health
Department:
Health
REPUBLIC OF SOUTH AFRICA

National Policy for Lodging an Appeal Against a Medicine-Related Decision of the National Essential Medicines List Committee

July 2021 – Version 2.0

Version	Date	Changes
Initial (v1.9)	May 2020	n/a
Second (v2.0)	July 2021	Amended to included updated declaration of interest form (May 2021 version) Approved by Director General (submission signed) Version control table added

Contents

ABBREVIATIONS

AMD	Affordable Medicines Directorate
EDP	Essential Drugs Programme
EML	Essential Medicines List
ERC	Expert Review Committee
NDoH	National Department of Health
NEMLC	National Essential Medicines List Committee
STG	Standard Treatment Guideline

DEFINITIONS

Essential Medicine: A medicine that satisfies the priority health care needs of the population and is selected with due regard to disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness.[1]

Essential Medicines List (EML): The list of medicines determined by the National Essential Medicines List Committee (NEMLC) appointed by the Minister of Health and maintained by the Essential Drug Programme (EDP) of the Affordable Medicine Directorate (AMD). The National EML is deemed to satisfy the priority health care needs of the population.

Essential Drugs Programme (EDP): The unit established in terms of the National Drug Policy (1996) within the AMD, which aims to ensure that affordable, good quality essential medicines are available at all times in adequate amounts, in appropriate dosage forms, to all citizens[2] by implementation of the Standard Treatment Guidelines (STGs) and Essential Medicines List (EML).

Medicine Review: A structured, critical appraisal of evidence relating to use of a medicine, based on academic peer-reviewed evidence to determine quality, safety, efficacy and affordability of such medicine, and used to inform policy and decision-making in the selection of medicine.

Standard Treatment Guidelines (STGs): The implementation mechanism of the EML which provides guidance to health care professionals on the use of medicines which appear on the EML and consists of a collection of chapters containing disorder

[1] World Health Organization. Essential Medicines and Health Products. (http://www.who.int/medicines/services/essmedicines_def/en/ - accessed 05/02/2017)
[2] Minister of Health. National Drug Policy for South Africa. Pretoria, 1996.

groups, background information on the disorder, treatment regimens, as well as other relevant information.

Working Day: Any day other than a Saturday, Sunday or gazetted or statutory holiday.

1. INTRODUCTION

The Essential Drugs Programme (EDP) is one the pillars of the public health system in South Africa. The National Essential Medicines List Committee (NEMLC) is mandated by the Minister of Health to select essential medicines for the three levels of care, namely primary, secondary and tertiary/quaternary. The selection of essential medicines follows a rigorous, evidence-based and peer reviewed process. Expert Review Committees (ERCs), consisting of experts from various fields in the public and private sectors, are established to review the evidence available and make recommendations to the NEMLC.

Once a decision has been made on a medicine by the NEMLC, this is published on the website of the National Department of Health (NDoH) and in the EML Clinical Guide mobile application ("app"). In order to ensure equity and fairness, an appeal may be lodged by any person on a decision made by the NEMLC within 60 days of the publication of such decision on the website of the NDoH.

2. PURPOSE OF THE POLICY

The purpose of this policy is to provide guidance on the procedure for lodging an appeal against a decision made by the NEMLC regarding a medicine.

3. OBJECTIVES OF THE POLICY

The objective of the policy is to provide a transparent and equitable method for an appeal to a NEMLC decision in the development of the National Standard Treatment Guidelines (STGs) and Essential Medicines List (EML), based on fair and evidence-based medicine principles.

4. SCOPE OF THE POLICY

The document provides details relating to the grounds on which an appeal may be lodged, the constitution of an Appeal Panel, the process to be followed in lodging an appeal, the consideration of an appeal and communication of the outcome of such an appeal. Standardised templates to be used are also provided.

The policy does not apply to documents produced during the review process or requests for corrections of minor factual or typographical errors. These requests will be reviewed during the standard STG and EML review process.

5. LEGISLATIVE PROVISIONS

Constitution of the Republic of South Africa (Act 108 of 1996)[3]

Section 27 of the South African constitution provides “access to health care services” as a basic human right for citizens. As such, all reasonable measures must be taken to ensure that this right is protected, promoted and fulfilled within the limits of available resources.

National Health Act (Act 61 of 2003)[4]

The National Health Act states the requirements for the establishment of “a system of co-operative governance and management of health services, within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality health care services”.

The Medicines and Related Substances Act (Act 101 of 1965)[5]

The Act provides the legislative provision for the regulation of medicines to ensure safety, efficacy and quality.

6. GROUNDS FOR APPEAL

The grounds for appeal include only the following circumstances relating to a decision published on a medicine by NEMLC:

1. The NEMLC has failed to act fairly or in accordance with its Terms of Reference; or
2. The decision of the NEMLC is unreasonable in light of the evidence that was submitted to the ERC and then the NEMLC.

The Appeal Panel will generally not rehear evidence or be persuaded by repetition of points previously submitted. unless the appeal falls within one of the categories above.

The following will not be considered by the Appeals Panel and is required to be submitted as a new motivation through the standard process:

1. Evidence published after publication of the NEMLC recommendation; or

[3] Republic of South Africa. 1996. *Constitution of the Republic of South Africa, Act 108 of 1996*. Pretoria, South Africa.
[4] Republic of South Africa. 2003. *National Health Act (Act No. 61 of 2003).* Pretoria, South Africa.
[5] Republic of South Africa. 1965. *Medicines and Related Substances Act (Act No. 101 of 1965).* Pretoria, South Africa.

2. Information that is not applicable to the matter at hand that is being appealed (e.g. an appeal to consider an alternative indication for an approved or non-approved health technology).

7. CONSTITUTION OF AN APPEAL PANEL

The Appeal Panel will consist of five (5) clinical experts appointed by the Chairperson of NEMLC and the Director: Affordable Medicine Directorate (AMD), chosen based on the grounds for appeal (including legal representation, as required). The Chairperson of NEMLC or a person delegated by the Chairperson of NEMLC will chair the Appeal Panel, and the EDP will serve as the secretariat.

Members of the NEMLC who participated in decision-making relating to the subject of an appeal may not be part of the Appeal Panel dealing with that matter. A member of the Appeal Panel must recuse himself or herself if it transpires that he or she has any direct or indirect personal interest in the outcome of the appeal and must be replaced for the duration of the appeal by another appointed person with similar knowledge.

The Appeal Panel must include at least one member of the ERC that made the original recommendation to NEMLC on the matter in question. The appellant may nominate one person who is appropriately qualified to be appointed to serve on such an Appeal Panel.

The NEMLC Confidentiality and Declaration of Interest policies are applicable to all members of an Appeal Panel and declarations, and must be reviewed by the Director: AMD prior to convening of the Appeal Panel. In reviewing the documentation submitted by the appellant, the Appeal Panel should not consult with any other member of the NEMLC, except for the Chairperson of NEMLC as required.

8. PROCESS TO LODGE AN APPEAL

The appeal may be lodged by any affected natural or juristic person, namely a user, health care service provider or health establishment..

Any appeal shall be lodged with the EDP within 60 working days from the day of publication of the decision made relating to the STGs and EML on the NDoH website (www.health.gov.za). Relevant appeals received by other units within NDoH or by Provincial Pharmaceutical and Therapeutics Committees should be forwarded to EDP for consideration.

Only appeals submitted in compliance with the process provided below will be considered.

Intention to Lodge an Appeal
The intention to lodge an appeal (template provided in Appendix 2) is submitted in writing to the EDP, by means of an email to SAEDP@health.gov.za.

The submission must contain (i) an introductory statement indicating clearly the matter to be appealed, and (ii) the permitted grounds on which of the appeal is being made.

EDP informs NEMLC that an intention to lodge an appeal has been received.

Screening
EDP reviews the intention to lodge an appeal, classifies the ground for appeal and makes a decision whether the appeal lodged meets the criteria for an appeal, as specified in Section 6 (Grounds for Appeal).

The Director: AMD informs the appellant accordingly, providing reasons for this decision and where applicable, an explanation why such an appeal will not be considered. Examples of such cases may include, but are not limited to, situations where the medicine in question is currently under review, in which case the EDP may request the appellant to submit comment for inclusion in the review cycle (Appendix 3), or there are no grounds for the appeal as the information provided by the appellant regarding the status of the medicine is not correct. Such a response must be provided within 14 days of receipt of the intention to appeal.

The EDP will maintain a database of reference numbers and related status of applications received.

Appeal Documentation Sent and Reviewed
In cases where a decision has been taken that the appeal will be considered, EDP provides the appellant with the evidence reviewed by NEMLC and the documentation required, including the Appeal Form (Appendix 4) within 14 days of the decision regarding the validity of the appeal.

The appellant reviews the evidence provided and decides whether or not to pursue the appeal.

The appellant indicates in writing to EDP whether or not he/she wishes to pursue the appeal within 14 days of receipt of the documentation.

If the appellant wishes to pursue the appeal, a completed Appeal Form accompanied by the NEMLC Medicine Motivation Form and additional supportive evidence (where applicable) which has not been considered by the NEMLC, is submitted to EDP no later than 45 working days after receipt of the Appeal Form and evidence reviewed by the NEMLC.

The NEMLC chairperson and the Director: Affordable Medicines Directorate appoints an Appeal Panel.

The documentation relating to the intention to lodge an appeal is provided to the panel by the EDP.

EDP screens the appeal documentation submitted by the applicant and indicates to the appellant within 60 days from receipt of the documentation from the appellant on the evidence submitted to accompany the appeal letter are sufficient. EDP may request further information and evidence regarding the documentation submitted by the appellant within these 60 days, which is then to be provided within 60 days from the appellant.

If the EDP determines whether the appeal meets the specified criteria, and if the evidence provided is insufficient will request additional evidence. The EDP sends complete documentation to the Appeal Panel.

Review of the Appeal

The Appeal Panel reviews the documentation provided by EDP. The Appeal Panel may, if it deems necessary, call for oral evidence or argument from the appellant and any person to appear before it at a time and place specified, to answer questions or to produce any document. Any person may be called upon who:

- may be able to give information concerning the subject of the appeal; or
- has in his/her possession or under his/her control, any document which has a bearing on the subject of the appeal.

The EDP may determine the date, time and place for the meeting of the Appeal Panel and shall communicate these in writing to the appellant, members of the Appeal Panel and Director: AMD. Meetings may be conducted telephonically/electronically if required.

The recommendation of the Appeal Panel is tabled at a meeting of the NEMLC within 120 days after the decision is made by the panel.

The NEMLC may request further information from the ERC of origin or Appeal Panel prior to taking a final decision.

The NEMLC makes the final decision regarding the appeal.

The appellant is informed of the outcome of the appeal within 30 days of the final decision by the NEMLC.

9. ROLES AND RESPONSIBILITIES OF STAKEHOLDERS

A description of the main stakeholders and their roles and responsibilities are outlined below in Table 1:

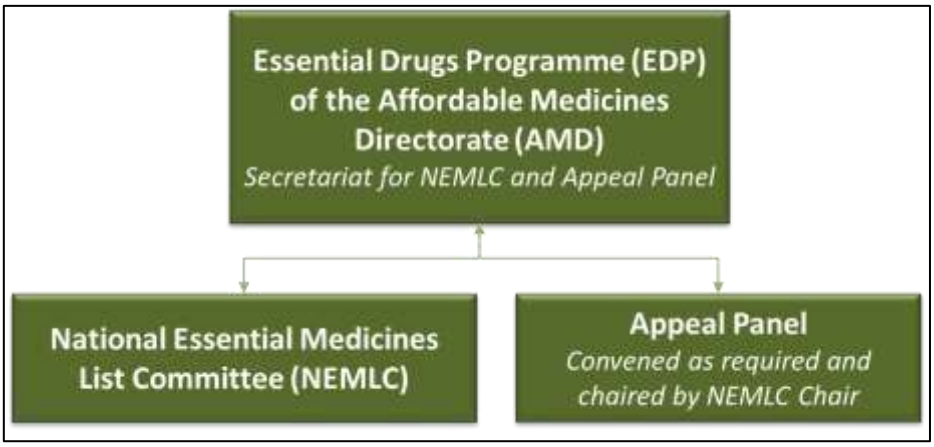
Table 1: Stakeholder Roles and Responsibilities

Stakeholder	Roles and Responsibilities
Appellant	Complete the Appeal Forms and NEMLC Medicine Motivation Form with all relevant data required for the Appeal Panel's review; Respond timeously to EDP and the Appeal Panel when information is requested.
Appeal Panel	Review the appeal on a decision made by NEMLC; Obtain additional information as needed; Provide recommendations on the outcome of the appeal.
Essential Drugs Programme (EDP)	Coordinate the process of appeal with the appellant, Director: AMD, NEMLC and Appeal Panel; Communicate outcomes of appeals to relevant stakeholders.
National Essential Medicines List Committee (NEMLC)	Review decisions following recommendations made by the Appeal Panel. Makes the final decision (ratify decision)
Director: Affordable Medicines Directorate	Constitute the Appeal Panel with relevant clinical experts; Review Declaration of Confidentiality and Declaration of Interest of the proposed Appeal Panel members and appellant representative prior to the commencement of the appeal process.

10. COMMUNICATION

Communication will follow a two-way path between the EDP of the AMD, NEMLC and the Appeal Panel, as shown below:

Figure 1: Communication between EDP, NEMLC and Appeal Panel



11. APPENDIX

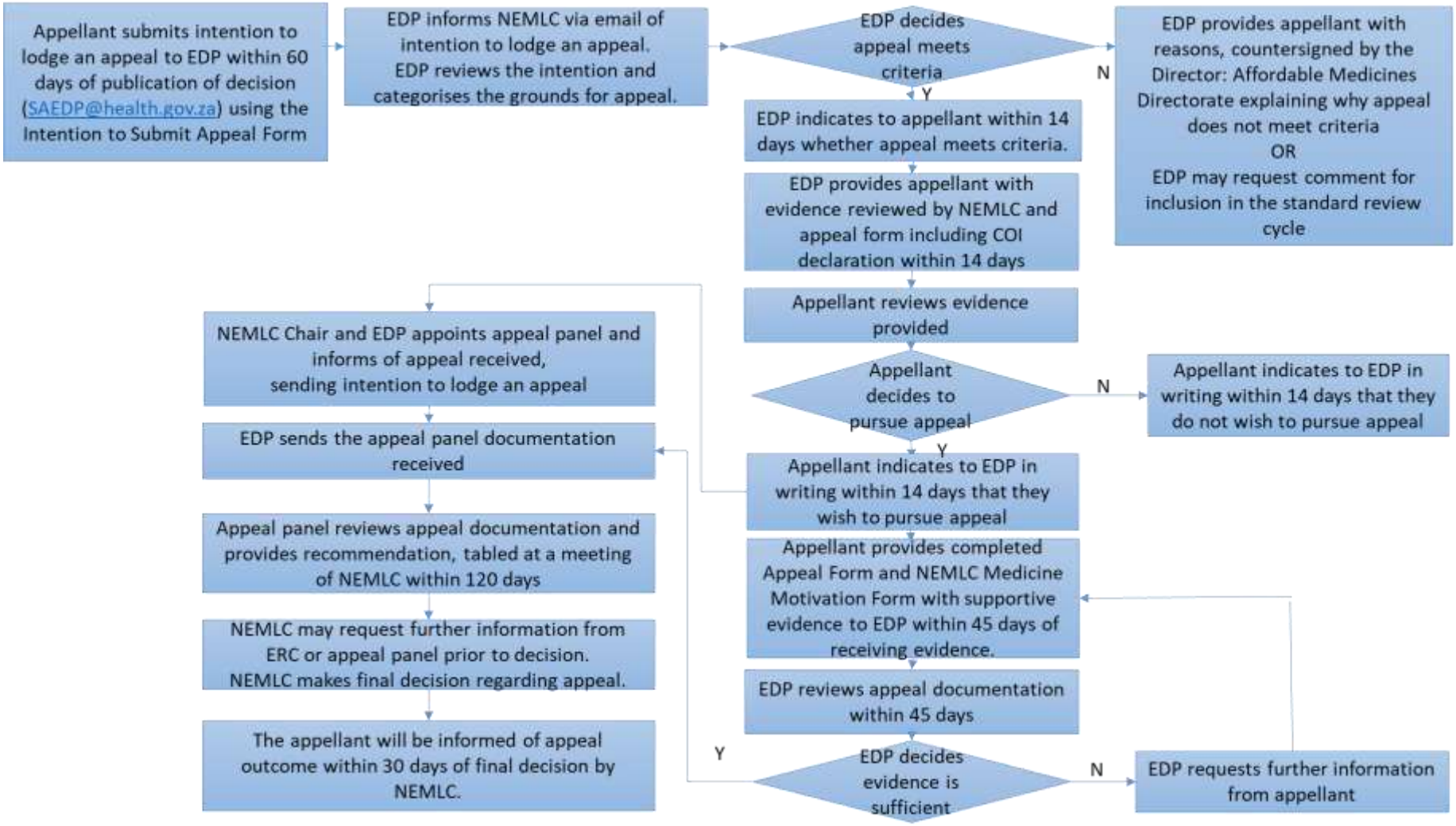
Appendix 1: Appeals Process Flow Diagram

Appendix 2: Letter of Intention to Lodge an Appeal

Appendix 3: Request to Submit Comment Rather than Appeal

Appendix 4: Appeal Form

Appendix 1: Appeals Process Flow Diagram



Appendix 2: Intention to Lodge an Appeal

INTENTION TO LODGE AN APPEAL TO THE NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE ON A MEDICINE-RELATED DECISION

SCOPE

Once a decision has been made on a medicine by the NEMLC, this is published on the website of the National Department of Health (NDoH) and in the EML Clinical Guide mobile application ("app"). In order to ensure equity and fairness, an appeal may be lodged by any person on a decision made by the NEMLC within 60 days of the publication of such decision on the website of the NDoH.

The grounds for appeal include only the following circumstances relating to a decision published on a medicine by NEMLC:

1. The NEMLC has failed to act fairly or in accordance with its Terms of Reference; or
2. The decision of the NEMLC is unreasonable in light of the evidence that was submitted to the ERC and then the NEMLC.

The Appeal Panel will generally not rehear evidence or be persuaded by repetition of points previously submitted. unless the appeal falls within one of the categories above.

The following will not be considered by the Appeals Panel and is required to be submitted as a new motivation through the standard process:

1. Evidence published after publication of the NEMLC recommendation; or
2. Information that is not applicable to the matter at hand that is being appealed (e.g. an appeal to consider an alternative indication for an approved or non-approved health technology).

INSTRUCTIONS

This form should be submitted to the Essential Drugs Programme (EDP) via email on SAEDP@health.gov.za. Please allow 14 working days for processing of the application.

MEDICATION DETAILS

Medicine (INN): *https://www.whocc.no/atc_ddd_index/*	
Indication (ICD10 code): *http://apps.who.int/classifications/icd10/browse/2016/en*	
Dosage form and route of administration:	
Treatment regimen (dose, frequency, duration):	

BRIEF EXPLANATION OF APPEAL

The intention to lodge an appeal form is the first opportunity to present points for appeal. Thus, it is important that this is submitted correctly, presented clearly and contains the necessary information, as explained below. If the form received is not appropriate (e.g. insufficient supporting information or the relevance of the appeal points is unclear), or does not fall within 1 or more of the grounds of appeal (see above), it is possible that the appeal will be dismissed as 'not valid'.

The submission must contain an introductory statement clearly indicating the matter to be appealed, and on which of the permitted grounds the appeal is being made.

The brief explanation must include the following information:

- the ground(s) of appeal (numbered separately for every new ground, with sub-numbering for each new point within each ground e.g. Ground 1(a), 1(b) and so on)
- the aspect(s) being appealed against
- the reasons why the aspect(s) of the final draft guidance or technology appraisal/HST process being appealed against fall within the specified ground(s) of appeal, in enough detail to demonstrate an arguable case
- the concluding statement.

MOTIVATOR'S DETAILS

Name:	**Date submitted:**
Qualification:	**Registration number:**
Telephone Number:	**Email Address:**
PTC Name and Address (if relevant):	**PTC Contact Details:**

By completing this form, the appellant understands that any request for further information relating to the appeal that is not received within 60 days of date of request will result in the appeal being closed.

Adaptation of NICE Guide to the technology appraisal and highly specialised technologies appeal process, 2014.
https://www.nice.org.uk/process/pmg18/chapter/making-an-appeal

NDoH INTERNAL EDP REVIEW:

Date reviewed:	
EDP reviewer(s) name(s):	
Ground(s) of appeal:	
Appeal valid/not valid:	
Director AMD sign-off:	
Action, going forward:	
Reference number:	
Date response submitted to appellant:	

Appendix 3: Request to Submit Comment Rather than Appeal

Dear Sir/ Madam,

Thank you for the Intention to Lodge an Appeal dated [XX/XX/XXXX]. Please note that the disorder for which your appeal refers is/ will be open for public comment as part of the medicine review cycle from [XX/XX/XXXX] to [XX/XX/XXXX].

Therefore, we urge you to provide comment on the relevant disorder, rather than lodging an appeal.

Thanks and Regards,

The Essential Drugs Programme

Appendix 4: Appeal Form

APPEAL TO THE NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE ON A MEDICINE-RELATED DECISION

SCOPE

Once a decision has been made on a medicine by the National Essential Medicines List Committee (NEMLC), this is published in the EML Clinical Guide Application and on the website of the National Department of Health (NDoH). In order to ensure equity and fairness, an appeal may be lodged by any member of the public on a decision made by NEMLC.

INSTRUCTIONS

Please note that an intention to lodge an appeal should be filed with and acknowledged as a valid appeal by the Essential Drugs Programme (EDP) prior to this form being completed.

Please attach a completed NEMLC Medicine Motivation Form, together with body of peer-reviewed evidence to support this application and submit via email on SAEDP@health.gov.za

Note: Only content relating to the approved intention to appeal will be reviewed; please cite the reference number accordingly.

Reference number:

Date:

MEDICATION DETAILS

Medicine (INN): *https://www.whocc.no/atc_ddd_index/*	
Indication (ICD10 code): *http://apps.who.int/classifications/icd10/browse/2016/en*	
Dosage form and route of administration:	
Treatment regimen (dose, frequency, duration):	

EXECUTIVE SUMMARY OF APPEAL

MOTIVATOR'S DETAILS

Name:	**Date submitted:**
Qualification:	**Registration number:**
Telephone Number:	**Email Address:**
PTC Name and Address (if relevant):	**PTC Contact Details:**

DECLARATION OF INTERESTS

1. Have you or an immediate family member gained, or currently gain/s, monetary or other value in your/ their personal capacity from an interaction with any commercial entity* that has or may have an interest in the activities of the committee?

Please select: **Yes** ☐ **No** ☐ **If Yes**, please provide details below:

Person involved **Yourself or family member relationship**	**Commercial entity*** **Name and details**	**Details of Interest** **Refer to AMD Conflict of Interest Policy**
☐ yourself ☐ family Relationship:		
☐ yourself ☐ family Relationship:		
☐ yourself ☐ family Relationship:		
☐ yourself ☐ family Relationship:		
☐ yourself ☐ family Relationship:		

2. Are you employed by or contracted to an organisation or institution that gained, or currently gains monetary or other value from an interaction with any commercial entity*, which has or may have an interest in the activities of the committee and decisions made by the committee?

Please select: **Yes** □ **No** □ **If Yes**, please provide details below:

Organisation or Institution **Name**	**Commercial entity*** **Name and details**	**Details of Interest** **Refer to AMD Conflict of Interest Policy**

**Commercial entity means any commercial company, organisation, individual, group or association that has or may have a direct or indirect interest in the decisions and work undertaken by a committee, and includes legal or natural persons who (i) own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant commercial entity; (ii) are controlled by; or (iii) are under common control of a commercial entity and includes non-profit entities, as well as researchers and research organisations such as universities.*