter has been amended according to amendment 3 dating from 01.07.03. The present paragraph does not reflect that amendment since it reflects amendment 2 of 01.06.02.	Accepted
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<p>JAR-FCL 3.065 State of licence issue</p> <p>(a) An applicant shall demonstrate the satisfactory completion of all requirements for licence issue to the Authority of the State under whose Authority the initial medical examination and assessment and the training and testing for the licence were carried out. Following licence issue, this State shall thereafter be referred to as the ‘State of licence issue’ (see JAR-FCL 3.010(c)).</p> <p>(b) Further ratings may be obtained under JAR-FCL requirements in any JAA Member State and will be entered into the licence by the State of licence issue.</p> <p>(c) For administrative convenience, e.g. revalidation, the licence holder may subsequently transfer a licence issued by the State of licence issue to another JAA Member State, provided that employment or normal residency is established in that State (see JAR-FCL 1.070). That State would thereafter become the State of licence issue and would assume the responsibility for licence issue referred to in (a) above.</p> <p>(d) An applicant shall hold only one JAR-FCL licence (aeroplane) and only one medical certificate at any time.</p> <p>[Amdt. 2, 01.06.02]</p> <p>JAR-FCL 1.065 State of licence issue (See JAR-FCL 1.010(c))</p> <p>(a) An applicant shall demonstrate the satisfactory completion of all requirements for licence issue to the Authority of [] the ‘State of licence issue’ (see JAR-FCL 1.010(c)).</p> <p>(b) [In circumstances agreed by both Authorities, an applicant who has commenced training under the responsibility of one Authority may be permitted to complete the requirements under the responsibility of the other Authority.] [The agreement shall allow for:</p> <p>(1) theoretical knowledge training and examinations; (2) medical examination and assessment; (3) flight training and testing,</p>				

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The Authorities shall agree the ‘State of licence issue’.]

[(c)] Further ratings may be obtained under JAR–FCL requirements in any JAA Member State and will be entered into the licence by the State of licence issue.

[(d)] For administrative convenience, e.g. revalidation, the licence holder may subsequently transfer a licence issued by the State of licence issue to another JAA Member State, provided that employment or normal residency is established in that State (see JAR–FCL 1.070). That State would thereafter become the State of licence issue and would assume the responsibility for licence issue referred to in (a) above.

[(e)] An applicant shall hold only one JAR–FCL licence (airplane) and only one medical certificate at any time.

[Amdt. 1, 01.06.00; Amdt. 2, 01.08.02; Amdt. 3, 01.07.03]

JAR-FCL 3.090

001	CJAA	(e) Authorisation. An AME will be authorised for a period not exceeding three years. Authorisation to perform medical examinations may be for Class 1 or Class 2 or both at the discretion of the Authority. To maintain proficiency and retain authorisation an AME should complete at least ten aeromedical examinations each year. For re-authorisation the AME shall have completed an adequate number of aeromedical examinations to	After lifting the age limit for AME's some legal handle for the AMS to terminate their authorisation was proposed by the LST. A new paragraph corresponding to JAR-FCL 3.010 (c) (1) was inserted.	Accepted
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		<p>the satisfaction of the AMS and shall also have undertaken relevant training during the period of authorisation (see AMC FCL 3.090). Authorisation is invalid after the AME reaches 70 years of age.</p> <p>(f) Enforcement. A JAA Member State may at any time in accordance with its national procedures revoke any Authorisation it has issued in accordance with the requirements of JAR-FCL if it is established that an AME has not met, or no longer meets, the requirements of JAR-FCL or relevant national law of the State of license issue.</p>		
024	G. Freid, Britannia Airways, Stockholm	We disagree with the deletion of the 70 years limit to AME but agree(s, JS) with the proposed additional text.		Rejected

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027	AEA	Agree with the deletion of the age limit for Authorised Medical Examiners, provided the “clarifying requirements” assessing the AMEs incapability are developed coherently and in cooperation with stakeholders.	Whereas deletion of an arbitrary age limit is generally supported by AEA, it is felt that assessing poorly performing AMEs is difficult. AEA looks forward to the development of precise and nondiscriminatory criteria for revoking or suspending an AME authorisation.	Accepted

JAR-FCL 3.140, title

020	CAA Switzerland	Cardiovascular system - Coronary artery disease	The term “coronary artery disease is more often used than “ischaemic heart disease” Both terms mean the same heart disease (see textbook of heart disease, E.Braunwald)	Accepted
035	CIMP	Cardiovascular system – Coronary artery <i>and ischaemic heart disease</i>	We prefer the original title: “Cardiovascular system – Coronary artery disease” . Explanation: 1) The term “Coronary artery disease” is more often used than the term “Ischaemic heart disease”. 2) Both terms (“Coronary artery disease” and “Ischaemic heart disease”) are used to describe the same heart disease. This is nicely shown when checking the term “Ischaemic heart	Accepted

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			disease" in the index of the textbook "Heart Disease, E. Braunwald et al."; then you find the text: "see Coronary artery disease".	

JAR-FCL 3.140, (a)

019	CAA Switzerland	Applicants with suspected coronary artery disease cardiac ischaemia or previous ischaemic cardiac event shall be investigated...	Someone may have a previous ischaemic cardiac event which is of significance, but he may actually not have any cardiac ischaemia.	<p>Rejected</p> <p>In subparagraph (c) it is mentioned "after an ischaemic event..." Even though some contention might result from the word "after" (meaning of "immediately after" vs. synonym to "previous") the majority rejected the proposal, because nothing originally not intended should be introduced and no case resulting in a wrong decision was known.</p>
036	CIMP	Applicants with suspected <i>cardiac ischaemia or previous ischaemic cardiac event</i> shall be investigated.	Someone may have a previous ischaemic cardiac event which is of significance, but he may actually not have any cardiac ischaemia.	
022	Europe Air Sports	...(a) Applicants with suspected evidence of cardiac ischaemia shall be investigated.	1. The word 'suspicion' should be replaced by the word 'evidence of'. Suspicion is something which is present in the mind and suspicion can never be proved or disproved. Therefore the word has no place in a document with legal status. I am aware of, support and have incorporated the	

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			<p>Swiss proposal on terminology.</p> <p>2. The JAR is not clear on who should do the further investigation, except that it should be by a cardiologist approved by the AMS. In the decade since the first version of the JAR 3, there have been great advances in the technical capability of treating cardiac ischaemia by interventional means. While originally the investigation was required to measure risk for reasons of aeromedical certification, it is now more likely that investigation is clinically indicated to assess the opportunity for active treatment. In those circumstances the aeromedical assesment should be postponed until the completion of treatment. However guidance on this should be in the Manual, not the regulations.</p>	
043	CIMP	idem	"suspected of" should be replaced by "evidence of" due to the legal implications of the former term	

JAR-FCL 3.250, (e)

037	CIMP	..., estimation of <i>plasma serum</i>	If there is a correction in paragraph	Accepted
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		lipids and serum cholesterol is required at the ...	3.130 (e) (serum lipids), the same correction must be made here (estimation of serum lipids and serum cholesterol).	
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JAR-FCL 3.260, title

038	CIMP	Cardiovascular system – Coronary artery and ischaemic heart disease	We prefer the original title: " Cardiovascular system – Coronary artery disease ". Explanation: 1) The term "Coronary artery disease" is more often used than the term "Ischaemic heart disease". 2) Both terms ("Coronary artery disease" and "Ischaemic heart disease") are used to describe the same heart disease. This is nicely shown when checking the term "Ischaemic heart disease" in the index of the textbook "Heart Disease, E. Braunwald et al."; then you find the text: "see Coronary artery disease".	Accepted
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JAR-FCL 3.260, (a)

018	CAA Switzerland	Applicants with suspected cardiac ischaemia or previous ischaemic cardiac event shall be investigated...	Someone may have a previous ischaemic cardiac event which is of significance, but he may actually not have any cardiac ischaemia.	Rejected In subparagraph (c) it is mentioned "after an ischaemic event..." Even though some contention might result from the word "after" (meaning of "immediately after" vs. synonym to "previous") the majority rejected the proposal, because nothing originally not intended should be introduced and no case resulting in a wrong decision was known.
039	CIMP	Applicants with suspected cardiac ischaemia or previous ischaemic cardiac event shall be investigated.	Someone may have a previous ischaemic cardiac event which is of significance, but he may actually not have any cardiac ischaemia.	

JAR-FCL 3, Appendix 1 to Subparts B & C (5)

017	CAA Switzerland	5 In suspected asymptomatic coronary artery disease, exercise electrocardiography shall be required and , followed , if necessary, by further tests (myocardial perfusion scanning, coronary angiography or equivalent investigations acceptable to the AMS) which shall show no evidence of myocardial ischaemia or significant coronary artery stenosis.	Old fashioned examination. Stress echocardiography has replaced it.	Accepted Because the medical culture varies between different countries (in the UK myocardial perfusion scanning was not replaced by stress echocardiography) myocardial perfusion scanning and stress echocardiography should be mentioned. The proposed new text reads: 5 In suspected asymptomatic coronary artery disease, exercise electrocardiography
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
		followed by scintigraphy or stress echocardiography and/or coronary angiography.]		shall be required [and, <i>followed</i> , if necessary, <i>by further tests (myocardial perfusion scanning, stress echocardiography, coronary angiography or equivalent investigations acceptable to the AMS) which shall show no evidence of myocardial ischaemia or significant coronary artery stenosis.</i> followed by scintigraphy or stress echocardiography and/or coronary angiography.]

JAR-FCL 3, Appendix 1 to Subparts B & C (6)

016	CAA Switzerland	6 <i>After an ischaemic cardiac event, including revascularisation, applicants without symptoms shall have reduced any vascular risk factors (e.g. <u>smoking, blood pressure, blood lipids</u>) to an appropriate level (e.g. <u>by medication with platelet aggregation inhibitors, physical exercise, weight reduction</u>). Drugs when used only to control cardiac symptoms are not acceptable. All applicants</i>	The risk factors and the prevention treatment of them should be defined.	Rejected Even though ICAO describes risk factors and such an important information should be readily available (Section 1 is available on the JAA website for the public), the majority felt, that the information about cardiovascular risk factors should not be part of the requirements but mentioned in the JAA Manual of Civil Aviation Medicine only.
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
		<i>should be on acceptable secondary prevention treatment.</i>		

JAR-FCL 3, Appendix 1 to Subparts B & C (6)

015	CAA Switzerland	<p>(a) an symptom limited 12-lead exercise ECG (symptom limited to Bruce Stage IV, or equivalent), which a cardiologist acceptable to the AMS interprets as showing no evidence of myocardial ischaemia nor rhythm disturbance; Scintigraphy and/or stress echocardiography may be required if the ECG is abnormal at rest;</p> <p>(b) a left ventricular ejection fraction of 0.50 without significant abnormality of wall motion such as dyskinesia, hypokinesia or akinesia and a normal right ventricular ejection fraction;</p> <p><i>an echocardiogram (or equivalent test acceptable to the AMS) showing satisfactory left ventricular function with no important abnormality of wall motion (such as dyskinesia or akinesia) and a left ventricular ejection</i></p>	24 hour ECG is one of the best test to identify risks.	<p>Rejected</p> <p>Even though some delegates held a 24 hour ambulatory ECG for a mandatory essential to identify incapacitation risks due to potential malignant rhythm disturbance caused by vulnerable scar tissue, the majority rejected the proposal.</p>
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
		<p><i>fraction of 50% or more;</i> [(c) a 24-hour ambulatory ECG, showing no significant conduction disturbance, nor complex, nor sustained rhythm disturbance.]</p> <p>[(c) a 24-hour ambulatory ECG, showing no significant conduction disturbance, nor complex, nor sustained rhythm disturbance;]</p> <p><i>(d) in cases of angioplasty/stenting, a myocardial perfusion scan (or equivalent test acceptable to the AMS) which shall show no evidence of reversible myocardial ischaemia. If there is any doubt about myocardial perfusion in other cases (infarction or bypass grafting) a perfusion scan will also be required;</i></p> <p>(d e) a coronary angiogram shall show <30% stenosis in any vessel remote from any myocardial infarction and no functional impairment of myocardium subtended by any such vessel.</p>		

Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
		<i>Further investigations, such as a 24 hour ECG, may be necessary to assess the risk of any significant rhythm disturbance.</i>		

JAR-FCL 3, Appendix 1 to Subparts B & C (6) (c)

014	CAA Switzerland	<p>[(c) a 24-hour ambulatory ECG, showing no significant conduction disturbance, nor complex, nor sustained rhythm disturbance.]</p> <p><i>in cases of angioplasty/stenting, a myocardial perfusion scan stress echocardiography (or equivalent test acceptable to the AMS) which shall show no evidence of reversible myocardial ischaemia. If there is any doubt about myocardial perfusion in other cases (infarction or bypass grafting) a perfusion scan will also be required;</i></p>	Much better test (now “golden standard”).	<p>Accepted</p> <p>Because the medical culture varies between different countries (in the UK myocardial perfusion scanning was not replaced by stress echocardiography) myocardial perfusion scanning and stress echocardiography should be mentioned. The proposed new text reads:</p> <p>[(c) a 24-hour ambulatory ECG, showing no significant conduction disturbance, nor complex, nor sustained rhythm disturbance.]</p> <p><i>in cases of angioplasty/stenting, a myocardial perfusion scan or stress echocardiography (or equivalent test acceptable to the AMS) which shall show no evidence of reversible myocardial ischaemia. If there is any doubt about myocardial perfusion in other cases (infarction or bypass grafting) a perfusion scan</i></p>
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
				<i>will also be required;</i>

JAR-FCL 3, Appendix 1 to Subparts B & C (6) (d) (last paragraph)

023	CAA Switzerland	<i>Class 2 applicants having fulfilled the criteria mentioned in paragraph (6) may fly unrestricted, but the AMS may require a period of flying with a safety pilot before solo flying is authorised. Class 2 applicants (for renewal/revalidation) can fly, at the discretion of the AMS, with a safety pilot limitation (OSL) having completed at least Only an exercise ECG to the standards in 6 (a) above.</i>	It is not quite clear, who can fly without OSL restriction.	Accepted
040	CIMP	AMS assessment: Successful completion of the six month review will allow Class 1 applicants to fly multipilot (OML). Class 2 applicants may fly unrestricted, but the AMS may require a period of flying with a safety pilot before solo	This text must be rewritten (especially the one about the AMS assessment of Class 2 applicants). Explanation: 1) The term applicant always means new applicants and renewal applicants; thus " <i>Class 2 applicants may fly unrestricted, but the...</i> is not precise.	Rejected It was stated that the term "applicants " relates to initial as well as to renewal or revalidation examinations. It was felt that the present wording would be clear and would permit AMSs to allow for restricted flying after at least an exercise ECG and unrestricted flying after completion of the

Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
		flying is authorised. Class 2 applicants (for renewal/revalidation) can fly, at the discretion of the AMS, with a safety pilot limitation (OSL) having completed at least an exercise ECG to the standards in 6 (a) above.	2) " <i>Class 2 applicants (for renewal/revalidation) can fly, at the discretion...</i> ". Probably the idea is, that Class 2-applicants (not initial applicants), having fulfilled the criteria mentioned above in this section 6, can fly unrestricted (and those having performed only an exercise ECG have a OSL-limitation). But the text is not clear for this. We recommend a wording in which Class 2-applicants, having fulfilled the criteria mentioned above in this section 6, can fly unrestricted (and not to make a category of "OSL-limitation , if having completed at least an exercise ECG"). But an addition has to be made in which a OSL-limitation may be considered for special situations.	complete review concerning Class 2 applicants.

Appendix 1 to Subparts B and C para 7 (a)

004	CAA – United Kingdom	'(1)...The test shall <i>should</i> be to maximum effort or symptom limited'	This concerns the administration of an exercise test and the NPA states that it ' <i>shall</i> ' be to maximum effort. However the cardiology working group recommended (Bern LSST(M) meeting, November 2003) that the word ' <i>should</i> '	Accepted
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
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			is more suitable. This is because there is no objective method for assessing whether or not maximum effort has been given by the applicant and therefore making this mandatory is not appropriate.	
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Appendix 1 to Subparts B and C para 7 (c)

007	CAA – United Kingdom	<p>(2) Complete right bundle branch block</p> <p>(i) Initial Class 1 certification may be considered by the AMS if the applicant is under age 40 years. If over age 40 years, initial Class 1 applicants should demonstrate a period of stability, normally 12 months.</p> <p>(ii) Unrestricted Class 1 revalidation/renewal may be considered <u>if the applicant is under age 40 years. after a 12 month period with a</u> An OML <u>should be</u> applied <u>for 12 months for those over 40 years of age.</u></p>	Paragraph (2)(i) indicates that an unrestricted Class 1 medical certificate may be considered on application for an initial applicant under 40 years, but for those who are renewing/revalidating (ii) indicates that a mandatory period of 12 months with an OML is necessary. This seems to be a drafting error. The proposed text brings (ii) into line with (i).	Accepted
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
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Appendix 1 to Subparts B and C para 7 (c) (6) Ablation

041	CIMP	<i>Class 1 applicants having undergone successful catheter ablation shall be restricted to OML operations for ...</i>	The spelling is not correct: <i>catheder ablation</i> should be written: <i>catheter</i> ablation.	Accepted
025	CAA – United Kingdom	Class 1 applicants having undergone successful catheter ablation shall be restricted to OML operations for at least one year, unless an electrophysiological study, undertaken at a minimum of two months after the ablation, demonstrates satisfactory results. <i><u>For those in whom the long term outcome cannot be assured by invasive or non-invasive testing, an additional period of restriction and/or observation may be necessary.</u></i>	Applicants who have an abnormal ECG prior to ablation can usually be monitored for abnormalities by noting persisting abnormalities or changes on the ECG after the procedure. However, not all individuals have an abnormal pathway that can be monitored in this way. For such individuals, who do not have an electrophysiological study to determine successful ablation, an additional period of observation should be considered before removing the OML limitation to ensure that risk has returned to that appropriate to unrestricted certification.	
031	ALPA, International	Class 1 applicants having undergone successful catheter ablation <u>may</u> need to be restricted to multi-pilot operations. Asymptomatic applicants who have undertaken a 24-hour Holter	The US FAA has used the above protocol to certify over 100 airline pilots who have undergone catheter ablation. A post-procedure electrophysiological study is performed only where <u>clinically</u>	Rejected The representative of the FAA confirmed that there was nothing like "OML" limitation under FAA legislation. The decision has to be referred to the

Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
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		monitor, no sooner than three months following the ablation procedure, may be returned to unrestricted flight duty. For continuous certification, the pilot must submit repeat satisfactory 24-hour Holter monitors at 12 month intervals.	indicated.	FAA .
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Appendix 1 to Subparts B and C para 7 (d)

042	CIMP	<i>The AMS assessment Class 2 should follow the Class 1 assessment procedures. An OSL or OPL restriction may be considered.</i>	<p>This text must be rewritten.</p> <p>It is the first time that an OPL-restriction is mentioned in the JAR-Medical-cardiovascular requirements. If OPL-restriction is a possible form of restriction, then it changes the "philosophy" of all requirements. Or - with other words - in many other cardiovascular sections the OPL-restriction could also be applied. We think that this OPL-restriction has to be reconsidered, but in a broader sense; thus it might need a new, longer lasting debating process about this subject.</p>	<p>Rejected</p> <p>The OPL limitation exists, it will be used for the first time and will allow for matching the risk involved, which is less in Class 2 pilots.</p>
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Appendix 3 to Subparts B and C para 3

Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
005	CAA – United Kingdom	<p>Established chronic inflammatory bowel disease (Crohn's Disease, ulcerative colitis) is disqualifying. For <i>In cases of</i> ulcerative colitis, certification (Class 1 and 2) may be considered by the AMS if there is full remission (minimum of one year) and, for Class 1, <i>minimum medication only</i> is not required. <i>Systemic steroids are not acceptable.</i> For <i>In cases of</i> Crohn's disease, recertification (Class 1 <i>and Class 2</i>) and certification (Class 2) may be considered by the AMS <i>if there is full remission (minimum of one year, without medication) and, for Class 1, disease was minimal and has been completely excised surgically, and medication is not required.</i></p> <p>Regular follow up is required and a Class 1 'OML' or Class 2 'OSL' restriction may be appropriate.</p>	<p>Some cases of ulcerative colitis are well controlled on minimal medication and it is unnecessarily restrictive to refuse to consider such cases. Further, some cases of Crohn's disease, which had very localised disease that has been completely excised surgically and who require no medication, do very well and could be considered for certification without compromising flight safety. Some minor changes to the English are also suggested.</p>	Accepted
032	ALPA, International	<p>For ulcerative colitis, certification (Class 1 and 2) may be considered by the AMS if there is full remission for three months with no medication or if minimal medication is taken, such as Asulfidine or other salicylate-based</p>	<p>US FAA certification experience has shown that many pilots with inflammatory bowel disease follow an intermittent course with mild exacerbations at irregular intervals. We believe the proposed policy is therefore</p>	Noted

Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
		drug (without significant side effects).	unnecessarily restrictive.	

Appendix 16 to Subparts B and C, hearing requirements

028	AEA	In the last paragraph, the first sentence “ Frequency thresholds should also be determined for 4000 and 6000 Hz” should be deleted and the following sentence amended as follows: “ Frequency thresholds may also be determined, at the discretion of the AMS, for 250, 4000, 6000 and 8000 Hz.”	The suggested text appears to delete the requirements for determination of frequency thresholds at 4 and 6 kHz, only to then go on to say that these should be determined. From the explanatory notes, it would appear that 4000 and 6000 Hz “may” be determined at the discretion of the AMS, like 250 Hz and 8000 Hz.	<p>Accepted</p> <p>Only the frequencies in the speech frequency band are relevant, therefore other frequencies should not be mentioned. New proposal:</p> <p>1 The pure tone audiogram shall cover at least the frequencies from 500 to 3000–8 000 Hz. Frequency thresholds shall be determined as follows:</p> <p align="right"> –250 Hz 500 Hz 1 000 Hz 2 000 Hz 3 000 Hz 4 000 Hz 6 000 Hz 8 000 Hz </p>
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
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IEM FCL 3.095(a)

006	CAA – United Kingdom	<p>Pulmonary function tests (3.155 and 3.275)</p> <p>Class 1 At initial then peak flow at first examination after age 30, 35, 40 then 4- then 5-yearly</p> <p>Class 2 Peak flow at initial then at age 40. Then 4-yearly. If indicated</p>	<p><i>Class 1: There seems little advantage in specifying a 5-yearly interval from 30 to 40 years, then 4-yearly. Flight safety is not likely to be affected if a 5-yearly measurement is made throughout, which would simplify the requirement.</i></p> <p><i>Class 2: The flight safety improvement in private pilots from regular peak flow measurements in an individual with no relevant history or examination findings is minimal. ICAO does not require such testing. Those who have relevant findings should have further evaluation i.e. 'if indicated'.</i></p>	<p>Accepted</p> <p>Remark:</p> <p>As the table gives an overview only, the requirements have to be changed first. A working paper on this matter will be prepared. This issue - already agreed on - will be enclosed in the next NPA together with the change of the resp. requirement.</p>
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IEM FCL 3.095(a) (b)

026	CAA – Sweden	<p>Current text: "At initial by AME then every 5 years if refractive error is over +/- 5 diopters"</p> <p>Proposed text: "At initial by AME. By a specialist at initial and then every 5 years if refractive error is over –5"</p>	<p>A comprehensive ophthalmological examination shall by definition be carried out by a specialist, with the exemption for initial class 2 examination. In case of a high refractive error recurrent specialist examinations are required, which should include also the initial examination. With hyperopia, refractive errors exceeding +5 diopters</p>	<p>Rejected</p> <p>As the table gives an overview only, the requirements had to be changed first. A working paper on this matter will be prepared.</p>
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
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			are not acceptable making the wording "over +5 diopters" inappropriate. Hence, the text should only read "over - 5 diopters".	
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IEM FCL 3.100, p 2-A-33, p 2-A-33

003	CAA – United Kingdom	IEM FCL 3.100 Medical certificates <i>Deletion of the form:</i> Notification of denial of medical certificate Notification of initial placing of limitation on medical certificate (2-A-338)	The notification of denial of a medical certificate is a useful form and should remain. The notification of initial placing of a limitation on a medical certificate is unnecessary because: 1. The limitation imposed is clear (it is on the certificate) 2. In the case of simple limitations e.g. requirement to use correcting lenses, it is unnecessary 3. With an operationally significant limitation, an explanation will inevitably be given to the pilot verbally and/or by letter.	Rejected The majority stated that the form would not be necessary as the AMS issues denials anyway, would not be used for legal reasons or would slow down procedures.
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IEM FCL 3.100, pp 2-A-29, 30, 31, 32

008	CJAA	see Annex2-008	The JIP group drafted improvements for the Medical Certificates, which were endorsed	Accepted
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
			<p>by the Licensing Director and have been entered to "JAA Administrative and Guidance Material - Section Five: Personnel Licensing" (JIP) already.</p> <p>The respective changes have to be reflected in JAR-FCL 3, IEM FCL 3.100, pp 2-A-29 to 32 as well.</p>	

IEM FCL 3, A, B, C - JAA Manual of Civil Aviation Medicine

029	AEA	The Manual should simply outline the principles of aviation medicine practice and provide guidance on appropriate reference material.	AEA feels that there is generally a lack of clarity of purpose for the Manual, given that information in it does not form part of the mandatory requirement. There is particular concern that the sections on malarial prophylaxis and on immunisation are outdated and that the 15 pages of guidance on fitness to operate after specific infectious diseases contain an inappropriate level of detail.	<p>Rejected and noted</p> <p>The Manual is a valuable and indispensable tool containing all relevant information for the daily work for everyone involved in aviation medicine, for some the only one available. The chapter "Tropical Medicine" had been written on behalf of and approved by the AEA and the AEA delegate. The level of detail in the 15 pages of guidance had been intended and approved by the AEA delegate as well. The author presented an actual update as comments on the current NPA (see comments 002 and 011) with up-to-date information. The fact that during NPA procedure informations might become outdated will be addressed by a</p>
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
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				new proposal to attach the manual to the JIP allowing for a quicker amendment cycle.
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IEM FCL 3, A, B, C - JAA Manual of Civil Aviation Medicine, page examination", Amendment 1, 7th paragraph *General-3, "The Aeromedical Health*

012	CJAA	During the health examination every detail is essential so that minor progressive changes can be noted at the earliest stages, often before symptoms become evident.	The context shows that the word "every" got obviously lost and should be reinserted.	Accepted A new text was proposed: During the health examination detail is essential care should be taken so that minor progressive changes can be noted at the earliest stages, often before symptoms become evident.
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IEM FCL 3, A, B, C - JAA Manual of Civil Aviation Medicine, page Risk Assessment", Amendment 1, "Private Pilots", 3rd paragraph *General-5, "The concept of Aeromedical*

013	CJAA	... be less than 1 per 10 ⁶ • <i>The concept of aeromedical risk assessment (continued)</i>	Due to the computer programme the header of the following page appears in the middle of the text. Furthermore, the superscript "6" does not appear as superscript and the	Accepted
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
		In general ...	period at the end of the sentence is missing. These mistakes should be corrected.	

IEM FCL 3, A, B, C - JAA Manual of Civil Aviation Medicine, Chapter 11, Aviation Psychiatry

033	ALPA, International	The section on aviation psychiatry is also comprehensive and the changes proposed reflect more current understandings of emotional illness. However, we do believe that both the US FAA and JAA should consider following the lead of the certification authorities in Canada and Australia and begin certifying, on a carefully limited basis, pilots diagnosed with depression but in successful remission on antidepressant medication. Dr. Don Hudson, ALPA's Aeromedical Advisor, has presented to the FAA a certification protocol under which this could be done in a sound clinical manner without degrading aviation safety. Depression is a relatively common, chronic disease that afflicts airline pilots at no less a rate than other professional groups. Over the last 20	see Annex 4 - 033	Noted Work on antidepressant medication is already under way within the LSST(M).
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
		<p>years, clinical psychiatry has made great strides in the treatment of this condition and ALPA believes that the worldwide certification authorities are now able to address this issue for pilot certification as they have addressed other diseases as medical therapies have advanced (for example, alcoholism and ischemic cardiac disease).</p> <p>We have included in our comments an article that appeared in the May 2004 issue of <i>Aviation, Space, and Environmental Medicine</i>, the Journal of the Aerospace Medical Association. The article reviews the present status of aeromedical regulation of depressive disorders and antidepressant medications.</p>		

IEM FCL 3, A, B, C - JAA Manual of Civil Aviation Medicine, Chapter 18, Tropical Medicine

002	CJAA	see Annex1 -002	The text was drafted roughly two years ago. In the meantime some significant developments and advancements of Tropical and Travel Medicine took place. This relates to some minor changes to the original proposal, some	Accepted
011	CJAA	see Annex 3-011		

Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
			<p>editorial changes and especially the introduction of a very effective drug - Atovaquone / Proguanil (Malarone®) - for chemoprophylaxis of Malaria, which is of utmost suitable for aircrew.</p> <p>The paragraphs of the original proposal to be amended are not reprinted as strike-through version. The respective new versions are printed as whole passages, the changes are printed in bold and are marked at the margin of the text with perpendicular lines.</p>	

IEM FCL 3, A, B, C - JAA Manual of Civil Aviation Medicine, Chapter 19, Medicine and Flying

021	T. Joergensen, Sterling, DK	<p>All recommendations of medication should - when specific drugs are mentioned - be followed by an ATC code (Anatomical Therapeutic Chemical Classification System) for the specific drug.</p> <p>The same ATC Classification System should be used on AMC OPS 1.745 First Aid Kit and AMC OPS 1.755 Emergency Medical Kit.</p>	Then we could easily find the national approved products.	Noted
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Comment number	Commentator	Proposed text/comment	Reason(s) for proposed text/comment	Response
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Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

Annex 1-002

Proposal for changes to the proposed Chapter 18 - Tropical Medicine

3.1 Exposure prophylaxis- general recommendations

Exposure Prophylaxis is avoiding those factors, which may cause or encourage health problems. It is the basis of all the precautions and prophylactic means against any disease, which can exist in the tropics and subtropics.

In the context of exposure prophylaxis, swimming and wading in tropical ponds, lakes or rivers should be discouraged (there is a danger of infection with schistosomiasis) as well as walking barefooted on beaches etc. (infection with ankylostoma). Wearing adequate footwear on the ordinary beach, or in the calm waters of exotic beaches, can protect against such infections such as ankylostoma, and the stings of maritime fauna (sea-urchin, stingray, corals). The inexperienced traveller may fear snake-bites. These and bites of scorpions are extremely rare, under normal travel arrangements.

Respiratory Tract Infections are often underestimated. Nevertheless, they remain the second-most common health disorder contracted abroad after travel diarrhoea. The reasons can include the change of climate, moving between hot and humid conditions outside, to the cool air in rooms with air-conditioning, cool draughts in cars and public transport, as well as temporary immune suppression due to sunburn. Dust and dirt from city streets are also main contributory factors. Exposure prophylaxis can be very important, if this type of problem is to be avoided.

Intensive **solar radiation** in low latitudes and altitude, reflection from water and snow surfaces, can result in significant UV exposure to the skin and eyes (More care is required in the southern hemisphere, where there is greater UV exposure due to the ozone gap). Acute dangers are photo-dermatitis, which causes sunburn, and can lead to meningeal irritation. In extreme cases, cerebral oedema may occur, in combination with excessive heat emission. Sunstroke can occur, with keratitis, conjunctivitis, snow blindness in mountain areas, and temporary immune suppression. The chronic consequences can result in skin tumours, accelerated aging of skin (due to destruction of elastic fibres), chronic photo-dermatitis and cataract. Adequate sun protection must be afforded, **especially during the strongest exposure around noon time**, by using the appropriate clothing, by wearing sensible headgear and by using sun cream with a high sun protection factor (at least factor 20) **and minimizing the time of exposure**. The so-called sun blockers should be water resistant and contain a high percentage of micro-pigments). The use of sunglasses is important.

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4.2.9 Meningococcal Meningitis

Meningococci exist worldwide, permanent epidemic areas, reach from Brazil in the west to the sub-Saharan Sahel Zone in Africa, to the Arabian Peninsula and to the Indian subcontinent. The African Meningitis belt is located in the Sahel Zone and south of it. Particularly during the dry periods (December to June) epidemics occur in intervals over several years, e.g. pilgrims to Mecca. The infection is spread by large groups of people, such as Mecca pilgrims and high density of housing, such as in shantytowns, slum or mass tented areas.

The causative agents are gram-negative diplococci, *Neisseria meningitidis*. Eight serogroups A, B, C, X, Y, Z, W 135 and W 29 exist. Within the Meningitis belt infections with serotype A can be found, whereas in middle Europe, Australia and North America, infections with serotypes B and C occur. Meningococci are transmitted face to face by droplet infection. The reservoir is the nasopharyngeal area of healthy carriers. During an epidemic, up to 10 % of the population are carriers that can infect mainly susceptible non-immune children. The clinical course varies between an asymptomatic infection of the nasopharyngeal tract, (this is the most frequent type) to an acute meningococcaemia with light fever and petechiae. This may develop in 10% of those with the asymptomatic infection. The more serious infection has a case fatality rate of about 10 %, especially in children and juveniles and leaves long time residuals in up to 20 %. **If close contact with infected persons has occurred over a period of several hours (> 8 h) such as within an aeroplane, a prophylactic dose of Rifampicin is recommended.**

Draft Comment/Response Document NPA-FCL 3 – 21 (Medical) – LSST(M) proposal to LST (after discussion LSST(M) # 9 Vilnius)

Draft Comment/Response Document NPA-FCL 3 – 21 (Medical)

The polysaccharide vaccine protects against sero-groups A and C or additionally sero-groups W 135 und Y. The immunization is effective 10 to 14 days after the last inoculation and lasts at least for three years. Those vaccinated should be older than two years.

Beside exposure prophylaxis, the vaccination is indicated for travel in rural basic areas and where there is close contact with the population in these areas. It is mandatory for pilgrims to Mecca (Art. 84, International Health Regulations). Serotype W 135 is responsible for the most infection in this group. Therefore, the vaccine protecting against this serotype is recommended and is mandatory from 2002 onwards. **For flight crews transporting pilgrims to Saudi Arabia on pilgrim flights the vaccination might be mandatory, whether entering the country or not.**

...

4.2.13 Tick Born Encephalitis

Tick born Encephalitis is a viral disease. The central European variant is also known as ESME or FSME, and occurs in Central and Eastern Europe, from Southern Germany and Switzerland to the Urals, and to the south of Sweden and Finland. The Far East or Russian variant, also known as RSSE, occurs from the Baltic States in the west, throughout Russia to the Pacific Ocean.

...

5.1 Malaria Prophylaxis

1. Exposure prophylaxis
2. Chemo -prophylaxis (medical prophylaxis)
3. Establish an early diagnosis and therapy.
If applicable standby therapy (probably malaria quick test)

There are three elements of malaria prevention, which are based on each other. The kind of prophylaxis (only exposure prophylaxis, or exposure prophylaxis with standby therapy, or exposure prophylaxis plus chemo-prophylaxis, probably in combination with standby therapy) depends on the destination, season, style and duration of stay, as well as individual factors such as previous diseases, probable medication and probable intolerance of anti-malarials. Furthermore, the risks of the adverse side effects of chemo-prophylaxis, have to be weighed up against how effective is the method of prophylaxis and how great is the risk of getting malaria. General recommendations for relevant malaria areas may be a great help for physicians giving advice for malaria prophylaxis.

The relevant recommendations have been worked out by several scientific organisations, adapted to the actual epidemiological situation and published. The recommendations of the WHO are published in the brochure "International Travel and Health" (WHO Library, Genf 2003 ref. <http://www.who.int/ith/english/index.htm>). A couple of national recommendations exist, too. The Swiss and German and some other National recommendations for example differentiate for countries, travel areas and seasons. Therefore, the preventative measures can be adapted to the local epidemiological situation.

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5.1.1 Exposure Prophylaxis

Exposure prophylaxis of Malaria is to protect against mosquito bites. It has to be carried out throughout the active time of the vectors – from dusk throughout the night to dawn. Exposure prophylaxis can reduce the risk of malaria by 90 %.

1. **Cover as much as possible of the body surface by fair-coloured, loose-fitting cotton clothes (Long trousers, long sleeves).**
2. **Uncovered skin should be treated with insect repellents (e.g. Bayrepel, DEET. Permethrin is not favoured in some countries). These products should not be used on damaged areas of skin or children < 2 yrs**
3. **Staying inside with closed rooms during evening and night. Rooms should be mosquito-proof: use mosquito screens, air conditioning, and if applicable insecticides.**
4. **Mosquito nets are recommended (they should be big enough not to be touched while sleeping, loose ends should be fixed under mattress). If applicable mosquito nets impregnated by Permethrin (judged critically in some countries).**

Electric vaporizers, mosquito coils and insecticides reduce the number of mosquitoes, but can produce possible irritating and toxic substances. Insecticides containing pyrethroids are often considered inappropriate.

5.1.2 Chemo-prophylaxis

The decision for an **additional** medical prophylaxis has to take into account, the risk of infection, the efficacy e.g. the resistance situation, and the adverse side effects. This is especially so for long-term prophylaxis where the side effects have to be balanced against the possible benefit. Therefore, the decision to use chemo-prophylaxis, and to use certain anti-malarials, has to be based on a meticulous risk-benefit-calculation. Chemo-prophylaxis does not replace, but supplements, exposure prophylaxis. **However, it has to be taken into account that no prophylactic drug is 100 % effective.**

As with antibiotics, the sub-therapeutic levels of an anti-malarial as used in chemo-prophylaxis, can result in resistance. Resistance exists using Chloroquine and other antimalarials, especially with *Pl. falciparum* and *Pl. vivax*. According to the resistance situation the WHO has defined **resistance areas** (A, B, C), for which certain prophylaxis regimes are recommended. These areas are not defined according to transmission of malaria. Therefore, the malaria risk does not depend on the resistance zone.

If a mission into an endemic area has to be started so early, that a sufficient blood level of the anti-malarial chosen cannot be achieved, a rapid saturation is possible with Chloroquine or Mefloquine. **Mefloquine is not approved for pi lots. However, chemo-prophylaxis with Atovaquone + Proguanil (Malarone®) has to be started only the day before entering the malaria risk area and is recommended instead**

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a) Chloroquine (Resochin®) + Proguanil (Paludrine®)

The effectiveness of this combination of two anti-malarial medications is only about 60 % ~~to 70%~~ (West Africa) **and should not be recommended, if a more effective, alternative drug like Atovaquone + Proguanil (Malarone®) is available.** It can be used over long periods continuously (Up to 100 g of Chloroquine, corresponding to continuous intake over 5 years, is harmless. For continuous intake – which normally does not apply for flight crew – an ophthalmological control is recommended every 2 years. The combination of Chloroquine and Proguanil **used to be** the only anti-malarial approved for pilots **before Atovaquone + Proguanil (Malarone®) was approved** Severe adverse **side effects** do not exist, for Chloroquine, short term stomach discomfort, flickering of eyesight, light dizziness, sleep disturbance occur rarely. **For Proguanil reversible loss of hair, ulceration of the mouth and stomach discomfort may occur rarely.** The medication should always be taken with food and with plenty of fluid. **Contraindications** for Chloroquine are psoriasis, retino-pathology, visual field defects, myasthenia gravis, glucose-6-phosphate dehydrogenase deficiency, hepatic porphyria, severe liver disorders, renal insufficiency and intolerance of 4-Aminochinolins. Contraindications for Proguanil are, severe renal insufficiency (reduction of dose necessary). A rapid saturation for chloroquine can be achieved by the intake of a weekly dose (2 Tablets) on 2 subsequent days. Subsequently, the chemo-prophylaxis has to be continued in a regular way. It has to be continued for 4 weeks after leaving the risk area.

Chloroquin + Proguanil (Resochin® + Paludrine®)

Generics: - 150 mg Chloroquine-Base resp. 100 mg Proguanil
Intake: - 2 Tbl. Resochin / w (with body weight > 80 kg: 3 Tbl), starting 1 week before mission, continuing
For 4 weeks after leaving risk area
- 2 x 1 Tbl. Paludrine / d, starting 1 day before mission, continuing for 4 weeks after leaving risk area
N.B.: - for better compatibility intake with lots of fluid at meal times.
- With continuous intake > 2 a ophthalmological control every 2 years
- In New Guinea there is resistance against Proguanil
- Chemo-prophylaxis is possible for children and in pregnancy
- Rapid saturation with Chloroquine using: 2 Tbl/d for 2 d

b) Mefloquine (Lariam®)

Mefloquine is not approved for pilots! If a pilot should take it by mistake, then that pilot must remain unfit for flying duties for four weeks, and then be observed to see if any neuro- psychiatric side effects have occurred.

Mefloquine in special circumstances can be used for flight attendants. The discussion about mefloquine for flight crew has not yet come to any fixed conclusions. Therefore until some conclusions have been reached, there is no reason why flight attendants should have to take the risk of using a less effective type of prevention, when this very effective anti-malarial for chemo- prophylaxis is available. Effectiveness is about 90 % in West Africa. Long-term intake is possible for up to 2 years. The **Side Effects** can include neuro- psychiatric symptoms (0,1 to 1 %)[There are some reports of a higher percentage]. Visual blurring can occur. Epileptic seizures have been reported as well as psychotic symptoms. These effects can be dose related and occur more frequently with rapid saturation, or therapeutic intake, or in women (higher blood levels). Side effects are more likely to occur after a second intake. When the chemo-prophylaxis is taken for the first time, it should be started 3 weeks before onset of any exposure, therefore, in order to change the prophylaxis regime in case of side effects. **If side effects occur, Mefloquine should never be used again.** Vice versa, if side effects are absent, Mefloquine should be tolerated well in the future, although there is no guarantee or clinical evidence to prove this. The

Contraindications include the first trimester of pregnancy when genetic abnormalities have been recorded. Three months

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after taking mefloquine, effective contraception is recommended. It should not be taken during the lactation period. It should not be given to children < 5 kg of body weight and / or < 3 yrs of age. It can cause cardiac conduction disturbances. It must not be taken with quinidine, or given to people with severe liver disorders, or with neuro psychiatric disorders, and of course, it must never be given to people with epilepsy. Interference with frequently used medicines such as beta-blockers, calcium antagonists and other anti arrhythmics should be considered. Even with diarrhoea Mefloquine can be sufficiently effective. A **rapid saturation** for mefloquine can be achieved by the intake of a weekly dose (1 Tablet) on 3 subsequent days. The prophylaxis with mefloquine should be started 1 week before the onset of a mission and continued for 4 weeks after leaving the risk area.

****Mefloquine should only be considered, where the risk of infection outweighs the probability of severe side effects. Because of the risk of both short term and long-term neurological side effects, mefloquine is forbidden for use in pilots****

Mefloquine (Lariam®)

Generic:	- 250 mg Mefloquine
Intake:	- 1 Tablet. /w, starting 1 week before exposure, continuing for 4 weeks after leaving risk area
N.B.:	- Intake with plenty of fluid
	- For women 3 months of effective contraception is recommended after intake
-	- Rapid saturation 1 x 1 Tbl for 3 d
-	- Rapid resistance to mefloquine has occurred in SE Asia. Resistant cases have now been reported in Africa.

c) Atovaquone + Proguanil (Malarone®)

According to preliminary results of scientific studies about the interference of Atovaquone / Proguanil with flight duties it seems likely, that there will not be any problems for aircrew. The combination of Atovaquone and Proguanil (Malarone®) is used by several airlines as Lufthansa and is approved for pilots by the FAA. The effectiveness is about 90 %, like that of mefloquine. It can be used for adults and for stays up to 28 days (soon to be prolonged up to 56 days and probably longer). As with mefloquine, it is recommended for chemo-prophylaxis in areas, where there is chloroquine resistance and for treatment of uncomplicated malaria. This combination is much better tolerated than mefloquine. The combination is not associated with neuropsychiatric adverse effects, impairment of psychomotor performance, mood changes, sleepiness and fatigue, especially under hypobaric conditions. **Side effects** are minimal and do not last very long, they may include: cough, gastrointestinal disturbance (nausea, vomiting, abdominal discomfort and pain, diarrhoea) and headache. **Contraindications** are severe liver disorders and severe renal insufficiency (Creatinine-Clearance < 30 ml/min). **Due to the short time of administering (1 day before up to 7 days after staying in a malaria risk area) the combination is particularly suitable for flight crews. Acceptability of the drug by the compliance of patients proved to be very high.**

Atovaquone + Proguanil (Malarone®)

Contents:	- Atovaquone (250 mg) + Proguanil (100 mg)
Intake:	- 1 Tablet. / d, starting 1 to 2 days before mission, continuing for 7 days after leaving risk area
	- Maximum stay in risk area 28 d (Longer term intake is under consideration.)
N.B.:	- effectiveness as mefloquine (90 %), tolerability better

d) Doxycycline

The antibiotic doxycycline is not officially approved for pilots yet, but it is being used in military pilots in high - risk areas, because of the lack of an effective alternative. It is not licensed for chemo-prophylaxis of malaria in some European Countries, but is used in the UK and the U.S. It is used for prophylaxis in areas with multi-resistant plasmodia (resistance against chloroquine, and proguanil, and mefloquine). This applies to the border areas between Thailand and Myanmar and Thailand and Cambodia. For the time being Doxycycline is regarded as effective as Atovaquone + Proguanil (Malarone®) or Mefloquine (Lariam®) for chemo-prophylaxis by some Societies for Tropical and Travel Medicine in Europe. It can be used instead of them, where these are recommended.

Side effects can include gastrointestinal disturbances (nausea, vomiting, diarrhoea), photo-dermatitis (care must be taken with solar radiation in tropical areas), very rarely it can cause increased intra-cranial pressure.

Contraindications are children < 8yrs, severe liver disorders.

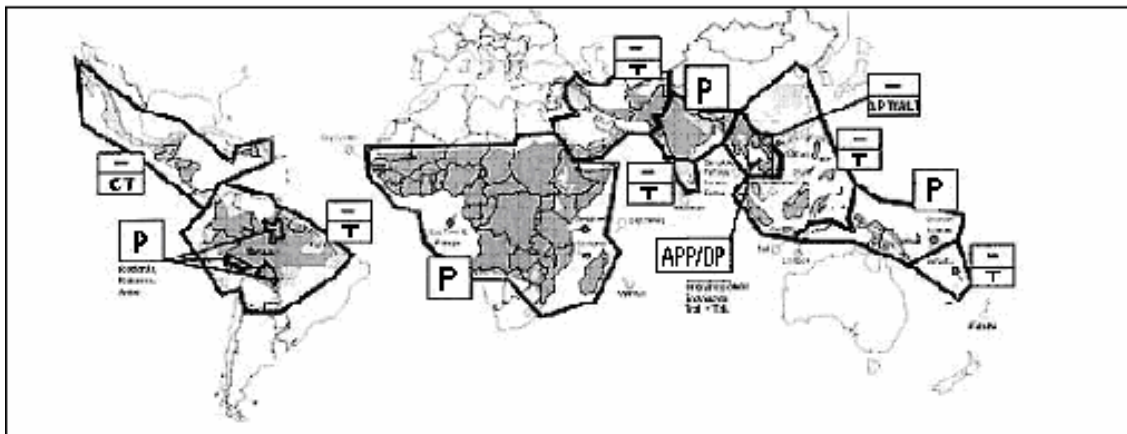
Doxycycline (several brand names)

- Content: - 100 mg Doxycycline
- Intake: - 1Tbl. / d
- N.B.: - Must be taken with plenty of fluid
- Contraindicated in children < 8 yrs and pregnant women
- Beware of photo-dermatitis (solar radiation!)

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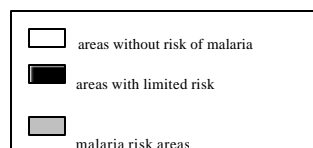
5.1.4 Special recommendations

An example for special recommendations are those of the Swiss/ German Societies of Tropical Medicine and various other Organisations, which differentiate their recommendations by countries, and even travelling areas within countries, seasons and duration of stay.



(after WHO International Travel and Health 2003, and SAR and DTG)

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P	Mefloquine (Lariam®), or Atovaquone / Proguanil (Malarone®), or Doxycyclin for Chemoprophylaxis
APP/DP	Atovaquone / Proguanil (Malarone®), or Doxycyclin for Chemo-prophylaxis
APT/ALT	no Chemo-prophylaxis but Atovaquone / Proguanil (Malarone®) or Artemether/Lumefantrin (Riamet®) for Standby-Therapy
T	no Chemo-prophylaxis but Mefloquine (Lariam®) or Artemether/Lumefantrin (Riamet®) for Standby-Therapy
CT	no Chemo-prophylaxis but Chloroquine (Resochin®) for Standby-Therapy

Recommendations for malaria prophylaxis (after DTG, 2003)

Geographic Region	Prophylaxis
Tropical Africa, Eastern Indonesia, Papua-New Guinea, Salomon Islands, Amazonian-Provinces	P
Indian Subcontinent north of line, Goa-Madras	P
Thailand (Provinces Trat and Tak)	APP / DP
Thailand (other provinces)	APT / ALT
Central America	CT
Other risk areas	T
In all malaria areas	Exposure prophylaxis

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6.2.3 Therapy

Therapy of amoebiasis (Modified after Lunzen, Tannich, Burchard, Dt. Ärzteblatt 93, 51 - 52)

Diagnosis	Drug	Dosage	Time of treatment
Luminal infection	Paromomycin	25 - 35 mg / kg / d , tid	7 days
	Diloxanidfuroat	3 x 500 mg p.o.	10 days
Amoebic dysentery	Metronidazole	3 x 10 mg/kg KG p.o. or i.v	10 days
	Tinidazole	2 g / d p.o.	5 days
Amoebic liver abscess	Metronidazole Severe cases additionally	3 x 10 mg/kg KG i.v.	10 days

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	Chloroquine	Initially 600 mg p.o., then 300 mg p.o.	2 days 2 - 3 weeks
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In invasive amoebiasis, a luminal infection is present as well and should be treated with Paromomycin or Diloxanidfuroat (available in the U.K.) after treatment with tissue amebicidal drugs like Metronidazol or Tinidazol and the amebic colitis has been cured. Success of intestinal eradication should be checked after about 6 weeks by microscopic stool diagnosis.

During medication with either drug, members of flight crew are not fit to fly. The **side effects** of the medication can include extra-pyramidal tremors and **a severe reaction with any form of alcohol. In asymptomatic luminal infection, fitness for flying is not restricted. Flight crew are not fit for flying duties with amoebic dysentery or with liver abscess or other manifestations. 2 weeks after successful treatment (proved by ultrasound, CCT, NMR, EEG depending on clinical manifestation), flight crew may return to duty.**

Annex 3-011

Proposal for changes to the proposed Chapter 18 - Tropical Medicine

1.2 Medical stress factors in the tropics

Not only geographic location and climate relate to possible health effects in areas outside the temperate zones. Therefore, the standard of development and life standard have to be considered as well. Regarding these facts medical advice given here is not restricted to the tropics proper but to Subtropics as well. On the other hand, some tropical countries have health systems similar to industrial countries and pose much less risk.

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Medical stress factors in the tropics can be caused by the climate, factors related to travel (jet lag, means of transport etc.), and insects (because of the warm climate). These insects can act as vectors of diseases. Other factors can be the low standard of hygiene, infectious diseases, socio-economic problems and psychosocial stress.

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3 Medical Travel Prophylaxis

Medical Travel Precautions:

1.	Exposure prophylaxis	- General recommendations - Protection against sun and climate - Food and beverage hygiene - Protection against insects
2.	Vaccination Prophylaxis	- Active (and passive) vaccinations
3.	Medical prophylaxis	- Malaria chemo-prophylaxis - Prophylaxis against travellers' diarrhoea (only exceptionally!)

3.1 Exposure prophylaxis – general recommendations

Exposure Prophylaxis is avoiding those factors, which may cause or ~~encourage~~ **deteriorate** health problems. It is the basis of all the precautions and prophylactic means against any disease, which can exist in the tropics and subtropics.

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4 Vaccinations

4.1 General Considerations

Vaccination is the most efficient means of prophylaxis for a number of infectious diseases. Vaccination is generally effective and well tolerated. Therefore it is one of the most efficient medical measures to hand. The individual is protected and the public are protected, because the vaccinated person cannot transmit the respective disease any more.

Flight crews are normally unfit for flight duties for at least 24 hours after a vaccination.

4.1.1 Information and Documentation

Vaccination requires personal informed consent. The person to be vaccinated has to be fully informed about the vaccination in sufficient time prior to a planned vaccination. The information should include a description of the disease to be prevented, and its treatment (What kind of vaccine is it? What if any, are the benefits, both individually and collective. What are the contraindications, possible side effects and what could be the complications. What is the duration of immune protection being given by the vaccination? What boosters will be required? What is the recommended behaviour after the vaccination?). All the information given should be documented and show that written consent has been given.

After any vaccination, the date, type, manufacturers-number, stamp and signature of the vaccinating physician has to be written down on the appropriate document (The international vaccination ~~passport~~ certificate of the WHO is one recommendation.). Any missing documentation of any former vaccination, prior to a booster vaccination, should not delay or

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even exclude a planned vaccination. A probable booster vaccination over and above the basic scheme does not normally have any side effects.

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4.1.3 Scheduling vaccinations

The immune protection afforded by vaccinations ...

For Booster immunizations the effective period of the respective vaccination has to be taken into account.

The effectiveness and the effective period of vaccinations (modified after Steffen, R., von Sonnenburg, F. in W. Lang, T. Löscher, Tropenmedizin in Klinik und Praxis, 3. Auflage, Thieme, 2000). This schedule is up to date as of Jun 2002, it should be checked periodically to see if there have been any changes.

Vaccination	Application	Effectiveness (%)	Effective from	Effective period
Cholera parenteral	i.d., s.c., i.m.	< 50	d 6 (first immunization), d 1 (booster *)	Officially 6 m Effective 3 – 6 m
Cholera oral (WC-BS)	p.o.	60 - 86	d 6 (first vaccination), d 1 (booster *)	Officially 6 m Effective 3 – 6 m
Cholera oral (CVD-103 HgR)	p.o.	13 - 100	d 6 (first immunization), d 1 (booster *)	Officially 6 m Effective 3 – 6 m
Diphtheria	i.m.	~ 80	4 w	5 (-10) yrs
ESME (Tick borne Encephalitis)	i.m.	99		> 3 yrs
Hepatitis A	i.m.	> 99	d 14 (evtl. d 0)	10 (- 30) yrs
Hepatitis B	i.m.	~ 90	d 30 – d 60	Responder lifelong
Influenza	i.m.	70 - 90		> 1 yr
Japanese Encephalitis	s.c.	> 90		> 4 yrs
Meningococcal Meningitis	s.c.	70 -90	d 7	1 – 3 yrs
MMR (Measles, Mumps, Rubella)	i.m.	90 - 95		lifelong
Pest	i.m.	?	A couple of d	6 m
Poliomyelitis (IPV)	i.m.	> 99	4 – 6 w	10 yrs
Poliomyelitis (OPV)	p.o.	> 99	4 w	Life-long
Tetanus	i.m.	> 99	4 w	10 yrs
Rabies	i.m. (s.c.)	> 99	~ 7 d	2 – 3 yrs
Tuberculosis (BCG)	i.c.	0 -80	Not sure	10 yrs
Typhoid F. Ty 21 a	p.o.	~ 70	d 14	1 – 3 yrs
Typhoid F. Vi	i.m.	~70	d 14	2 – 3 yrs
Yellow Fever	s.c.	> 99	d 10 (first immunization) d 1 (booster *)	Officially 10 yrs Effective lifelong ?

* If vaccinated within effective period of former immunization

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4.2 Vaccinations in Travel Medicine

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When briefing flight crews and other people who travel, a distinction has to be made between mandatory vaccinations, generally recommended vaccinations and specific travel vaccinations.

Mandatory vaccinations according to the WHO, used to be the vaccinations against **Smallpox**, Cholera and Yellow Fever. Smallpox was eradicated in the 70's of the last century. The injection type of vaccination against Cholera showed no sufficient effect, and was omitted from the list of mandatory vaccinations. Nevertheless one should be aware, that the vaccination against Cholera might be demanded by certain border controls. This is against the general practice and scientific findings. It is often done in order to extract money dishonestly, by exaggerating the risk.

The vaccination against Yellow Fever is now the only mandatory vaccination, when travelling to certain countries. Some countries (16 countries in tropical Africa and French Guyana) demand the vaccination for every person entering that particular country. Other countries require YF, only for those who have visited an endemic area within the last 6 days. The vaccination against meningo-coccal meningitis is mandatory for pilgrims who are travelling to Mecca. For flight crews taking pilgrims to Saudi Arabia, this vaccination is also mandatory.

The **generally recommended vaccinations** against Tetanus, Diphtheria and Poliomyelitis are also recommended as a matter of principle. The immunization status should be checked and a booster given if necessary. The combination vaccines are generally recommended. If a tetanus immunization is necessary because of an injury, a combination vaccine with diphtheria vaccine, or diphtheria and poliomyelitis vaccine, should be used.

The indication for **specific travel vaccinations** depends on the areas to be visited, the time (rainy or dry season etc.), the duration and the style of travel (staying in the hotel or travelling around during the layover). These vaccinations should ensure an optimal protection for the flight crew or the traveller. For members of flight crew, immunization for Hepatitis A and Yellow Fever are recommended in general, others depend on each and every situation.

Specific Travel Vaccinations

1. Hepatitis A
2. Hepatitis B
3. Typhoid Fever
4. Meningo-coccal meningitis
5. Rabies
6. Japanese B-Encephalitis
7. Cholera
8. ES ME (Tick Borne Encephalitis)

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4.2.4 Yellow Fever

Yellow Fever is endemic in the tropical rain forest zones of South America and Africa and is caused by a Flavivirus. Endemic and infectious zones can be readily distinguished. In **endemic zones** the virus circulates within a so-called sylvatic cycle between monkeys as reservoir and mosquitoes as vectors (Haemagogus and Sabethes mosquitos in South America, Aedes in Africa). In **infectious zones** (found within endemic zones) transmission to man occurs due to an urban cycle with anthropophilic Aedes mosquitoes as vectors. Epidemics can be caused in the same way.

Yellow Fever is a viral haemorrhagic fever. The severity of the disease varies from a virtually unnoticeable or mild course (especially found in endemic zones) to severe and even lethal, classic or haemorrhagic yellow fever. In the latter cases the general condition rapidly deteriorates, with failure of the liver and the kidneys. There is generalized haemorrhagic diathesis with haematemesis, melaena, metorrhagia, haemorrhages in the skin and mucosa. Involvement of heart and CNS are

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common. 7 to 10 days after onset of symptoms the patients may die. The mortality of yellow fever in general is 10 to 20 %, and up to 50 % with classical yellow fever.

Vaccination against YF is recommended when visiting endemic zones. It is mandatory when entering certain countries of the endemic zones and, after having visited endemic zones within the last 6 days, when entering certain other countries of the endemic zones and outside. The vaccination may also be necessary when travelling within countries of the endemic zones, e.g. Brazil and Ecuador. **Flight Crews should be vaccinated even if they only fly over endemic areas, because an immunization might be required after a diversion to an airport, which is in the endemic zone. Therefore all flight crew operating in Africa or Latin South America should be vaccinated against Yellow Fever.**

The vaccine consists of a highly effective, attenuated live vaccine. The substantial residual virulence of the vaccine should be taken into account when vaccinating patients who are immuno-suppressed (HIV positive patients can be immunized with a CD4-count > 400 / μ l.). The vaccine virus is bred on eggs or chicken fibro-blasts, therefore chicken protein allergy might be a contraindication or at least relative contraindication. On the day of vaccination, and for the three successive days after the vaccination, those who have had a vaccination, should not do anything requiring muscular exertion or exposure (e.g. sport, sauna or being out in the strong sun and receiving UV exposure). **Side effects** can be slight, local reactions at the site of inoculation (up to 10 % of those vaccinated). After, 4 – 6 days there may be more general reactions, such as an elevated body temperature and malaise (about 10 % of those vaccinated). The malaise, headache and muscle pain usually lasts for about 24 hours (2 – 5 % of those vaccinated).

Contraindications are acute febrile diseases within the last two weeks, immuno suppression and immune defects (see above), corticoid medication, allergy against chicken protein and age < 6m.

Only Authorized Vaccination Centres may give the Yellow Fever vaccine. These Centres only, certify the vaccination on the official vaccination certificate. The stamp is valid from ten days until 10 years after inoculation. In case of contraindications, an exemption certificate has to be given (The text should state that "No vaccination was possible on medical grounds"). One should be aware that the health authorities of certain countries might not acknowledge the exemption certificate.

Yellow Fever Vaccination

Indication	Travel into infection zones According to health regulations of certain countries for every visitor or after visits of endemic zones within the last 6 days
Vaccine	Live Vaccine of attenuated virus of 17 D - strain
Vaccination Scheme	<i>1 x 0,5 ml sub.cut or im.</i>
Effectiveness	Reliable, probably lifelong
Validity	As mandatory vaccination: from d₁₀ until 10yrs after vaccination
N.B.	Vaccination only by authorized vaccination centres Intervals to be observed with other live vaccines Care must be taken with the chicken protein allergy and HIV infection!

4.2.5 Hepatitis A

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Hepatitis A is an acute viral infection affecting the liver. The infection is predominantly self-limiting. In children the clinical course is mostly unnoticed. Even though the case fatality rate is overall only about 0,2 %, it increases by age (> 40 a: 2 %, > 50 a: 2,7. Moreover, recovery may take a couple of months, because of a protracted course or a delayed recovery.

Hepatitis A is acquired by fecal-oral transmission (especially in children by smear infection) by contaminated food and beverages. Raw seafood and oysters are a predominant source of infection. For exposure prophylaxis, good hygiene is effective because of the high resistance of Hepatitis A-virus against the environmental influence. In spite of this, vaccination is very effective because of the low hygiene standards and high rate of infectivity in the tropics.

A very effective, and inactivated type of vaccine, has existed since 1992. The effective period is 10 years. The new vaccine only needs two inoculations with an interval of six months in between. Even after the first inoculation an immune protection of six months to one year, can result. At the latest, two weeks before departure to tropical areas, the first inoculation should be given. Nevertheless, a later inoculation should not be omitted, because the immune protection will have built up a couple of days after arrival. Because of the high infection rate in children, even in first world areas in former days, a lot of the older aircrew might have had hepatitis A as a child even without knowing about it. Therefore, the titre of Anti-HAV of patients born before 1950-1960, with otherwise unexplained jaundice, or after a longer stay in third world areas, should be checked prior to the vaccination. Only patients with no titre (the threshold of immune protection being around, 20 IU/l) need a vaccination. Nevertheless, a vaccination of patients with titre of Anti-HAV is not harmful.

Hepatitis A Vaccination

Indication:	Wide indication, all travels overseas and to the Mediterranean and Eastern Europe encountering low hygienic standards Patients born before 1950-1960 depending on titre of Anti-HAV
Vaccine:	Inactivated vaccine (formalin activated virus) (HAVRIX®, VAQTA®, Epaxal®, HAVpur®)
Vaccination Scheme:	0 - 6 (to 12) months, i.m. Immune protection starts after 2 – 4 w for 6 to 12 m
Booster:	After 10yrs
N.B.:	Testing of titre of Anti -HAV in patients born before 1950-1960

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4.2.9 Meningococcal Meningitis

Meningococci exist worldwide, permanent epidemic areas, reach from Brazil in the west to the sub-Saharan Sahel Zone in Africa, to the Arabian Peninsula and to the Indian subcontinent. The African Meningitis belt is located in the Sahel Zone and south of it. Particularly during the dry periods (December to June) epidemics occur in intervals over several years, e.g. pilgrims to Mecca. The infection is spread by large groups of people, such as Mecca pilgrims and high density of housing, such as in shantytowns, slum or mass tented areas.

The causative agents are gram-negative diplococci, *Neisseria meningitidis*. Eight serogroups A, B, C, X, Y, Z, W 135 und W 29 exist. Within the Meningitis belt infections with serotype A can be found, whereas in middle Europe, Australia and North America, infections with serotypes B and C occur. Meningococci are transmitted face to face by droplet infection. The reservoir is the nasopharyngeal area of healthy carriers. During an epidemic, up to 10 % of the population are carriers that can infect mainly susceptible non-immune children. The clinical course varies between an asymptomatic infection of the nasopharyngeal tract, (this is the most frequent type) to an acute meningococcaemia with light fever and petechiae. This may develop in 10% of those with the asymptomatic infection. The more serious infection has a case fatality rate of about 10 %, especially in children and juveniles and leaves long time residuals in up to 20 %. **If close contact with**

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infected persons has occurred over a period of several hours (> 8 h) such as within an aeroplane, a prophylactic dose of Rifampicin is recommended.

The polysaccharide vaccine protects against sero-groups A and C or additionally sero-groups W 135 und Y. The immunization is effective 10 to 14 days after the last inoculation and lasts at least for three years. Those vaccinated should be older than two years.

Beside exposure prophylaxis, the vaccination is indicated for travel in rural basic areas and where there is close contact with the population in these areas. It is mandatory for pilgrims to Mecca (Art. 84, International Health Regulations). Serotype W 135 is responsible for the most infection in this group. Therefore, the vaccine protecting against this serotype is recommended and is mandatory from 2002 onwards. **For flight crews transporting pilgrims to Saudi Arabia on pilgrim flights the vaccination might be mandatory, whether entering the country or not.**

Vaccination against Meningococcal Meningitis

Indication	Long-time stay in risk areas. Travel into rural areas under basic conditions and with close contact with the local population in these high risk areas Mandatory for pilgrimage to Mecca or flight crew transporting pilgrims upon entry to Saudi Arabia Under certain circumstances probably required by certain countries upon entry from risk areas
Vaccine	Inactivated vaccine, depending on producer -Bivalent vaccine with serotypes A and C (A+C Mérieux®) -Tetravalent vaccine with serotypes A, C, W 135, Y (Mencevax ACWY®)
Vaccination Scheme	1 x 0,5 ml s.c.
Effectiveness	Reliable immune protection from 1 - 2 w after vaccination lasting 3yrs
N.B.	Mandatory vaccination valid from 10 d after until 3yrs after vaccination No protection against serotype B (Europe, South America)

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4.2.11 Japanese B-Encephalitis

Japanese B-Encephalitis is the most common viral encephalitis worldwide. The frequency differs between the Eastern Asia from Siberia, Korea and Japan to South East Asia and the Indian subcontinent as well as Taiwan, Philippines, the Mariane Islands and Guam. The disease has been spreading further worldwide in more recent years.

Birds are a reservoir, with an augmenting reservoir in pigs. The infection occurs in areas with rice paddies, where the vectors breed. The vector is the Culex mosquito, which is active from dawn to dusk. The virus circulates between these vectors and the reservoirs. Humans get infected when the density of the mosquito increases. Birds may carry the infection from the rural to the urban areas. Sporadic infections can occur all through the year. During the monsoon season the mosquito population can expand a great deal, causing epidemics.

In travellers Japanese B-Encephalitis is very rare. Nevertheless, an infection may be lethal. Beside exposure prophylaxis, the vaccination is indicated for individual travellers, who spend more than 4 weeks during the summer monsoon (May to October) in rural areas in endemic zones or who do extensive cross-country expeditions. This does not normally apply to flight crew. Only with extensive outdoor activities in endemic areas longer than 4 weeks duration is a vaccination warranted

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for flight crews. The inactivated vaccine contains inactivated virus from mouse brains (producers Biken or Connard). It is not licensed in every European country, but can be obtained by international pharmacies. In case of adverse side effects the immunizing physician is liable. Those to be vaccinated should be informed about this situation.

Vaccination against Japanese B-Encephalitis

Indication:	Individual travels >4 w in rural areas of endemic zones
Vaccine:	Inactivated vaccine with inactivated virus from mouse brain
Vaccination Scheme:	1 ml s.c on days 0 - 7 - 28 An alternative rapid scheme at days: 0 – 7 - 14 A booster after 1 – 2 years
Effective period:	4 years
Side effects:	local at site of inoculation (rare).

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4.2.13 Tick Born Encephalitis

Tick born Encephalitis is a viral disease. The central European variant is also known as ESME or FSME, and occurs in Central and Eastern Europe, from Southern Germany and Switzerland to the Urals, and to the south of Sweden and Finland. The Far East or Russian variant, also known as RSSE, occurs from the Baltic States in the west, throughout Russia to the Pacific Ocean.

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5.1 Malaria Prophylaxis

- 1. Exposure prophylaxis**
- 2. Chemo -prophylaxis (medical drug prophylaxis)**
- 3. Establish an early diagnosis and therapy.**
If applicable standby therapy (probably malaria quick test)

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5.1.1 Exposure Prophylaxis

Exposure prophylaxis of Malaria is to protect against mosquito bites. It has to be carried out throughout the active time of the vectors – from dusk throughout the night to dawn. Exposure prophylaxis can reduce the risk of malaria by 90 %.

- 3. Cover as much as possible of the body surface by fair-coloured, loose-fitting cotton clothes (Long trousers, long sleeves).**
- 4. Uncovered skin should be treated with insect repellents (e.g. Bayrepel, DEET. Permethrin is not**

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favoured

in some countries). These products should not be used on damaged areas of skin and children < 2 yrs

- 3. Staying inside with closed rooms during evening and night. Rooms should be mosquito-proof: use mosquito screens, air conditioning, and if applicable insecticides.**
- 5. Mosquito nets are recommended (they should be big enough not to be touched while sleeping, loose ends should be fixed under mattress). If applicable mosquito nets impregnated by Permethrin (judged critically in some countries).**

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a) Chloroquine (e.g. Resochin®) + Proguanil (Paludrine®)

The effectiveness of this combination of two anti-malarial medications is only about 60 % (West Africa) and should not be recommended, if a more effective, alternative drug like Atovaquone + Proguanil (Malarone®) is available. It can be used over long periods continuously (Up to 100 g of Chloroquine, corresponding to continuous intake over 5 years, is harmless. For continuous intake – which normally does not apply for flight crew – an ophthalmological control is recommended every 2 years. The combination of Chloroquine and Proguanil used to be the only anti-malarial approved for pilots before Atovaquone + Proguanil (Malarone®) was approved. Severe adverse **side effects** do not exist, for Chloroquine, short term stomach discomfort, flickering of eyesight, light dizziness, sleep disturbance occur rarely. For Proguanil reversible loss of hair, ulceration of the mouth and stomach discomfort may occur rarely. The medication should always be taken with food and with plenty of fluid. **Contraindications** for Chloroquine are psoriasis, retino-pathology, visual field defects, myasthenia gravis, glucose-6-phosphate dehydrogenase deficiency, hepatic porphyria, severe liver disorders, renal insufficiency and intolerance of 4-Aminochinolins. Contraindications for Proguanil are, severe renal insufficiency (reduction of dose necessary). A rapid saturation for chloroquine can be achieved by the intake of a weekly dose (2 Tablets) on 2 subsequent days. Subsequently, the chemo-prophylaxis has to be continued in a regular way. It has to be continued for 4 weeks after leaving the risk area.

Chloroquin + Proguanil (e.g. Resochin® + Paludrine®)

Generics: - 150 mg Chloroquine-Base resp. 100 mg Proguanil
Intake: - 2 Tbl. Resochin / w (with body weight > 80 kg: 3 Tbl), starting 1 week before mission, continuing for 4 weeks after leaving risk area
- 2 x 1 Tbl. Paludrine / d, starting 1 day before mission, continuing for 4 weeks after leaving risk area
N.B.: - for better compatibility intake with lots of fluid at meal times.
- With continuous intake > 2 a ophthalmological control every 2 years
- In New Guinea there is resistance against Proguanil
- Chemo-prophylaxis is possible for children and in pregnancy
- Rapid saturation with Chloroquine using: 2 Tbl/d for 2 d

b) Mefloquine (e.g. Lariam® or Mephaquine®)

Mefloquine is not approved for pilots! If a pilot should take it by mistake, then that pilot must remain unfit for flying duties for four weeks, and then be observed to see if any neuro- psychiatric side effects have occurred.

Mefloquine in special circumstances can be used for flight attendants. The discussion about mefloquine for flight crew has not yet come to any fixed conclusions. Therefore until some conclusions have been reached, there is no reason why flight attendants should have to take the risk of using a less effective type of prevention, when this very effective anti-malarial for chemo- prophylaxis is available. Effectiveness is about 90 % in West Africa. Long-term intake is possible for up to 2 years. The **Side Effects** can include neuro- psychiatric symptoms (0,1 to 1 %)[There are some reports of a higher
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percentage]. Visual blurring can occur. Epileptic seizures have been reported as well as psychotic symptoms. These effects can be dose related and occur more frequently with rapid saturation, or therapeutic intake, or in women (higher blood levels). Side effects are more likely to occur after a second intake. When the chemo-prophylaxis is taken for the first time, it should be started 3 weeks before onset of any exposure, therefore, in order to change the prophylaxis regime in case of side effects. **If side effects occur, Mefloquine should never be used again.** Vice versa, if side effects are absent, Mefloquine should be tolerated well in the future, although there is no guarantee or clinical evidence to prove this. The **Contraindications** include the first trimester of pregnancy when genetic abnormalities have been recorded. Three months after taking mefloquine, effective contraception is recommended. It should not be taken during the lactation period. It should not be given to children < 5 kg of body weight and / or < 3 yrs of age. It can cause cardiac conduction disturbances. It must not be taken with quinidine, or given to people with severe liver disorders, or with neuro psychiatric disorders, and of course, it must never be given to people with epilepsy. Interference with frequently used medicines such as beta-blockers, calcium antagonists and other anti arrhythmics should be considered. Even with diarrhoea Mefloquine can be sufficiently effective. A **rapid saturation** for mefloquine can be achieved by the intake of a weekly dose (1 Tablet) on 3 subsequent days. The prophylaxis with mefloquine should be started 1 week before the onset of a mission and continued for 4 weeks after leaving the risk area.

****Mefloquine should only be considered, where the risk of infection outweighs the probability of severe side effects. Because of the risk of both short term and long-term neurological side effects, mefloquine is forbidden for use in pilots****

Mefloquine (Lariam®)

Generic:	- 250 mg Mefloquine
Intake:	- 1 Tablet. /w, starting 1 week before exposure, continuing for 4 weeks after leaving risk area
N.B.:	- Intake with plenty of fluid
	- For women 3 months of effective contraception is recommended after intake
-	- Rapid saturation 1 x 1 Tbl for 3 d
-	- Rapid resistance to mefloquine has occurred in SE Asia. Resistant cases have now been reported in Africa.

c) Malarone® (Atovaquone + Proguanil)

According to preliminary results of scientific studies about the interference of Atovaquone / Proguanil with flight duties it seems likely, that there will not be any problems for aircrew. The combination of Atovaquone and Proguanil (Malarone®) is used by several airlines as Lufthansa and is approved for pilots by the FAA. The effectiveness is about 90 %, like that of mefloquine. It can be used for adults and for stays up to 28 days (soon to be prolonged up to 56 days and probably longer) **and for persons with body weight of more than 40 kg (These restrictions do not apply for the USA).** As with mefloquine, it is recommended for chemo-prophylaxis in areas, where there is chloroquine resistance and for treatment of uncomplicated malaria. This combination is much better tolerated than mefloquine. The combination is not associated with neuropsychiatric adverse effects, impairment of psychomotor performance, mood changes, sleepiness and fatigue, especially under hypobaric conditions. **Side effects** are minimal and do not last very long, they may include: cough, gastrointestinal disturbance (nausea, vomiting, abdominal discomfort and pain, diarrhoea) and headache. **Contraindications** are severe liver disorders and severe renal insufficiency (Creatinine-Clearance < 30 ml/min). **Due to the short time of administering (1 day before up to 7 days after staying in a malaria risk area) the combination is particularly suitable for flight crews. Acceptability of the drug by the compliance of patients proved to be very high.**

Atovaquone + Proguanil (Malarone®)

Contents:	- Atovaquone (250 mg) + Proguanil (100 mg)
Intake:	- 1 Tablet. / d, starting 1 to 2 days before mission, continuing for 7 days after leaving risk area

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N.B.:	- Maximum stay in risk area 28 d (Longer term intake is under consideration.) - effectiveness as mefloquine (90 %), tolerability better
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d) Doxycycline

The antibiotic doxycycline is not officially approved for pilots yet, but it is being used in military pilots in high - risk areas, because of the lack of an effective alternative. It is not licensed for chemo-prophylaxis of malaria in some European Countries, but is used in the UK and the U.S. It is used for prophylaxis in areas with multi-resistant plasmodia (resistance against chloroquine, and proguanil, and mefloquine). This applies to the border areas between Thailand and Myanmar and Thailand and Cambodia. **For the time being Doxycycline is regarded as effective as Atovaquone + Proguanil (Malarone®) or Mefloquine (Lariam®) for chemo-prophylaxis by some Societies for Tropical and Travel Medicine in Europe. It can be used instead of them, where these are recommended.**

Side effects can include gastrointestinal disturbances (nausea, vomiting, diarrhoea), photo-dermatitis (care must be taken with solar radiation in tropical areas), very rarely it can cause increased intra-cranial pressure.

Contraindications are children < 8yrs, severe liver disorders.

Doxycycline (several brand names)	
Content:	- 100 mg Doxycycline
Intake:	- 1Tbl. / d, starting 1 week before exposure, continuing for 4 weeks after leaving risk area
N.B.:	- Must be taken with plenty of fluid - Contraindicated in children < 8 yrs and pregnant women - Beware of photo-dermatitis (solar radiation!)

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5.1.3 ~~Standby Prophylaxis~~ Standby Emergency Treatment

In ~~Standby Prophylaxis~~ Standby Emergency Treatment patients ~~can~~ take an anti-malarial with them. This **should** be used ~~should~~ if symptoms suspicious of malaria (e.g. fever > 38,5 °C, pain in the head and limbs, nausea and malaise) **should** occur, at least one week after having entered a risk area. Standby ~~therapy prophylaxis~~ **Emergency Treatment can be recommended** in areas with low transmission risk, ~~or short stays, or~~ intolerance of anti-malarials **or where side-effects of chemo-prophylaxis outweigh the malaria-risk.** European recommendations, (e.g. Swiss and German Societies of Tropical Medicine, 2001) advise standby precautions. Furthermore, **Standby Emergency Treatment** should be recommended if chemo-prophylaxis with chloroquine / proguanil is used, particularly if a more effective prophylaxis cannot be used in pilots or where there is intolerance. **It can be considered especially in case of frequent short stops in endemic areas over a prolonged period of time. However, it does not replace exposure prophylaxis, which should be carried out meticulously.**

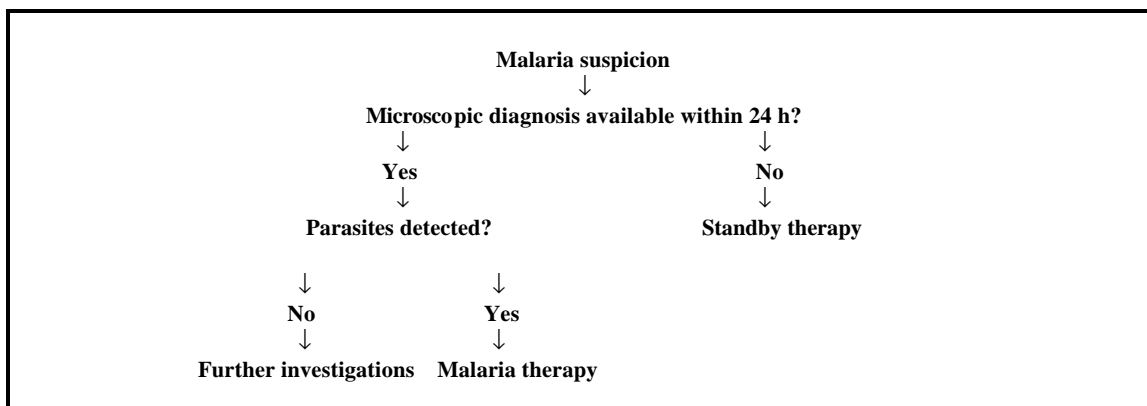
If fever or other symptoms suspicious of malaria occur and no doctor is available, the standby drug should be taken by way of self- medication. As soon as possible a physician trained in tropical medicine should be consulted. **After having taken the Standby Emergency Treatment, flight crew are not fit for flying duties for four weeks.**

Procedure if malaria is suspected

Requirements:	symptoms suspicious of malaria Stay in risk area for at least 7 d No doctor available for next 24 h
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*If applicable microscopic investigations have to be repeated every 6 h or in fever attacks

Depending on the destination, different drugs have been recommended for standby prophylaxis. Halo fantrin (Halfan®) and the combination of Pyrimethamin und Sulfadoxin (Fansidar®) are not now recommended by most European Societies of Tropical Medicine. This is due to a variety of serious side effects including cardiac arrhythmias.

In remote areas Standby Emergency Treatment can be appropriate, if malaria symptoms occur even though chemoprophylaxis has been taken and medical assistance is not available within the next 24 hours. The choice of drugs depends on the type of chemoprophylaxis taken before. Furthermore, a drug with no resistance in the respective area should be used. Because of lack of data no recommendation for Standby Emergency Treatment after chemoprophylaxis with Atovaquone/Proguanil can be given.

Choice of drugs for Standby Emergency Treatment according to previous chemoprophylactic regimen (International Travel and Health (2004), WHO, Geneva)

Prophylactic regimen	Standby Emergency Treatment
None	Chloroquine, for <i>P. vivax</i> areas only Mefloquine Quinine Artemether/Lumefantrine ^a Atovaquone/Proguanil ^a
Chloroquine alone / with Proguanil	Mefloquine Quinine
Mefloquine	Quinine ^b Quinine + Doxycycline/Tetracycline for 7 d ^b
Doxycycline	Mefloquine Quinine + Tetracycline for 7 d

^a Limited experience of drug interactions with other antimalarial drugs, therefore these drugs not recommended if taking already other antimalarial

^b Mefloquine to be resumed 7 days after last dose of Quinine

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Dosages in Standby ~~Therapy~~ Emergency Treatment

	Mefloquin (Lariam®) (Tbl. à 250 mg)	Atovaquon/Proguanil (Malarone®) (Tbl. à 250 mg/100 mg)	Artemether/Lumefantrin (Riamet®) (Tbl. à 20 mg/120 mg)	Chloroquine (Resochin®) (Tbl. à 150 mg)
d₁	Initially 3 Tbl. After 6 – 8 h 2 Tbl. After 6 – 8 h 1 Tbl.	Initially 4 Tbl.	Initially 4 Tbl. After 8 h 4 Tbl.	Initially 4 Tbl. After 6 h 2 Tbl.
d₂	-	4 Tbl.	2 x 4 Tbl.	2 Tbl.
d₃	-	4 Tbl.	2 x 4 Tbl.	2 Tbl.
Area	All malaria areas	All malaria areas	All malaria areas	Only in areas without chloroquine resistance

Guidelines for Standby Emergency Treatment (International Travel and Health (2004), WHO, Geneva)

- Consult a physician immediately if fever occurs 1 week or more after entering an area with malaria risk.
- If it is impossible to consult a physician and/or establish a diagnosis within 24 hours of the onset of fever, start the stand-by emergency treatment and seek medical care as soon as possible for complete evaluation and to exclude other serious causes of fever.
- Complete the stand-by treatment course and resume antimalarial prophylaxis 1 week after the first treatment dose. Mefloquine prophylaxis, however, should be resumed 1 week after the last treatment dose of quinine.
- Vomiting of antimalarial drugs is less likely if fever is first lowered with antipyretics. A second full dose should be taken if vomiting occurs within 30 minutes of taking the drug. If vomiting occurs 30–60 minutes after a dose, an additional half-dose should be taken. Vomiting with diarrhoea may lead to treatment failure because of poor drug absorption.
- Do not treat suspected malaria with the same drugs used for prophylaxis, because of the increased risk of toxicity and resistance.

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6.1 Travellers' diarrhoea

Travellers' diarrhoea is the most frequent disorder encountered in tropical and sub-tropical regions (at least 30 to 50 % of travellers). Risk and incidence increase with poor hygienic conditions. Eating with local people and food purchased from street vendors pose a special risk. Ice produced from unknown water sources is a common cause of travel diarrhoea.

The infection is acquired by fecal-oral transmission and is caused by contaminated food, beverages or smear/saliva infection. Causative agents are bacteria (e.g. enteric salmonella, pathogenic Escherichia coli, especially ETEC, Shigella, Yersinia and Campylobacter), their toxins (which can cause the food poisoning), several viruses (e.g. Rota and Norwalk virus) and protozoa. The most common are Amoeba and Giardia, and with increasing frequency Cryptosporidia. In acute diarrhoea, bacteria is the most common cause. In chronic diarrhoea, parasites are the most common cause.

Risk factors for travellers' diarrhoea

<p>Destination Season (in subtropical destinations) Duration of stay Style of stay (Hotel during Layover < circular tour < adventure trip) Lodging, low standard of hygiene Neglect of food and beverage hygiene</p>

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Reduced gastric acid (H₂-Blockers, Proton Pump Blockers, previous gastric resection)
Reduced immune response
Previous stay in third-world country (> 6 m before)

6.1.2 Clinical features and diagnosis

Normally travellers' diarrhoea starts on the third day of stay. **The Incubation period** can be only some hours, or up to several days. Bacterial and viral infections are usually of 6 to 12 hours. A shorter incubation (frequently only 30 minutes) is normally caused by food poisoning. Typical symptoms are, more than three liquid stools. Every type of diarrhoea can cause dehydration and a reduction of the electrolytes, potassium and bicarbonate. **The mean duration** is 3 to 4 days, 10 % may take more than one week, and only 1 % may result in a chronic form of diarrhoea (duration > 3 weeks).

Uncomplicated diarrhoea is common, presenting as gastroenteritis or entero-colitis with watery diarrhoea, rarely covered by mucus, diffuse abdominal pain, vomiting and temperatures of maximum 38,5°C. Typical for dysentery (up to 10 % of travel diarrhoea) are stools mixed with blood or pus (resulting from invasion of the colonic mucosa), intestinal cramps and fever up to > 40°C.

Most patients suffer a self-limiting disorder, and often by the time a visit is made to the physician, the symptoms have subsided. Therefore, a **diagnosis is not necessary** in most cases. If further diagnostic is intended, Salmonella, Shigella, Yersinia and Campylobacter should be checked for. Negative results do not rule out an infectious cause, because travel diarrhoea is almost always of an infectious origin. Many leukocytes detected by stool examination may indicate dysentery or invasive enteritis. However, in case of a fever > 38,5 °C and / or blood or pus, further diagnostic tests are mandatory.

6.1.3 Therapy

Symptomatic treatment – mostly as self-therapy (This information has to be given to flight crew) - and is usually sufficient. Fever > 38,5 °C and / or blood or pus, makes it necessary for a consultation with a doctor and the fever will require specific therapy.

a) Symptomatic Therapy

Fluid loss resulting from diarrhoea requires urgent fluid replacement. Motility inhibitors may be used as a supplementary measure:

Rehydration

- Mild cases: fruit juice, tea with sugar, broth, juice of coconut, in children, cola and salt sticks.
- More severe cases: solution recommended by WHO (sodium chloride 3.5 g, sodium bicarbonate 2.5 g, potassium chloride 1.5 g, glucose or sugar 40.0 g, water ad 1000 ml, available also as ready mix e.g. Elotrans®, Oralpädon®, Rehydrat, Dioralyte, etc or do it yourself solution with a 10ml spoonful of glucose or sugar, a 5ml teaspoon of salt or half salt/ half baking powder plus one litre of fluid.
- Fluid loss of > 10 % body weight: infusion therapy.

Motility Inhibitors

- Loperamid (Imodium®): initially 2 cps (4 mg), then 1 cps (2 mg) after every subsequent loose bowel movement
Max. 12 mg/24 h, not to be used for more than 48 hr, not to be used for children < 2 a or dysentery (fever or bloody diarrhoea).

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b) Specific Therapy

In case of cholera or infection with Shigella, parasites, typhoid fever or para-typhus a specific treatment by specific antibiotics is required. Otherwise a calculated antibiotic treatment can be prescribed for 3 to 5 days. Antibiotics do not replace fluid replacement! **Whilst taking antibiotic therapy, flight crew are unfit for flying duties, until they are fully recovered and the antibiotic therapy has been stopped.**

Antibiotic therapy for travellers' diarrhoea

Disease	Therapeutic Options
Diarrhoea without knowledge of the causative agent (calculated antibiotics)	Ciprofloxacin 2 x 500 mg/24 h for 3 – 5 days Norfloxacin 2 x 400 mg/24 h for 3 – 5 days Ofloxacin 2 x 200 mg/24 h for 3 – 5 days
Cholera	Tetracycline 2 x 500 mg/24 h for 5 days
Shigella	Ampicillin 2 - 4 x 500 mg/24 h for 5 days Trimethoprim/Sulfamethoxazol 160 mg/800 mg 2 x 1/24 h for 5 days Ciprofloxacin 2 x 500 mg/24 h for 3 – 5 days Norfloxacin 2 x 400 mg/24 h for 3 – 5 days Ofloxacin 2 x 200 mg/24 h for 3 – 5 days
Campylobacter	Azithromycin 1 x 500 mg for 3 days Erythromycin 4 x 500 mg/24 h for 7 days
Giardia	Tinidazole/Metronidazole 2 g as a single dose

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Annex 2 - 008

see attached file "4-2Annex 2 - 008MedCert" for further eference

Annex 4-033 :

See attached pdf file "4-3Annex 4-033AvPsyEdmunds" for further reference