IN THE REPUBLIC OF SINGAPORE
SINGAPORE MEDICAL COUNCIL INTERIM ORDERS COMMITTEE

Between

Singapore Medical Council

And

Dr Kay Aih Boon Erwin

… *Respondent*

Interim Orders Committee:
A/Prof Agnes Ng Suah Bwee (Chairman)
Dr Subramaniam Suraj Kumar
Prof Tan Puay Hoon
Ms Engelin Teh SC (Legal Assessor)

Counsel for the SMC:
Mr Chia Voon Jiet
Ms I-Lin Lee
(M/s Drew & Napier LLC)

Counsel for the Respondent:
Mr Julian Tay
Ms April Cheah
(M/s Lee & Lee)

DECISION OF THE INTERIM ORDERS COMMITTEE

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

Purpose of the Inquiry

1. This Interim Orders Committee ("**IOC**") was appointed under section 59A of the Medical Registration Act (Cap. 174) ("**MRA**") to inquire into and determine whether an interim order under section 59B(1) of the MRA should be made against Dr Kay Aih Boon Erwin ("**Dr Kay**") pending the conclusion of proceedings under Part 7 of the MRA.

The Medical Practitioner in question

2. Dr Kay is a medical practitioner registered under the MRA. At all material times, he was a general practitioner in private practice at Healthwerks Medical Centre (the "**Clinic**"). Dr Kay has been practising as a general practitioner for 25 years and is currently still in private practice.

Relevant facts giving rise to the Inquiry

3. On or about 24 December 2020, four practising paediatricians in Hospital A, provided to the SMC information regarding the practices of Dr Kay with respect to his investigations and management of children with Autism Spectrum Disorders ("**ASD**") and/or suspected to have ASD ("**Complaint**"). The said paediatricians are:

   3.1. Dr C1, a <designation redacted> at Hospital A;

   3.2. Dr C2, a <designation redacted> of Hospital A;

   3.3. Dr C3, a <designation redacted> at Hospital A; and

   3.4. Dr C4, a <designation redacted> of Hospital A

   (collectively, the "**Hospital A Paediatricians**").

4. According to Hospital A's website, Hospital A assesses and manages children from birth to seven years of age with a range of learning, behavioural, and developmental needs including ASD.

5. Amongst other things, Hospital A's Paediatricians informed the SMC of practices by Dr Kay in the management of children with ASD that they said were not based on evidence and had the potential of harm. These practices included the prescription of medications such as Fluconazole (or Diflucan, a trade name for Fluconazole) and Vancomycin to children with ASD. Hospital A's Paediatricians were of the view that the use of antibiotics and antifungal agents for the treatment of children with ASD was unnecessary and had the potential for harm.

6. Hospital A's Paediatricians stated that:

   6.1. They were deeply concerned about the practices of Dr Kay with respect to children with ASD and requested that the SMC investigate his practices further;

   6.2. Dr Kay may not be adhering to the current recommended clinical practice guidelines for the investigation and treatment of children with ASD;

   6.3. There was no evidence to support treatment with antibiotics or other alternative therapies;

   6.4. The AMS-MOH Clinical Practice Guidelines 1/2010 – Autism Spectrum Disorders in Pre-School Children (the "**CPG**") also stated that there was no role for alternative therapies in the management of children; and

   6.5. There was reason to believe that the unnecessary use of antibiotics and antifungal agents especially had the potential for harm.

7. The Complaint resulted in the appointment of a Complaints Committee ("**CC**"). Investigations by the CC led to the identification of at least three children (two of whom were the subject of

the Complaint) with ASD/suspected ASD who were treated by Dr Kay and prescribed with antibiotics and antifungal medications (such as Vancomycin and Fluconazole). The children are:

7.1. Patient A, date of birth - <date and month redacted> 2013;

7.2. Patient B, date of birth - <date and month redacted> 2017; and

7.3. Patient C, date of birth - <date and month redacted> 2017.

8. According to the medical records obtained from the Clinic:

8.1. On 2 July 2018, when Patient A was about five years of age, Dr Kay prescribed the following to Patient A:

8.1.1. 42 Fluconazole (or Diflucan, which is a trade name for Fluconazole) 50MG tablets, with instructions that Patient A consume three tablets daily for 14 days; and

8.1.2. 10 bottles of Vancomycin 500MG vials, with instructions that Patient A consume half a bottle, two times daily, for 10 days.

8.2. On 22 July 2020, when Patient B was about three years of age, Dr Kay prescribed the following to Patient B:

8.2.1. 14 Fluconazole (or Diflucan, which is a trade name for Fluconazole) 50MG tablets, with instructions that Patient B consume three tablets daily; and

8.2.2. 14 bottles of Vancomycin 500MG vials, with instructions that Patient B consume half a bottle, two times daily, for 14 days.

8.3. On 26 August 2020, when Patient C was about three years of age, Dr Kay prescribed to Patient C five bottles of Vancomycin 500MG vials, with instructions that Patient C consume half a bottle daily, for 10 days.

9. In the Complaint, it is stated that Vancomycin and Fluconazole are, respectively, strong antibiotic and antifungal medications which have the potential for harm when prescribed unnecessarily and in the absence of scientific basis.

10. At the time of the hearing by this IOC, the complaint by the SMC in respect of the information provided by Hospital A's Paediatricians was before the CC and had not yet been referred to a Disciplinary Tribunal. The CC has referred the matter to this IOC for the purpose of considering whether an order should be made under section 59B(1) of the MRA as being necessary for the protection of members of the public or as otherwise in the public interest, or in the interest of Dr Kay. In particular, the CC is concerned with Dr Kay's prescription of Vancomycin and Fluconazole without any scientific basis and/or indication.

11. Pending the determination by the CC, and if the Complaint is referred to a Disciplinary Tribunal, the determination by the Disciplinary Tribunal, the SMC submits that an interim order

should be made against Dr Kay. The SMC is not seeking an interim suspension order against Dr Kay but an order that Dr Kay's registration as a medical practitioner be conditional on his compliance with the following conditions and restrictions for a period of 18 months:

11.1. Dr Kay must not recommend, prescribe, or administer Vancomycin and/or Fluconazole (also known as Diflucan) to any patient of seven years of age or below under any circumstances, regardless of whether the prior approval of a fully registered medical practitioner is obtained;

11.2. Dr Kay must not recommend, prescribe, or administer Vancomycin and/or Fluconazole (also known as Diflucan) to all patients under his charge without the prior approval of a fully registered medical practitioner with a valid practising certificate, whose approval, Medical Council Registration Number and signature must be recorded electronically or in writing;

11.3. Dr Kay must keep a log of all patients to whom he has recommended, prescribed or administered Vancomycin and/or Fluconazole (also known as Diflucan) to, and must submit this log to the CC and the SMC within five calendar days of such recommendation, prescription, or administration;

11.4. Dr Kay must inform the SMC of all clinics at which he practises or intends to practise as a general practitioner or as a locum doctor;

11.5. Dr Kay must inform any organisation or person employing him for medical work that his registration is subject to the above conditions; and

11.6. Any other restrictions that the IOC sees fit to impose,

(collectively, the "**Conditions**").

12. Dr Kay, however, submits that the IOC should not make any order under section 59B(1) of the MRA as such an order would be unnecessary for the protection of members of the public, nor would it be, otherwise, in the public interest and/or in Dr Kay's own interest.

Framework adopted by the IOC

13. Section 59B(1) of the MRA provides as follows:

> "**59B**.—(1) Where, upon due inquiry into any complaint or information referred to it, an Interim Orders Committee is satisfied that it is necessary for the protection of members of the public or is otherwise in the public interest, or is in the interests of the registered medical practitioner concerned, that his registration be suspended or be made subject to conditions or restrictions, the Interim Orders Committee may make an order —
>
> (a) that his registration in the appropriate register be suspended for such period not exceeding 18 months as may be specified in the order (referred to in this Part as an interim suspension order); or
>
> (b) that his registration be conditional on his compliance, during such period not exceeding 18 months as may be specified in the

> order, with such conditions or restrictions so specified as the Interim Orders Committee thinks fit to impose (referred to in this Part as an interim restriction order)."

14. From the aforesaid provision, it follows that the IOC can only order a suspension of Dr Kay's registration or subject his registration to conditions, where it is satisfied that it is:

    14.1. necessary for the protection of members of the public;

    14.2. otherwise in the public interest; or

    14.3. in the interest of Dr Kay.

    (See the decision of the IOC for Dr Wee Teong Boo dated 9 May 2017 ("***Wee Teong Boo***") at [9], the decision of the IOC for Dr Ler Teck Siang dated 7 March 2019 ("***Ler Teck Siang***") at [11], the decision of the IOC for Dr Chan Herng Nieng dated 18 June 2020 ("***Chan Herng Nieng***") at [17], and the decision of the IOC for Dr Ong Kian Peng Julian dated 18 June 2020 ("***Ong Kian Peng Julian***") at [18].)

15. It is the SMC's submission that in arriving at its decision on whether to impose an interim order, the IOC's task is to consider whether the allegations in any complaint or information referred to it, irrespective of their truth or falsity, justify the suspension or conditional registration of the medical practitioner. To determine this, a two-pronged approach is adopted (see *Wee Teong Boo*, which involved alleged sexual criminal offences of rape and outrage of modesty, at [31]):

    15.1. First, the IOC must assess the extent to which the medical practitioner poses a risk to the members of the public against an assessment of the potential adverse consequences if an interim order is not made against the medical practitioner.

    15.2. Second, the IOC has to balance the interests of the medical practitioner with the interests of the public — making a determination proportionate to the perceived risk to members of the public and/or to protect the public interest.

16. As set out in *Wee Teong Boo* (and confirmed in *Ler Teck Siang* at [12], *Chan Herng Nieng* at [20], and *Ong Kian Peng Julian* at [21]), the following principles are relevant to the IOC's determination of whether an interim order should be made and of the appropriate interim order to be made:

    16.1. The IOC's task is not a fact-finding one, nor is its remit to make any judgment on the merit of the criminal charges where allegations of criminal offences were involved (*Wee Teong Boo* at [32], *Ler Teck Siang* at [12.1]) or to make any judgment of the merits of the allegations in a complaint or the potential outcome of pending Disciplinary Tribunal proceedings (*Chan Herng Nieng* at [20.1], *Ong Kian Peng Julian* at [21.1]). Applied to the present case, it is similarly not the IOC's remit to make a judgment on the merit of the allegations in the information referred to the IOC or the potential outcome of the pending Complaints Committee proceedings or potential Disciplinary Tribunal proceedings.

    16.2. The purport of section 59B(1) of the MRA is that the IOC must assess the risk of harm to members of the public, as well as what is in the public interest and what is in the

medical practitioner's interests. The IOC must assess the gravity of the consequences of the risk (if it materialises) as well as whether the risk is high or low (*Wee Teong Boo* at [33], *Ler Teck Siang* at [12.2], *Chan Herng Nieng* at [20.2], and *Ong Kian Peng Julian* at [21.2]).

16.3. In determining the appropriate order to be made, the IOC will take into consideration the severity of the allegations made against the medical practitioner and the nature of the harm to the public (if true). If the allegations against the medical practitioner are of an extremely serious nature and the nature of the harm to the public (if true) is grave, an appropriately robust order from the IOC may be justified. In assessing risk, the IOC will also consider whether the charges (or in this case, the complaint) arose from an isolated incident, and whether the doctor has remained free from complaints. The IOC will also give due weight to considerations of proportionality (*Wee Teong Boo* at [39], *Ler Teck Siang* at [12.3], *Chan Herng Nieng* at [20.3], and *Ong Kian Peng Julian* at [21.3]).

16.4. With regard to the public interest and the maintenance of public confidence in the medical profession in Singapore, the applicable test is as stated in the UK case of *NH v General Medical Counsel* [2016] EWHC 2348 (Admin) (at [12]): "*[W]ould an average member of the public be shocked or troubled to learn, if there is a conviction in this case, that the doctor had continued to practice whilst on bail awaiting trial?"* (*Wee Teong Boo* at [43], *Ler Teck Siang* at [12.4], *Chan Herng Nieng* at [20.4], and *Ong Kian Peng Julian* at [21.4]).

17. In addition, as the provisions of the MRA on interim orders are modelled after United Kingdom legislation, the IOC can take guidance from the UK General Medical Council (see *Wee Teong Boo* at [37]). It is relevant to refer to *Imposing Interim Orders: Guidance for the Interim Orders Tribunal, Tribunal Chair and Medical Practitioners Tribunal* ("***Guidance on Imposing Interim Orders***") issued by the UK General Medical Council Guidelines 23 to 25 from the section on "Test applied":

"**Test applied**

23 The IOT must consider, in accordance with section 41A, whether to impose an interim order. If the IOT is satisfied that:

a in all the circumstances that ***there may be impairment of the doctor's fitness to practise which poses a real risk to members of the public, or may adversely affect the public interest*** or the interests of the practitioner;

and

b after ***balancing the interests of the doctor and the interests of the public,*** that an interim order is necessary to guard against such risk,

the appropriate order should be made.

24 In reaching a decision whether to impose an interim order an IOT should consider the following issues:

a The ***seriousness of risk to members of the public*** if the doctor continues to hold unrestricted registration. In assessing this risk the IOT should consider the seriousness of the allegations, the weight of the information, including information about the likelihood of a further incident or incidents occurring during the relevant period.

b ***Whether public confidence in the medical profession is likely to be seriously damaged*** if the doctor continues to hold unrestricted registration during the relevant period.

c ***Whether it is in the doctor's interests*** to hold unrestricted registration. For example, the doctor may clearly lack insight and need to be protected from him or herself.

25 In weighing up these factors, the IOT must carefully consider the ***proportionality of their response*** in dealing with the risk to the public interest (including patient safety and public confidence) and the adverse consequences of any action on the doctor's own interests."

[emphasis added]

The SMC's Case

18. It is noted that the SMC is not seeking an interim suspension order against Dr Kay but an order subjecting Dr Kay's registration to the proposed Conditions set out at paragraph 11 above.

19. The SMC submits that given the potential harm and serious adverse effects from the unnecessary prescription of Vancomycin and Fluconazole to children aged seven and below, and the fact that at least three patients have been identified to have received similar treatment from Dr Kay, there is a serious risk of harm to the public, in particular, to young children aged seven (7) and below, if Dr Kay is not restrained from prescribing the said antibiotic and antifungal medications and that it is necessary for the protection of the members of the public and in the public interest that the Conditions be imposed.

(1) An interim order is necessary for the protection of members of the public

20. It is the SMC's submission that the basis for the Conditions sought to be imposed are:

20.1. Four paediatricians from Hospital A saw fit to raise their concerns with regards to Dr Kay's treatment and management of young children with ASD to the SMC. All four of Hospital A's Paediatricians are on the Register of Specialists for Paediatric Medicine, and two of them are the <designations redacted> of Hospital A. In making their allegations against Dr Kay in respect of his practices, Hospital A's Paediatricians have done so with their combined expertise of four specialists in paediatric medicine. Bearing this in mind, it is submitted that their concerns should be given significant weight by the IOC; and

20.2. It should be noted that Vancomycin and Fluconazole are strong antibiotic and antifungal medications, which are potentially dangerous and harmful if prescribed without scientific basis.

21. In respect of the nature of the harm that may be caused, the SMC referred to the CPG which states that:

    21.1. Antibiotics and anti-yeast medications are complementary alternative therapies that are not recommended in pre-school children with ASD because of insufficient evidence for efficacy and potential harm or adverse effects;

    21.2. A child's pre-school years are vulnerable;

    21.3. Healthcare professionals caring for pre-school children with ASD should advise parents and caregivers to avoid using any antibiotics in view of the potential for harm;

    21.4. Intestinal dysbiosis and immune dysregulation in children with ASD was suggested to contribute to autism symptoms, but intestinal candidial over-growth was not observed during endoscopy in children with ASD. Rather, an overgrowth of yeast and pathogenic bacteria may result from frequent prolonged courses of antibiotic treatment;

    21.5. Evidence on the efficacy of Vancomycin in children with ASD was inconclusive;

    21.6. There are serious adverse effects associated with indiscriminate use of antibiotics, including the emergence of antibiotic-resistant bacteria such as vancomycin–resistant *Staphylococcus aureus* and vancomycin-resistant *Enterococcus spp*; and

    21.7. Chronic use of anti-fungal therapy is associated with hepatotoxicity and exfoliative dermatitis.

22. The SMC acknowledges that the CPG was published in March 2010 and is listed on the Ministry of Health's website as guidelines that have been withdrawn as five years have passed since its publication. However, the SMC submits that such automatic withdrawal does not mean that the contents of the CPG is now wrong or outdated. Rather, it is simply to be treated with caution since the CPG is "only as current as the evidence that supports them, and new evidence can supersede recommendations made in the [CPG]". Further, the SMC notes that Hospital A's Paediatricians continued to cite the CPG in the Complaint, which meant that Hospital A's Paediatricians believe that current evidence and research do not supersede the recommendations and views expressed in the CPG with regard to the prescription of antibiotic and antifungal medications.

23. The SMC reiterates that:

    23.1. Fact-finding is not a task of the IOC, and making a conclusive determination as to the harm caused in the prescription of Vancomycin and Fluconazole is not within the IOC's remit;

    23.2. The IOC is to consider the consequences of the risk (if it materialises), whether the risk is high or low, and the nature of the harm to the public (if true). It is not the function of the IOC to determine if the consequences of the risk will materialise or whether the harm to the public is true; and

23.3. Therefore, in the present case, reference to the CPG is made insofar as it enables the IOC to understand Hospital A's Paediatricians' allegations and concerns with regard to Dr Kay's practices – it is not for the IOC to determine if Hospital A's Paediatricians' allegations are true or not.

24. While it is not the role of the IOC to determine whether Dr Kay had in fact prescribed Vancomycin and/or Fluconazole without scientific basis, the SMC submits that the Complaint strongly suggests that there is a high risk that Dr Kay is doing so.

25. According to the Complaint, two of the three patients were children on follow-up with Hospital A for ASD. However, when they were seen by one of the paediatricians from Hospital A, in both cases, the children were advised to stop taking them. The SMC submits that this strongly suggests that there is a high risk that Dr Kay is prescribing Vancomycin and/or Fluconazole to children with ASD in the absence of scientific evidence and basis.

26. While Dr Kay has submitted a Written Explanation responding to Hospital A's Paediatricians' allegations, the SMC submits that fact-finding is not the task of the IOC and the IOC's remit is not to judge the merits of Hospital A's Paediatrician's allegations or the potential outcome of the pending CC proceedings or potential Disciplinary Tribunal proceedings. The IOC is concerned with the consequences of the risk of harm if it materialises.

27. The SMC points out that the risk of harm posed to the public concerns a vulnerable group in society, namely, young children with ASD aged seven and below, and Dr Kay's prescription of Vancomycin and/or Fluconazole is not isolated to a single child, but to at least three children (that is presently known to the IOC).

28. In this regard, the SMC brought to the IOC's attention that:

28.1. Hospital A's Paediatricians wrote to the SMC in respect of "*[n]on evidence-based practices in the management of* ***<u>children with [ASD]</u>*** *with potential of harm to patients*" [emphasis SMC's];

28.2. Hospital A's Paediatricians stated that Dr Kay "may not be adhering to the current recommended clinical practice guidelines for the investigation and treatment of ***<u>children with ASD</u>***" [emphasis SMC's];

28.3. The information provided by Hospital A's Paediatricians to the SMC also suggested that Dr Kay's practices related to not a single case, but to other patients "***<u>over the past few years, continuing to date</u>***" [emphasis SMC's];

28.4. Hospital A's Paediatricians practise at Hospital A, where <u>children with ASD of seven years of age or younger</u> are managed; and

28.5. The CPG suggests that its application to pre-school children refers to children who are seven years of age or younger.

29. The SMC submits that children who are of seven years of age or below are very young and are highly vulnerable members of the public, particularly as they are still developing and growing. Hospital A's Paediatricians' allegations are serious and if true, *i.e.*, that Dr Kay is prescribing

antibiotic and antifungal medications unnecessarily without scientific basis, would mean that Dr Kay is needlessly subjecting young children with ASD to the harm that the consumption of Vancomycin and/or Fluconazole may cause. Given the vulnerability of these children, the consequences of the risk materialising would be severe. The IOC notes that the Conditions sought by the SMC applies to all children aged seven and below, and not only to children formally diagnosed with ASD or suspected to have ASD. The SMC's explanation is set out below.

30. First, not all children with ASD may have been formally diagnosed with ASD or be identified to be suspected to have ASD before the age of seven or at the time they consult with Dr Kay. Second, while the patients concerned in this inquiry relate to children with ASD / suspected ASD, there is still a risk that Dr Kay could be prescribing such medications to young children aged seven and below without scientific basis and/or indication, who may not have ASD but whom the SMC is not aware of because the information it received was from Hospital A, which only specialises in treating children with ASD aged seven and below. In the circumstances, the SMC submits that it would be necessary for the purposes of these proceedings to protect all young children aged seven and below from the risk of harm from the prescription of Vancomycin and/or Fluconazole by Dr Kay, regardless of whether they have been diagnosed with ASD.

31. The SMC further submits that the risk to public safety if Dr Kay is allowed to continue practising must also be considered in the context of Dr Kay being in private practice as a general practitioner. Being in private practice, there may be less institutional oversight of his activities. The level of supervision and internal checks and balances would depend on the clinics at which he works. As a general practitioner, he is also likely to receive young children as patients. Hospital A's Paediatricians have similarly expressed that, as Dr Kay practises in the private healthcare setting, there is limited opportunity for the review of his practices by doctors in the public healthcare institutions and children would often have already completed or already started consuming unnecessary medications by the time they consult with other doctors in such public health institutions.

32. Both Patient A and Patient B had already consumed Vancomycin and Fluconazole prescribed to them by Dr Kay before they had consulted with Hospital A. The implications of this are two-fold. First, while only the prescriptions of Vancomycin and/or Fluconazole to Patient A, Patient B, and Patient C have come to the attention of Hospital A, there is the risk that other children had been prescribed and will continue to be prescribed Vancomycin and/or Fluconazole by Dr Kay if he is left to practise without restriction. Second, without the Conditions being put in place, even if patients who had been prescribed Vancomycin and/or Fluconazole by Dr Kay are subsequently seen by other doctors, there is the inevitable risk that harm from Dr Kay's prescription of such medications may have already been occasioned as the patient would have already started consuming such medications.

33. It is SMC's submission that the proposed Conditions are a necessary precaution as it will eliminate the risk of children, seven (7) years of age or below, who are young and extremely vulnerable, from being prescribed Vancomycin and/or Fluconazole without scientific evidence and being subject to the harm of such prescriptions by Dr Kay.

(2) An interim order is in the interest of the public

34. The SMC submits that further, or in the alternative, the imposition of the Conditions on Dr Kay's practice is in the public interest as there is a risk that public trust and confidence in the profession would be undermined if the profession were to grant Dr Kay full liberty to continue practising uninhibited, whilst awaiting the determination of the CC or, if an inquiry is to be held by a Disciplinary Tribunal, the determination of the Disciplinary Tribunal.

35. It is the SMC's position that ensuring the applicable standard of care is provided to patients is important in upholding public trust and confidence in the medical profession and that the prescription of medication by a medical practitioner is a unique privilege and must never be abused. The SMC refers to its Ethical Code and Ethical Guidelines (2016 Edition) ("**SMC ECEG**") which emphasises this:

> "**1. Why the Ethical Code and Ethical Guidelines?**
>
> (1) As a member of the medical profession, you are held in the highest esteem by the public and society, who depend on a reliable and trustworthy healthcare system and look to you for the relief of their suffering and ailments. Much trust is therefore vested in you to do your best by both. This trust is contingent on the profession maintaining the highest standards of professional practice and conduct. You must therefore strive to continually strengthen the trust that has been bestowed.
>
> **The Ethical Code**
>
> (1) Patients and the public must be able to trust you implicitly with their lives and wellbeing. To justify this trust, you have to maintain a good standard of care, conduct and behaviour. The SMC prescribes the Ethical Code which you are required to uphold. These principles are applicable to a wide variety of circumstances and situations. Adherence to the Ethical Code will enable society to have trust and confidence in the profession."

36. The SMC ECEG also requires medical practitioners to adhere to the below so as to enable the public to have trust and confidence in the profession:

> "**A1. Duty of care**
>
> In clinical practice, the care of your patient is your primary concern. To provide the best possible care means:
>
> …
>
> (4) You must provide a standard of medical care that is rational and based on a balance of evidence and accepted good clinical practice.
>
> (5) You must offer your patients treatments that are beneficial. Treatments are not legitimate just because there is little evidence of harm or because they are widely employed. You must have sufficient reason to believe that they are beneficial to your patients.
>
> …

B5. Prescription of medicine

Doctors have the unique privilege of prescribing medicine and treatments. This is a serious responsibility and must never be abused. Prescribing responsibly means:

…

(2) You must prescribe, dispense or supply medicines only on clear medical grounds arrived at through sufficient clinical information and after considering the available evidence and what is accepted by the profession as good clinical practice.

…

B6. Untested practices

Patients expect doctors to offer only treatments or therapies that will benefit them while minimising harm. Offering appropriate treatment to patients means:

(2) You must treat patients only according to generally accepted methods, based on a balance of available evidence and accepted best practices.

…

(3) Except for innovative therapy, treatments that are not generally accepted must be offered to patients only in the context of formal and approved clinical trials which would be subject to the ethics of research.

…"

37. Pursuant to the SMC ECEG, the SMC submits that doctors are under the overarching duty to provide an appropriate standard of care provided to patients under their care. They must (a) ensure that the care is based on a balance of evidence and accepted good clinical practice; (b) offer treatments that they have sufficient reason to believe are beneficial; (c) prescribe medicine only on clear medical grounds, arrived at after conspiring the available evidence and what is accepted by the profession as good clinical practice; and (d) treat patients only according to generally accepted methods, based on a balance of available evidence and accepted best practices. Where treatments are not generally accepted, they can only be offered to patients in the context of formal and approved clinical trials. Indeed, it is essential for the public to remain confident that medical practitioners provide an appropriate standard of care to them, especially in the prescription of strong medications such as Vancomycin and Fluconazole.

38. The SMC submits that public confidence in the medical profession would likely be shaken if the public becomes aware that a doctor has been allowed to continue practising unrestricted before allegations (that they are prescribing medications without scientific evidence with the potential for harm to young children seven years of age or younger) are conclusively dealt with. This is especially so when the allegations are made not only by fellow doctors, but by specialists in paediatric medicine practising at a public healthcare institution specialising in the treatment of young children.

39. It is the SMC's position that even if Dr Kay had prescribed Vancomycin and Fluconazole to Patient A and Patient B, and prescribed Vancomycin to Patient C, with their parent's and/or caregiver's consent, this does not detract from the potential damage to public confidence. As espoused in the SMC ECEG, patients (and parents and caregivers of young patients) put their trust in doctors to make proper prescriptions on clear medical grounds. They must be able to trust doctors implicitly with their lives and wellbeing.

(3) The Conditions are warranted in the present case and are proportionate to the risk of harm to the public and the risk of damage to public confidence

40. The SMC highlights that this appears to be the first local case where information pertaining to a doctor's professional services, particularly, his prescription of medication, was referred to an IOC and points to Guideline 28 of the *Guidance on Imposing Interim Orders* which expressly considers that an interim order may be imposed in respect of a doctor's clinical care and professional knowledge:

> "**Allegations of poor performance/substandard clinical care**
>
> **28** The test for imposing an order may be met where there is information that a doctor's clinical skills and/or professional knowledge and competence are, or are likely to be, such that they pose a real risk to members of the public if they were to continue without restriction. Such cases may include either a series of failures to provide a proper standard of care, or one particularly serious failure. Consideration should be given to making an order both for the protection of the public and in the public interest including to maintain public confidence and to maintain and promote proper professional standards and conduct for doctors."

41. The SMC refers to interim orders imposed by the UK IOC or Interim Orders Panel against doctors following allegations related to the prescription of medicine which have been upheld and extended in length by the English High Court:

41.1. In *R. (on the application of Madan) v General Medical Council* [2001] EWHC Admin 322, a medical practitioner applied to the English High Court to challenge the decision of an IOC of the General Medical Council. The IOC had suspended the medical practitioner's registration for 18 months following allegations of inappropriate and irresponsible prescriptions of appetite suppressants by her. The medical practitioner's application was dismissed.

41.2. In *R. (on the application of General Medical Council) v Berry* [2009] EWHC 332 (Admin), the General Medical Council applied to the English High Court for an order to extend an interim order put in place by an Interim Orders Panel of the General Medical Council. The IOC had considered that the public interest required the imposition of a number of conditions on a medical practitioner's registration following allegations that, amongst others, he had failed to ensure that controlled drugs were properly provided to his patients over a long period of time and prescribed potentially addictive medication that was not clinically indicated in many instances, without the informed consent of the patient and for his own personal financial benefit. The extension was granted.

42. The SMC submits that the proposed Conditions sought are proportionate because they are no more restrictive than necessary to mitigate the risk of harm to the public or damage to public confidence. The Conditions only prohibit Dr Kay from prescribing Vancomycin and/or Fluconazole to young children aged seven and below, but allow Dr Kay's prescription of such medications to other age groups provided he obtains the approval of a fully registered medical practitioner with a valid practising certificate.

43. The SMC further submits that the proposed Conditions are not intrusive or unduly burdensome on Dr Kay. The Conditions such as informing the SMC of all clinics at which he practises or intends to practise as a general practitioner or as a locum doctor, submitting a log of every patient with ASD that he consults with and/or treats, and informing any employer that his registration is subject to the Conditions are administrative, and do not impose a substantial burden on Dr Kay. More importantly, these requirements will enable the SMC to monitor Dr Kay's compliance with the Conditions and ensure the protection of the public.

44. As regards the Conditions relating to Dr Kay's prescription of Vancomycin and Fluconazole, the SMC submits that Dr Kay will still be able to continue his medical practice and to continue treating his patients, save that he cannot prescribe Vancomycin and/or Fluconazole to children of seven years of age or younger. The Conditions do not prohibit any other aspects of Dr Kay's treatment of children including prescribing Vancomycin and/or Fluconazole to patients of other age groups so long as another registered medical practitioner approves the same. The SMC submits that the Conditions ensure that any prescription of Vancomycin and/or Fluconazole by Dr Kay is supported by a second opinion and would prevent Dr Kay from causing harm to the public by unnecessarily prescribing these medications. Further, the Condition that he cannot prescribe Vancomycin and/or Fluconazole to children of seven years of age or younger is not unduly restrictive in view of the potential risk of harm that could result from such prescriptions and, particularly as Dr Kay is part of a group of six doctors under Healthwerkz Medical Group, in that Dr Kay would be able to obtain the necessary approval should such prescription be made safely and with scientific basis.

45. The SMC submits that the proposed Conditions are clear and leave no ambiguity as to how compliance is to be achieved. The costs of complying with the proposed Conditions, if any, are minimal, and in any event are outweighed by the need to safeguard against the risk of harm.

46. The SMC further submits that after balancing Dr Kay's interests and the interest of the public, the proposed Conditions are necessary and proportionate in the present circumstances and that there would be little, if any, disruption to Dr Kay's current practice. At the same time, young patients, of seven years or below, with ASD or who are suspected to have ASD would be protected from the risk of harm from prescription of Vancomycin and/or Fluconazole. Public confidence in the medical profession in Singapore would also be preserved with the imposition of the proposed Conditions.

(4) The Conditions should be imposed for a period of 18 months

47. The SMC submits that an interim order of 18 months should be imposed as the Complaint is currently still pending before the CC which has yet to make a determination as to whether the complaint should be referred for formal inquiry by a Disciplinary Tribunal.

48. Pursuant to section 59C of the MRA, the IOC (or another IOC appointed in its place) is bound by law to review the order within six months from the date on which the order was made, and subsequently, to further review it at three-monthly intervals for so long as the order is in force. At these review hearings, the IOC may revoke or vary the interim order that was previously made, replace an interim suspension order with an interim restriction order, or replace an interim restriction order with an interim suspension order: section 59D of the MRA. However, the IOC does not have the power to extend the duration of the existing interim order under section 59D of the MRA and would have to apply to the General Division of the High Court to extend the duration of the interim order under section 59F of the MRA.

49. Therefore, given the uncertainty of when the CC proceedings or, if an inquiry is to be held by a Disciplinary Tribunal, the Disciplinary Tribunal proceedings will conclude, the SMC submits that the maximum period of suspension of 18 months is appropriate. Otherwise, in the event that any interim order imposed on Dr Kay lapses before the CC proceedings or, if an inquiry is to be held by a Disciplinary Tribunal, before the Disciplinary Tribunal proceedings have concluded, Dr Kay will be allowed to practise unrestricted and the SMC will be required to apply to the High Court under section 59F of the MRA to seek an extension of the interim order.

50. In any case, an interim order will only be in force until the end of the specified period or the date on which "relevant proceedings" are concluded, whichever is the earlier: section 59G(1) of the MRA. For the purposes of the present case, the "relevant proceedings" would conclude:

    50.1. when the Complaints Committee makes an order under section 49(1) of the MRA that no formal inquiry by a Disciplinary Tribunal is necessary (and provided (i) no appeal to the Minister for Health under sections 49(10) or 49(11) of the MRA was made against that decision within 30 days after being notified of the determination of the Complaints Committee or such an appeal was withdrawn; or (ii) the Minister makes an order under sections 49(13)(*a*) or 49(13)(*d*) of the MRA); or

    50.2. when the Complaints Committee refers the matter for formal inquiry by a Disciplinary Tribunal, and the Disciplinary Tribunal (i) makes an order under section 53(2) which has taken effect; or (ii) dismisses the matter under section 53(4) of the MRA – see section 59G(2)(*b*) of the MRA.

51. Therefore, seeking an interim order for a period that is longer than the duration of the CC proceedings or, if an inquiry is to be held by a Disciplinary Tribunal, longer than the Disciplinary Tribunal proceedings, will not result in any prejudice to Dr Kay, since under section 59G(1) of the MRA, any interim order made will no longer be in force once the CC or, if an inquiry is to be held by a Disciplinary Tribunal, the Disciplinary Tribunal proceedings have concluded.

52. In conclusion, the SMC submits that there is strong basis for the IOC to impose the proposed Conditions on Dr Kay's registration for a period of 18 months, and that such an order is necessary for the protection of members of the public and is in the public interest.

<u>Dr Kay's Case</u>

53. It is Dr Kay's case that both Fluconazole and Vancomycin are therapeutic products locally registered with the Health Sciences Authority. Fluconazole is an antifungal medication used to

treat a variety of fungal infections. Oral Vancomycin is a poorly absorbed antibiotic used to treat anaerobic enteric infections. Both medications are safe and approved for use in children.

54. Dr Kay's position is that he did not treat these patients' ASD as they were already being seen at Hospital A for that condition, but what he did was to treat their co-occurring medical conditions associated with ASD by *inter alia* prescribing antibiotics and antifungal agents to treat the bacterial overgrowth/infections and yeast/fungal overgrowth/infections respectively.

(1) Principles Relevant in Deciding Whether an Interim Order should be made by IOC

55. Dr Kay sets out the principles applicable to the determination of whether an order under section 59B(1) should be made by the IOC as follows:

    55.1. The IOC's task is not a fact-finding one, nor is its remit to make any judgment on the merit of the criminal charges (*Wee Teong Boo 2017* at [32] and *Ler Teck Siang* at [12]).

    55.2. The IOC's task is to assess the risk of harm to members of the public, as well as what is in the public interest and what is in the medical practitioner's interests (*Wee Teong Boo 2017* at [33] and *Ler Teck Siang* at [12]).

    55.3. In assessing the risk of harm to members of the public, the IOC will take into consideration the severity of the allegations made against the medical practitioner and the nature of harm to the public (if true). The IOC will also consider whether the Complaint arises from an isolated incident, and whether the doctor has remained free from complaints prior to and after the Complaint. The IOC will also give due weight to considerations of proportionality (*Wee Teong Boo 2017* at [39] and *Ler Teck Siang* at [12]).

    55.4. With regard to the public interest and the maintenance of public confidence in the medical profession in Singapore, as the relevant provisions of the MRA on interim orders are closely modelled after section 41A(1) of the UK Medical Act 1983, the IOC can be guided by the experience of the UK (*Wee Teong Boo 2017* at [37]). The applicable test is as stated in the UK case of *NH v General Medical Counsel* [2016] EWHC 2348 (Admin) at [12]: "*[W]ould an average member of the public be shocked or troubled to learn, if there is a conviction in this case, that the doctor had continued to practice whilst on bail awaiting trial?*" (*Wee Teong Boo 2017* at [43]).

56. Essentially, Dr Kay agrees with the SMC as to the principles that are relevant in considering whether an interim order should be made by the IOC.

(2) Principles Relevant to Prescription of Medication

57. With regard to the principles relevant to prescription of medication, Dr Kay refers to the SMC ECEG which states that doctors "*must prescribe, dispense or supply medicines only on clear medical grounds arrived at through sufficient clinical information and after considering the available evidence and what is accepted by the profession as good clinical practice*".

58. He also refers to the accompanying SMC Handbook on Medical Ethics (2016 Edition) ("**Handbook**") which states that:

> "Prescription of medicines can only really be appropriate when you have sufficient information about your patients, either personally acquired or provided to you by another doctor or healthcare professional. **Such information is usually obtained through good history-taking, clinical findings and/or relevant investigations**…
>
> …
>
> The appropriate prescription of medicines is **based on rational medical grounds**. Such grounds are arrived at by **considering available evidence of the drugs' efficacy and safety for the purposes prescribed as well as general acceptance by the profession that the drugs are of net benefit to patients**. In the practice of medicine, **the rationale for the use of drugs or any treatment is based on a combination of evidence and accepted practice, the balance between them being quite variable**. Some treatments that have never been the subject of formal clinical trials are well-accepted to be of net benefit to patients and it would be unethical to now conduct such trials, given the time-tested benefits of these treatments and the possible harm to patients if not treated. In general, you should be able to explain your rationale for prescribing treatment."
>
> (emphasis Dr Kay's)

(3) No Interim Order should be made under section 59B(1) of the MRA

59. It is Dr Kay's case that no order should be made under section 59B(1) of the MRA as such an order would be unnecessary for the protection of members of the public, nor would it be otherwise in the public interest and/or in Dr Kay's own interest to make such an order, for the following principal reasons:

    59.1. Dr Kay's prescription of Fluconazole and/or Vancomycin to the three patients was clinically indicated;

    59.2. Dr Kay's prescription of Fluconazole and/or Vancomycin to the three patients was supported by scientific evidence and safe; and

    59.3. Dr Kay's case is completely distinguishable from past published grounds of decisions of the IOC where interim orders were made under section 59B(1) of the MRA.

A. Dr Kay's prescription of Fluconazole and/or Vancomycin to the three patients was clinically indicated

60. Dr Kay submits that he prescribed Fluconazole and/or Vancomycin to the three patients only in the presence of clear medical grounds arrived at through sufficient clinical information, obtained through history-taking, clinical findings, and relevant investigations.

61. Dr Kay sets out the key aspects of his treatment and management of the three patients relevant to the prescription of Fluconazole and/or Vancomycin as follows:

    i. The prescription of Fluconazole and Vancomycin to Patient B was clinically indicated

62. Patient B's mother first brought him to consult Dr Kay on 6 June 2020 when Patient B was about 2 years old. A diagnosis of severe ASD had already been made at Hospital A, and Patient B had regular follow-up appointments there.

63. Amongst other matters, Patient B's mother informed Dr Kay that Patient B had eczema, poor immune status, constipation, and behavioural issues such as hyperactivity, irritability and frequent meltdowns. Dr Kay suspected a gastrointestinal issue given its prevalence in children with ASD. Patient B was also noted to exhibit inappropriate laughing, giggling, inattention, high pitched squealing, sugar cravings and skin rashes, which were symptoms suggestive of a yeast infection. These are generally accepted signs and symptoms of yeast overgrowth and consistent with observations.

64. Given the history presented, Dr Kay ordered a stool test which showed a calprotectin level of 98 ug/g, indicating gut inflammation, as well as an organic acids test which showed that markers of bacterial and yeast metabolites were present, indicating dysbiosis.

65. Dr Kay explained the results of these investigations to Patient B's parents. In view of the gut inflammation proven by raised calprotectin and likely caused by gut bacteria and yeast as shown in the investigations, he discussed the option of treatment with oral Vancomycin and oral Fluconazole, and also discussed the alternative of only offering probiotics to Patient B. The parents understood the risk and benefits. As such, a short course of oral Vancomycin and oral Fluconazole was prescribed for 14 days along with probiotics. Only one course of medications was given.

66. At subsequent visits, Patient B's health condition improved notably. In particular his eczema, constipation and behavioural symptoms improved, and he fell sick less frequently. Patient B's mother was pleased with his improvements and provided a testimonial.

ii. The prescription of Fluconazole and Vancomycin to Patient A was clinically indicated

67. Patient A and his mother first saw Dr Kay on 16 April 2018 when Patient A was around 5 years old. He had been diagnosed with ASD when he was about 3 years old at Hospital A and his ASD was managed at Hospital A.

68. Among other things, Patient A's mother reported late-onset or regressive autism that he had aberrant eating behaviour, hyperactivity, sleeping problems, past improvement with a gluten free and casein free diet and current undigested food in his stool suggestive of malabsorption or maldigestion. She also reported acutely increased inappropriate laughter and silly behaviour suggestive of yeast symptoms. Dr Kay suspected a gastrointestinal disorder and a possible yeast infection.

69. Based on the history presented, Dr Kay ordered an organic acids test which showed markers of bacterial and yeast metabolites, indicating dysbiosis. Although Dr Kay recommended a stool calprotectin test, this was not eventually performed as the parents were unable to collect a stool sample.

70. On 2 July 2018, Dr Kay explained the results to Patient A's mother, and stated that without calprotectin levels, he would not know whether the child had gut inflammation or not, however he explained that the history and clinical symptoms did suggest gut inflammation and that the

organic acids test suggested gut infection with bacteria and yeast. Dr Kay thus offered the following treatment options:

70.1. Do nothing;

70.2. Start a re-trial of gluten-free and casein-free diet for 3 months;

70.3. Take probiotics and certain vitamins; and/or

70.4. Take a short course of antibiotics and antifungal agents.

71. The parents opted for the fourth option, and Dr Kay discussed the risks, benefits and side effects with them. Accordingly, he prescribed oral Vancomycin at a dosage of 250mg twice a day for 10 days, and prescribed Fluconazole at a dosage of 3 (50mg) capsules daily for 14 days. He also prescribed probiotics to maintain healthy gut flora.

72. At a subsequent follow-up review, notable improvements such as increased spontaneous language communication were reported.

iii. The prescription of Vancomycin to Patient C was clinically indicated

73. Dr Kay first saw Patient C on 3 June 2019 together with her parents, when she was about 2 years old. She had been noted by Hospital A to have developmental delay, however there was no formal diagnosis of ASD at that time. Early intervention had already been commenced by Hospital A.

74. Patient C has weak muscle tone, was hyper-excitable, would cry for no reason, possibly suggestive of pain, and had sleep problems. On examination, she was noted to have a distended abdomen (for her small stature), enlarged cervical lymph nodes and weak muscle tone. Dr Kay suspected that Patient C might have gastrointestinal issues and poor immune function on the basis of the history taken and his examination of her.

75. Based on the history presented, Dr Kay ordered a stool culture. Two samples on separate occasions were taken as the first was of insufficient quantity. There was a light growth of aeromonas caviae (a pathogen) which was abnormal, and scant growth of yeast (trichosporon species). The second sample revealed heavy growth of klebsiella pneumoniae. Calprotectin levels were elevated at 137ug/g and rose to 198ug/g indicating intestinal inflammation which might be caused by acute infection. The stool tests also revealed occult blood. Finally, stool IgA, a marker of local gut immune function, was borderline low at 11, in contrast to normal levels of 20-160.

76. When Dr Kay next saw Patient C on 22 July 2019, he explained to her parents that she had an acute gut bacterial infection and yeast infection and he prescribed medications to treat these conditions.

77. Patient C improved, stopped crying without reason, sleep improved, eye contact was better as noted on 28 August 2019. Over the course of the next year and a half, Dr Kay ordered a repeat stool culture as she still had problems with daily bowel movement on 13 January 2020 to monitor for progress and assess if her gastrointestinal issues were fully addressed. Although

stool calprotectin levels were significantly improved, they were still persistently high at 108ug/g. These results were discussed on 26 August 2020, and a management plan was discussed with the parents in view of the underlying gut inflammation likely caused by anaerobic bacteria commonly found in children with ASD reported in clinical research. Dr Kay offered the option of repeating the stool culture test, or treating Patient C with a trial of oral Vancomycin which targets anaerobic bacterial. Parents were counselled extensively about the risks and benefits of oral Vancomycin. The parents consented to a trial of oral Vancomycin, and Dr Kay prescribed 250mg per day for 10 days. He had suggested that they recheck the calprotectin again three months later.

78. Patient C eventually stopped crying without reason, her abdominal distension reduced, and her sleep improved. Her father was pleased with her improvement and provided a testimonial.

B. Dr Kay's prescriptions of Fluconazole and/or Vancomycin to the three patients was supported by scientific evidence and safe

79. Dr Kay submits that his management and treatment of the three patients with oral Fluconazole and/or oral Vancomycin was grounded in scientific evidence, and was based on rational medical grounds. In prescribing such medications, Dr Kay considered the available evidence of the drugs' efficacy and safety for the purposes prescribed balanced with general acceptance by the profession that the drugs are of net benefit to patients.

i. The prescription of Fluconazole was supported by scientific evidence and safe

80. Dr Kay submits that there is scientific evidence and medical literature in support of his treatment of Patient B's and Patient A's yeast infestations and dysbiosis with Fluconazole and highlights scientific evidence which is summarised as follows:-

80.1. Children with ASD frequently suffer from gastrointestinal abnormalities, with an altered intestinal microbial community both at the bacterial and fungal level. Dr Kay refers to a study where children with ASD displayed a different fungal community structure compared to neurotypical subjects, in particular a relative abundance of Candida.

80.2. While the majority of healthy children did not harbour yeast overgrowth in their gut, a higher prevalence was found in patients with suspected or diagnosed ASD. Although Candida is often benign, scientists have noted that some autistic people have excessive amounts of Candida albicans in their intestinal tract. As Candida grows, it releases ammonia and biotoxins. Fluconazole coupled with probiotic supplements is one of the safe methods to treat yeast overgrowth and rebalance the intestinal bacteria and yeast, and Candida albicans and several other Candida strains were found susceptible to Fluconazole.

80.3. In a case study published in 2012, on the basis that multiple Candida species were found suggesting a lower-GI fungal overgrowth, Fluconazole at a dosage of 100mg daily for 30 days was successfully used to treat signs and symptoms of fungal overgrowth, including behavioural episodes and rashes in a child with ASD.

81. Dr Kay submits that Fluconazole is relatively safe for paediatric patients and when the Fluconazole dosage is limited to the therapeutic limit of < or = to 12mg/kg, there are no significant effects on liver toxicity.

82. The dosages of Fluconazole which he prescribed to Patient B and Patient A were within the safe limits for their age and weight, within the therapeutic dose limit of up to 12mg/kg/day: both Patient B and Patient A did not suffer any side effects due to Fluconazole, but in fact benefitted from the medication.

ii. The prescription of Vancomycin was supported by scientific evidence and safe

83. It is Dr Kay's view that the alteration of the gut microbiome or dysbiosis with an overgrowth of anaerobic bacteria, such as specific clostridium subtypes, desulfovibrio, suterella strains and low prevotella microbiota, is found to be higher in children with ASD. He refers to a finding where these types of bacteria can be successfully targeted by a prescription of oral Vancomycin in children with ASD.

84. Given the clinical and investigative results which suggested the presence of gastrointestinal issues, Dr Kay's clinical judgment was that the three patients' symptoms were caused by the overgrowth of anaerobic gut bacteria such as clostridia, i.e. the types of bacterial overgrowths more commonly detected in children with ASD, and that they would benefit from taking a course of oral Vancomycin as it specifically targets and is highly effective against such anaerobic bacteria.

85. Dr Kay's position is that oral Vancomycin is a glycopeptide with a high molecular weight of about 1,450g/mol. It therefore has poor oral absorption, minimal systematic effects and is approved for paediatric use and safe for consumption.

86. In prescribing Vancomycin to the three patients, Dr Kay states that he adhered to an acceptable paediatric therapeutic dosage not exceeding 40mg/kg body weight per day in divided doses of not more than 2,000mg per day, limiting prescriptions to short and adequate courses as follows:

86.1. Patient B was prescribed oral Vancomycin at a dosage of 250mg twice daily for 14 days.

86.2. Patient A was prescribed oral Vancomycin at a dosage of 250mg twice daily for 10 days.

86.3. Patient C was prescribed oral Vancomycin at a dosage of 250mg once daily for 10 days.

87. Dr Kay submits that the risks, as with any other antibiotics, were diarrhoea and nausea, but these risks were low. As an added precaution, Dr Kay prescribed various probiotics to the three patients when they were consuming antibiotics to counteract any potential alterations to the gut microbiome brought about by antibiotic treatment e.g. antibiotic-associated diarrhoea.

88. None of the three patients suffered any side effects due to Vancomycin and instead benefitted from the medication.

iii. *The prescription of Fluconazole and Vancomycin were in accordance with accredited training received by Dr Kay*

89. Dr Kay submits that his prescription of Fluconazole and Vancomycin to the three patients accorded with the best practices he learnt from training by attending various accredited conferences/training programmes to keep up to date with medical developments in the area of paediatric patients with ASD and that there no evidence that he poses any risk to members of the public that necessitates the making of an interim order.

C. Dr Kay's case is completely distinguishable from past published grounds of decisions of the IOC where interim orders under section 59B(1) of the MRA have been made

90. Dr Kay distinguishes his case from the earlier decisions of the IOC i.e. *Wee Teong Boo*, *Ler Teck Siang*, *Ong Kian Peng Julian* and *Chan Herng Nieng* where the IOC had either suspended the registration of the practitioner or subjected the registration to conditions or restrictions. Four (4) of these decisions involved allegations of sexual misconduct while one (1) involved the falsification of results of a HIV blood test amongst other criminal offences. Dr Kay submits that these cases are completely different from his case in terms of the nature and severity of allegations levied, degree/risk of harm, stage of proceedings and media scrutiny and that it would be wholly unprecedented for an interim order under section 59B(1) of the MRA to be made against a medical practitioner in Dr Kay's circumstances.

91. Dr Kay submits that his case is distinguishable from the aforesaid cases on four counts:

91.1. First, Dr Kay's case involves allegations of prescriptions of an antibiotic and/or an antifungal medication to three paediatric patients. It was never alleged that these prescriptions were wrong in and of themselves, but that they were made allegedly *in absence of scientific evidence*, which Dr Kay denies and which in any event can be debunked by overwhelming scientific evidence and medical literature. He submits that his case is wholly different from the grave allegations in the cases above, all of which involve serious criminal offences (*Wee Teong Boo 2017 and 2019, Ler Teck Siang*) and/or sexual misconduct (*Wee Teong Boo 2017 and 2019, Ong Kian Peng Julian, Chan Herng Nieng*).

91.2. Second, in terms of the nature of harm, the degree of harm in Dr Kay's case is exponentially less than those in the cases above. In the cases above, actual harm was done to patients and the general public – patients were the victims of egregious sexual misconduct/impropriety (*Wee Teong Boo 2017 and 2019, Julian Ong, Chan Herng Nieng*) or public officers were deceived and official secrets leaked (*Ler Teck Siang*) – whereas none of Dr Kay's patients have suffered any harm from the conduct alleged. Furthermore, Dr Kay contends that there is no potential harm in his prescription of Fluconazole and Vancomycin because he has made these prescriptions only where there were clinical indications to do so, backed up by investigation results. Moreover, paediatric patients with ASD make up a small minority (less than 1%) of Dr Kay's patient load, therefore the risk of the potential harm materialising is extremely low.

91.3. Third, in all the above cases, the doctors were either charged/convicted of criminal offences or charged for professional misconduct by the SMC. By contrast, Dr Kay faces

no such proceedings. Accordingly, it is not in the public interest or in Dr Kay's interest to intervene in his GP practice.

91.4. Fourth, Dr Kay's case has attracted no media scrutiny at all, unlike all the above cases. As such there is no amplified potential for public confidence in the medical profession to be undermined if nothing is done.

92. Dr Kay submits that it is therefore unprecedented to subject a medical practitioner in Dr Kay's circumstances to an interim order under section 59B(1) of the MRA. Such an order would be totally unnecessary for the protection of members of the public, or otherwise in the public interest and/or in Dr Kay's own interest.

<u>Decision of the IOC</u>

93. Both the SMC and Dr Kay are in agreement on the principles relevant in determining whether an interim order under section 59B(1) ought to be made. However, while the SMC is of the view that the factual situation in the current case warrants the imposition of the Conditions, it is Dr Kay's position that no interim order should be made.

94. At the hearing on 19 July 2021, Dr Kay's Counsel referred the IOC to the case of *The General Medical Council v Dr Christopher Ogbonna Obasi* [2019] NIQB 27 ("**Obasi**") for his proposition that the IOC should only make an interim order under section 59B(1) if it is satisfied that a *prima facie* case against Dr Kay has been made out.

95. While Counsel for the SMC agrees that there must be a *prima facie* case before the IOC can make an interim order under section 59B(1), Counsel submits that the threshold is not a high threshold and that such threshold has been met in that the Complaint was made by four paediatric specialists in Hospital A who were treating the same three patients to whom Dr Kay had prescribed Fluconazole and Vancomycin; and these paediatric specialists had expressed deep concern in relation to such prescription and its potential for harm.

96. It is undisputed that Dr Kay did prescribe Fluconazole and Vancomycin to Patient A and Patient B, and Vancomycin to Patient C, all of whom were below the age of seven (7) at the time of the prescriptions. Counsel for both parties agree that it is not the task of the IOC to determine if Dr Kay's prescription of Fluconazole and Vancomycin to the three patients were based on scientific evidence and/or generally acceptable medical practice. However, applying ***Obasi***, the IOC must be satisfied that the SMC has established a *prima facie* case against Dr Kay. In this instance, given that four well respected paediatricians practising in a public healthcare institution specialising in the assessment and management of children with learning, behavioural and developmental needs, including ASD (who treated the same three patients), saw fit to file a formal complaint against Dr Kay regarding this matter, we find that the threshold of a *prima facie* case has been met.

97. The IOC is of the view that there will be risks of potential harm to members of the public if Dr Kay is not restricted from prescribing Fluconazole and Vancomycin to young children below the age of seven (7), pending the CC proceedings, and if the Complaint is referred to a Disciplinary Tribunal, pending the determination of the Disciplinary Tribunal. The consequence of such risks to children below the age of seven (7), a particularly vulnerable group who are still developing and growing, must be given due weight. Given that the incidents relied

on by the SMC and the potential harm referred to do not involve Dr Kay prescribing Fluconazole and Vancomycin to any patient above the age of seven (7), we do not find it necessary to restrict him from prescribing such medication to patients above the age of seven (7).

98. We agree with the submission by Counsel for the SMC that the public trust and confidence in the medical profession may be undermined if it is made known to the public that four specialists in paediatric medicine had raised their concerns regarding Dr Kay's conduct, yet he was allowed to continue to practise without any restrictions, pending the determination of relevant disciplinary proceedings. On the other hand, Dr Kay's current practice would face little disruption if he is simply prohibited from prescribing such medication to children below the age of seven (7).

99. Having fully considered all the facts and circumstances and the respective written and oral submissions of the SMC and Dr Kay, the IOC is satisfied that it is not necessary for the protection of members of the public and in the public interest that Dr Kay's registration as a medical practitioner should be suspended. The IOC is also of the view that the circumstances of the case do not warrant imposing all the conditions or restrictions proposed by the SMC which are unnecessarily restrictive to the practice of Dr Kay.

100. However, the IOC is of the view that an interim order to restrict Dr Kay from prescribing Vancomycin and/or Fluconazole (also known as Diflucan) to any patient of seven (7) years of age or below under any circumstances is necessary for the protection of the members of the public and in the public interest. Following such restrictions, and to ensure Dr Kay's compliance with the interim order, Dr Kay must also inform any organisation or person employing him for medical work that his registration is subject to the aforesaid condition.

<u>The Order of the IOC</u>

101. We order that with effect from 19 July 2021, the registration of Dr Kay as a medical practitioner is to be made subject to the following conditions or restrictions, for a period of 18 months or until the conclusion of the proceedings against Dr Kay under Part 7 of the MRA, whichever is sooner:-

101.1. Dr Kay must not recommend, prescribe, or administer Vancomycin and/or Fluconazole (also known as Diflucan) to any patient of seven (7) years of age or below under any circumstances; and

101.2. Dr Kay must inform any organisation or person employing him for medical work that his registration is subject to the above condition.

<u>Publication of Decision</u>

102. We order that the Grounds of Decision be published with the necessary redaction of identities and personal particulars of persons involved.

Dated this 19th day of July 2021.