

THE ROYAL AUSTRALIAN COLLEGE OF GENERAL PRACTITIONERS

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| 1. | POLICY TITLE | ENDORSEMENT POLICY |
| 1.1 | Policy number: | CO-O-024.2 |
| 1.2 | Category: | Organisational |
| 1.3 | Approval date: | 8 August 2014 |
| 1.4 | Revision due date: | 7 July 2017 |
| 1.5 | Unit responsible | Office of the President and CEO |

2. POLICY DECLARATION

- 2.1 This Policy determines the rules and procedures for the Endorsement or Acceptance of Products by the RACGP.
- 2.2 Request for RACGP evaluation and recognition of a Product must be considered against this Policy or, if applicable, the RACGP Advertising and Sponsorship Policy.
- 2.3 This Policy is approved by Council.

3. BACKGROUND

3.1 Context

- 3.1.1 The RACGP from time to time is asked to evaluate Products, to recognise those demonstrating credibility in satisfaction of uniform, non-discriminatory and transparent evaluation criteria.
- 3.1.2 As a result of an evaluation, the RACGP may Endorse (highest recognition) a Product, or Accept it as a clinical resource (lesser recognition).
- 3.1.3 Endorsement and Acceptance bestow certain rights and benefits. Among these is the RACGP connection to Products, which is an important marker of quality recognised by general practitioners, and influential in promoting the Product's adoption.

3.2 Strategic objectives

The objectives of this Policy are:

- 3.2.1 to set out clear evaluation criteria to be satisfied by Applicants seeking to have Products Endorsed or Accepted by the RACGP;
- 3.2.2 to determine and distinguish between the evidentiary requirements needed for Products to be Endorsed or Accepted;
- 3.2.3 to set parameters and procedures for the evaluation of Products; and
- 3.2.4 to stipulate the terms upon which Products are Endorsed or Accepted.

3.3 Scope

- 3.3.1 This Policy prescribes the criteria, procedures and terms for obtaining the evaluation of Products for Endorsement or Acceptance by the RACGP.
- 3.3.2 This Policy does not apply to:
 - (a) Products:
 - (1) in which the RACGP holds a complete or partial ownership interest; or
 - (2) which are the subject of specific contractual arrangements between the RACGP and the party offering the Product;
 - (b) advertising otherwise covered under the RACGP Advertising and Sponsorship Policy;

- (c) advertising otherwise covered under editorial guidelines such as for the Australian Family Physician publication; or
- (d) activities accredited under the RACGP QI&CPD Program.

3.4 Definitions and interpretation

In this Policy:

- 3.4.1 “**Accept**” means, in respect of a Product, the determination by Council or its delegate to recognise the Product as an “RACGP Accepted Clinical Resource”, and **Accepted** and **Acceptance** have corresponding meanings.
- 3.4.2 “**Applicant**” means the person or entity submitting a Product for evaluation.
- 3.4.3 “**Application**” means an application for Endorsement or Acceptance of a Product.
- 3.4.4 “**Application Fee**” means the fee payable under clause 4.1.
- 3.4.5 “**Appraisal Instrument**” means the appraisal instrument for assessing the quality of clinical guidelines, such as the AGREE II Instrument published by the Agree Collaboration and available at <http://www.agreecollaboration.org>.
- 3.4.6 “**Endorsement**” means, in respect of a Product, the determination by Council or its delegate to recognise a Product as “Endorsed by the RACGP”, and **Endorse** and **Endorsed** have corresponding meanings.
- 3.4.7 “**Endorsement Fee**” means the fee payable under clause 4.3.
- 3.4.8 “**Event**” takes its common meaning, and may include a single event, a series of events, or a campaign.
- 3.4.9 “**Guideline Development Material**” means any material evidencing the rigorous high-quality procedures utilised by an organisation in internal development of Guidelines including (as appropriate) the evidence base, formulation, evaluation (whether by peer review, independent trialling, or otherwise) and testing.
- 3.4.10 “**Guidelines**” means any evidence based guidelines intended to apply to any information resources or research, clinical and/or evaluation activities whether or not in a clinical context.
- 3.4.11 “**Product**” means any good or service offered or proposed to be offered, in any medium, for commercial exploitation or otherwise (including by a “not-for-profit” organisation) in a market, and includes Guidelines or Events.
- 3.4.12 In the event of any inconsistency between this Policy and the Constitution, the Constitution prevails.
- 3.4.13 All references in this Policy are to this Policy itself, unless otherwise indicated.

4. PROCEDURE

4.1 Application

- 4.1.1 An Applicant may apply to the RACGP to have a Product evaluated.
- 4.1.2 Applications must include:
 - (a) a fully completed Application using the prescribed form; and
 - (b) supporting documentation satisfying clause 4.3.
- 4.1.3 Upon receipt of an Application, the RACGP will evaluate the Product to determine whether it is appropriate for Endorsement or Acceptance. The RACGP may evaluate Products which are:

- (a) free of conflicts of interest;
- (b) appropriate for general practice;
- (c) useful in guiding clinical management;
- (d) considered in the context of the patient's setting; including in relation to co-morbidities and patient preferences; and
- (e) generally appropriate for being Endorsed or Accepted.

4.1.4 The RACGP will not evaluate Products it considers:

- (a) are unsupported by adequate clinical evidence;
- (b) promote goods or services which are:
 - (1) not aligned with the RACGP's views on a particular condition or treatment; or
 - (2) controversial;
- (c) unreasonably undermine or conflict (excluding bona fide market competition) with the intent or purpose of any Products then Endorsed or Accepted by the RACGP;
- (d) do not accord with the RACGP's mission, purpose and strategic direction; or
- (e) have the potential to bring the RACGP into disrepute.

4.1.5 If the RACGP determines the Product is suitable for evaluation, it will notify the Applicant, providing details of the Application Fee, and an estimate of the subsequent Endorsement Fee (payable only if the Product is successfully evaluated).

4.1.6 Following receipt of the Application Fee, the RACGP must submit the Product for peer review by individuals claiming expertise in the relevant field of endeavour (who may or may not be general practitioners) against the relevant evaluation criteria.

4.2 Timeframes

4.2.1 The RACGP will use best endeavours to evaluate the Product and respond to the Applicant within 8 weeks.

4.2.2 This timeline is aspirational, and will be affected by events such as where:

- (a) the Product requires extensive evaluation;
- (b) the Product is provisionally considered to not comply with the required evaluation criteria, in which case the RACGP may:
 - (1) consult with the Applicant regarding any actual or potential impediments;
 - (2) request variations or further submissions to the Product (or the Application) to comply with the evaluation criteria; and
 - (3) where applicable, duly consider any variations of further submissions made by the Applicant; or
- (c) the RACGP considers it appropriate for whatever reason.

4.3 Determination

4.3.1 Following evaluation, a recommendation is made to the RACGP Council for their approval. If Council determines a Product is appropriate for Endorsement or Acceptance, it may Endorse or Accept that Product (as applicable). This Endorsement or Acceptance may be conditional, as determined by the RACGP.

4.3.2 The RACGP will promptly notify the Applicant of the RACGP's determination. This notification must include:

- (a) details of the determination;

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- (b) details of any conditions of the proposed Endorsement or Acceptance;
- (c) a copy of the then current Terms of Licence of RACGP Intellectual Property; and
- (d) an invoice and tax receipt for the Endorsement Fee payable.

4.3.3 An Applicant may agree to the terms of this Endorsement or Acceptance by:

- (a) confirming its agreement by written notice; and
- (b) (where applicable) paying the Endorsement Fee.

4.4 Fees

4.4.1 The Application Fee and the Endorsement Fee must be set according to the prescribed fee schedule, as revised from time to time by the RACGP and published on its website.

4.4.2 In determining applicable fees, the RACGP may consider salient circumstances, such as:

- (a) the nature of the Applicant;
- (b) the ideology, purpose or benefit (actual, potential or perceived) of the Product to general practice, the RACGP or to the community in general;
- (c) any charitable or not-for-profit aspects; or
- (d) any other relevant consideration warranting a reduction or waiver Application Fee and/or Endorsement Fee.

4.4.3 All fees are stated as GST exempt amounts, with GST payable on top of that amount.

4.4.4 Where necessary, Applicants must permit access to an independent auditor to verify compliance

5. EVALUATION

5.1 Endorsement

All Products must satisfy the following criteria in order to be Endorsed:

- 5.1.1 possess inherent quality and integrity of design and/or manufacture;
- 5.1.2 possess a degree of consistency in performance generally considered acceptable in the market-place for Products of that nature in accordance with its intended purpose or outcome;
- 5.1.3 be legally and environmentally compliant, safe, clearly labelled and ideally accompanied with clear instructions as to use, restrictions or limitations (as appropriate);
- 5.1.4 accord with all applicable standards (including those prescribed by the Therapeutic Device Evaluation Committee);
- 5.1.5 be relevant to the conduct of general practice by assisting to:
 - (a) improve the quality of care provided by general practitioners;
 - (b) improve health of our practice population;
 - (c) improve the professional lives of general practitioners; or
 - (d) otherwise “add value” for general practitioners or the RACGP;
- 5.1.6 be promoted, marketed and offered by reputable and solvent entities possessing ethics, integrity, philosophy and image consistent with those of the RACGP;

- 5.1.7 complement and not compete with existing or proposed RACGP activities or Products; and
- 5.1.8 ideally, be capable of integrating with and used by clinical software.

5.2 Guidelines

Further to clause 5.1, Guidelines being evaluated for Endorsement must satisfy the following additional criteria:

- 5.2.1 be produced to National Health and Medical Research Council guidelines standard;
- 5.2.2 be rigorously and transparently evidence informed;
- 5.2.3 be current and based on best available evidence;
- 5.2.4 demonstrate substance and integrity in supporting Guideline Development Material or assessment by an Appraisal Instrument (as appropriate);
- 5.2.5 be free of advertising (actual or perceived) of any commercially available Product with which the Applicant is in any way associated for commercial reward;
- 5.2.6 be balanced and comprehensive (including where relevant providing additional sources of information and support);
- 5.2.7 possess clinical relevance and clarity of presentation;
- 5.2.8 support shared decision making where relevant;
- 5.2.9 be in-line with and not contradict existing RACGP recommendations contained in RACGP resources;
- 5.2.10 be supported by:
 - (a) documentation evidencing a “*strongly recommend*” result by self-assessment utilising an Appraisal Instrument; or
 - (b) appropriate Guideline Development Material establishing credibility of the Guidelines,and
 - (a) particulars of the extent to which general practitioners have been involved in development of the Guidelines;
 - (b) an outline of the strategy for dissemination and implementation of the Guidelines in general practice; and
 - (c) the extent (if any) to which the Guidelines will have national relevance.

5.3 Events

Further to clause 5.1, Events being evaluated for Endorsement must satisfy the following additional criteria:

- 5.3.1 the RACGP must have been involved in the development of the Event;
- 5.3.2 satisfactory educational (or otherwise) content;
- 5.3.3 the commencement and end dates, and the area(s) in which the Event will take place, must be clearly articulated; and
- 5.3.4 be in-line with and not contradict existing RACGP strategic principles.

5.4 Accepted Clinical Resources

A Product may be Accepted if the RACGP considers it makes a useful contribution to general practice, but where it:

- 5.4.1 does not satisfy the requirements for Endorsement articulated in clause 5.1;
- 5.4.2 does not have recommendation and evidence grading;
- 5.4.3 has limited or not clearly described supporting evidence base in the Application or relevant literature; or

5.5 Exercise of discretion

- 5.5.1 All RACGP assessments or evaluations made under this Policy are done so in the RACGP's sole and unfettered discretion.
- 5.5.2 Payment of the Application Fee does not guarantee an outcome, and the RACGP is under no obligation to Endorse or Accept a Product it evaluates.
- 5.5.3 The RACGP accepts no liability or responsibility for any advice or recommendations it receives in the evaluation of a Product.

6. ENDORSEMENT/ACCEPTANCE RIGHTS AND LICENCE

6.1 Endorsed Products

The Applicant for an Endorsed Product may use:

- 6.1.1 the phrase "*Endorsed by the RACGP*"; and
 - 6.1.2 the RACGP Endorsement logo (as supplied),
- but only in association with that Product and only for the period of Endorsement.

6.2 Accepted Clinical Resources

The Applicant for an Accepted Product may use:

- 6.2.1 the phrase "*RACGP Accepted Clinical Resource*"; and
 - 6.2.2 the RACGP Acceptance logo (as supplied),
- but only in association with that Product and only for the period of Acceptance.

6.3 Licence

- 6.3.1 All licence and other rights granted to an Applicant in connection with the RACGP's Endorsement or Acceptance of their Product are subject to:
 - (a) the Applicant's payment of the Endorsement Fee; and
 - (b) this clause 6.3.
- 6.3.2 Unless otherwise notified by the RACGP in writing, Endorsement or Acceptance of a Product (and all rights attached) expires after [3] years.
- 6.3.3 During the period of Endorsement or Acceptance, the Applicant must:
 - (a) comply with all conditions imposed by the RACGP;
 - (b) only use the provided logos in relation to the Product;
 - (c) not misrepresent the scope of their licence;
 - (d) comply with the RACGP Logo Usage Guide, and not use the provided logos in any unauthorised manner, or alter or amend in any way the design elements of the logo;

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- (e) comply with the Terms of Licence of RACGP Intellectual Property, as supplied and amended from time to time;
- (f) ensure the Product remains substantially identical with the evaluated Product (Applicants must seek prior written consent for any such change and pay all appropriate fees, before the Endorsement or Acceptance continues for the changed Product); or
- (g) satisfy any quality assurance audit the RACGP may randomly conduct in respect of compliance of the Applicant and/or the Product with the terms of the Endorsement or Acceptance.

6.3.4 During the period of Endorsement or Acceptance, the Applicant must not:

- (a) breach any of its obligations concerning the Endorsement or Acceptance of the Product; or
- (b) engage in any conduct that may damage the RACGP's reputation or standing.

6.3.5 The RACGP may terminate the Applicant's licence granted under this Clause 7.3 and any Endorsement or Acceptance (as appropriate) for any breach of clause 6.3.3 or a breach of clause 6.3.4.

7. REGISTER OF ENDORSEMENTS

The RACGP shall maintain current a register of Accepted and Endorsed Products, and may publish it on its website.

8. CONFIDENTIALITY

8.1 Publicity

The Applicant must not make any press or other public announcements or releases in connection with the Product evaluation process without the prior approval of the RACGP of the form, content and manner of the announcement or release, unless is required by law or by a stock exchange.

Making any press or other public announcements or releases in connection with a Product's proposed Endorsement or Acceptance prior to receiving official notification of such may impact on the evaluation of that Product.

8.2 Maintaining Confidentiality

Unless required by law, the RACGP agrees to keep details of the Applicant's confidential. The RACGP will only use or disclose information about the Product to the extent necessary to evaluate it.

9. CONTACT AND ENQUIRIES

Representatives and Endorsements Coordinator

The Royal Australian RACGP of General Practitioners

Email: reps&endorsements@racgp.org.au

Phone: 03 8699 0334