QCAT

Queensland Civil and Administrative Tribunal

CITATION:	*Ladhams v Medical Board of Australia (No 2)* [2014] QCAT 286
PARTIES:	Dr Andrew Ladhams (Applicant) v Medical Board of Australia (Respondent)
APPLICATION NUMBER:	OCR005-14
MATTER TYPE:	Occupational regulation matters
HEARING DATE:	17 March 2014
HEARD AT:	Brisbane
DECISION OF:	**Judge Alexander Horneman-Wren SC, Deputy President** **Dr Sandra Congdon** **Dr Harpreat Moudgil** **Jennifer Felton**
DELIVERED ON:	14 April 2014 (*ex tempore*)
DELIVERED AT:	Brisbane
ORDERS MADE:	**1. Confirm the Decision of the Medical Board of Australia of 20 December 2013 to take immediate action in respect of the registrant.** **2. Remove conditions 1, 2, 3 and 4 imposed by the Medical Board of Australia on the registrant's registration on 20 December 2013.** **3. In lieu of the conditions removed, impose the following conditions:** **a. For the purposes of these conditions, Lyme Disease includes any illness caused by an organism known as *Borrelia burgdorferi* (including any strains of that organism, namely *Borrelia garinii*, *Borrelia afzelii* and *Borrelia burgdorferi* (*stricto senso*)).** **b. The practitioner must not diagnose and/or treat Lyme**

Disease without his having obtained a positive diagnosis of Lyme Disease from a laboratory accredited by the National Association of Testing Authorities (NATA) using Centres for Disease Control (CDC) criteria.

c. The practitioner must not treat any patient for Lyme Disease with intravenous antibiotics without having referred the patient to an Infectious Diseases Specialist for the development of a written medical treatment plan. Before referring any patient to an Infectious Diseases Specialist, the practitioner must first obtain the approval of the Medical Board of Australia to refer patients to that specialist for that purpose.

d. The practitioner must only treat any patient referred to an Infectious Diseases Specialist pursuant to condition 3 in accordance with the written medical treatment plan developed by the Specialist.

CATCHWORDS :

HEALTH PRACTITIONER – MEDICAL PRACTITIONER – LICENCES AND REGISTRATION – OTHER MATTERS – where the registrant applied for a review of conditions placed upon his registration after immediate action was taken by the Board – where the registrant diagnoses Lyme Disease – where the diagnoses is, at times. made in contradiction to clinical testing – where the clinical testing is not undertaken by an accredited laboratory – where the registrant, at times, treats Lyme Disease with a peripherally inserted central catheter line – whether the registrant's diagnoses and treatment gives rise to a real and serious risk to the public

Health Practitioner Regulation National Law (Queensland), s 156, s 157, s 199
Queensland Civil and Administrative Tribunal Act 2009 (Qld), s 20, s 21(2)(b),

Azam v Medical Board of Australia [2013] QCAT 611
Pearse v Medical Board of Australia [2013] QCAT 392
Shahinper v Psychology Board of Australia [2013] QCAT 593

APPEARANCES and REPRESENTATION (if any):

APPLICANT: Dr A Ladhams appeared for himself

RESPONDENT: Ms KA McMillan QC instructed by Rodgers Barnes and Green Lawyers

REASONS FOR DECISION

[1] The existence, diagnosis and treatment of Lyme Disease are matters of considerable controversy within the medical profession in Australia. Views are greatly divided as to whether there even exists an indigenous Lyme Disease in this country.

[2] Dr Ladhams, who is the applicant in these proceedings, is a Lyme treating doctor. He is also one of the doctors who has formed the Australian Chronic Infectious Diseases Society ('ACID'). That society has published the ACID-BASE (*Borrelia* and Severe Emerging Infectious Diseases) Guidelines.

[3] Dr Ladhams says that he has over seven years experience with chronic fatigue and Lyme patients. During which time he has treated over 1000 patients, many of whom, he says, have had tertiary or neurologic Lyme Disease. He has received training and mentorship from Lyme treating practitioners from Australia, the United States of America and the United Kingdom. As will be evident, Dr Ladhams is one of those Australian medical practitioners who believes in the existence of *Borrelia* in Australia.

[4] Lyme Disease is caused by an organism known as *Borrelia burgdorferi*. It is known to occur in the temperate regions of North America, Europe and Asia. It is a tick borne disease transmitted by hard shell (Ixodid) ticks.

[5] The extent of the disagreement about Lyme Disease within the medical community in Australia is evident from an advice to clinicians issued by the Commonwealth of Australia's Chief Medical Officer ('CMO') on 8 August 2013. In that advice, the CMO said:

> There is debate within the community about the existence of indigenous Lyme Disease in Australia. This is because some Australians, who have not travelled overseas to endemic areas have developed symptoms similar to those of Lyme Disease. However, a causative organism and its vector for Lyme Disease have yet to be formally identified in Australia.

[6] To assist the investigation into the presence of Lyme Disease in Australia the CMO established a Clinical Advisory Committee on Lyme Disease ('CACLD') to provide him with advice on the identification and characterisation of a causative microorganism and vector within Australia; the best diagnostic pathway in Australia; and appropriate treatment options for any Australian cases. Dr Ladhams has met with the CMO in November 2013 as part of the advisory committee's investigations.

[7] The intellectual divide between members of the medical profession is also apparent from a discussion paper issued by the CACLD. The discussion paper was issued after the first meeting of the CACLD. In respect of the question of the existence of Lyme Disease the discussion paper said:

> It was acknowledged at the first meeting by the chair that professionally there were two sides to the debate regarding Lyme Disease. Based on the member interviews it is clear there is a spectrum with members positioned around two main points. A cluster who believe that an indigenous form of Lyme Disease exists in Australia and the other cluster around the middle of the spectrum who are not prepared to exclude the existence of an indigenous form, but who require proof of its existence. When asked about the form of proof, the common response was the identification and characterisation of a causative microorganism. Identifying a causative microorganism would also require identifying the indigenous haematophagous vector. The identification and characterisation of a causative microorganism and vector would shift the centre clustered members into the definite existence of an indigenous causative agent cluster.

[8] In respect of how the disease might be diagnosed the paper said:

> The use of domestic and international pathology services was raised by many of the members. To satisfy the current Australian requirements for reimbursement, a laboratory requires accreditation to AS ISO 15189 (Medical laboratories – Particular requirements for quality and competence). This standard is based on ISO 15189:2007 and is the foundation for National Pathology Accreditation Advisory Council's requirements for National Association of Testing Authorities, Australia/Royal College of Pathologists of Australasia ('NATA/RCPA') accreditation. Some members felt the requirement for medical testing accreditation was not appropriate while other members felt having an accredited and recognised quality management system in place was a benchmark for performance.

[9] As to the divergence of views as to how the disease may be treated even in confirmed cases the paper said:

> Again a spectrum of opinion was revealed in discussion with members. ... The spectrum of opinion was more of a dichotomy roughly aligning with the positions of the Infectious Diseases Society of America ('IDSA') and the International Lyme and Associated Diseases Society ('ILADS'). IDSA treatment guidelines recommend short course (2–3 weeks) therapy with a single antimicrobial. ILADS treatment guidelines recommend long course

(months to years) therapy with multiple cycling antimicrobials plus other pharmaceutical agents.

[10] Those matters serve to place in context the present application which is a review of the Medical Board of Australia's decision to take immediate action against Dr Ladhams in the form of the imposition of conditions on his registration.

[11] On 20 December 2013, the Queensland Medical Interim Notifications Group ('QMING'), acting as the delegate of the Medical Board of Australia, decided to impose conditions on Dr Ladhams registration. Conditions 1, 2 and 3 were in the following terms:

> (1) The practitioner must not treat Lyme Disease in any patient without first obtaining an opinion from an infectious disease specialist who is a Fellow of the Royal Australia College of Physicians (FRACP) which:
>
> (a) states the patient suffers with Lyme Disease; and
>
> (b) prescribes the treatment regimen to be followed by the practitioner.
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> (2) The practitioner must not request the insertion of, nor insert, a peripherally inserted central catheter or any other form of central venous catheter into any patient.
>
> (3) The practitioner must not provide treatment to any patient which may cause a Jarisch-Herxheimer response to such treatment outside of a licensed hospital at which the practitioner holds credentials to perform such treatment.

[12] Section 156 of the Health Practitioner Regulation National Law (Queensland) ('the National Law') relevantly permits the taking of immediate action against a registered health practitioner by a national board if the board reasonably believes that because of the practitioners conduct, performance or health the practitioner poses a serious risk to persons; and that it is necessary to take immediate action to protect public health or safety.

[13] On 14 November 2013 the Acting Executive Director of Medical Services at the Sunshine Coast Hospital and Health Service notified the Australian Health Practitioner Registration Authority ('AHPRA') that a patient of Dr Ladhams had been brought by ambulance to the emergency department of the Nambour General Hospital complaining of hives, dizziness and lethargy. She had a temperature of 38.8 degrees Celsius. Prior to arrival at the emergency department the ambulance service had contacted Dr Ladhams who advised that she may have been having a Jarisch-Herxheimer reaction, or a possible infection associated with her peripherally inserted central catheter ('PICC') line. The patient had a PICC line inserted one week prior, and had had four courses of the antibiotic Ceftriaxone administered intravenously through the PICC line. The patient had been diagnosed with Lyme Disease and was in the initial stage of a three month treatment.

[14] The provisional diagnosis of the patient at the hospital was pyrexia of unknown origin. On review the impression was pyrexia secondary to PICC line, or query Lyme Disease or viral infection. The PICC site had some signs of pus. The patient's temperature increased to 39 degrees in the early hours of the following morning and the PICC line was removed as a cautionary measure. The tip of the PICC line was sent to pathology.

[15] At 4 pm on 17 October 2013, the patient discharged herself from the hospital against medical advice. The consultant at the hospital spoke with Dr Ladhams. That conversation is reported in the notification as not having gone well. It is recorded that Dr Ladhams stated that the PICC line had been removed from the patient for no reason and without his consent. It was noted that Dr Ladhams consent was not required for the removal of a PICC line from a patient under the care of the hospital.

[16] The notification referred to Lyme Disease existing in Europe and the USA and noted that the patient had not travelled to the USA and had no history of tick bite. In fact, the progress notes of the hospital record that the patient had no history of overseas travel; not just to the USA. The notification stated that it was of concern to the acting executive director that the patient believed that her pyrexia was caused by the antibiotics working against the Lyme Disease as she had been advised by Dr Ladhams. It stated that the insertion of PICC lines had known complications and should only be inserted if indicated. The notification said:

> There is a real concern that there is an over medicalisation and treatment of vulnerable patients who have complex medical histories and are seeking answers, reassurance and a diagnosis where one has been unable to be provided by the medical profession.

[17] The notification concluded by providing links to the CMO's advice to clinicians and to the CACLD discussion paper on Lyme Disease.

[18] On 22 November 2013 AHPRA wrote to Dr Ladhams informing him of the notification. It stated that an assessment, presumably of the notification, raised three concerns. Those concerns were:

> (1) whether or not Dr Ladhams had diagnosed patients with Lyme Disease: a disease which had not been proven to exist in Australia;
>
> (2) whether or not because of those diagnoses Dr Ladhams had provided patients with inappropriate treatment; and
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> (3) whether or not he had received consent from a patient who was depicted in a video published on YouTube, by Dr Ladhams, on 15 October 2013, prior to filming and publishing the video.

[19] This third concern did not arise from the notification. It had arisen in an email from legal counsel for Queensland Health to the chairperson of the QMING on 12 November 2013.

[20] AHPRA's letter further informed Dr Ladhams that the QMING had, on 20 November 2013, proposed to take immediate action in relation to his

registration under s 156 of the National Law in the form of conditions, which were provided with that letter. The proposed conditions were that:

> (1) Dr Ladhams must only insert central venous catheter or PICC line in patients at a licensed hospital where he holds credentials to perform such procedures; and
>
> (2) he must only provide treatment which, on the balance of probabilities, could cause a Herx response to patients at a licensed hospital where the practitioner holds credentials to perform such treatment.

[21] AHPRA set out the QMING's basis for its reasonable belief that Dr Ladhams' performance posed a serious risk to persons and that it was necessary to take the immediate action to protect public health and safety. The basis for those beliefs included that the notification of 14 November 2013 raised concerns that Dr Ladhams had diagnosed patients with Lyme Disease, which was a disease not prevalent in Australia, and that following such diagnosis he was providing treatment to patients for that disease. It also stated that the notification indicated that the diagnosis of Lyme Disease in the patient was not clinically supported as she had never travelled to the USA and had no history of tick bite. It was further said that it was not known whether Dr Ladhams had appropriately informed his patients that Lyme Disease was not confirmed in Australia and, as such, the diagnosis and treatment may be considered unconventional medicine, which may have contravened aspects of the Medical Board of Australia's Good Medicine Practice – a Code of Conduct for Doctors in Australia.

[22] It referred to the YouTube video having been placed on a public website by Dr Ladhams. The letter stated that it appeared to the committee from the information it had received and the video that the treatment of providing medication via a PICC line was occurring in an environment which did not appear to be a clinical environment for such care. It was also said that it appeared to the committee that Dr Ladhams had anticipated that the patient would undergo a convulsive response to the medication which he had administered, and that the adoption of such a course in the environment depicted in the video placed patients at significant risk of harm.

[23] The proposed conditions can be understood in light of the following statement as to the risk posed by Dr Ladhams and the amelioration of that risk.

> The committee was of the view that the insertion of a central venous catheter or PICC lines is associated with a significant risk to patient safety. The committee considered that amelioration of the risk required insertion of such PICC lines under ultrasound guidance and within a sterile environment. The committee also considered that, if you reasonably foresaw that the treatment you afforded the patient would result in a Herx-type reaction, the clinical scenario placed the patient at significant risk of harm as it was possible that the patient would require urgent resuscitation efforts. If such care was afforded in the environment

> depicted in the video, it appeared that the appropriate equipment and practitioners would not be available to you.
>
> The committee was uncertain as to whether or not you had inserted such lines in the appropriate environment. The committee was of the view that, if insertion of such lines had occurred in the environment depicted in the video, than [sic] such conduct was inappropriate and placed the patient at serious risk of harm. Such conduct, if established, would be conduct of a lesser standard than that which might reasonably be expected of you by the public or your professional peers.

[24] Dr Ladhams was invited to make a response via either a written or verbal submission. This was in accord with the requirements of s 157 of the National Law. Dr Ladhams availed himself of the opportunity to provide a response in writing. In that submission, Dr Ladhams confirmed that he had diagnosed patients with Lyme Disease, or more correctly as he submitted, with an infection with the spirochete *Borrelia burgdorferi sensu lato stricto*. He said that the diagnoses were made on objective and subjective grounds. The objective grounds being mainly on the basis of serologic response or polymerase chain reaction positive testing of tissue.

[25] He identified that a number of his patients who had been diagnosed by him or another doctor and were being treated for Lyme Disease had acquired the malady when visiting Lyme endemic regions in the United States of America and had returned to Australia with the illness. He referred to these patients as having Lyme Disease in the true context of the illness. In respect of the other patients, he identified 52 per cent as having travelled overseas, although, not always to Lyme endemic regions. He postulated that those patients may have obtained the pathogen from an overseas source. Dr Ladhams disputed the contention that Lyme Disease had not yet been proven to exist in Australia and provided a range of literature in support of the existence of an indigenous *Borrelia* species and '*other pathogenic, zoonotic and pleomorphic organisms causing multisystem, arthritic, neurologic and other illness*.'

[26] He referred to the recent meeting between Lyme treating physicians and the CMO and his advisors on 21 November 2013. He contended that the statement in AHPRA's letter to him that Lyme Disease '*had not yet been proven to exist in Australia*' indicated ignorance of the highest order.

[27] On the issue of whether he had provided inappropriate treatment to those patients who he had diagnosed with Lyme Disease, Dr Ladhams stated that he had provided treatment in accordance with appropriate guidelines based on the patient's clinical history, examination findings and appropriate investigations. He provided copies of the ACID-BASE guidelines, of which he is a co-author, and guidelines from various international bodies in support of his contention that he had provided appropriate treatment.

[28] He denied having published the YouTube video. The patient filmed and uploaded the video herself. He provided evidence from the patient to that effect.

[29] He stated that he himself never placed or sited PICC lines. That was done at radiological practices by, he assumed, suitably qualified radiologists.

[30] In respect of the issues concerning the "Herx" reaction, Dr Ladhams responded that such reactions were, '*an unfortunate, yet unavoidable outcome of treatment for borreliosis and other infectious illness*'.

[31] Dr Ladhams' response was supported by, amongst other things, a number of testimonials from patients who had received treatment from him. Dr Ladhams' practice had put out a call for such testimonials by urgent email on 22 November 2013.

[32] On 6 December 2013, the QMING met again to consider Dr Ladhams. The QMING had before it a show cause agenda paper which had been prepared by AHPRA after having received Dr Ladhams' submissions. The issues identified in that agenda paper were those raised in the letter to Dr Ladhams of 22 November 2013, plus the further issue of whether or not his use of patient testimonials in his submissions constituted inappropriate use of patient information. At its meeting on 6 December 2013, the QMING again decided to propose to take immediate action against Dr Ladhams. The serious risks identified in the minutes of the QMING meeting were that:

> (1) Absent a definitive, reliable diagnosis of Lyme Disease, any treatment places the public at risk of harm.
>
> (2) Based on the notification material, the practitioners submissions and the accompanying documents, the practitioner has provided at least three patients with treatment for alleged Lyme Disease through use of Ceftriaxone administered by PICC line.
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> (3) The practitioner's patients, who are allegedly diagnosed with Lyme Disease, are placed at risk of harm if they suffer from an infection or reaction as a result of the Ceftriaxone administered by PICC line in circumstances where a diagnosis of Lyme Disease has not been confirmed by an NATA or FDA accredited laboratory.

[33] The QMING considered it necessary to take immediate action because,

> (1) The practitioner's diagnosis of Lyme Disease absent NATA or FDA laboratory confirmation and use of Ceftriaxone administered by PICC line to allegedly treat patients with Lyme Disease raises significant concerns about his professional judgment and whether he is able to practice in a competent and ethical manner as expected by a qualified general practitioner.
>
> (2) As a qualified general practitioner, the practitioner holds a position of trust and authority in relation to his patients. The imposition of conditions preventing him from treating patients who he diagnoses with Lyme Disease in circumstances where the disease has not yet been proven to

> exist in Australia will prevent patients from receiving what may be unsound and unproven treatment.

[34] On that occasion, the QMING decided to again propose conditions concerning the insertion of PICC lines and the provision of treatment which might cause a "Herx" reaction. Additionally, the condition was proposed that Dr Ladhams not treat Lyme Disease in any patient without first obtaining an opinion from an infectious disease specialist which stated that the patient suffered from the disease. The proposed conditions also required that the diagnosis be confirmed by reference to testing at a National Association of Testing Authorities ('NATA') or Food and Drug Administration ('FDA') accredited laboratory before Dr Ladhams could treat the patient for Lyme Disease. It also required that the infectious disease specialist prescribe the treatment regimen to be followed by Dr Ladhams. Effectively, that further proposed condition was a prohibition on Dr Ladhams diagnosing Lyme Disease himself and a prohibition upon his determining the treatment to be undergone by any of his patients for Lyme Disease.

[35] On 10 December 2013, AHPRA notified Dr Ladhams of the further proposed immediate action. Dr Ladhams was invited to make a further submission in response. He did so on 17 December 2013. A further show cause agenda paper was prepared on 19 December 2013. The issues of clinical care raised in that agenda paper were whether or not Dr Ladhams had provided patients with treatment that placed patients at risk of infection by administering antibiotics via a PICC line and whether or not the alleged Jarisch-Herxheimer reaction in two patients was caused by the administration of antibiotics by that means.

[36] The diagnosis of Lyme Disease was not identified as a clinical issue as it had been in AHPRA's letter to Dr Ladhams of 22 November 2013, the show cause agenda paper of 6 December 2013, the QMING decision of 6 December 2013, and AHPRA's further letter to Dr Ladhams of 10 December 2013. The absence of the diagnosis of Lyme Disease as a clinical issue in the 19 December 2013 show cause agenda paper may be understood from the discussion of the reasons for the recommendation which it made to QMING, as set out in the agenda paper.

[37] The reasons referred to the various materials that Dr Ladhams had provided in support of his first submission. It noted the advice of the CMO, indicating that he had convened a clinical advisory committee to advise him on issues concerning Lyme Disease. The reasons then stated,

> It is not necessary or appropriate for the committee (QMING) to comment upon the existence of Lyme Disease in Australia, and the committee will await further advice from the CMO in relation to the findings of the clinical advisory committee.

[38] The serious risk identified and the reasons set out in the agenda paper were that the notifications and Dr Ladhams' submissions and

accompanying documents indicated that he had provided at least three patients with antibiotics through a PICC line, resulting in one of those patients presenting for treatment at an emergency department, and that there was no indication that patients are aware of the potential complications that may arise from the insertion of a PICC line to administer antibiotics, including the possible risk of infection or adverse reaction. It was said that Dr Ladhams may place patients at serious risk of harm if he continued to provide patients with antibiotic treatment via a PICC line.

[39] The reasons stated that it was necessary to take the immediate action because the imposition of conditions preventing Dr Ladhams from inserting PICC lines, or requesting their insertion, would prevent any further patients from being exposed to a risk of infection from the insertion of such a device and any potential reactions to the antibiotic treatment, such as an alleged "Herx" response. The reasons particularly stated, that,

> Further conditions in relation to the practitioner's diagnosis of Lyme Disease are unnecessary, as there is inconclusive evidence to confirm or disprove the presence of Lyme Disease in Australia.

[40] Under a heading of "Analysis", the agenda paper recorded the following,

> Within the Australian medical and research community there is currently no scientific-based evidence to conclusively confirm or disprove the presence of Lyme Disease in Australia or the appropriate treatment for patients with the disease. While the presence of Lyme Disease remains contentious, it cannot be concluded that the practitioner has provided unconventional treatment to patients.
>
> The focus of the recommendations is on the practitioner's treatment of patients and potential risk of infection, based on the use of a PICC line to administer antibiotics.

[41] The primary conditions proposed were:

> (1) The practitioner must not request the insertion of, nor insert, a peripherally inserted central catheter, or any other form of central venous catheter in any patient.
>
> (2) The practitioner must not provide treatment to any patient which may cause a Jarisch-Herxheimer response to such treatment outside of a licensed hospital at which the practitioner holds credentials to perform such treatment.

[42] The QMING further considered the matter on 20 December 2013. The reasons for QMINGs decisions recited and adopted the comments in the 19 December agenda paper concerning the diagnosis of Lyme Disease, including that it was unnecessary and inappropriate for QMING to comment on its existence in Australia. As recommended, it stated QMING would await further advice from the CMO.

[43] The serious risks which QMING identified were those set out in the agenda paper. QMING also adopted the reasons why the conditions

were necessary as set out in the agenda paper, including that further conditions in relation to the diagnosis were unnecessary.

[44] In its letter of 20 December 2013 informing Dr Ladhams of the decision to take immediate action against him, AHPRA recited the serious risks as determined by the QMING on the recommendation in the agenda paper. It also set out QMING's reasons why the conditions were necessary as also adopted from the agenda paper. The serious risks were all to do with the treatment of patients with antibiotics through PICC lines. The risks range from the insertion of the line to adverse reaction. The identified serious risks had nothing to do with the diagnosis of Lyme Disease. Likewise, the necessity for the conditions did not identify any issue concerning the diagnosis of Lyme Disease. In fact, conditions in relation to the diagnosis of Lyme Disease were said to be unnecessary.

[45] Notwithstanding the identified risks and need for the conditions, the conditions imposed, as set out above, included a prohibition on Dr Ladhams treating Lyme Disease without the diagnosis being confirmed by a specialist in infectious diseases.

[46] Whilst the decision of the Board to take immediate action in relation to a practitioner under s 156 of the National Law is an appellable decision under s 199, for reasons developed in *Pearse v Medical Board of Australia* [2013] QCAT 392 at [24] – [37], the appeal in this Tribunal proceeds as a review under s 20 of the *Queensland Civil and Administrative Tribunal Act* 2009 (Qld) ('the QCAT Act'), which is to be decided as a fresh hearing on the merits, the purpose of which is to produce the correct and preferable decision.

[47] The Tribunal must decide, on the material before it, whether it reasonably believes that because of his conduct or performance, Dr Ladhams poses a serious risk to persons, and that it is necessary to take immediate action to protect public health and safety. This requires identification of any serious risk posed and the particular aspects of Dr Ladhams' conduct or performance which caused or cause that risk. It also requires, if relevant risk is identified, identification of the particular action necessary to protect public health and safety.

[48] I have set out the history of the matter at considerable length, because it provides some context to the consideration of the present application. Although not an appeal as such from the Board's decision, this proceeding can be informed by the approach taken by the Board: see *Pearse* at [48]; *Shahinper v Psychology Board of Australia* [2013] QCAT 593 at [17]. The show cause agenda papers, decisions of QMING, and notifications to Dr Ladhams are documents relevant to the Tribunal's review of the decision, pursuant to s 21(2)(b) of the QCAT Act.

[49] The Board now proposes different conditions to those imposed by its decision of 20 December 2013. The conditions which the Board now proposes are annexure F to the Board's submissions. Those conditions are, materially:

(1) The practitioner is prohibited from:

(a) diagnosing Lyme Disease; and

(b) providing any medical care, treatment or advice to any patient who the practitioner has diagnosed or considers may qualify for a diagnosis of Lyme Disease, save and except as permitted by these conditions.

(2) In respect of any patient who the practitioner has diagnosed or considers may qualify for a diagnosis of Lyme Disease:

(a) if the practitioner wishes the patient to remain his patient, the practitioner must refer that patient for specialist medical advice from an infectious diseases specialist; or

(b) otherwise must refer the patient to another general practitioner.

(3) The practitioner may only refer a patient referred to in condition (2) to an infectious diseases specialist who has been approved in writing by the Board. The practitioner may seek the Board's approval of one or more infectious disease specialists.

(4) The practitioner may only provide medical care, treatment, or advice to patients for Lyme Disease:

(a) about whom the practitioner has sought and obtained a specialist's medical advice, including a written medical treatment plan; and

(b) if the practitioner's care, treatment and advice is consistent with the specialist's medical advice including the written medical treatment plan prepared by the medical specialist, which must be current.

[50] There are other conditions proposed which go to record keeping and other matters relevant to substantiation and compliance. Those proposed conditions seek to prohibit Dr Ladhams from diagnosing or treating Lyme Disease, save in certain circumstances. They are, therefore, broader in their proposed operation than the presently imposed restrictions upon Dr Ladhams' ability to provide treatment for Lyme Disease. The Board submits that the extension of the conditions to also place restrictions on diagnosis '*is necessary to address the risks arising from an incorrect diagnosis of Lyme Disease and the consequential failure to treat another underlying illness*'.

[51] The conditions currently imposed on Dr Ladhams' registration prohibiting the insertion of, or the request for insertion of, any PICC lines in patients, and prohibiting treatment that may cause a Jarisch-Herxheimer response other than in a hospital at which he holds credentials to perform such treatment, are to be removed. The Board submits that it is unnecessary to maintain those conditions because the conditions now proposed will require that any such diagnosis will be on a sure footing and will require Dr Ladhams to comply with a treatment plan advised by a specialist. The Board submits that the current conditions may, in fact, prevent Dr Ladhams from treating a patient in accordance with the specialist treatment plan if it included the use of a PICC line. This, it is said, was unintended.

[52] In those submissions is an implied acknowledgment that the treatment of appropriately confirmed cases of Lyme Disease with intravenous antibiotics may be considered appropriate by infectious disease specialists. The conditions now proposed by the Board, and the submissions made in support of them, are said to be based upon the expert opinion of Professor Michael Whitby. Professor Whitby is registered in Australia in the specialties of internal medicine, infectious diseases, pathology (medical microbiology), sexual health medicine and public health medicine. Professor Whitby has practiced as an infectious disease physician for over 20 years. He is eminently qualified. He is a fellow of a numerous colleges and faculties. He is a professor of medicine and the head of the Greenslopes Clinical School, University of Queensland.

Does Dr Ladhams pose a serious risk to persons?

[53] In its submissions, the Board contends that Dr Ladhams' diagnosis and treatment of Lyme Disease poses a serious risk in two respects. First, that the treatment of patients on the basis of an uncertain diagnosis exposes those patients to risks of treatment which cannot be justified. Secondly, that the treatment of patients for a condition, the diagnosis of which is uncertain, exposes those patients to a risk that the underlying condition will remain undiagnosed and untreated. Each of these identified serious risks relates to the uncertainty of the diagnosis of Lyme Disease.

[54] In the first instance, the Board has identified certain risks associated with the treatment provided to Lyme Disease patients by Dr Ladhams. Those risks include infections and clotting through the use of PICC lines, and adverse consequences from the use of certain medications prescribed by Dr Ladhams. However, those risks, per se, are not identified as the serious risk to persons for the purpose of taking immediate action under s156. The serious risk is that the identified risks of treatment are unjustified given the uncertainty of the diagnosis. Implicit in the Board's submission is a recognition that the identified risks of treatment may be justified if there is certainty to the diagnoses.

[55] Similarly, in the second instance, the Board identifies certain risks associated with misdiagnosis of Lyme Disease in patients who do not, in fact, suffer from that disease. Those risks include providing false hope to patients with poor prognosis and the unjustifiable use of PICC lines when the treatment provided through those lines cannot benefit the patient. The Board also identifies the obvious risk that any underlying condition from which the patient actually does suffer will not be treated, the treatment being directed to a non-existent condition.

[56] Again, the treatment provided to the patient, per se, is not said to be the serious risk posed by Dr Ladhams. Rather, it is that in treating for Lyme Disease, the diagnosis of which is uncertain, the serious risk is that any underlying condition will remain undiagnosed and untreated.

[57] It is to be noted that each of the serious risks now identified by the Board relate to diagnosis. This is to be contrasted with the reasoning in the show cause agenda papers and the decisions of the QMING which, over time, shifted focus from diagnosis and concentrated upon the risks of actual treatment.

[58] The serious risks identified now are, however, consistent with the first condition currently imposed on Dr Ladhams' registration.

[59] Professor Whitby describes the serious risks which he considers exists in these terms:

> Dr Ladhams is making a diagnosis of Lyme Disease, a condition which is not, at this time, known to exist in Australia, based on laboratory evidence from organisations not accredited by their national testing authorities and utilising methodology which is not generally accepted as being appropriate. The risks of therapy with a PICC line are accepted daily in medicine but are very much balanced by the excellent outcome that a patient will obtain or the prevention of deterioration where infections are treated this way with antibiotics. In a patient who has no infection, there is no benefit from an insertion of a PICC line, no benefit from the administration of antibiotics and thus all risk with no compensatory upside.
>
> By requiring Dr Ladhams to seek approval of an infectious diseases physician, before initiating such therapy, this essentially means that the patient's diagnosis of Lyme Disease will be placed on a sure footing, as most infectious diseases physicians would wish to justify their diagnosis with support of laboratory evidence from an NATA accredited laboratory and a laboratory which will provide a Medicare rebate to their patient for their tests. In that way, any adverse consequences from potential intervention with antimicrobial therapy, no matter how it is delivered, can be balanced against a proven diagnosis of Lyme Disease and, again, it could be expected that infectious diseases physicians will follow conventional guidelines for therapy in such a circumstance. And, in many cases, oral agents will provide an acceptable outcome.

[60] From that opinion, it is clear that Professor Whitby does not entirely discount the treatment of diagnosed Lyme Disease with intravenous antibiotics delivered by means of a PICC line in appropriate cases.

[61] In answer to a specific question as to any risk posed by the long-term use of particular antibiotics, Professor Whitby again referred to the lack of any benefit to balance the risk of such treatment where the diagnosis of the disease was incorrect. The further risk which he identified was not in the use of the particular antibiotics, per se, but their intravenous administration for prolonged periods. Implicit in Professor Whitby's identification of the issue as long-term use of intravenous antibiotics is some acceptance of the use of IV antibiotics in the short term, and longer term use of oral antibiotics.

[62] The evidence of the extent of diagnosed cases of Lyme Disease and co-infections by Dr Ladhams and the methodology by which those diagnoses are made strongly suggests that there is a risk of misdiagnosis.

[63] Central to the risk of misdiagnosis, in my view, is a fundamental belief, firmly held by Dr Ladhams and, it would seem, other Lyme treating doctors, that Lyme Disease can only be diagnosed clinically. In a paper authored by Dr Ladhams, sent to the office of the Chief Medical Officer in April 2013, entitled, 'A Brief Dissertation on Lyme Disease', Dr Ladhams says:

> Tests to detect Lyme Disease are unreliable. Lyme Disease is, at best, a clinical diagnosis, with objective testing providing only an adjunct to diagnosis. Testing modalities such as serology, western blotting, IFA polymerase chain reaction, CD57 culture, fluorensic in situ hybridisation assist with the diagnosis but should not be relied upon to diagnose patients in Lyme-endemic areas. In agreement with specialists from the USA, the presence of a co-infection certainly indicates a strong possibility of Lyme infection. I prefer to use a modified ILADS scoring system.

[64] Similarly, in the ACID-BASE guidelines, version 1.3, co-authored by Dr Ladhams, Dr Peter Mayne and Dr Richard Schloeffel from the Australian Chronic Infectious Diseases Society, it is stated:

> The diagnosis of LD and its co-infections is often initially made clinically due to the lack of confirmatory pathology results. The gold standard diagnosis is a history of tick exposure and development of classical symptoms confirmed EM positive sero conversion IGG and IGM positive, a positive tissue microscopy, a positive western blot and a positive PTR test. In an ideal world, this would categorically diagnose LD in Australia. Unfortunately, the above situation is not very common.

[65] In *Advanced Topics in Lyme Disease Diagnostic Hints and Treatment Guidelines for Lyme and Other Tick-Borne Illness*, 15th edition, by Dr Joseph Burrascano, a Board member of the International Lyme and Associated Diseases Society, a publication which was provided by Dr Ladhams to the Board in support of his response to the proposed immediate action, it is said that:

> I must very strongly emphasise that all diagnoses of tick-borne infections remains a clinical one. Clinical clues will be presented later in this monograph but testing information is briefly summarised below.
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> Lyme borreliosis is diagnosed clinically as no currently available test, no matter the source or type, is definitive in ruling in or ruling out infections of these pathogens or whether these infections are responsible for the patient's symptoms. The entire clinical picture must be taken into account, including a search for concurrent conditions and alternate diagnoses and other reasons for some of the presenting complaints. Often much of the diagnostic process in late disseminated Lyme involves ruling out other illnesses and defining the extent of damage that might require separate evaluation and treatment.

[66] In stark contrast, Professor Whitby gave evidence that Lyme Disease cannot be diagnosed on clinical symptoms. The diagnosis must be on appropriate blood tests; particularly a positive western blot test conducted by a NATA accredited laboratory (or an FDA accredited laboratory in the USA) and interpreted by Centres for Disease Control and Prevention (CDC) criteria. He said it is a disease which is difficult to

diagnose clinically but one which, with appropriate serology, becomes all too clear.

[67] Professor Whitby has only treated five or six patients with diagnosed Lyme Disease in his long career. Dr Ladhams, on the other hand, in 2013 alone, diagnosed 507 positive cases of *Borrelia* from a population of 1062 individual patients who self-presented with chronic illness. This represents approximately 48 per cent of those patients. Of those diagnosed, 405, or approximately 80 per cent, were said to have tested positive. However, that was not through testing conducted through NATA accredited laboratories. The remaining 20 per cent are described by Dr Ladhams as being '*Borrelia testing negative, clinically positive*'.

[68] This serves to demonstrate the primacy placed upon clinical diagnosis of Lyme Disease by Dr Ladhams. Even when non-NATA accredited laboratories returned a negative result, approximately 10 per cent of the total number of presenting patients were clinically diagnosed with Lyme Disease.

[69] In my view, the methodology applied by Dr Ladhams demonstrates some bias towards diagnosing Lyme Disease. Each patient who presents is requested to complete a checklist of current symptoms. The checklist used was that published by Dr Burrascano in his work to which I have referred. The first question asked in relation to the patient's current illness was whether they had suffered a tick bite.

[70] The checklist was then a list of symptoms which are considered by Lyme-testing doctors as being clinically associated with the disease.

[71] More recently, Dr Ladhams has developed his own 'Modified Point System for the Clinical Diagnosis of Australian Tick-Borne Disease or Self-infection'. The list, again, commences with 'tick bite with reaction'. It again proceeds to list symptoms or other factors evidently associated with tick-borne disease by Dr Ladhams. Dr Burrascano's symptom checklist is included. The criteria are then scored. Any patient who scores above 10 falls in the diagnostic range of 'confirmed chronic infection'. Anyone who scores between 8 and 10 falls in the range of 'suspected stealth infection'. Anyone else, including those who score zero, are said to fall within 'low index of suspicion for chronic self-infection or its sequelae'.

[72] In making submissions to the Tribunal, Dr Ladhams gave the impression that one of the considerations brought to bear in the process of a positive diagnosis clinically for Lyme Disease was the absence of a diagnosis of some other condition which might explain the patient's symptoms. This seems, with respect, inherently unsound science.

[73] This evidence provides a sufficient basis upon which to form a reasonable belief that the risk of misdiagnosis is real and serious. It also supports the conclusion that a misdiagnosis of Lyme Disease or other related condition gives rise to a real and serious risk that some other

condition from which the patient suffers will remain undiagnosed and untreated. This is particularly so when there appears to be a predisposition or bias towards the diagnosis of Lyme Disease.

[74] I also believe that, given these risks, it is necessary to impose conditions of Dr Ladhams' registration. I do not, however, believe that the conditions presently imposed upon Dr Ladhams, or those now proposed by the Board, are appropriate to manage the identified risks. Any conditions imposed should address the relevant risks specifically, and otherwise be the least onerous possible: see *Shahinper v Psychology Board of Australia* [2013] QCAT 593 and *Azam v Medical Board of Australia* [2013] QCAT 611.

[75] The conditions which the Board now propose would permit Dr Ladhams to simply refer the patient to another GP who holds the same beliefs as Dr Ladhams and who follows the same diagnostic methods and treatment regimes. Such a condition may wholly fail to protect against the identified risk.

[76] The conditions proposed by the Board also effectively prohibit Dr Ladhams from making a diagnosis of Lyme Disease in all circumstances. This goes beyond the risks identified in the Board's submissions which were based upon the evidence of Professor Whitby. Those risks are those which emerge from the uncertainty of the diagnosis of Lyme Disease, and its prolonged treatment with intravenous drugs.

[77] If Dr Ladhams is required to obtain a proven diagnosis of Lyme Disease, or related *Borrelia* infection, through a positive western blot test conducted by a NATA accredited laboratory, using CDC criteria, the risk arising through uncertainty of diagnosis will be removed. Professor Whitby referred to this diagnostic methodology as the "gold standard" and one which allows a "definitive diagnosis".

[78] The further risk of prolonged intravenous antibiotic treatment would be removed by requiring Dr Ladhams to refer any patient who he is intending to treat with intravenous antibiotics to an infectious disease physician approved by the Board for the development of a written medical treatment plan, and requiring him to treat the patient only in accordance with that plan. This would not seem an onerous condition because Dr Ladhams has identified in his evidence that only 16 of 1028 patients were treated with intravenous antibiotics.

[79] Those conditions, with relevant conditions related to approval of specialists, keeping of records, monitoring and so forth, would serve to protect the public from the identified risks. They will not prohibit Dr Ladhams from treating Lyme Disease but will restrict his capacity to do so to cases in which the diagnosis has been appropriately confirmed; and will prevent his ability to do so with intravenous antibiotics save as recommended by the specialist. Such treatment will still be available to

the patient if it is advised by an approved specialist in infectious diseases.

[80] The orders which I shall make are as follows:

1. Confirm the Decision of the Medical Board of Australia of 20 December 2013 to take immediate action in respect of the registrant.

2. Remove conditions 1, 2, 3 and 4 imposed by the Medical Board of Australia on the registrant's registration on 20 December 2013.

3. In lieu of the conditions removed, impose the following conditions:

    3.1 For the purposes of these conditions, Lyme Disease includes any illness caused by an organism known as *Borrelia burgdorferi* (including any strains of that organism, namely *Borrelia garinii*, *Borrelia afzelii* and *Borrelia burgdorferi* (*stricto senso*)).

    3.2 The practitioner must not diagnose and/or treat Lyme Disease without his having obtained a positive diagnosis of Lyme Disease from a laboratory accredited by the National Association of Testing Authorities (NATA) using Centres for Disease Control (CDC) criteria.

    3.3 The practitioner must not treat any patient for Lyme Disease with intravenous antibiotics without having referred the patient to an Infectious Diseases Specialist for the development of a written medical treatment plan. Before referring any patient to an Infectious Diseases Specialist, the practitioner must first obtain the approval of the Medical Board of Australia to refer patients to that specialist for that purpose.

    3.4 The practitioner must only treat any patient referred to an Infectious Diseases Specialist pursuant to condition 3 in accordance with the written medical treatment plan developed by the Specialist.