Australian Government
Department of Health
Therapeutic Goods Administration

Consultation on the definition of Central Circulatory System (CCS) in the Australian medical device regulations

Stakeholder consultation

Version 1.1, January 2021

TGA Health Safety Regulation

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

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Introduction

The Australian Government endorsed a significant program of reform to further strengthen the regulation of medicines and medical devices in Australia. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates these products and is responsible for implementing the Government's reforms.

In 2015, the Report of the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) made 58 recommendations for reform of the regulatory framework for medicines and medical devices in Australia. The Australian Government Response to the Review of Medicines and Medical Devices Regulation was released in September 2016. The Government accepted 56 MMDR recommendations including Recommendation 20.

Recommendation 20 states that the regulation of medical devices by the Therapeutic Goods Administration (TGA) should, where possible, align with the European Union (EU) framework.

Background

Medical devices are regulated in Australia having regard to the risks (to the individual or public health) considered in the context of the device's intended use. All devices carry some level of potential risk, and the TGA applies scientific and clinical expertise to ensure assessments and decisions are made based on the balance between the benefits and the risks.

The risk classification of medical devices take into account factors such as potential harm, level of invasiveness, duration of use, reliance on power, where in the human body the device is used, intended purpose, the end user (consumers or a person with appropriate knowledge and expertise), etc.

Current CCS Definitions

The definition of the CCS within the Australian medical device framework is reflected in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations), and was established from 2002.

When the Regulations were developed prior to 2002, TGA considered advice from an expert panel, and in taking a risk based approach, included the common iliac arteries in the definition of CCS.

In November 2003, a study group convened by the Global Harmonisation Task Force (GHTF)[1] defined the central circulatory system to include the common iliac arteries, which was aligned with the Australian (AU) definition.

This was further adopted in the International Medical Device Regulators Forum's (IMDRF)[2] final definitions document, authored by the steering committee, in November 2012. In contrast, the

[1] The GHTF was founded in 1993 by the governments and industry representatives of Australia, Canada, Japan, the European Union, and the United States of America. The purpose of the GHTF was to encourage a convergence in standards and regulatory practices related to the safety, performance and quality of medical devices. www.who.int/medical_devices/collaborations/force/en/ www.imdrf.org/ghtf/ghtf-archives.asp

[2] The IMDRF was created in February 2011 as a voluntary group of medical device regulators from around the world to build on the strong foundational work of the GHTF, aiming to accelerate international medical device regulatory harmonization and convergence. www.imdrf.org

EU CCS definition does not include the common iliac arteries (as set out in the EU regulations 2017/745).

In the AU Regulations, the definition states:

central circulatory system means the system in a human being comprising the following vessels:

(a) arteriae pulmonales; (b) aorta ascendens; (c) arteriae coronariae; (d) arteria carotis communis; (e) arteria carotis externa; (f) arteria carotis interna; (g) arteriae cerebrales; (h) trucus brachicephalicus; (i) venae cordis; (j) venae pulmonales; (k) venae cava superior; (l) venae cava inferior; (m) arcus aorta; (n) thoracica aorta; (o) abdominalis aorta; (p) arteriae ilica communis.

The EU regulation 2017/745, chapter 1 – Definitions specific to classification rules states:

'Central circulatory system' means the following blood vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior.

The Health Canada Medical Devices Regulations SOR/98-282 state:

central cardiovascular system means the heart, pericardium, pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aorta, inferior and superior vena cava, renal arteries, iliac arteries and femoral arteries. (*système cardiovasculaire central*) which extends to include the iliac and femoral arteries and is more extensive than both the EU and AU (and IMDRF) definitions.

Comparison of blood vessels in the AU, EU and Health Canada definition of the CCS

AU Regulations	***EU MDR***	***Health Canada Medical Devices Regulations SOR/98-282***
(a) arteriae pulmonales	arteriae pulmonales	pulmonary arteries
(b) aorta ascendens;	aorta ascendens	aorta
(c) arteriae coronariae;	arteriae coronariae	coronary arteries
(d) arteria carotis communis;	arteria carotis communis	common carotid arteries
(e) arteria carotis externa	arteria carotis externa	
(f) arteria carotis interna;	arteria carotis interna	
(g) arteriae cerebrales;	arteriae cerebrales	cerebral arteries
(h) trucus brachicephalicus;	truncus brachiocephalicus	brachiocephalic artery
(i) venae cordis;	venae cordis	cardiac veins
(j) venae pulmonales;	venae pulmonales	pulmonary veins
(k) venae cava superior;	vena cava superior	inferior and superior vena cava
(l) venae cava inferior;	vena cava inferior	
(m) arcus aorta;	arcus aortae	aorta
(n) thoracica aorta;	aorta descendens to the bifurcatio aortae	
(o) abdominalis aorta;		
(p) arteriae ilica communis.		iliac arteries
		femoral arteries
		renal arteries
		heart
		pericardium

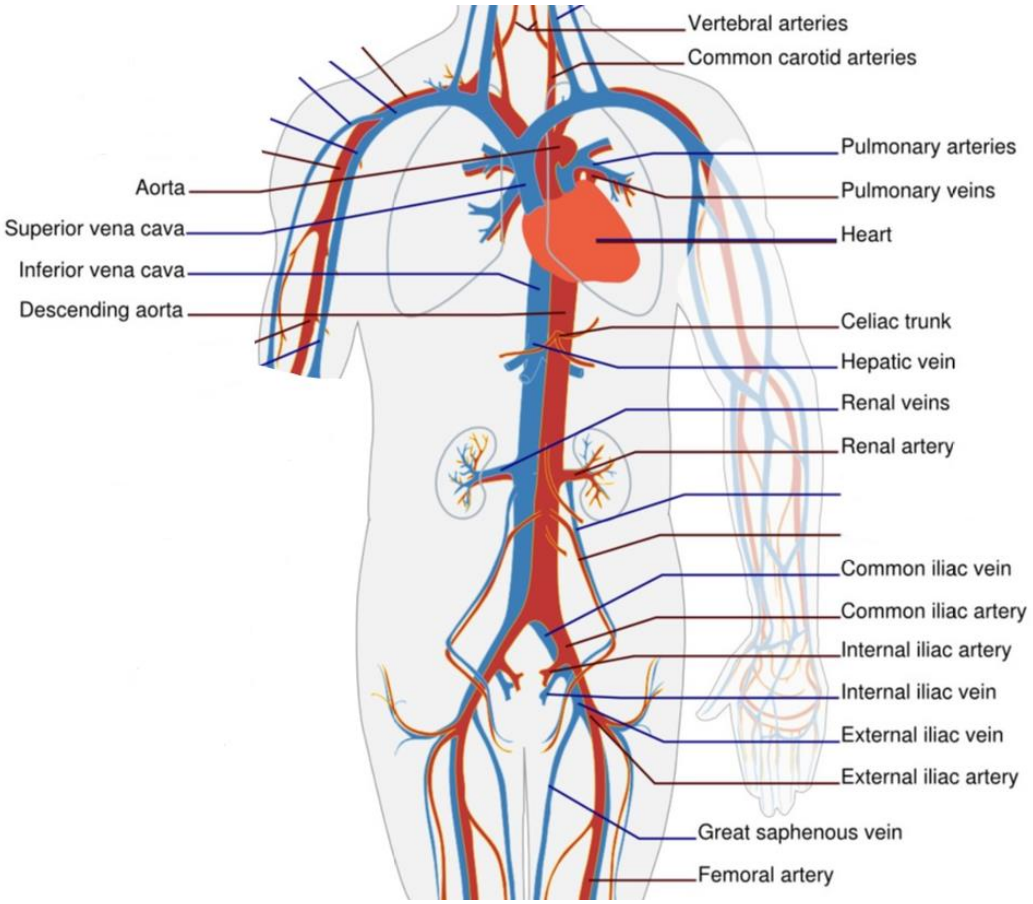

Image: https://upload.wikimedia.org/wikipedia/commons/e/ee/The_circulatory_system.png. Modifications were made to remove names of irrelevant vessels.

As the IMDRF work to harmonize medical device regulation, some jurisdictions align with the IMDRF CCS definition (including Singapore).

Previous consultation

In relation to the alignment with the EU framework, in 2019, the TGA published a consultation paper (Proposed changes to the classification of medical devices used in direct contact with the heart, central circulatory system and central nervous system) that proposed to not amend the definition of CCS in AU medical devices regulations.

TGA received 3 submissions to the consultation, whereby 2 submissions requested the definition of CCS be amended to align with the EU; and another submission raised the issue of misalignment. TGA agreed to undertake further discussions in relation to the issue.

The implications of the differing definition means that some devices are a higher classification in AU (Class III), while they remain at a lower classification in EU (Class IIa).This means to supply to the AU market, a manufacturer needs to obtain further conformity assessment documentation and have suitable clinical evidence commiserate with the Class III classification.

This Consultation

The focus of this paper is to obtain feedback on whether the current definition for the Central Circulatory System (CCS) remains suitable in relation to the risks posed by medical devices used within the CCS.

Issue

In developing the Regulations in the early 2000's, a risk based approach was taken to include the iliac arteries in the definition of the CCS. This definition was adopted by the GHTF and subsequently the IMDRF.

Devices that are affected by the differing definitions across jurisdictions may include, guidewires, stents, catheters, depending on where within the body these devices are intended to be used. A guidewire that is used in the iliac arteries in the EU may be classified as Class IIa, however, in the AU, it is classified as Class III if it comes into contact with the iliac arteries as it therefore comes into contact with the CCS as per the AU definition. Therefore, safety and performance of the devices are subject to greater oversight.

Taking into account new and existing feedback from previous consultations, the TGA is reviewing the AU definition of CCS and is requesting further feedback in relation to this definition, to determine whether any changes should be made.

In October 2020, the TGA sought feedback from the Advisory Committee on Medical Devices (ACMD) with regard to the definition of the CCS and the level of risk posed by devices in contact with the common iliac arteries. The committee noted that the renal, iliac and femoral arteries would usually be considered to be part of the CCS, but that for our risk classification purposes, it would be useful to seek feedback more broadly on the safety of devices that are used within these vessels.

What we invite you to do

In your submission, we ask you to consider and respond to the questions below, and to provide comments on the issues outlined in this consultation paper.

Questions:

1. Do you have any feedback in relation to the risk classification of devices in contact with the common iliac artery and/or other blood vessels of the CCS?

2. Are there any other issues relevant to the safety and performance of devices in contact with the common iliac artery?

How to submit your feedback

Your input and feedback will help inform any changes to the Regulations in relation to the definition of CCS. In addition to the scope of this consultation, we will welcome other feedback on definition of CCS, as well as feedback on our consultation process.

You can submit your feedback using our **online survey tool**
https://consultations.health.gov.au/tga/definition-central-circulatory-system

Please direct any queries via email to devicereforms@tga.gov.au.

This survey closes at 5pm on 10/2/2021

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch	October 2020
V1.1	Minor changes to content.	Medical Devices Branch	January 2021

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