

# Staff Instruction

Subject: Medications and Aviation Medical Certification

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#### 1.0 Introduction

## 1.1 Purpose

(1) The purpose of this document is to provide guidance for consistency in assessing aviation Medical Certificate (MC) applicants with respect to the safe and acceptable use of medications in the aerospace environment.

#### 1.2 Applicability

(1) This Staff Instruction (SI) is applicable to Transport Canada (TC) Civil Aviation Medicine (CAM) Branch personnel, contractors, Civil Aviation Medical Examiners (CAMEs), and other personnel appointed by the Director of Civil Aviation Medicine (DCAM) to be involved in the assessment of MC applicants.

### 1.3 Description of changes

(1) Not applicable.

# 2.0 References and requirements

#### 2.1 Reference documents

- (1) The following reference materials may be used in conjunction with this document:
  - (a) <u>Aeronautics Act</u> (R.S.C., 1985, c. A-2)
  - (b) Canadian Aviation Regulations (CARs), Part IV, subpart 4
  - (c) Staff Instruction (SI) 404-001 Issue 01 Aeromedical Risk Assessment and Risk Management (RDIMS 14833813)
  - (d) SI 424-001 Issue 01 Aviation Medical Review Board Terms of Reference (RDIMS 14918090)
  - (e) SI 404-002 Issue 01 Civil Aviation Medicine Cannabis Policy (RDIMS 15099194)
  - (f) Canadian Armed Forces Flight Surgeon Guideline 1900-01 Medications and Aircrew

#### 2.2 Cancelled documents

- (1) Not applicable.
- **2.3 Definitions and abbreviations** (additional abbreviations will be described in the Appendices)
- (1) The following **abbreviations** are used in this document:
  - (a) **AA:** Aeronautics Act
  - (b) AMO: Aviation Medical Officer
  - (c) CAM: Civil Aviation Medicine
  - (d) **CAME**: Civil Aviation Medical Examiner
  - (e) **ICAO**: International Civil Aviation Organization
  - (f) MC: Medical Certificate

(g) MER: Medical Examination Report

(h) **eMER**: electronic Medical Examination Report

(i) RAMO: Regional Aviation Medical Officer

(j) SI: Staff Instruction

(k) **TC**: Transport Canada

# 3.0 Background

- (1) Medications of all types prescription, non-prescription, herbal, and natural medications have the potential to pose risks to aviation safety. Section 1.1 of the Physical and mental requirement under Annex II of Standard 424 indicates that applicants must be free of any unsafe "effect or side effect" of any prescribed or non-prescribed medication in order to be eligible for aviation medical certification.
- (2) The purpose of this SI is to provide guidance for consistency in assessing MC applicants with respect to the safe and acceptable use of medications in the aerospace environment. A case-by-case evaluation is generally required, due to the complexity of interacting factors in each individual treatment scenario. To facilitate individualized evaluation while ensuring consistency in approach, this SI provides several Appendices to assist in decision-making.
- This SI complements, but does not replace, the requirement for physicians to apply sound clinical judgement, experience, and discretion.

## 4.0 Assessment process

#### 4.1 CAME examination and applicant reporting obligations

- (1) As part of the aviation medical examination, CAMEs are required to ask MC applicants about all medication use, including all prescription, non-prescription, herbal and natural medications currently in use or that have been used since the last aviation examination (even if discontinued). MC applicants are obligated to disclose this information and not make any false representations, in accordance with section 7.3(1) of the AA.
- (2) At each examination, CAMEs should remind MC applicants that self-medication is not recommended and to contact their CAME when commencing new medications or changing doses of medication before undertaking aviation duties.

#### 4.2 Renewal by CAME

- (1) In general, CAMEs may renew MCs for applicants if they are on medications that have been previously reviewed and approved by CAM <u>for that individual</u>. Both the underlying medical condition for which the medication is taken and the medication type and dosing must be stable.
- (2) In order to assist CAMEs in assessing other medications, the following reference information is provided:
  - (a) Appendix A is a non-exhaustive list of high-risk medications that are not considered compatible with aviation safety. CAMEs may not renew applicants who are taking these medications and must request CAM review, unless the medication has already been approved by CAM in accordance with para 4.2(1) for that individual.

- (b) **Appendix B** is a non-exhaustive list of **low-risk medications** that may be considered compatible with aviation medical certification, if in the CAME's clinical judgement their use and the underlying medical condition are unlikely to affect aviation safety.
- (c) Appendix C is a non-exhaustive list of factors to assist in assessing applicants taking medication for compatibility with aviation. CAMEs should refer to this annex when assessing medications that are not in any of the Annexes or if there is doubt about a medication that is generally considered low risk (Appendix B).
- (3) CAMEs who are making an assessment of a medication for an individual are required to document the following in the MER, at a minimum:
  - (a) The name, dose, frequency, and route of administration of the medication;
  - (b) Dose stability;
  - (c) Details of the underlying medical condition being treated, including stability and compatibility with certification;
  - (d) The absence of any problematic factors after including primary effects, side-effects, or interactions with other medications that could affect aviation safety.
- (4) CAMEs who are uncertain about whether an applicant's use of medication is compatible with aviation certification should either consult with their RAMO before renewing an MC or not renew the MC.
- (5) The preservation of aviation and public safety must be the primary consideration in assessing whether an applicant's use of medication is compatible with aviation certification. Notwithstanding the guidance provided in this SI, CAM might deem certain treatments to be incompatible with certification in individual circumstances.

#### 4.3 Assessment and approval by CAM

- (1) CAM will assess applicants using medications that could affect aviation safety on a case-by-case basis. The assessment must consider the interaction of multiple factors. Some medications may only be compatible with aviation in individual circumstances with specific risk mitigation measures in place. Certain medications are considered incompatible with aviation regardless of the individual case or risk mitigation measures, and certification of applicants using such medications is not generally possible.
- (2) **Appendix C** is a non-exhaustive list of factors that may be used in assessing applicants taking medications. Other considerations not captured in Appendix C may be relevant in individual cases. Appendix C is intended to complement not replace experience, medical judgement, and specialized expertise that informs CAM decision-making.
- (3) If CAM has doubt about whether an applicant may be certified while taking a given medication, the preservation of aviation and public safety will prevail as the overriding consideration, and a conservative approach will generally be taken.

#### 5.0 Information management

(1) Management of aviation medical information shall be in accordance with TC departmental and CAM Branch practices.

# 6.0 Document history

(1) Not applicable.

# 7.0 Contact us

(1) For more information contact: <u>NCRCivAvMedicineInquiries-EnquetesMedecineAeroCivRCN@tc.gc.ca</u>

# Document approved by

Tyler Brooks Director Civil Aviation Medicine

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# Appendix A — High risk medications

#### (1) General

- (a) This is a non-exhaustive list of high-risk medications that are <u>not</u> considered compatible with aviation safety.
- (b) CAMEs <u>may not renew applicants</u> who are taking these medications and <u>must request</u>

  <u>CAM review</u>, unless the medication has been previously reviewed and approved by CAM

  <u>for that individual</u> and the underlying medical condition and the medication dosing

  previously approved are both stable.
- (c) If an applicant has previously taken any of these medications, they may be considered for renewal when enough time has elapsed for complete elimination of the medication with no residual side-effects (ie. "washout" time), as long as there is no disqualifying medical condition present. While the general rule-of-thumb is to wait 5 half-lives, some medications may require more time to be compatible with aviation medical certification.

#### (2) Medication types

- (a) Alpha blockers EXCEPT for medications used for benign prostatic hypertrophy (e.g. Tamulosin)
- (b) Anticholinergics (e.g. Scopolamine, tolterodine, and oxybutynin)
- (c) Antidepressants
  - (i) See Psychiatry SSRI Guideline directive on monotherapy with non-sedating SSRI/SNRI antidepressant that may be approved by RAMO/AMOs
  - (ii) antidepressant medications prescribed for indications other than mood-related diagnoses (e.g. neuropathic pain) also require RAMO/AMO review and approval
- (d) Antihistamines known to have anticholinergic or sedating effects
  - (i) Including diphenhydramine (Benadryl) and dimenhydrinate (Gravol)
- (e) Anti-Parkinsonian medications very high risk; exceptions not generally granted
- (f) Antipsychotics very high risk; exceptions not generally granted
- (g) Antiretroviral therapy (ART)/ reverse transcriptase inhibitors (RTIs)
- (h) Anti-seizure / anti-epileptic / anti-convulsant medications very high risk; exceptions not generally granted
- (i) Benzodiazepines
- (j) Cancer medications
  - (i) Including chemotherapy and Immunomodulating agents (ImiDs) like lenalidomide (Revlimid), pomalidomide (Pomalyst), and thalidomide (Thalomide).
- (k) Cannabinoids very high risk; exceptions not generally granted. See Ref 2.1(1)(e), Civil Aviation Medicine Cannabis Policy
- (I) Cardiac glycosides
  - (i) Including digoxin (Lanoxicaps, Lanoxin, Digibind) and digitoxin (Crystodigin)
- (m) Dementia medications very high risk; exceptions not generally granted
- (n) Disease Modifying Antirheumatic Drugs (DMARDs)
- (o) Glycemic control medications, including insulin

- (p) Isoretinoin (Accutane®)
- (q) Mood stabilizers very high risk; exceptions not generally granted
- (r) Muscle Relaxants
  - (i) Methocarbamol
  - (ii) Cyclobenzaprine
  - (iii) Metaxalone
  - (iv) Tizanidine
  - (v) Baclofen
- (s) Nitroglycerin/ cardiac nitrates very high risk; exceptions not generally granted
- (t) Opioids very high risk; exceptions not generally granted
  - (i) Including morphine, codeine, diacetylmorphine (heroin), hydrocodone, hydromorphone, oxycodone, oxymorphone, meperidine, fentanyl, sufentanil, alfentanil, methadone, propoxyphene, and other narcotic analgesics.
  - (ii) Other medications with opioid receptor activity regardless of reason for use (e.g. Eluxadoline)
- (u) Psychostimulants / amphetamines and other medication used to treat Attention Deficit Hyperactivity Disorder (ADHD) very high risk; exceptions not generally granted
- (v) Sedatives, including hypnotics (e.g. zopiclone and zolpidem) high risk. Limited use may be permitted when used as part of an approved protocol within a recognized Fatigue Risk Management System, which includes minimum grounding periods after use.
- (w) Smoking cessation medications other than nicotine replacement
- (x) Steroids, systemic
- (y) Any other medications which warn against driving or operating heavy machinery while using the medication

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# Appendix B — Low risk medications

#### (1) General

- (a) This is a non-exhaustive list of low-risk medications that may be considered compatible with aviation medical certification, if in the CAME's clinical judgement the use and the underlying medical condition are unlikely to affect aviation safety. CAMEs are required to document the following in the MER, at a minimum:
  - (i) The name, dose, frequency, and route of administration;
  - (ii) Dose stability;
  - (iii) The underlying medical condition being treated, including stability and compatibility with certification;
  - (iv) The absence of any problematic factors after ground testing, including primary effects, side-effects, or interactions with other medications that could affect aviation safety.
- (b) Notwithstanding the general acceptability of these medications, CAM may deem these treatments to be incompatible with certification in individual circumstances.

#### (2) Medication Types

- (a) Analgesics, non-opioid and non-cannabinoid (e.g. acetaminophen)
- (b) Antacids and proton pump inhibitors
- (c) Antidiarrheals (e.g. Loperamide 16 mg daily or less)
- (d) Antifungals
- (e) Antibiotics
  - (i) <u>Except</u> minocycline (refer to RAMO)
- (f) Antihistamines, non-sedating
  - (i) Including Ioratadine (Claritin) and fexofenadine (Allegra)
  - (ii) clemastine (Travist), and cetirizine (Reactine) may be considered as second-line medications if no sedating effects in ground testing
- (g) Antihypertensives
  - (i) <u>Except</u> sympatholytics, guanethidine, most alpha blockers (e.g. prazosin may be acceptable), high dose kaliuretic diuretics (> 25 mg hydrochlorothiazide or equivalent), clonidine, and methyldopa (refer to RAMO)
- (h) Antivirals
  - (i) Including Acyclovir, famcyclovir, and valacyclovir
- (i) Asthma medications (if well controlled and within CAM guidelines; RAMO assessment for initial applicants and new onset may be required)
  - (i) Short acting ß2 agonists (SABA)
    - (A) Including terbutaline, salbutamol, and albuterol
  - (ii) Long acting ß2 agonists (LABA)
    - (A) Including formoterol and salmeterol
  - (iii) Inhaled gluco-corticosteroids (ICS)

- (A) Including fluticasone, budesonide, and beclomethasone
- (j) Contraceptives
- (k) Estrogen or androgen hormone treatment
- (I) Erectile dysfunction medications
  - (i) Including sildenafil (Viagra®) and vardenafil (Levitra®) if no adverse effects, including colour vision effects
  - (ii) Tadalafil (Cialis®) is not recommended due to long half-life
- (m) Gout prophylaxis
  - (i) Allopurinol is acceptable after 14-day grounding on initial treatment to ensure no gout attack is precipitated
- (n) Lipid lowering medications
  - (i) Including statins, cholestyramine, ezetimibe, and fenofibrate
- (o) Nicotine replacement therapy
- (p) Non-steroidal anti-inflammatory drugs (e.g. ibuprofen)
- (q) Topical treatments for skin conditions
- (r) Topical drops for glaucoma
- (s) Thyroid hormone replacement
- (t) Vitamin/Mineral supplements

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# Appendix C — Considerations for assessing medications

#### (1) General

- (a) This is a non-exhaustive list of of factors to consider in assessing whether an applicant's use of medication is compatible with aviation certification.
- (b) CAMEs should refer to this list when assessing applicants taking medications that are not listed in Appendix A or if there is doubt about a medication that is generally considered low risk listed in Appendix B. Any questions should be referred to the RAMO.
- (c) CAM may refer to these factors in assessing applicants taking medications. Other considerations not captured in this list may be relevant in individual cases. This list is intended to complement - not replace - experience, medical judgement, and specialized expertise that informs CAM decision-making.
- (d) It is essential that the decision-making process, including an analysis of relevant considerations and mitigating measures, be fully documented in the MER. Incomplete documentation may result in processing delays for an MC application, or cancellation of an MC renewed by a CAME.

#### (2) Considerations

- (a) Is aviation medical certification possible with the underlying medical condition? If NO, then no further assessment of the medication is necessary, as the underlying medical condition is not compatible with aviation medical certification.
- (b) **Is the treatment effective at managing the underlying medical condition**? If NO, then consider discontinuation of medication if it is not compatible with aviation medical certification.
- (c) Is the treatment considered new, off-label, experimental, or part of a clinical trial? If YES, such medications are not generally considered compatible with aviation medical certification. Refer to RAMO.
- (d) Are less-concerning alternative treatments available? Have they been tried and failed? Less-concerning alternative treatments should be tried before considering a medication that may not be compatible with aviation medical certification.
- (e) Are there effects or side-effects that could affect aviation safety? If YES, then the medication is not compatible with aviation medical certification.
- (f) **Is the dose stabilized?** If NO, aviation medical certification will not be considered until the dosing is stabilized.
- (g) Are there any potential concerning interactions with other concurrent treatments? If YES, then aviation medical certification may not be possible with concurrent treatments. Refer to RAMO.
- (h) Are there any potential effects of the flight environment (e.g. pressure, acceleration, oxygen availability, temperature) which could interact with the treatment? If YES, then medication may not be compatible with aviation medical certification. Refer to RAMO.
- (i) Has the individual completed successful "ground testing" of the medication at the intended dose? If NO, ground testing should be completed before considering aviation medical certification. Refer to RAMO.
- (j) With reference to the Risk Matrix in SI 404-001 "Aeromedical Risk Assessment and Risk Management," is the risk level acceptable? Can the risk be mitigated? If NO, then medication is not compatible with aviation medical certification.

(k) Is the treatment acceptable to other stakeholders (e.g. other Canadian government departments, international regulators, industry)? If NO, then medication may not be compatible with aviation medical certification. Refer to RAMO.

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