SINGAPORE MEDICAL COUNCIL
DISCIPLINARY COMMITTEE INQUIRY FOR DR PANG AH SAN
HELD ON 14 TO 16 JULY, 18 JULY, 4 AUGUST, 30 SEPTEMBER AND 15 OCTOBER 2014

Disciplinary Committee:
Prof Lee Eng Hin - Chairman
Prof V Anantharaman
A/Prof Sonny Wang
Ms Serene Wee - Lay Member

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Counsel for SMC:
Ms Chang Man Phing
Ms Charmaine Neo
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Respondent (Appeared in Person):
Dr Pang Ah San

GROUNDS OF DECISION OF THE DISCIPLINARY COMMITTEE

(Note: Certain information may be redacted or anonymised to protect the identity of the parties.)

INTRODUCTION

1. The Respondent, Dr Pang Ah San ("**Dr Pang**"), is a registered medical practitioner under the Medical Registration Act (Cap. 174) (2004 Ed.) ("**the Act**"). Dr Pang faced three charges of professional misconduct under section 45(1)(d) of the Act (the "**Charges**"). Dr Pang had about 26 years of experience at the time of the Charges and practised surgery at Mount Alvernia Hospital ("**MAH**").

2. All the Charges against Dr Pang concern the breach of Clause 4.1.4 of the Singapore Medical Council's ("**SMC**") Ethical Code and Ethical Guidelines ("**ECEG**"). Clause 4.1.4 reads as follows:

> "*A doctor shall treat patients according to generally accepted methods and use only licensed drugs for appropriate indications. A doctor shall not offer to patients management plans or remedies that are not generally accepted by the profession, except in the context of a formal and approved clinical trial.*
>
> *A doctor who participates in clinical research must put the care and safety of patients first. If a doctor wishes to enter a patient into a clinical trial, he must ensure that the trial is approved by an ethics committee and conforms to the Good Clinical Practice Guidelines. In addition, informed consent must be obtained from the patient.*
>
> *It is not acceptable to experiment or authorise experiments of research which are not part of a formal clinical trial and which are not primarily part of treatment or in the best interest of the patient, or which could cause undue suffering or threat to the life of a patient.*"

3. The Charges arose from Dr Pang having provided treatment—outside the context of a formal and approved clinical trial—to Mdm P1, Mr P2 and Mdm P3 (the "**Patients**") where such treatment was allegedly not generally accepted by the profession. These treatments (the "**Treatments**") concerned the insertion of a "loop" percutaneous endoscopic gastrostomy tube ("**Loop PEG Tube**"). A Loop PEG Tube is an external feeding device inserted directly into the stomach and is used by patients who are unable to swallow.

4. The complaint that gave rise to the Charges was lodged with the SMC on 29 September 2010 by Dr Harold Tan, a Director in the Regulatory Compliance and Enforcement Division of the Ministry of Health ("**the Complaint**"). The Complaint was the result of two emails the Ministry of Health received in October 2009 from Dr PW1, the then Chairman of MAH's Ethics Committee ("**EC**"). The Complaint was investigated by the SMC's Complaints Committee ("**CC**"). The Respondent did not submit a formal explanation to the CC but sent two short letters dated 20 July 2011 and 26 January 2013.

5. The Notice of Inquiry served on Dr Pang sets out the Charges (as amended) as follows:

> "*Notice is hereby given to you that in consequence of a complaint made against you to the Medical Council, an inquiry is to be held by the Disciplinary Committee into the following charges against you:*
>
> 1. *That you, DR PANG AH SAN, a registered medical practitioner under the Medical Registration Act (Cap. 174) ("**Medical Registration Act**"), are charged that whilst practising at Mount Alvernia Hospital, between 20 October 2007 and 5 November 2007, you provided treatment to Mdm P1 (the "**Patient**") that was not generally accepted by the profession outside the context of a formal and approved clinical trial, in breach of Clause 4.1.4 of the Singapore Medical Council's Ethical Code and Ethical Guidelines (the "**ECEG**").*
>
> *Particulars*
>
> *i) Clause 4.1.4 of the ECEG provides, amongst other things, that a doctor shall not offer to a patient remedies that are not generally accepted by the profession except in the context of a formal and approved clinical trial;*
>
> *ii) On or about 24 October 2007, you recommended the insertion of a "loop" percutaneous endoscopic gastrostomy tube (a "**Loop PEG Tube**") for the Patient;*
>
> *iii) The Loop PEG Tube was a novel device in that it differed from the normal percutaneous endoscopic gastrostomy tube in terms of design and inserted position, and was therefore not a device that was generally accepted by the profession;*
>
> *iv) Accordingly, the pre-operative procedures and protocols, the insertion of the Loop PEG Tube as well as the post-procedure*

treatment and protocols all ought to have been carried out only in the context of a formal and approved clinical trial;

v) *On 25 October 2007, you performed surgery on the Patient to insert a Loop PEG Tube, and you did so outside the context of a formal and approved clinical trial;*

vi) *Following the insertion of the Loop PEG Tube, you provided post-operative care and monitoring of the Patient outside the context of a formal and approved clinical trial;*

and that in relation to the facts alleged, you have been guilty of professional misconduct within the meaning of section 45(1)(d) of the Medical Registration Act.

2. *That you, DR PANG AH SAN, a registered medical practitioner under the Medical Registration Act, are charged that whilst practising at Mount Alvernia Hospital, between 24 January 2008 and 5 February 2008, you provided treatment to Mr P2 (the "**Patient**") that was not generally accepted by the profession outside the context of a formal and approved clinical trial, in breach of Clause 4.1.4 of the ECEG.*

<u>Particulars</u>

i) *Clause 4.1.4 of the ECEG provides, amongst other things, that a doctor shall not offer to a patient remedies that are not generally accepted by the profession except in the context of a formal and approved clinical trial;*

ii) *On or about 29 January 2008, you recommended the insertion of a "loop" percutaneous endoscopic gastrostomy tube (a "**Loop PEG Tube**") for the Patient;*

iii) The Loop PEG Tube was a novel device in that it differed from the normal percutaneous endoscopic gastrostomy tube in terms of design and inserted position, and was therefore not a device that was generally accepted by the profession;

iv) Accordingly, the pre-operative procedures and protocols, the insertion of the Loop PEG Tube as well as the post-procedure treatment and protocols all ought to have been carried out only in the context of a formal and approved clinical trial;

v) On 31 January 2008, you performed surgery on the Patient to insert a Loop PEG Tube, and you did so outside the context of a formal and approved clinical trial;

vi) Following the insertion of the Loop PEG Tube, you provided post-operative care and monitoring of the Patient outside the context of a formal and approved medical trial;

and that in relation to the facts alleged, you have been guilty of professional misconduct within the meaning of section 45(1)(d) of the Medical Registration Act.

*3. That you, DR PANG AH SAN, a registered medical practitioner under the Medical Registration Act, are charged that whilst practising at Mount Alvernia Hospital, between 17 February 2009 and 6 March 2009, you provided treatment to Mdm P3 (the "**Patient**") that was not generally accepted by the profession outside the context of a formal and approved clinical trial, in breach of Clause 4.1.4 of the ECEG.*

<u>Particulars</u>

i) Clause 4.1.4 of the ECEG provides, amongst other things, that a doctor shall not offer to a patient remedies that are not

generally accepted by the profession except in the context of a formal and approved clinical trial;

ii) *On or about 17 February 2009, you recommended the insertion of a "loop" percutaneous endoscopic gastrostomy tube (a "**Loop PEG Tube**") for the Patient;*

iii) *The Loop PEG Tube was a novel device in that it differed from the normal percutaneous endoscopic gastrostomy tube in terms of design and inserted position, and was therefore not a device that was generally accepted by the profession;*

iv) *Accordingly, the pre-operative procedures and protocols, the insertion of the Loop PEG Tube as well as the post-procedure treatment and protocols all ought to have been carried out only in the context of a formal and approved clinical trial;*

v) *On 19 February 2009, you performed surgery on the Patient to insert a Loop PEG Tube, and you did so outside the context of a formal and approved clinical trial;*

vi) *Following the insertion of the Loop PEG Tube, you provided post-operative care and monitoring of the Patient outside the context of a formal and approved clinical trial;*

and that in relation to the facts alleged, you have been guilty of professional misconduct within the meaning of section 45(1)(d) of the Medical Registration Act."

THE FACTS

6. A summary of the significant facts, which were substantially not in dispute, are as follows:

6.1. Dr Pang submitted an application to the MAH EC in November 2006 to conduct a pilot study on the feasibility of adding gastropexy (apposition) to the standard percutaneous endoscopic gastrostomy tube (a "**PEG**"). However, Dr Pang subsequently withdrew this application because of a failure to obtain funding for the project.

6.2. Dr Pang filed an application for a patent for the "LOOPPEG™ 3G", a device substantially similar to the Loop PEG Tube sometime in October 2007 (before his initial consultation with the first Patient). The patent was granted on 31 August 2009.

6.3. All the Patients were elderly, in poor health, and were on nasogastric tube feeding.

6.4. Dr Pang recommended the Treatment to all the Patients—i.e. the insertion of a percutaneous endoscopic gastrostomy tube in a loop configuration as opposed to the standard PEG which is a direct feeding tube not in loop formation.

6.5. Dr Pang did not submit any clinical trial application, prior to the Treatments, to the MAH EC for the Loop PEG Tube for use on the Patients.

6.6. Between 20 October 2007 and 5 November 2007, Dr Pang provided treatment to Mdm P1. On 25 October 2007, Dr Pang performed surgery on her and inserted a Loop PEG Tube.

6.7. Between 24 January 2008 and 5 February 2008, Dr Pang provided treatment to Mr P2. On 31 January 2008, Dr Pang performed surgery on him and inserted a Loop PEG Tube.

6.8. Dr Pang registered a trademark for the LOOPPEG on 14 November 2008.

6.9. Between 17 February 2009 and 6 March 2009, Dr Pang provided treatment to Mdm P3. On 19 February 2009 Dr Pang performed surgery on her and inserted a Loop PEG Tube.

6.10. The surgery and post-operative care in the case of the Patients was not carried out in the context of a clinical trial.

6.11. Dr Pang submitted an application dated 6 October 2009 to MAH's Ethics Committee ("**EC**") to conduct a survey on the patients' and caregivers' satisfaction with Loop PEG Tube. The name of the study was "*Patients' and Caregivers' Experience with the use of LOOPPEG®*" and the device in the study was the LOOPPEG™ 3G tube—a device substantially similar to the Loop PEG Tube. This was not an application for the conduct of a clinical trial on the LOOPPEG.

6.12. On 7 October 2009, the MAH EC considered this application:

6.12.1. Dr Pang gave a presentation to the EC. During this presentation, the minutes record Dr Pang as stating that "*3G tube and the Loop PEG are not considered as clinical trial. According to the Singapore Guidelines for Good Clinical Practice (SGGCP), clinical trials are those with medicinal components.*" The minutes also stated: "*Dr Pang explained that 3G tube and Loop PEG fall outside the clinical trials, according to definition of SGGCP.*"

6.12.2. Some members of the EC raised queries about Dr Pang's proposed study. The EC concluded that the proposed study ought to be carried out in the context of a formal clinical trial. Dr Pang disagreed that a clinical trial was required.

6.12.3. The EC instructed Dr Pang to re-write the proposal as a protocol for a clinical trial, including information on how the patients would be selected and what additional treatments would be required.

6.12.4. The EC also informed Dr Pang that he was "*not permitted to do the Loop PEG in MAH*".

6.13. By reason of Dr Pang's application process, Dr PW1 learned that Dr Pang had already performed the Loop PEG Tube treatment on four patients—three of whom were the Patients. Dr PW1's investigations led to MAH's Quality Assurance Committee reviewing the Patients' records. Dr PW1 also enquired into (i) how Dr Pang obtained consent from the Patients (ii) the safety of the Loop PEG Tube and (iii) the length of the Patients' stays in hospital and whether the treatments given to the Patients were different from those normally given.

6.14. As a result of these enquiries, on 19 October 2009, Dr PW1 raised some concerns with the Health Regulation Division of MOH by way of email to Dr P4, a Senior Director. Dr PW1 also referred the matter to Dr P5 of the MOH, Regulatory Division on 23 October 2009 under the question:

> "*What is MOH* [sic] *ruling concerning obtaining Medical Consent for dementia or stroke patients for major surgery or treatment? Does this "Committee of two people" exists* [sic] *and is it enforced in all hospitals?*" Dr PW1 also stated that in his opinion, Dr Pang's procedures were "*a clinical trial as it involved* [sic] *new treatment, even though [Dr Pang] stated that the device is not under clinical trial requirements*."[1]

6.15. In the meantime, Dr Pang had re-written his study protocol on the "*LOOPPEG™ 3G TUBE*" and re-submitted it to the MAH EC on 26 November 2009. However, in view of Dr PW1's investigations and the referral to MOH, the EC did not consider Dr Pang's fresh application.

6.16. No approval was ever given to Dr Pang to conduct a study on, or use in surgery, the Loop PEG Tube or the "LOOPPEG™ 3G".

7. For the sake of completeness, Dr Pang also carried out a Loop PEG Tube treatment on another patient on 7 July 2008. This treatment gave rise to a separate complaint to the SMC which became the subject matter of another DC inquiry. That DC found that Dr Pang had intentionally and deliberately ignored his ethical obligations under

[1] Email from Dr PW1 to Dr P5, dated 23 October 2009, CB 155

Clause 4.1.4 by giving treatment that was not generally accepted by the profession outside the context of a formal and approved clinical trial and found him guilty of professional misconduct under the Act. Dr Pang appealed this decision to the Court of Three Judges.

8. In that case, the issues the Court of Three Judges had to determine were:

8.1. The applicability of Clause 4.1.4 to Dr Pang's conduct;

8.2. The interpretation of Clause 4.1.4, particularly the meaning of "*not generally accepted*";

8.3. Whether the Loop PEG Tube was not generally accepted by the profession; and

8.4. Whether Dr Pang's conduct on the facts—not dissimilar to the Treatments in the present DC inquiry—amounted to professional misconduct.

9. The Court ultimately held that the DC had not erred in finding Dr Pang to have breached Clause 4.1.4. The Court's Grounds of Decision are reported at *Pang Ah San v Singapore Medical Council* [2014] 1 SLR 1094 ("***Pang v SMC***").

ISSUES FOR DETERMINATION

10. To determine whether Dr Pang is guilty of professional misconduct under the Charges, the following issues need to be considered:

10.1. Does Clause 4.1.4 apply to Dr Pang?

10.2. If Clause 4.1.4 does apply, are the Treatments "*generally accepted*" by the medical profession and therefore not required to have been conducted in the context of a formal and approved clinical trial?

10.3. If the Treatments were required by Clause 4.1.4 to have been conducted in a formal and approved clinical trial, did the conduct amount to professional misconduct?

First issue—Does Clause 4.1.4 of the ECEG apply to Dr Pang?

a) The general applicability of Clause 4.1.4

11. All of the charges are based on a breach of Clause 4.1.4 of the Ethical Guidelines. The ECEG is published as one document with five sections, namely (1) an introduction, (2) the SMC Physician's Pledge (3) Ethical Code, (4) Ethical Guidelines, and (5) Disciplinary Process. Dr Pang argued that he was not bound by the Ethical Guidelines, maintaining that he was only bound by the Physician's Pledge and the Ethical Code. Dr Pang based his argument on the eleventh promise of the Physician's Pledge which refers to the Ethical Code but not to the Ethical Guidelines when it states:

> "*I solemnly pledge to … comply with the provisions of the Ethical Code; and … make these promises solemnly, freely and upon my honour.*" (emphasis added).

He also pointed to the following passages of the Ethical Guidelines:

> "*The Ethical Code enunciated in the previous section shall be applied to clinical practice and all areas of professional activity conducted by doctors*"

and

> "*[d]octors must use the Code as a yardstick for their own conduct and behaviour.*"[2] (emphasis added)

He took these passages as justification for the proposition that the Ethical Code states that he is *only* bound by the Ethical Code and not by the Ethical Guidelines—due to the absence of a reference to the Ethical Guidelines. His argument was that the Ethical Code intentionally excluded the application of the Ethical Guidelines and that the Ethical Code was the stand-alone "*yardstick*" to evaluate a doctor's conduct. To quote from Dr Pang's own submissions:

> "*To be sure, in the very last sentence (breath), the [Ethical Code] re-emphasised its role as the yardstick. It did not surrender that role to Clause 4.1.4. I quote:*

[2] Dr Pang's submissions, dated 9 August 2014, [19]-[21]

> '*Endeavour to abide by the* Ethical Code *when making use of modern or new (novel) technology in treatment modalities, communication means or information handling.'*
>
> *Note that the last sentence (breath) did not say 'Ethical Code and Ethical Guidelines' or 'ECEG'. To ensure that there would be no confusion regarding the yardstick to be used to measure professional conduct, a warning was added to the clauses (i.e. [Ethical Guidelines]): 'The Ethical Code enunciated in the previous section shall be applied to clinical practice and all areas of professional activity conducted by doctors.*
>
> *Therefore, the charges are wrong because they used a wrong yardstick (Clause 4.1.4).*" (Emphasis in the original)

12. Dr Pang also sought to argue that because the Charges related to clinical trials—and because clinical trials involve research—he was only obliged to comply with the research oriented Bioethics Advisory Committee Singapore, *Research Involving Human Subjects Guidelines for IRBs* 2004 (the "**BAC Guidelines**"). Essentially, Dr Pang's argument on this point was that he could not be bound by both the BAC Guidelines and the ECEG as they were mutually exclusive. He also argued that because the BAC Guidelines were issued in 2004, two years after the ECEG, Clause 4.1.4. had become "*obsolete*" and therefore inapplicable.[3]

13. In the alternative, Dr Pang argued that a doctor was bound by the Ethical Guidelines only insofar as the Guidelines were not inconsistent with the Ethical Code. Dr Pang argued that Clause 4.1.4—in particular the phrase "*in the context of a formal and approved clinical trial*"—was inconsistent with the Ethical Code. In Dr Pang's view, the phrase was inconsistent with the Code because it effectively disguised not generally accepted treatment as a clinical trial. The result, according to Dr Pang, was that patients in a clinical trial would receive treatment that was not generally accepted. Dr Pang regarded this as unethical, as being against the letter, spirit and intent of the

[3] Dr Pang's email to the DC, dated 7 January 2014, at [11], CB 285

Physician's Pledge and the Ethical Code.[4] He concluded that it would be "*ethically abhorrent*" for him to comply with Clause 4.1.4:

> "*[I]n my treatment of the Patients, to be compliant with the [Physicians' Pledge, the [Ethical Code], MOH Directive 1A.2006, BAC Guidelines, the Medicines Act, the Health Products Act and the Medical Registration Act, I had to ignore Clause 4.1.4 which is in conflict with higher authorities.*"[5]

14. We do not agree with Dr Pang's arguments. In the first place, the Ethical Guidelines, the Ethical Code and the Physician's Pledge are all incorporated into one document published by the SMC under the title *Singapore Medical Council Ethical Code and Ethical Guidelines*. It is intended to be read holistically as one document.

15. We also cannot agree with Dr Pang's interpretation. Dr Pang's contention that the Ethical Guidelines do not apply to him is an incorrect reading of the Physicians' Pledge. It is also internally inconsistent with the ECEG as a whole which states that the Guidelines apply in conjunction with the Code. The Introduction to the ECEG states:

> "*The SMC has the role of promulgating the Ethical Code and Ethical Guidelines on acceptable professional practice and behaviour and has the responsibility to exercise its duty to discipline members of the profession who fail to uphold the high standards demanded by society.*
>
> *…*
>
> *The Ethical Guidelines elaborate on the application of the Code and are intended as a guide to all practitioners as to what SMC regards as the minimum standards required of all practitioners in the discharge of their professional duties and responsibilities in the context of practice in Singapore. It is the view of the SMC that serious disregard or persistent failure to meet these standards can potentially lead to harm to patients or bring disrepute to the profession and*

[4] Dr Pang's letter to the DC, dated 14 July 2014, at [22]
[5] Dr Pang's Closing Submissions, at [22]

> *consequently may lead to disciplinary proceedings*." (emphasis added)

16. The Ethical Guidelines themselves make it clear that the Ethical Guidelines are binding and applicable on all doctors. The Preamble to the Ethical Guidelines states:

> "*The following section provides interpretation and guidance on how the Code shall be applied … doctors shall conscientiously study the guidelines, endeavour to follow them and extend their application to areas that may not be addressed specifically. Breaches of these guidelines could lead to doctors … ultimately [facing] disciplinary proceedings for professional misconduct*." (emphasis added)

The ECEG concludes by saying: "*The Ethical Code and Ethical Guidelines provide a guide as to what types of conduct could amount to professional misconduct*." (emphasis added)

17. In our view, the Ethical Code must be read in conjunction with the Ethical Guidelines. This was articulated in *Low Cze Hong v Singapore Medical Council* [2008] 3 SLR(R) 612 (*Low*) when it held that the ECEG serves

> "*a crucial role in providing an ethical 'compass' to guide doctors on what the acceptable standards are from which a departure may constitute professional misconduct*"[6]

and

> "*[T]he SMC Ethical Code [and Ethical Guidelines] is an embodiment of the ethical values the SMC strives to inculcate in each member of the medical profession … it is imperative for doctors to internalise the ethical responsibilities under the SMC Ethical Code [and Ethical Guidelines] and to duly perform them[.]*"[7] (emphasis added) (Note: the Court contracted the phrase "*SMC Ethical Code and Ethical Guidelines"* and for the purposes of the judgment defined it as the truncated "*SMC Ethical Code*"—see paragraph 21 of that judgment).

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[6] *Low Cze Hong v Singapore Medical Council* [2008] 3 SLR(R) 612 at [37]
[7] *Low Cze Hong v Singapore Medical Council* [2008] 3 SLR(R) 612 at [86]

18. The High Court in *Low also* held that

> "*The spirit and purpose of the ECEG is to uphold the trust and confidence in the medical profession by setting out standards of good medical practice which all doctors should apply in all areas of a doctor's clinical practice.*"[8] (emphasis added)

Clearly the ECEG must be complied with both in letter and spirit and Clause 4.1.4 applies to Dr Pang.

19. We also disagree with Dr Pang's alternative argument that it is unethical for doctors to comply with Clause 4.1.4 because they would be performing not generally accepted treatments on patients. This position is devoid of logic. The very basis of a clinical trial is to provide a safe harbour where not generally accepted treatments can be practised—with oversight and accountability to an ethics committee.

b) The specific applicability of Clause 4.1.4

20. Dr Pang also sought to argue that even if Clause 4.1.4 applied to him, the Treatments were not caught by it. The relevant part of Clause 4.1.4 reads:

> "*A doctor shall not offer to patients, management plans or remedies that are not generally accepted by the profession, except in the context of a formal and approved clinical trial.*" (emphasis added)

Dr Pang contended that the Loop PEG Tube was a "*device*" and not a "*remedy*" and therefore the Treatments were not caught by Clause 4.1.4.[9] We do not agree. Clause 4.1.4 of the ECEG is intended to be read broadly and not narrowly. It is a strained interpretation to regard the Loop PEG Tube device not as a "*remedy*". The Court of Three Judges in *Pang v SMC* held:

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[8] *Pang Ah San v Singapore Medical Council* [2014] 1 SLR 104 at [28]

[9] Dr Pang's Submissions, dated 4 August 2014, [17]-, and 14 July 2014, [23]

> "*Plainly the term* "*remedy*" *embraces a very broad category of cures or treatments and includes the loop-PEG procedure, other surgical procedures, and uses of medical devices*."[10] (emphasis added)

21. Next, Dr Pang argued that the "*clinical trial*" that Clause 4.1.4 contemplated was limited to clinical trials specifically conducted under the statutory scheme as contemplated in the Health Products Act (Cap 122D, 2007 Rev Ed) ("**HPA**") and the Medicines Act (Cap 176, 1985 Rev Ed) ("**MA**"). These are the only two statutory regimes regulating clinical trials. The HPA is inapplicable to the Loop PEG Tube because the Loop PEG Tube cannot be considered as a "*medical device*" under the HPA. Nor can the Loop PEG Tube fall under the MA—because the MA pertains to the "*administration of … medicinal products*". Because the Loop PEG Tube did not fall under these two statutes, Dr Pang concluded that the Treatments fell outside of the ambit of Clause 4.1.4. We do not agree.

22. Clause 4.1.4 applies to clinical trials in general not just those dealt with under the HPA and the MA. The Loop PEG Tube was capable of being conducted in the context of a clinical trial. Dr Pang could have applied to an EC or an Institutional Review Board ("**IRB**") to conduct a clinical trial. Just because the device did not fall under the direct regulation of the MA or the HPA does not mean that a clinical trial is not required. The Court in *Pang v SMC* expressly stated:

> "*The term 'clinical trial' in the context of Clause 4.1.4 merely means any trial which is 'approved by an ethics committee', which 'conforms to the Good Clinical Practice Guidelines', where applicable, and where 'informed consent' has been obtained from the patient*."[11]

23. There are other avenues—apart from the MA and HPA regime—which contemplate a clinical trial being performed. The National Medical Ethics Committee's Ethical Guidelines on Research Involving Human Subjects of 1997 ("**NMEC Guidelines**") provide for clinical trials for research involving human experimentation, including trials of new medical devices and other forms of clinical study that require the participation of human subjects. On the face of it, this would include a trial of a device such as the

[10] SMC's Opening Statement, at [52]
[11] *Pang v SMC*, at [30] and [70]

Loop PEG Tube. The NMEC Guidelines require such clinical trials to be vetted by a hospital Ethics Committee:

> "*hospital ethics committees vet for ethical considerations, all research protocols that involve human experimentation be they clinical trials or drug trials, trials of new medical devices, new procedures and any other forms of clinical studies that require the participation of human subjects or the use of human tissues and organs.*"[12] (emphasis added)

24. The NMEC Guidelines, and the fact that clinical trials can be conducted for "*medical devices*", have been confirmed by the BAC Guidelines (which are binding on Dr Pang—a point he conceded). The Loop PEG Tube procedure falls under paragraph 3.7 of the BAC Guidelines because it is an invasive procedure:

> "**Direct Human Biomedical Research**. *This comprises any kind of human biomedical research that involves any direct interference or interaction with the physical body of a human subject … [T]he trial or use of a medical device on a human subject … all qualify as Direct Human Biomedical Research[.]*" (emphasis added)

Any research on the Loop PEG Tube is therefore *"Direct Human Biomedical Research"*. Paragraph 3.9 of the BAC Guidelines is clear that any such "*Direct Human Biomedical Research*" should be reviewed by an Independent Review Board ("**IRB**") before any clinical trial can be conducted:

> "*Every research programme involving Direct Human Biomedical Research should be reviewed and approved by a properly constituted ethics committee or IRB.*"

25. Therefore, in our view, it cannot be said that Clause 4.1.4 only applies to clinical trials under the HPA and MA. We prefer an interpretation that is consistent with the spirit and purpose of the ECEG—which is to uphold trust and confidence in the medical profession by setting out the minimum standards of good medical practice. This

[12] Quoted in the BAC Guidelines, at [2.26]

interpretation applies with even more force considering that the Treatment is an invasive insertion of a device which involves an unknown and potentially high level of risk.

Second issue—Are the Treatments "*generally accepted*" by the medical profession and therefore not required to have been conducted in the context of a formal and approved clinical trial?

26. The Prosecution's case was that Dr Pang breached his ethical obligations under Clause 4.1.4 when he performed the Treatments outside the context of a formal and approved clinical trial—because the Treatments were novel and not generally accepted by the profession. To recapitulate, the first paragraph of Clause 4.1.4 states:

> "*A doctor shall treat patients according to generally accepted methods and use only licensed drugs for appropriate indications. A doctor shall not offer to patients management plans or remedies that are not generally accepted by the profession, except in the context of a formal and approved clinical trial.*"[13] (emphasis added)

27. The case of *Pang v SMC* set out a three-step test to determine whether a treatment is "*generally accepted*" and therefore not required to be conducted within the confines of "*a formal and approved clinical trial*":

> "*[T]he first step of the analysis is to decide whether a particular treatment is significantly different from the standard treatment. If the treatment is significantly different from the standard treatment, the second step of the analysis is to determine if it constitutes innovative treatment, hence triggering the prohibition against innovative treatment. If the treatment constitutes innovative treatment, the third step of the analysis is to decide if the treatment constitutes therapy administered in the best interests of the patient, which is exempted from the prohibition against innovative treatment.*" (emphasis added)

[13] *Pang v SMC* at [73]

Applying this framework, the following issues arise:

a) Was the Treatment "*significantly different*" from the standard treatment?
b) Was the Treatment "*innovative*"—which is to say, was there "*general acceptance*" of the treatment by the medical profession?
c) Was the treatment "*therapy*" or "*research*"?

a) Was the treatment "*significantly different*" from the standard treatment?

28. A treatment that is "*significantly different*" from the standard treatment will be caught by the prohibition in Clause 4.1.4.[14] Factors such as the increase in the amount of risk, the addition of new types of risks, and a significant increase in the degree of ignorance of risks will be used to assess whether a particular treatment is "*significantly different*".[15]

29. Dr Pang argued that the Loop PEG Tube was not new but was a variation or adaptation of the standard technique. In his words: "*The word* ["Loop-PEG"] *may be new, but it does not mean that the tube or method is new. … No surgeon in the know considered the loop-PEG a new surgical procedure.*" [16] He explained any perceived differences with the standard PEG as incremental innovation and modification.[17] However, Dr Pang adduced no independent evidence of this.

30. The Prosecution submitted that the Loop PEG Tube differs from the standard tube in both design and insertion position. Professor PE, the prosecution's expert, opined that the difference between the two was a "*considerable difference*".[18] Professor PE described the Treatment as *"novel*":

> "*[A] comparison made between the 'standard' PEG and the Loop PEG has led me to conclude that the Loop PEG has <u>deviated from</u>*

[14] *Pang Ah San v SMC*, at [57]
[15] *Pang Ah San v SMC,* at[57]
[16] Letter from Dr Pang to Dr Lee, MOH Regulatory Compliance Division, dated 12 February 2010, CB 169
[17] Letter from Dr Pang to Dr Lee, MOH Regulatory Compliance Division, dated 12 February 2010, CB 169
[18] Expert Report of Professor PE, at [24], CB 24

> *the 'standard' PEG in design and inserted position and is hence 'novel' by definition.*"[19]

and

> "*[T]he loop PEG is novel in design and inserted position. Importantly, when compared with the standard PEG which had been used widely for the past three decades, the inserted Loop PEG appeared deficient in reducing the risk of peritoneal contamination from leakage of gastric content.*"[20] (emphasis added)

31. The first and most obvious difference between the standard and the Loop PEG Tube is the configuration of the Loop PEG Tube. The Loop PEG Tube is in a 'loop' formation. The standard tube is inserted directly into the stomach with no 'loop' or exit.

32. A second major difference between the two devices, according to Professor PE, pertains to the risk of stomach leakage. Both the radial rotation of the Loop PEG Tube and the difficulties in securing the Loop PEG Tube at the site of penetration (and the stomach wall) could lead to leakage of stomach contents into the peritoneal cavity. Professor PE observed that the Loop PEG Tube did not have a mechanism to prevent the radial rotation of the whole loop.[21] This could lead to the displacement of the fenestrations of the loop resulting in leakage of stomach contents.[22] If this occurred in the peritoneal cavity the leakages could be fatal. In short, the Loop PEG Tube increased the risk of leakage, or at the very least, it resulted in a significant increase in the degree of ignorance of risk. By contrast, the standard PEG, which is not in loop formation, is not vulnerable to this particular risk.

33. Dr Pang responded that the radial rotation on the Loop PEG Tube could be controlled in a variety of ways, such as: (i) Varying the segment of tube that is locked between the stomas; (ii) using a secondary loop or a smaller calibre tube; (iii) narrowing the width between the stomas; (iv) controlling the elevation of the lock above the skin; and (v) anchoring the tube at the stomas with sutures. Dr Pang's explanations in this regard were intended to demonstrate that the Loop PEG Tube did not really diverge

[19] Expert Report of Professor PE, at [7], CB 11
[20] SMC's Opening Statement, at [35]
[21] Dr Ti's Report, AB 20-22 at [36(i)(c)]
[22] Dr Ti's Report, AB 20-22 at [36(i)]

from the standard PEG and that the associated risk was therefore not substantially different.[23]

34. With regard to securing the Loop PEG Tube at the site of penetration, Professor PE gave evidence that the Loop PEG Tube did not have a mechanism to keep the stomach and abdominal walls apposed. Apposition of the stomach wall to the abdominal wall—also known as gastropexy—is required to seal off the penetration site and facilitate the healing of the tube tract. Inadequate apposition can result in leakage of gastric content into the peritoneal cavity[24] and increases the risk of peritonitis. The standard PEG method relies on an internal 'bumper' and an external 'bolster' to provide the necessary apposition to secure the stomach. These bolsters seal off the opening in the stomach wall caused by the penetration of the standard PEG and are sutureless. This facilitates the formation of a secure tract around the tube, which reduces the risk of leakage of stomach contents into the peritoneal cavity.[25]

35. In response to this point, Dr Pang downplayed the importance of the bumpers and bolsters, asserting that the "*current teaching for standard PEG*" is not to use bolsters as "*[t]here is no need for 'sealing off' by bolsters*".[26] He also maintained that "*loose PEGs*" had been used since 2006 and that "*natural apposition (gastropexy)*" occurred with the Loop PEG Tube[27] therefore making it not dissimilar to the standard PEG. Dr Pang also argued that, in any event, the absence of bumpers and bolsters and other such mechanisms was a positive difference because without them the tube was easier to change and maintain.[28] Dr Pang also drew attention to the fact that the Loop PEG Tube did not have the drawback of 'buried bumper syndrome' a complication arising with bumpers (although, as the Prosecution pointed out, this would be mitigated with 'soft' bumpers in any event).

36. In addition to these differences (configuration, radial rotation and apposition), the Loop PEG Tube differs from the standard PEG in another obvious way. Owing to its

[23] Dr Pang's Closing Submissions, at [28e]
[24] Expert Report of Professor PE, at [29], CB 18
[25] Expert Report of Professor PE, at [12], CB 13
[26] Dr Pang's 'Response to the Expert Professional Opinion of SMC', dated 29 December 2013, at [16]-[17], CB 269
[27] Dr Pang's 'Response to the Expert Professional Opinion of SMC', dated 29 December 2013, at [21], CB 271
[28] Dr Pang's 'Response to the Expert Professional Opinion of SMC', dated 29 December 2013, at [23], CB 271

loop form the Loop PEG Tube requires a double penetration of the abdominal and stomach walls for the entrance and then exit of the tube, i.e. two stomas. The standard PEG tube requires only one stoma. Whatever surgical risks exist in performing one stoma are potentially increased in the case of the Loop PEG Tube which requires two stomas when compared to the standard tube.

Conclusion on the evidence

37. We accept Professor PE's evidence. We find that the Loop PEG Tube is significantly different from the standard PEG. In our view, the Loop PEG Tube is a novel device. The potential rotation of the tube and the concerns over the apposition of the stomach and abdominal walls necessitate this conclusion. The Loop PEG Tube's loop configuration and the necessity of a double stoma also create significant differences.

38. Apart from the physical differences of design, methodology and insertion, the Loop PEG Tube added new and unknown risks into the equation. The standard tube appears to present less risk. Dr Pang admitted under cross-examination that the standard tube was "*low risk*". Elsewhere in Dr Pang's own literature, he described the standard tube as "*safe, producing a stoma that fits the tube snugly, with a low risk of leakage*".[29]

39. Although Dr Pang suggested various ways to limit the rotation of the tube, we agree with Professor PE that there was nothing in the Loop PEG Tube that was used at the material time to prevent inadvertent rotation of the loop.[30] We accept his view that with the Loop PEG Tube there is no hitching of the stomach at the site of the insertion into the abdomen wall, creating the risk of inadvertent axial rotation of the tube allowing intra-peritoneal displacement of the tube opening. In fact, Dr Pang subsequently proposed a change to the configuration of the Loop PEG Tube to a double loop to prevent radial rotation (but this was not in use at the material time).

40. On the evidence as a whole, we find that the Loop PEG Tube is significantly different from the standard tube.

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[29] Pang A S, "A new feeding tube which is secure and easy to change" Singapore Medical Journal 2009; 50(7): 740-742 at 740

[30] Expert Report of Professor PE, at [28], CB 18

b) Were the Treatments "*generally accepted*" by the medical profession?

41. The expression "*not generally accepted by the profession*" was interpreted in *Pang v SMC* to mean "*not generally known or used*". For a treatment to be "*generally accepted*" a positive act of acceptance from the medical profession is required; a lack of rejection by the profession is insufficient to constitute the treatment as "*generally accepted*".[31] General acceptance is based on scientific affirmation by the profession rather than on the mere fact that it is practised by a large number of doctors. The Court of Three Judges in *Low Chai Ling v Singapore Medical Council* [2013] 1 SLR 83 at [42] said:

> "*The DC rightly rejected the applicant's argument that a medical treatment was 'generally accepted' for the purposes of [Clause] 4.1.4 of the ECEG if it was widely practised by a large number of medical practitioners … . The assessment of whether or not a particular medical treatment is generally accepted must be scientific rather than empirical. Illegitimate or unethical practices are not legitimised merely because large numbers of doctors engage in them.*"

Where the potential benefits and risks of a particular treatment—and the ability to control these—have approached a level of predictability and are acceptable to the medical community in general the treatment can be regarded as generally accepted.[32]

Evidence of general acceptance by usage

42. Dr Pang argued that the Loop PEG Tube method was generally accepted by the profession because it was widely used. He alleged:

> "*The … [Loop PEG Tube] method is … used widely all over the world, for at least 30 years now. … No surgeon in the know considered the loop-PEG a new surgical procedure.*" [33]

[31] *Pang v SMC*, at [48] and [54]
[32] *Pang v SMC*, at [56]
[33] Letter from Dr Pang to Dr Lee, MOH Regulatory Compliance Division, dated 12 February 2010, CB 169

However, he produced no independent evidence to substantiate this assertion.

43. Conversely, Professor PE's opinion was that the Loop PEG Tube had not been performed by other surgeons or gastroenterologists at the material time. This was not contradicted. His evidence was that the Treatment was not generally accepted by the profession. Professor PE's view was that the Loop PEG Tube was "*novel*". We are also mindful of the Court of Three Judges' comments in *Gobinathan Devathasan v Singapore Medical Council* that "*[a] novel treatment, by its very definition, cannot be said to be generally accepted.*"[34]

44. In fact, Dr Pang ultimately conceded that the Loop PEG Tube was unique and had never, to his knowledge, been used by another doctor before. During cross-examination, the Chairman of the DC asked Dr Pang:

> Chairman: "*In relation to the stomach, has this loop been used by another (doctor) before, or described by anyone before?*"
>
> Dr Pang: "*To my knowledge, no.*"

45. To add to this, Dr Pang himself admitted in cross-examination that in the case of Mdm P1 the first case of Loop PEG Tube was a "*learning process*".

46. As such, we find that there was no evidence to justify a conclusion that the Loop PEG Tube was generally accepted by the profession.

47. For the sake of completeness, we add that Dr Pang also argued that the Loop PEG Tube was generally accepted and used by the profession when considered from the point of view of each of its component elements. Dr Pang pointed at each constituent element of the Loop PEG Tube and argued that because each discrete part was generally accepted, the device as a whole must also be generally accepted.[35] We reject this argument. The Loop PEG Tube as a device must be viewed as a whole

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[34] *Gobinathan Devathasan v Singapore Medical Council* [2010] 2 SLR 926 at [28]
[35] SMC's Closing Submissions, at [69]

unit, and assessed in the form it is received by a patient in the course of the treatment.

Evidence of general acceptance in medical literature

48. Notwithstanding the lack of general usage, was the Loop PEG Tube received into the body of medical literature at the material time? The case of *Gobinathan Devathasan v Singapore Medical Council*[36] laid down certain factors to assist a Court or Disciplinary Committee in determining whether a treatment was "*generally accepted*". These requirements are:

48.1. There had to be at least "*one good study*";
48.2. The results of the study can be reproduced under similar conditions and parameters that the study was conducted under;
48.3. The results of the study have been published;
48.4. The study has been peer reviewed;
48.5. The study had 'clear-cut' results and the sample used was statistically significant;
48.6. The study had to be subject to some form of control (for example, randomised double-blind trials).

49. There was no medical literature published on the use of the Loop PEG at the time that Dr Pang performed the Treatments. This was a fact conceded by Dr Pang under cross-examination. In fact, Dr Pang's own chronology records under the date 15 July 2009: "*The **first** medical journal article on loop-PEG and LOOPPEG™ 3G Tube is published (Technical Note in the July issue of SMJ)*" (emphasis added).[37] It should be noted that this article was written by Dr Pang himself about five months *after* the Treatment was performed on the last Patient on 19 February 2009.

50. The Loop PEG Tube was discussed in the medical literature only after the Treatments. Most of this literature was authored or co-authored by Dr Pang. The Prosecution made much of this fact describing such medical literature as "*self-serving*". In our view, the self-authorship of the articles does not necessarily mean

[36] [2010] 2 SLR 926; SMC Closing Submissions at [37]
[37] R12, page 2 of the Chronology

that the articles are not beneficial to the inquiry. However, we do not have to decide this, because the real issue is what was in the medical literature *at the time of the Treatments*. And there was nothing.

Conclusion on the evidence

51. Taking into account the lack of usage by other practitioners and its non-existence in the medical literature at the material time, we find that the Loop PEG Tube was not generally accepted by the profession.

c) Were the Treatments therapy or research?

52. Not every treatment that is not generally accepted requires a clinical trial. An experimental treatment that is not generally accepted but is administered primarily in the best interests of the patient may under certain circumstances be exempted from having to be conducted within a clinical trial.[38] Paragraph 3 of Clause 4.1.4 provides:

> "*It is not acceptable to experiment or authorise experiments of research which are not part of a formal clinical trial and which are not primarily part of treatment or in the best interest of the patient, or which could cause undue suffering or threat to the life of a patient.*"

53. "*Therapy*" is undertaken with the primary intention of benefitting a patient. Innovative therapies are generally single interventions intended to manage or solve a particular and unique clinical problem[39]—especially where the risks are not significantly increased.[40] For example—an innovative treatment used on a critically ill patient, where the innovative method could reasonably be expected to benefit the patient, and where time is not available to seek formal EC approval—would fall under this exemption.

[38] *Pang v SMC*, at [64] and [125]
[39] *Pang v SMC*, at [62] – [63]
[40] *Pang v SMC,* at [57]

54. Similarly, treatment is more likely to be "*therapy*" where its primary purpose is not to gain new knowledge beyond the needs of the patient.[41] Additionally, where the standard treatment is wanting or ineffective an innovative treatment is more likely to be considered as therapy.[42] In short, therapy is patient-centric. It is customised for each patient. On the other hand, where treatments have the primary purpose of generating new information or to test a hypothesis it will invariably be labelled as "*research*".[43]

55. Dr Pang submitted that the Treatments were experimental and innovative and were administered in the best interests of the Patients. He alleged that he "*[varied] a surgical procedure*"[44] and "*tailor[ed] the operation to fit [the Patients] perfectly*"[45] and that the Loop PEG Tube was an "*incremental innovation*". He contended that it was his sole intention to benefit the Patients, as the standard tube was ineffective, and that any deviation from the standard methods was simply a progressive modification to ensure the best result for the Patient.[46] Dr Pang argued that the Treatments were not research and relied on the dictum from the Court of Three Judges in *Pang v SMC* at [71]:

> "*When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is 'experimental', in the sense of new, untested or different treatment, does not automatically place it in the category of research.*"[47]

56. Where a "*conflict*" exists in determining whether a treatment was "*research*" or "*therapy*" Dr Pang argued that, according to the BAC Guidelines, the DC would have to resolve the issue by assessing "*the integrity of the physician*".[48] Dr Pang also contended that because none of the Patients needed, wanted or consented to a

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[41] *Pang v SMC*, at [62]-[63]
[42] *Pang v SMC, at* [72]
[43] *Pang v SMC*, at [62] and [65]
[44] Dr Pang's Closing Submissions, at [40d]
[45] Dr Pang's email the DC, dated 7 January 2014, at [12], CB 285
[46] Letter from Dr Pang to Dr Lee, MOH Regulatory Compliance Division, dated 12 February 2010, CB 168
[47] *Pang v SMC*, at [71]
[48] Letter from Dr Pang to Dr Lee, MOH Regulatory Compliance Division, dated 12 February 2010, CB 168

clinical trial the Treatments could not have been research.[49] He also submitted that the Patients would derive no benefit from being in a clinical trial,[50] whereas in the Treatments the Patients received the best clinical management and treatment they could get.[51] Dr Pang also argued that the hallmark of research is randomisation (to achieve randomised control), which required a large number of patients—which made it unlikely that the Treatments, given only to three patients, were research.

Conclusion on the evidence

57. We do not agree with Dr Pang that the Treatments were "*therapy*". In our view, the Treatments were research. It is not up to a doctor to subjectively determine whether a new treatment is therapy or research. There are objective criteria for such a determination. If doubt exists on whether a clinical trial is appropriate, the matter should be referred to an Ethics Committee or IRB. Dr Pang was wrong in deciding that the procedure he performed on the Patients were therapy—especially as he was aware of the innovative aspects of the procedure having previously applied to the MAH Ethics committee for a lesser modification to the standard PEG in 2006. Clearly, Dr Pang was not ignorant of the proper procedure. In this case, the procedure was an elective one, not an emergency. Dr Pang had time to seek formal approval for the Treatments.

58. We find that Dr Pang performed the Treatments with a motive to gather data to validate the Loop PEG Tube as a form of treatment. That the Patients happened to benefit does not change the fact that he was primarily seeking information. Dr Pang performed the Treatments to test a hypothesis which went beyond the immediate and direct needs of the Patients. In any event, the Treatments were not necessarily objectively in the best interests of the Patients. The Treatments were not generally accepted and brought new, unknown and possibly increased risks.

59. The Treatments were identically performed and Dr Pang did not customise the Loop PEG Tube to fit the unique needs of each Patient. There was no evidence to suggest that the standard PEG treatment was wanting or ineffective, thereby requiring an

[49] Dr Pang's letter to the DC, dated 14 July 2014, at [23]
[50] Dr Pang's Closing Submissions, at [27]
[51] Dr Pang's Closing Submissions, dated 9 August 2014, at [8]

innovative improvement to the *status quo*. In fact, the evidence points in the opposite direction: the standard treatment was not ineffective and contained less risk. Under cross-examination Dr Pang agreed that the standard PEG was safe and should not be discarded.

60. Concerning Dr Pang's argument that "*[t]he Patients needed and wanted therapy, not clinical trial*"[52]—the Patients' subjective intentions are irrelevant. While a patient may benefit from research, the proper analysis is to objectively characterise the relationship as either doctor-patient or as researcher-subject.[53] His argument that research requires a large number of randomised patients applies in particular to randomised controlled trials. Research in the early phases can be carried out on a small number of patients that are not randomised.

61. Dr Pang had the burden to demonstrate that the Treatments were therapy and not research.[54] We do not consider him to have adduced sufficient evidence to have discharged this burden on a balance of probabilities. For the reasons set out above, we find the Treatments to be research and not therapy.

d) Conclusion to issue 2

62. In our view, first, the Loop PEG Tube departs significantly from the standard treatment. Second, this Treatment has not been validated by reliable research methods and has not earned general acceptance from the medical community. Third, we do not consider Dr Pang to have used the Loop PEG Tube primarily as therapy in the cases of the Patients. We consider the Treatments to have been research. Therefore, insertion of the Loop PEG Tube should have been performed in the context of a formal and approved clinical trial as required by Clause 4.1.4.

e) What the finding is not based on

63. Before moving to the next issue, it is appropriate for us to mention that the safety or otherwise of the Loop PEG Tube is not a directly relevant factor in our determination

[52] Dr Pang's letter to the DC, dated 14 July 2014, at [23]
[53] *Pang v SMC*, at [65]
[54] *Pang v SMC*, *at* [68]

of whether the treatment was generally accepted or not. Both parties sought to emphasise the safety or otherwise of the Loop PEG Tube. The relevant issue is whether the device was "*generally accepted*". The courts have held that "*patient safety*" is not "*a crucial factor in determining general acceptance*" and a DC should not use the test of patient safety to reach a "*conclusion of non-general acceptance*".[55]

64. In reaching this conclusion we also did not find it relevant that no harm was caused to the Patients, or that Dr Pang had obtained the Patients' consent with regard to the new procedure. Dr Pang argued that if the family, patient and doctor all consent to a treatment no ethical issue arises (we do not agree with this). Nor do we find it relevant that Dr Pang honestly believed that the Loop PEG Tube was based on sound scientific principles and was better than the standard treatment. Dr Pang breached Clause 4.1.4 because he performed novel treatments that were not generally accepted by the medical profession and he did not seek or obtain approval from an Ethics Committee to have the procedures performed within the context of a clinical trial.[56]

Third issue—Did Dr Pang's conduct amount to professional misconduct?

65. The test to determine professional misconduct, as established in *Low*, is as follows: Has there been an intentional and deliberate departure from the standards observed or approved by members of the profession of good repute and competency?[57]

66. The Prosecution submitted that Dr Pang had intentionally and deliberately breached his ethical obligations as set out in the ECEG because:

66.1. He was aware that the Loop PEG Tube was different from the standard treatment;

66.2. There were no published articles on the Loop PEG Tube, and no one else was using the Loop PEG Tube except for Dr Pang—a fact which Dr Pang knew;

66.3. Dr Pang was aware that there was an EC at MAH—by virtue of prior applications he had made to conduct other studies—but he did not seek

[55] *Gobinathan Devathasan v Singapore Medical Council* [2010] 2 SLR 926 at [48]
[56] *Pang v SMC*, at [120]
[57] *Low Cze Hong* at [37] and SMC's Closing Submissions, at [90]

approval from the EC or any other IRB to carry out a clinical trial in relation to the Loop PEG Tube; and

66.4. Dr Pang intentionally and deliberately took the position that he did not need to conduct a clinical trial.

67. We agree with the Prosecution that Dr Pang knew that the Loop PEG Tube treatment significantly differed from the standard treatment. We also agree that it was within Dr Pang's knowledge that no other doctors were using the Loop PEG Tube or similar treatments and that there was no other literature on the treatment. Dr Pang knew that the treatment was not generally accepted by the profession.

68. We also agree that Dr Pang was well aware of the existence and role of the MAH Ethics Committee. As mentioned above, Dr Pang submitted an application to the MAH Ethics Committee in November 2006 to conduct a pilot study to prove the feasibility of adding gastropexy (apposition) to the standard PEG. The MAH EC gave Dr Pang in principle approval to conduct the pilot study, expressly stating that the approval was only given to enable Dr Pang to obtain funding from the National Medical Research Council.[58] However, due to a failure to qualify for the funding, Dr Pang wrote to MAH to inform the hospital that the proposed pilot study had not been submitted for funding support. Thus, Dr Pang was acquainted with the existence and role of the MAH EC. However, notwithstanding that he never obtained consent to conduct a clinical trial or perform the Loop PEG Tube treatment, Dr Pang continued to carry out the Treatment on patients labelling them as "*therapy*".[59]

69. A finding that Dr Pang deliberately ignored Clause 4.1.4—and its associated ethical responsibilities—is further justified by Dr Pang's own admissions. A major plank of his argument was in fact that Clause 4.1.4 was not applicable to him. He maintained under cross-examination that he, in his own words, "*intentionally and deliberately ignored 4.1.4*".[60]

70. The only possible conclusion on the evidence is that Dr Pang intentionally and deliberately ignored his ethical obligations. Accordingly, in our determination a

[58] Letter from MAH to Dr Pang, 8 November 2006, CB 121
[59] SMC's Closing Submissions, at [98] and [100]
[60] R1, [21]

conclusion of professional misconduct is wholly justified. We accordingly find Dr Pang guilty of professional misconduct on all three of the Charges.

71. It also bears stating that the finding of professional misconduct is not premised on whether or not he used an unsafe device on a Patient. If that were the standard, doctors would be free to use all manner of devices that are safe but not generally accepted. On the facts, all three of the Patients were not affected by any of Professor PE's immediate safety concerns such as leakage into the peritoneal cavity. Nor is this finding dependent on the fact that Dr Pang had patented a device similar to the Loop PEG Tube and therefore had commercial interests in the device. Dr Pang's misconduct is due to him deliberately and intentionally administering the Treatments outside of a formal and approved clinical trial.

Preliminary objections raised by Dr Pang

72. Dr Pang raised a preliminary objection that the charges do not arise from the Complaint dated 29 September 2010. Dr Pang made much of the fact that the correspondence between MAH EC's Chairman Dr PW1 and MOH concerned issues of consent and conflict of interest.[61] As the Charges do not deal with patient consent, Dr Pang raised the objection that the Charges do not arise from the original complaint. In his words:

> "*The charges, however, say nothing about conflict of interest. Instead they are about the 'context of a formal and approved clinical trial' (or research). This phrase is present in the body of each charge, and in four out of six particulars. Thus the complaint and the charges differ significantly. I submit that there is a breach of the rules of natural justice.*"[62]

73. We dismissed this objection. We are satisfied that the Charges arise from the Complaint. The Complaint was concerned with, *inter alia*, the fact that Dr Pang had performed a not generally accepted procedure using the Loop PEG Tube, *as well as* possible conflicts of interest. These issues were repeated in MOH's letter to Dr Pang

[61] Letter from Dr Pang to SMC CC, dated 20 July 2011, CB 245
[62] Dr Pang's letter to the DC, dated 14 July 2014, page 5

dated 2 February 2010. Dr Pang responded to these issues in his letter to MOH dated 12 February 2010. Dr Pang stated in his closing submissions that the MOH letter of complaint raised concerns about "*the ethics of [my, Dr Pang's] actions*"[63] and acknowledged the same under cross-examination.

74. Dr Pang also argued that the Charges were ambiguous and not sufficiently particularised. However, it is clear to us that there can be no mistaking what the Charges entail. The essential ingredients of the Charges, viz. that treatment was generally not accepted by the profession and that the treatment was not carried out in the context of a formal and approved clinical trial are clear.

CONCLUSION AND SENTENCING

75. Having considered all of the submissions tendered by the parties and having taken into account all of the circumstances of the case, the DC now determines that the appropriate sentence to be as follows, and so orders:

(a) That the registration of the Respondent in the Register of Medical Practitioners shall be suspended for a period of **6 months** in total; being a suspension of a period of 3 months for each Charge, with the first and second Charges to run consecutively and the third Charge to run concurrently with the second Charge.

(b) That the Respondent shall pay a fine of **$10,000** in respect of the Charges;

(c) That the Respondent be censured;

(d) That the Respondent shall give a written undertaking to the Singapore Medical Council that he will not be engaged or offer any treatment plan or treatment which includes the insertion of the Loop PEG Tube or any variation thereof outside the context of a formal and approved clinical trial unless he obtains a waiver or exemption from the need to obtain such approval to use the same on patients from the appropriate authorities;

[63] Dr Pang's Closing Submissions, at [12]

(e) That the Respondent shall provide a written undertaking to the SMC to comply with the provisions of the Ethical Code and Ethical Guidelines, and any future prevailing version of these; and

(f) That the Respondent shall pay the full costs and expenses of and incidental to these proceedings, including the full costs of the solicitor to the Singapore Medical Council and the full costs of the Legal Assessor on an indemnity basis.

76. In the course of determining the sentence we took into consideration Dr Pang's complete lack of remorse for his actions. As discussed above, Dr Pang had already been subject to a prior DC inquiry into his use of the Loop PEG Tube under circumstances similar to those of the Treatments. The previous DC also found him guilty of misconduct. Dr Pang appealed this decision of the DC to the High Court where he was unsuccessful. The High Court released its judgment affirming the DC's decision on 29 November 2013. Thereafter, Dr Pang was served with a Notice of Inquiry which pertained to these Charges on 10 December 2013. Notwithstanding the reasoning in the High Court judgment, Dr Pang chose to reprise the same arguments that he had raised in the appeal before this DC even though they had previously been unsuccessful twice. He continued to assert that Clause 4.1.4 did not apply and that he did not have to follow it. In our view this demonstrates a total lack of remorse or oblivious stubbornness on Dr Pang's part. He was either unwilling or unable to recognise the error of his ways.

77. Apart from Dr Pang's lack of remorse, the above sentences take into account seven other aggravating factors on the part of Dr Pang which influenced our determination on sentencing.

78. First, it was clear to us that Dr Pang had a commercial interest in performing the Treatments. In October 2007, shortly before the procedure on Mdm P1 (relating to the first Charge), Dr Pang filed an application for the patent of a device which was, for all intents and purposes, the Loop PEG Tube. In August 2008, he filed an application for a trademark concerning the word "*LOOPPEG*". His usage of the Loop PEG Tube on the Patients was never in a life-or-death situation and there was no independent evidence that the standard treatment was not ineffective. It is a reasonable inference

that he was in some measure motivated to perform the Treatments to obtain data which would ultimately further his commercial considerations. We regard this as an aggravating factor for the purposes of sentencing.

79. Second, Dr Pang's offering of the Treatment to the Patients was not necessarily in their best interests. Accordingly, we regard the trust of the Patients, and their families where they provided consent, to have been abused.

80. Third, Dr Pang, through administering the Loop PEG Tube did cause unnecessary suffering to the Patients. Dr PW1's investigations and the MAH's Medical Advisory Board's Quality Assurance Committee's report revealed that the Patients had significantly more lengthy stays in hospital after their procedures when compared with patients who had the standard treatment. The Patients also had to endure two stomas and were exposed to the increased risk of leakage.

81. Fourth, Mdm P1, to whom the first Charge related, was the first ever case where the Loop PEG Tube was used on a patient. Without the safeguards of a clinical trial, this appears to us reckless and highly experimental.

82. Fifth, the deliberateness of Dr Pang's misconduct is of grave concern to us. The evidence shows that Dr Pang knew at all material times of the existence and role of the MAH EC and yet intentionally chose not to adhere to the ethical requirements governing not generally accepted treatments.

83. Sixth, Mdm P3, to whom the third Charge related, was operated on about four months *after* Dr Pang was informed that a Complaints Committee had been formed to investigate his conduct. In fact, two weeks before Dr Pang performed the Treatment on Mdm P3, the Chairman of the CC had written to Dr Pang requesting further information and clarification on the Loop PEG Tube. However, notwithstanding the clear knowledge that his conduct pertaining to the Treatment was under review he defiantly continued to offer and then perform the Treatment.

84. Seventh, after the CC had directed a formal inquiry into Dr Pang's conduct by a DC, Dr Pang published an article on the use of the LOOPPEG® 3G tube which makes

reference of its use on a fifth patient, a Mr P6. This too is a further indication of his brazen disregard for the disciplinary process and Ethical Guidelines.

85. We also award the SMC costs on an indemnity basis due to what can only be described as Dr Pang's wilful and deliberate wasting of time and costs. In our view, in light of the prior DC's decision which was affirmed by the Court of Three Judges, many of Dr Pang's arguments were doomed to failure. His temerity in adopting this approach was nothing other than a callous disregard for the decision in *Pang v SMC* and the disciplinary process as whole, thereby wasting a considerable amount of time and costs.

86. Our award of costs is also influenced by Dr Pang's general attitude towards these proceedings which we find to be insolent and recalcitrant. His slew of letters to counsel for the Prosecution and some of his submissions contained offensive and objectionable remarks which far exceeded the bounds of proprietary, let alone the laws of defamation and, in some cases, contempt of court. We do not consider it necessary or appropriate to reprise them here. This strategy only produced an inordinate amount of additional and unnecessary work for SMC's counsel and introduced an unsavoury tone that is unacceptable and unbefitting the man and the noble profession he serves. In this regard, Dr Pang has only himself to blame for the costs order we had ordered.

87. In addition, we order that these Grounds of Decision be published.

88. The Inquiry is hereby concluded.

Dated this 15th day of October 2014.