

THE HIGH COURT
IN THE MATTER OF SECTION 51 (1) THE PHARMACY ACT, 2007 AND
IN THE MATTER OF AN APPLICATION BROUGHT BY COLIN LANNON, A REGISTERED
PHARMACIST

[2022] IEHC 80
[2021 196 MCA]

BETWEEN

COLIN LANNON

APPLICANT

AND

COUNCIL OF THE PHARMACEUTICAL SOCIETY OF IRELAND

RESPONDENT

JUDGMENT of Ms. Justice Egan delivered on the 11th day of February, 2022

Introduction

1. This is an application pursuant to s. 51 (4) of the Pharmacy Act, 2007 (“the Pharmacy Act”) by Mr. Colin Lannon (“the applicant”) seeking the cancellation of the decision of the Council (“the Council”) of the Pharmaceutical Society of Ireland (“the PSI”) to suspend his registration as a pharmacist for a two-month period as a result of a finding against him of poor professional performance.

Factual background

2. The applicant has been a registered pharmacist for over fourteen years and in 2014 became a supervising pharmacist in Lannon’s Late Night Pharmacy, Sligo (“the pharmacy”).
3. In July 2018, the applicant became the subject of a fitness to practice complaint (“the complaint”) made to the PSI by Ms. Kate Mulvenna, Head of Pharmacy Function at the Health Service Executive (“HSE”), regarding a course of dispensing by the pharmacy of a medication called Kalydeco. This is an expensive “high-tech” drug used as a treatment for cystic fibrosis which can only be prescribed by a designated specialist registered medical practitioner. All patients taking such medication are required to attend for three monthly medical reviews to facilitate clinical monitoring and in order for their prescription to be renewed. The dispensing, the subject matter of the complaint, was to two children in one family (“the two patients”), both suffering from cystic fibrosis, who had been approved by Professor Des Cox, consultant in paediatric respiratory medicine at Our Lady’s Hospital, Crumlin, for “lifelong treatment” with Kalydeco. The two patients’ prescriptions for Kalydeco were duly renewed over time with the last prescription being valid up to July 2017. Notwithstanding the absence of valid prescriptions, the pharmacy continued to dispense Kalydeco to the two patients during a period of eight months between August 2017 and February 2018. The applicant personally dispensed this medication to the two patients on only the first occasion. However, he was at all material times the supervising pharmacist and was responsible for all operations of the pharmacy.
4. The complaint became subject of a fitness to practice inquiry which was conducted by the Professional Conduct Committee (“the PCC”) of the PSI on 24th and 25th February, 2021. It was alleged that the applicant was guilty of poor professional performance in (a) supplying, or permitting the supply, to two minors of a “prescription only” high-tech

medication in the absence of any valid prescription on eight occasions in relation to each minor and (b) failing to ensure that there was any adequate compliance with the standard operating procedures of the pharmacy for the management of high-tech medicines.

5. At the PCC inquiry the applicant was represented by a solicitor who cross examined witnesses and made submissions on his behalf. The applicant did not call any witnesses nor himself give any evidence before the PCC. His solicitor informed the PCC that although the applicant had intended to be present to address the PCC, he was unwell and unable to do so because of side effects following a Covid-19 vaccine injection given on the second day of the PCC inquiry.

The PCC report

6. On 9th April, 2021 the PCC produced a report ("the PCC report") finding, beyond a reasonable doubt, that the applicant was guilty of poor professional performance in relation to each of the allegations in the notice of inquiry. The PCC recommended to the Council that the applicant's registration was suspended for a period of two months and that thereafter the following conditions should attach to his registration:
 - a) That he should not act as a supervising pharmacist, superintendent pharmacist or a sole practitioner for a period of nine months;
 - b) That he be prohibited from practising other than under the supervision of a senior and experienced registered pharmacist acceptable to the PSI, for a period of nine months or for such further time as is recommended by the appointed pharmacist;
 - c) That during the period of nine months he must not work as a locum or undertake any work where he is the sole pharmacist unless approved by the appointed pharmacist and with the prior agreement of the PSI and;
 - d) That he discharge all costs associated with these requirements.
7. The PCC report sets out in detail the reasons for the recommended sanction. The PCC accepted the evidence of the expert pharmacist Mr. Keith O'Hourihane MPSI, that the applicant's poor performance was not only serious but also fell far below what would be expected of a supervising pharmacist; that the applicant's poor professional performance was at, or very close to, the most serious end of the spectrum; that a pharmacist must determine whether or not a prescription is appropriate and, where it is not, must undertake due process in the form of a call or email to the prescribing medic before dispensing; that any genuine difficulty in producing a prescription could easily have been addressed by inquiry but that the applicant simply chose to ignore his professional obligations in respect of the patients; that in the context of the high-tech scheme, with its particular conditions and requirements for which pharmacists receive a special additional fee, the pharmacist's professional obligation is correspondingly greater and the pharmacist's role in this aspect of patient care is critical; and that the lack of quarterly reviews by Professor Cox might have had serious and life-threatening effects upon the patients. The PCC was further concerned by the applicant's failure, as supervising

pharmacist, to engage in internal supervision and control of any kind within the pharmacy.

8. The PCC sought a fair and proportionate sanction, in the light of the seriousness of the poor professional performance, such that the applicant would learn from the process and be deterred from repetition and in order to inform the wider profession of its views on such wrongdoing. The PCC's paramount consideration was the protection of the public interest, including the need to protect the public from professional wrongdoing and to maintain trust in the profession and in the PSI's regulation of the profession.
9. The PCC was not persuaded that the applicant had insight into his conduct and expressed concern with the approach he had adopted at the inquiry as exemplified by: the applicant's reliance upon the fact that he did not personally dispense the prescriptions; his argument that the dispensing's were potentially justified by the fact that the "lifelong prescription" box had been ticked on the HSE forms; his argument that a valid prescription had in fact been in place (when that transpired not to be the case); his contention that this presented a case of ethical dilemma because depriving the children of essential medication was undesirable; and his trenchant attacks on HSE personnel and Crumlin Hospital. Although the PCC emphasised that it drew no adverse inference from the applicant's exercise of his right to deny the allegations or from his decision not to give evidence, this meant that nothing of substance had been put before the PCC to explain the reason for the applicant's repeated poor professional performance.

Council's decision on sanction

10. A hearing on sanction before the Council took place on 25th June and 2nd July, 2021. In contrast to his approach before the PCC, the applicant appeared before the Council, accepted responsibility for his actions and answered questions from members of Council. In addition, the applicant also engaged an expert pharmacist witness Mr. Noel Stenson MPSI, who prepared a report in respect of the applicant's prescribing practices generally and concluded that, aside from these events, the applicant practiced professionally at a high level.
11. Ultimately, the Council imposed the sanctions recommended by the PCC. The reasons provided by the Council for the sanctions were as follows:

"The Council adopted the reasons given by the PCC for its recommendation as to sanction. In addition, the Council carefully considered the submissions on the applicant's part and the presentation by the applicant to the Council, the particular responsibilities of a supervising pharmacist, the principles of sanctioning including consistency of sanctioning, that sanction must be a proportionate response to the particular facts of the case, the necessity to maintain public confidence in the profession and the role of suspension in deterrence of poor professional performance by the registrant and the profession and in signalling to the registrant, the profession and public, the disapproval with which poor professional performance is regarded. The Council considered that suspension will act in the public interest as a deterrent to inappropriate behaviour and a signal to the applicant, the profession

and the public about what is regarded as inappropriate behaviour by a supervising pharmacist and the Council referred to its sanctions guidance in this regard.”

12. The transcripts demonstrate that both the PCC and the Council’s legal assessors specifically advised the regulator on the importance of proportionality, the need to give sufficient weight to mitigating factors and to treat the applicant with as much leniency as possible, the desirability of consistency in sanctioning and the importance of insight.
13. At the hearing before the Council, the applicant himself gave evidence fully accepting that he had made a serious omission in failing to ensure adequate prescriptions were presented in respect of each of the supplies of Kalydeco. The applicant also gave evidence to the court to similar effect.

The High Court Proceedings

14. In the affidavit grounding his appeal the applicant states that on reflection, he should have approached the PCC inquiry differently. He had taken an overly benign view of his actions and had not fully appreciated his responsibilities as a supervising pharmacist. He accepted that lines of cross examination were pursued on his behalf which may have been taken as suggesting an attempt to minimise his conduct or shift blame to others. The applicant regretted not giving evidence before the PCC because he felt unwell. With the benefit of hindsight, he acknowledged that it would have been wiser to seek an adjournment to give him an opportunity to demonstrate his contrition and genuine remorse. Essentially, the applicant accepted that it was reasonable for the PCC to have taken the view that he had lacked insight. However, the applicant maintains that he demonstrated insight before the Council and that appropriate weight was not given to this by the Council. The applicant submits that any period of suspension will have a serious impact upon him reputationally and financially.

Issue for the court

15. The appeal is specifically and solely directed towards the cancellation of the suspension order. The applicant is not appealing against the finding of poor professional performance and fully accepts that he must be sanctioned for his conduct. Whilst he believes that the other conditions which the Council have attached to his registration are harsh, he accepts them. It is notable that since 1st September, 2021, the applicant has stepped down as supervising pharmacist and taken up a position of support pharmacist at the pharmacy where he now works.

The Legislation

16. It is necessary, in the first instance to set out a number of the provisions of the Pharmacy Act which are germane to this application. Under s. 47 of the Pharmacy Act, on completing an inquiry the PCC makes a written report to the Council specifying the subject matter of the complaint, the evidence presented and its findings. Although the PCC has no power to impose a sanction, it generally makes a recommendation on sanction.
17. Pursuant to s. 48 (1)(b) of the Pharmacy Act the Council may impose one or more of the following disciplinary sanctions:

- (i) *an admonishment or a censure,*
 - (ii) *the attachment of conditions to the registration of the pharmacist or retail pharmacy business, which may include restrictions on practice or, as the case may be, the carrying on of the business,*
 - (iii) *the suspension of the registration for a specified period,*
 - (iv) *the cancellation of the registration,*
 - (v) *a prohibition for a specified period on applying for restoration to the register.”*
18. The jurisdiction of the High Court on pharmacy matters arises pursuant to ss. 51 and 52 of the Pharmacy Act. If the Council has imposed a disciplinary sanction, other than an admonishment or censure, this does not take effect unless and until it is confirmed by the High Court on an application under either ss. 51 or 52. S. 51, which is the relevant provision for the purposes of the present application, sets out the jurisdiction of the court to cancel a disciplinary sanction on foot of an application for cancellation.
19. S. 51 (3) provides that the court “*may consider any evidence adduced or argument made to it, whether or not adduced or made to a committee of inquiry.*”
20. S. 51 (4) vests the court with broad powers to cancel a decision, or make any other order it sees fit, and provides as follows:
- “The High Court may, on an application for an order under subs. (1)—*
- (a) *make any other order it considers just, including an order confirming or modifying the decision, and*
 - (b) *give the Council any direction and direct how the costs of the application are to be borne.*”
21. A supervising pharmacist, such as the applicant, is a registered pharmacist who has 3 years’ post-registration experience and who is in whole-time charge of the carrying on of the retail pharmacy business at the premises of the said business and not at any other premises. Supervising pharmacists are responsible for all of the operations of the pharmacy even when absent.

The nature of the High Court’s jurisdiction in respect of this application for cancellation

22. This is the first case in which the High Court’s power to cancel a disciplinary sanction of the PSI has been invoked. This court is guided by the relevant jurisprudence concerning s. 75 of the Medical Practitioners Act, 2007 (“the 2007 Act”), which is very similar to s. 51 of the Pharmacy Act. Although the former provision deals with an appeal against the Medical Council’s decision to sanction and the latter with the cancellation of a decision on sanction, both allow the court to consider any evidence adduced or argument made, whether or not adduced or made before the regulator. S.51 of the Pharmacy Act provides

that the court may confirm or modify the PSI decision or make any other order it considers just. To similar effect, s. 75 of the 2007 Act provides that the court may confirm or cancel the Medical Council decision and replace it with such other decision as the court considers appropriate including imposing a different sanction or no sanction at all. S. 51 of the Pharmacy Act provides that the court may make any other order it considers just and give the PSI any direction. Likewise, s. 75 of the 2007 Act provides that the court may give the Medical Council such directions as it considers appropriate. Both sections provide that the court may direct how the costs of the appeal are to be borne.

23. In substance therefore there is little difference between the scope of the court's powers under s. 51 of the Pharmacy Act and s. 75 of the 2007 Act. Clearly the observations of Charleton J. in *Andrea Hermann v. Medical Council* [2010] IEHC 414 on the test, which the court should apply where sanction alone is appealed under s. 75 of the 2007 Act, are also applicable to this application for cancellation under s. 51 of the Pharmacy Act. In that respect, Charleton J. stated at para. 10 of his judgment:

"The question arises as to what test should the court apply to the issue of sanction where that issue alone is appealed to the court under s.75 of the Act? It is urged that some form of curial deference should be exercised by the High Court towards decisions of the Medical Council. The Fitness to Practice Committee of the Medical Council is a specialist body dealing with complaints of professional misconduct on a frequent basis. The members of the Committee have ready access to relevant precedents and are therefore in a position to assess both the nature of the conduct complained of, and where it fits as to category, gravity, and the type and severity of penalty that has been established as appropriate by prior decisions. I have no doubt that the Medical Council should take this approach as a general guide to the imposition of penalties. I am also satisfied that it is not the only principle which is applicable. Guidelines derived from previous sanctions establish both an appropriate level of knowledge among members of the Medical Council and also informs medical practitioners and their legal representatives as to what kind of sanction may be faced in an event of a finding being made of misconduct. That, while an appropriate guide, is not completely restrictive. No court exercising a sentencing jurisdiction ever regards itself as boxed in by sentencing precedent. Exceptional circumstances can arise which move one category of case from a particular band of gravity into a higher or lower category. Mitigation of circumstances should be considered to see if some particular factor lessens the gravity of the appropriate response. Consistency of appropriate sanction against medical practitioners is, however, important for the reasons which I have mentioned and to ensure the continued trust of the public in the medical profession; one of the fundamental purposes inherent in the relevant sections of the Act of 2007."

24. Charleton J. then considered various English authorities to the effect that curial deference should be uppermost in the mind of any court or appellate tribunal considering an appeal against sanction and went on to observe:

"Having taken the principles that I have referred to into account, and having considered the role that sanctions against medical practitioners fits within the scheme of complaint inquiry, finding and response inherent in the Act of 2007, I have to come to the view that the High Court, considering an appeal under s. 75 of the Act, is deliberately vested by the Oireachtas with powers of such an amplitude that it is required to exercise its own analysis of whatever evidence as to sanction is put before it. The Medical Council retains the burden of proving that the sanction was correct. The Court, in considering whether to cancel the relevant decision, to replace it with a different decision or to impose no sanction on the practitioner, is obliged to assess what is appropriate in light of the findings of fact which led to the imposition of the sanction by the Medical Council in the first instance. That decision, and the reasoning underpinning it, should not be ignored. Rather, that decision and the justification contained within the document imposing the sanction is the primary material under appeal and on which the hearing is based. In considering the question of the sanction, the Court's focus should be both on the conduct underpinning the sanction and the reasoning of the Medical Council in arriving at its decision. Because of the relatively greater experience of the Medical Council in imposing sanctions, its knowledge as to relevant precedents and the expert nature of the task undertaken, the High Court, on an appeal as to sanction, should treat the decisions of the Medical Council with respect. An independent view should be taken as to what ought to be done. Where an error has been made in the context of a sanction which is otherwise appropriate, then it should be corrected. If, however, the level of sanction is one which is justified by the material before the Medical Council, then the Court would need to find a specific reason for altering it on the evidence presented on the appeal."

25. In *Dowling v. An Bord Altranais* [2017] IEHC 62, Ní Raifeartaigh J. considered the proper approach of the court to an application for cancellation of a decision on sanction under s. 39 (3) of the Nursing Act 1985 ("the 1985 Act"). Although s. 39 of the 1985 Act considered in *Dowling* is not quite as similar to s. 51 of the Pharmacy Act as is s. 75 of the 2007 Act considered in *Hermann*, the court's analysis of the appropriate approach to applications for cancellation of sanction is nonetheless of considerable assistance in the present application. After considering the *Hermann* decision Ní Raifeartaigh J. stated:

"Although the powers of the High Court in an application such as that in Hermann are not the same as those available to the Court in the present application, the concept of curial deference, in the sense of affording considerable respect to the decision of an expert professional body, nonetheless appears to me to be a sensible approach to adopt in nursing cases also ... I would consider it important to give considerable weight to the views of the Board and to depart from its views only if those were clearly disproportionate or had been arrived at in a manner which was not legally sound."

26. Also, in *Council of the Pharmaceutical Society of Ireland v. XY* (Unreported, ex tempore judgment, High Court, 21st July 2021), Irvine P. considered the court's jurisdiction under

the Pharmacy Act, in an application pursuant to s. 52 of the Pharmacy Act to confirm a sanction imposed by the PSI. Irvine P. acknowledged that, even in the context of an application pursuant to s. 52 of the Pharmacy Act, the Pharmacy Act does not restrict the court such that it must confirm the Council's decision in the absence of a good reason not to do so; and that the court is not bound by the strictest type of *Wednesbury* reasonableness in which the court will only set aside a decision which is so unreasonable that no reasonable decision maker could have taken it (*Associated Provincial Picturehouses Limited v. Wednesbury Corporation* [1948] I K.B. 223). As the court's jurisdiction under s. 51 of the Pharmacy Act is broader than that arising under s. 52 of the Pharmacy Act, the same observation would apply a *fortiori* to the court's approach in this case.

27. Accordingly, the current application is best understood as something of a hybrid. First, the applicant argues that the sanction of suspension is disproportionate and that the PCC and more particularly the Council did not have regard to specific matters to which they ought to have had regard in making the decision on sanction. As argued, this aspect of the application constitutes an appeal against error/appeal on the record which is essentially based on the papers that were before the PCC and the Council. Secondly, the applicant makes a *de novo* challenge, in effect, involving fresh oral evidence to the court, both from the applicant himself and from the expert pharmacist witness called on his behalf, Mr. Stenson.
28. This form of hybrid appeal is permissible pursuant to s. 51 of the Pharmacy Act. However, in harmony with the approach in the *Hermann* and *Dowling* decisions, in approaching such a hybrid appeal, the court must nonetheless have regard to the regulatory body's specialist knowledge, which the court does not have, and afford considerable respect to the regulator's decision. Although the court will take an independent view of the appropriate level of sanction, it remains incumbent upon the applicant to identify an error in approach by the Council or a specific reason for altering a level of sanction justified by the material before the PSI.
29. Importantly the court has heard a portion only of the evidence that was before the PCC. The court has had the benefit of all of the core documents which were before the PCC and the Council, together with the transcripts of both proceedings. However, this is no substitute for hearing the evidence of the relevant witnesses. Particularly, in relation to the relative seriousness of the applicant's conduct, the PCC had a distinct advantage over both the Council and the court.

Principles in relation to sanction

30. The relevant principles applicable to sanctioning in professional disciplinary matters were elucidated by Finlay P. in *Medical Council v. Dr. Michael Murphy* [1984] 6 JIC 2901 in which he stated:

"First, I have to have regard to the element of making it clear by the order ... to the medical practitioner concerned, the serious view taken of the extent and nature of his misconduct, so as to defer him from being likely, on resuming practice to be

guilty of like or similar misconduct. Secondly, it seems to me to be an ingredient though not necessarily the only one that the order should point out to other members of the medical profession the gravity of the offence of professional misconduct and thirdly, and this must be some extent material to all these considerations, there is the specific element of the protection of the public which arises where there is misconduct and which is, what I might describe as the standard in the practice of medicine. I have as well an obligation to assist the medical practitioner with as much leniency as possible in the circumstances."

31. These principles were cited with approval by Charleton J. in *Hermann* in which the court considered a sanction of the Medical Council suspending the applicant from practice for one year and also ordering that the applicant undergo a period of retraining for three years. Charleton J. considered that the penalty imposed by the Medical Council was proportionate and justified in the circumstances and held that a graduated approach had to be adopted towards sanction depending on the level of seriousness of the conduct and the level of risk posed by the practitioner. The court stated:

"The scheme of the Act therefore involves, in its mildest form, correction as a first gradation. In such cases the Medical Council may admonish or fine a doctor or issue a written censure. Some of these incidents may involve bringing a doctor to his or her senses. It is clear that there is an overlap in the more serious of these milder cases with the necessity to mark in an appropriate way the nature of the misconduct or lack of competence through attaching conditions to registration, and restricting the practice by the doctor of medicine. These restrictions can include a requirement for retraining, perhaps coupled with an undertaking not to practice during that time. Where a doctor is shown not to be dependably safe in the practice of one form of medicine a transfer to another division is appropriate. This kind of response rarely if ever overlaps with the earlier division and moves into the most serious category of cases where a suspension of registration, cancellation of registration and a prohibition for a substantial time against a practitioner applying for re-registration can be involved. I see no reason why in the most serious cases that this cannot be a lifetime ban on the practice of medicine. Correction, rehabilitation and punishment mark out the potential approaches by the Medical Council within these three major but sometimes overlapping categories of appropriate response to misconduct or lack of competence. To rigidly divide these responses into categories would be to undermine the scheme of the Act whereby the Fitness to Practice Committee, in making a recommendation to the Medical Council, and the Council itself, are entrusted with the important task of ensuring that the practice of medicine delivers its expected service to the public through being highly competent, safe and reliable. In the mildest cases of admonishment little danger may be involved to the public. When that category shades into the instances where it is necessary to issue a censure in writing, or to attach conditions to registration while restricting the practice of medicine that may be engaged by the practitioner, the category of misconduct or lack of competence has become more serious. It is clear from the scheme of the Act of 2007 that the approach by

the Medical Council should involve protecting the public and reassuring them as to the standards that medical practitioners will at all times uphold; requiring that medical practice is by those who are properly trained and appropriately qualified to safely engage in the areas of medicine where they hold themselves out to be experts. In that and the other more serious category, the protection of the public is paramount to the approach of the Medical Council. The reputation of the medical profession must, in those instances be upheld. This exceeds in importance, where the misconduct is serious, the regrettable misfortune that must necessarily be visited upon a doctor."

32. Ní Raifeartaigh J. observed in *Dowling*, that the first three matters referred to by Charleton J. in *Hermann* related to the seriousness of the conduct, the principle of deterrence and the protection of the public, which interrelated considerations reflect the inherent purpose of the regulation of professions. The Pharmacy Act thus confers on the PSI certain essential duties including the responsibility to promote high standards of professional conduct among pharmacists. The scheme whereby the PCC conducts inquiries and the Council imposes sanctions sits squarely within those duties.
33. Bearing all of the above in mind, I turn to consider the five reasons advanced by the applicant as to why the court should cancel the suspension order: first that the Council mischaracterised the seriousness of the conduct at issue; secondly that there is a disparity in the sanction imposed on the applicant compared with other pharmacists against whom similar findings have previously been made; thirdly that the Council failed to engage with evidence of insight on the part of the applicant when the matter came before it; fourthly that the Council failed to engage with the expert evidence before it demonstrating that, apart from the prescriptions in issue, the applicant's prescribing practices were impeccable; and fifthly that the Council was insufficiently lenient and failed to give appropriate weight to mitigating factors.

Mischaracterising the seriousness of the conduct

34. The PCC and the Council graded the applicant's poor professional performance "*at or very close to, the most serious end of the spectrum.*" The applicant accepted that as a matter of principle all conduct which amounts to poor professional performance is serious; that the failure to exercise due diligence in dispensing the supplies of Kalydeco was a serious omission; and that the requirement for three monthly ongoing specialist review was very important to the safe and effective management of the two patients. He nonetheless argued that the Council mischaracterised the seriousness of the conduct in question because:
- The applicant had an unblemished record;
 - The applicant only personally dispensed this medication to the patients on one occasion;

- The unauthorised dispensing was for a single medication for a single family; and there was no wider failing on the applicant's part and the finding of poor professional performance related to these specific instances only;
 - The two patients required the medication and would suffer adverse consequences if they did not receive it;
 - The failure by the applicant did not cause harm to the two patients who had been on this medication continuously since these events and would likely require it for the rest of their lives;
 - There were a number of "moving parts" in this case in addition to the actions of the applicant in dispensing the prescriptions, such as that the two patients were not reviewed for a period of 11 months by the Paediatric Respiratory Consultant who had previously provided the prescriptions for Kalydeco;
 - The dispensing occurred in an established pharmacist-customer relationship;
 - Neither the applicant nor pharmacy gained financially from dispensing the medication, save for the standard prescription fee.
35. These same factors were urged upon both the PCC and the Council, were the subject of detailed legal advice by their respective legal assessors and were in substance addressed in the PCC report, which was adopted by the Council. This does not prevent the court from determining that insufficient weight was placed upon these factors. Allowing for the respect that must be paid to the decision of the regulator, the court conducted its own independent assessment of these factors.
36. Whilst it is accepted that the applicant had an otherwise unblemished record, this does not result in the conduct at issue being of itself less serious.
37. The fact that the applicant personally dispensed this medication on one occasion only does not greatly assist him. His obligation, as supervising pharmacist, was to ensure that, irrespective of whether medication was indicated for life-long use, it was not to be dispensed without an appropriate prescription. Pharmacists and supervising pharmacists in particular are subject to heightened responsibility in the case of high-tech medication. PSI Guidance dated 2nd January 2015, "*Good Dispensing Practice – High Tech Scheme*", emphasises that the high-tech scheme operates as a patient specific pharmaceutical care and treatment programme with a nominated pharmacy responsible for a specific patient and for their complete and complex medication and health needs. Continuous patient specific monitoring by the pharmacist is thus mandatory. Central to this scheme is an appreciation that, regardless of who dispenses the medication, the supervising pharmacist always has primary responsibility for the pharmaceutical care and treatment programme under the high-tech scheme.
38. The high-tech scheme is consultant lead: only a consultant may write a valid prescription (save perhaps in cases of temporary emergency). In the case of three-month

prescriptions such as those issued to the two patients, once the three supplies have been dispensed, it is essential that clinical review takes place before a further prescription is issued or further medication dispensed. Such review was central to the two patients' care so as to avoid potential adverse consequences from taking the medication.

39. The applicant argued that his conduct could be viewed as a single or isolated incident. I do not agree. Whilst the dispensing was of a single medication to a single family, it persisted over a lengthy period of time during which the applicant completely failed to perform his role as supervising pharmacist such that the two patients obtained medication without appropriate medical input from their treating consultant. Unfortunately, the dispensing of the medication, notwithstanding the absence of the required clinical review, effectively facilitated the absence of periodic clinical reviews of the two patients.
40. At no time was this irregular dispensing identified or noticed by the applicant as supervising pharmacist. During the course of the hearing before the court it became apparent that the applicant had not at any stage examined, or even looked at, the relevant high-tech prescriptions, as he was required to do. Had he done so, the fact of the expiration of the prescriptions would have been plainly evident. The applicant's repeated supply of Kalydeco without a valid prescription demonstrated little regard for or appreciation of the seriousness of the matter and the potential risk to the two patients. It would be very difficult to conclude otherwise
41. Although fortuitously, the continued dispensing of Kalydeco did not cause harm to the two patients, it is the risk of harm from the relevant conduct and not merely the presence or absence of actual harm which is the key consideration for the regulator and also for the court. It cannot be disputed that the lack of clinical review of the two patients such as occurred in this case, could have had very serious consequences.
42. The applicant also submits that weight ought to be attached to the possibility that he may have been motivated by misplaced empathy or compassion for the patients and their family and/or was placed in an ethical dilemma in relation to dispensing. I cannot accept that. The evidence was that the applicant was not even aware that the medication was being dispensed without a valid prescription as he never sought to confirm this one way or another.
43. The applicant argued that there were a number of "*moving parts in this case*" and that, for whatever reason, the two patients were not reviewed by their consultant nor provided with high-tech prescriptions for a period of eleven months. In my view this serves only to heighten, rather than lower, the obligation on the applicant not to dispense without a valid prescription. Dispensing medications under such circumstances completely ignored the tripartite relationship in a case of high-tech medications between consultant, patient and pharmacy. Therefore, although the two patients in this case clearly required the medication and could have suffered adverse consequences if it was not provided, this does not and cannot lessen the severity of the applicant's conduct in issue.

44. I find that the seriousness of the applicant's conduct was not mischaracterised by the PCC or the Council. As pointed out in the *Hermann* and *Dowling* cases, the PCC and the Council have significant familiarity with and expertise in these matters and are in a position to assess, on a comparative basis, the nature of the conduct complained of and where it fits as to category, gravity and severity. In addition, the regulator is well placed to assess where on the spectrum of severity the proposed sanction should fall when compared to other sanctions proposed by it. Exceptional circumstances can arise which may move a particular case, into a higher or lower category band of gravity, but the court does not accept that the PSI mischaracterised the seriousness of the conduct in issue, as alleged by the applicant.
45. In so finding, I am also influenced by the fact that Mr. Stenson, the expert pharmacist, who gave evidence to the court on behalf of the applicant, did not in any way demure or depart from the views on the seriousness of the conduct in issue as expressed by the expert pharmacist, Mr. O' Hourihane, by the PCC or by the Council. Mr. Stenson did not suggest that the PSI had mischaracterised the seriousness of the conduct; that the conduct was not at the most serious end of the spectrum; nor that the sanction imposed was too severe.
46. The applicant contrasts his own conduct with that in issue in *Hermann* and *Dowling*. There is no doubt but that the conduct in *Hermann* was viewed by the court as very firmly within the most serious category of professional misconduct. However, in *Hermann*, the sanction imposed was a one-year suspension and a period of three years' retraining which is clearly a more significant sanction than that selected in this case. Likewise, in *Dowling*, where the conduct in issue was also at the upper end of the spectrum, the sanction recommended, and ultimately set aside by the court, was erasure, the most severe sanction possible. Therefore, there is little to be gained from comparing the seriousness of the conduct in this case with that in issue in *Hermann* and *Dowling*. That is to address only one side of the proportionality scales, the seriousness of the conduct, without having full regard to the fact that the severity of the sanction in the cited cases was significantly greater than in this instance.

Disparity in the sanction vis a vis comparators

47. The applicant's submissions to the Council on sanction emphasised the importance of consistency in sanctioning and referred to seventeen different comparators to demonstrate that his conduct was not at the most serious end of the spectrum and that the sanction was more severe than that imposed on other pharmacists in similar or equivalent circumstances.
48. The applicant submits to the court that there is no evidence that the Council engaged with those comparators and that it made no attempt to explain why his case deserved a "*markedly more severe sanction*".
49. It is important to mention that many of the comparator cases urged upon the Council by the applicant were from newspaper articles to which the applicant accepted only limited

weight may be attached. Other cases, although based on publicly available information on the PSI website, were accepted by the applicant to be distinguishable.

50. The applicant confined his challenge to one particular comparator which he argued is “on all fours” with the present case. That particular case concerned dispensing of high-tech medication on multiple occasions without a valid prescription to four different patients. In that case the sanction imposed by the PSI was a less severe censure together with certain conditions, rather than suspension. However, the pharmacist in this comparator case made admissions and tendered an apology early in the fitness to practice process, which is of relevance in the context of sanctioning.
51. Irrespective entirely of such distinction, I am not persuaded that merely because the applicant can draw the attention of the court to one case, bearing factual similarities but resulting in a lesser sanction, the sanction imposed must necessarily be viewed as disproportionate. Rather, as pointed out by Charleton J. in *Hermann*, whilst consistency of sanctioning is important, precedents and sanctioning guidelines, prepared by a relevant regulatory body in relation to appropriate sanctioning, are not restrictive. The court is not boxed in by sanctioning precedent.
52. A clear failure to adhere to published sanctioning guidelines could be a legal error, but it is difficult to see how not following the sanctioning decision in a single prior matter could ever amount to legal error. It is clear from the advice given by the legal assessor that the Council was fully directed on the relevance of consistency as a guide but not as a straightjacket, to the Council’s considerations on sanction. The PSI is best placed to weigh similarities or distinctions as between a particular case before it and previous cases, insofar as they may be relevant. The court must approach, with some scepticism, submissions that a particular case is on all fours with a prior case given the court’s lack of knowledge when attempting to calibrate the case before it against the comparator argued as a precedent. For this reason, I do not believe that the contended for disparity between the sanction imposed is a reason for setting aside the sanction imposed by the Council.
53. It was not incumbent upon the Council to distinguish in detail each of the seventeen comparators urged upon it. The very number of those comparators would have made that an unproductive task. It would have been helpful if the Council had included in its decision an explanation of why the more pertinent comparators did not alter its conclusion that the sanction recommended by the PCC was appropriate. However, it is evident from the record that the Council correctly understood the significance of consistency and the limited value of the specific comparators urged.

Failure of the Council to engage with evidence of insight

54. The applicant was legally represented at the inquiry and put forward a positive defence, as he was entitled to do. The PSI was equally entitled to conclude that the positions adopted by the applicant before the PCC were in many instances untenable, wholly irrelevant and mutually inconsistent and further that, at least before the PCC, the applicant had displayed a lack of insight.

55. The applicant argued that any lack of insight was no longer a factor at the sanction hearing before the Council or before the court. At the Council sanction hearing, the applicant specifically addressed the PCC finding that he lacked insight, apologised for his conduct and outlined changes in his practice to prevent such a lapse from occurring in the future. The applicant acquitted himself well before both the Council and the court. It is also notable that the applicant ceased to operate as a supervising pharmacist in September 2021 in deference to the conditions imposed by the Council, even though it was not strictly speaking necessary for him to do so unless and until the sanction was confirmed by the court. This demonstrates an attitude of respect towards the inquiry process and towards the Council's sanction for which the applicant must be commended.
56. That said, I regret that I cannot accept the applicant's submission that this demonstration of insight long after the event must be an over-riding consideration for the court when assessing the proportionality and validity of the sanction itself. In this respect, the applicant places significant reliance upon the following passage from Ní Raifeartaigh J.'s judgment in *Dowling*:

"The second factor referred to by the Committee was the issue of insight. The question of insight appears to me to be also highly relevant to mitigation; it is relevant to such matters as whether a professional who has been found guilty of professional misconduct might require some form of rehabilitation (as was ordered in the Hermann case) as well as the likelihood of their engaging in any such misconduct again in the future (the risk of future offending). These factors must be relevant to whether it was appropriate to impose the ultimate sanction of erasure in the present case. At the hearing before the Court, it was pointed out on behalf of the Board that the Act's provisions allow for the restoration of a nurse to the register after being erased. It does not seem to me that the availability of the remedy of restoration removes from the Board the obligation of considering the question of the nurse's insight at the time of the imposition of the sanction. It would not be appropriate, in my view, for the Board to take the view that the seriousness of the offence warranted erasure and that the insight (displayed at hearings several years before the imposition of the sanction) could be subsequently dealt with by restoration. All mitigating factors should be considered at the time of the imposition of sanction." (emphasis added)

57. The applicant submits that the principle to be drawn from this passage is that the Council and the court must primarily, if not exclusively, consider the presence or absence of insight at the sanction hearing or at the court hearing itself. That is incorrect. In the passage cited, the learned judge was considering whether it was appropriate to impose the ultimate sanction of erasure and was dealing with the regulator's argument that the availability of the remedy of restoration meant that mitigating factors such as insight would fall for consideration at the restoration stage. It was in response to this argument that the court pointed out that all mitigatory factors should be considered at the time of the imposition of the sanction. The court did not imply that the presence or absence of insight, prior to the sanction hearing, is either irrelevant or of little relevance.

58. The applicant relied upon Gomez "*The Regulation of Healthcare Professionals: Law, Principle and Process 2nd ed. vol. 2*" which recognised the tension between a registrant's right to maintain innocence throughout the inquiry hearing, and the weight to be attached to an apparent lack of insight, which such an approach may suggest, at a subsequent sanction hearing. The applicant argues that it would be wrong to equate the maintenance of innocence with a lack of insight and that the court is obliged to consider the issue of insight afresh.
59. This is too narrow an approach. The continued denial of poor professional performance and the apparent lack of insight displayed by the applicant at all times up to the sanction hearing before the Council remains relevant. Failure by a practitioner to accept allegations made at an inquiry is not an aggravating factor, but it might reduce the level of mitigation available on foot of a later acceptance of responsibility. A practitioner is entitled to maintain his innocence, in challenging matters at the inquiry and after its conclusion, but in doing so it is inevitable that he cannot argue at a later sanction hearing that he had insight at the relevant time. In this case, there is no requirement to ignore the fact that, up to the sanction hearings in June and July of 2021, the applicant adopted a particular attitude which the PCC fairly characterised as displaying a lack of insight.
60. The applicant argues that insight is a process and that sometimes it takes being found guilty for a person to accept responsibility and to develop the requisite level of insight. This may be so. However, even if insight is a process, insight gained several years post event is insight of a different quality to that which presents at an earlier stage. In this particular case, years passed between the events giving rise to the inquiry, which occurred between August 2017 and February 2018, and the PCC inquiry in February 2021 at which no insight was evident. Thereafter, only a short number of months passed between the inquiry report in April 2021 and the Council sanction hearing in June/July 2021, when that insight was demonstrated.
61. Lest there be any doubt, I do not find that the applicant's expressions of regret and acceptance of responsibility are disingenuous or contrived. The applicant presented as an honest and conscientious witness. I have no difficulty in finding that he could not, in any sense, now be characterised as unfit to practice. Indeed, I think it is fair to say that as a result of these events, the applicant is likely to have an acute appreciation of his obligations as a pharmacist under the high-tech scheme and otherwise.
62. However, insight gained at this late stage and by such a process of attrition, is not a factor of such weight as to render invalid the recommended sanction. Insight is generally viewed by regulators, and indeed by the courts, as the best protection against a particular practitioner repeating the conduct in issue. In this case, the court fully accepts that the applicant is highly unlikely to repeat the conduct in issue. This insight means that the protection of the public against the risk of the applicant committing future similar misconduct is not of particular relevance in this case. However, there are other important elements to the public interest which are engaged, such as pointing out to the profession the gravity and seriousness of conduct such as this; the upholding of professional

standards and of the integrity of the fitness to practice regime and maintaining public trust in the profession by reassuring the public as to the standards to be upheld by practitioners and as to the PSI's regulation of pharmacists and pharmacies. In short, there exists a public trust in pharmacists that they comply with their professional duty and public health and safety often depends upon this trust. As pointed out by Charleton J. in *Hermann*, in the case of serious misconduct, the reputation of the profession must be upheld and, where the misconduct by the practitioner is serious, the importance of protecting public health and safety exceeds the regrettable misfortune that may be visited upon that practitioner.

63. Whilst the applicant's current insight is relevant, it does not render the recommended sanction disproportionate. The court would have taken a different view if the period of suspension had been longer. Bearing in mind the seriousness of the conduct, the length of time over which it continued, the length of time which the applicant took to develop insight and the uniquely heightened obligations of pharmacists in the high-tech scheme, the sanction selected of two months suspension of registration is not disproportionate, unduly lacking in leniency or unreasonable.
64. The applicant is correct in contending that his attitude before the Council was materially different from that before the PCC: The Council's decision on sanction might have set out in more detail the insight then demonstrated by the applicant and further articulated the purpose of the sanction of suspension. However, as the court is at large in outlining its own reasons for the selection of an appropriate sanction, and as it is agreed that this is not a matter for remittal, I need go no further in this regard.

The failure of the Council to engage with the evidence from Mr. Stenson

65. The applicant also argues that the Council failed to engage with the evidence, of Mr. Stenson, his expert pharmacist. Mr. Stenson undertook an independent audit of the applicant's professional practice and pre-prepared a report for consideration by the Council. Mr. Stenson found that, save for these events, the applicant's practice complied with the rules and regulations governing pharmacy practice in Ireland; that the applicant practiced professionally at a high level and with a firm eye on the continued improvement of his practice; and that he was dedicated to the safety of his patients.
66. At the Council sanction hearing, counsel for the Registrar made submissions critical of the report, stating that it lacked specificity in failing to detail the nature of the audit, the timeframe of review of the applicant's prescribing practices or the number of prescriptions reviewed. I consider those criticisms to be valid. Indeed, Mr. Stenson prepared a further report for the court to clarify some of these very matters.
67. Even Mr. Stenson's second report required some clarification which he provided by way of oral evidence to the court. The court is fully satisfied that the applicant now complies with good dispensing practices and that the poor professional performance in issue occurred in an otherwise unblemished practice. This is a mitigating factor to which the court can have regard.

68. Overall, however neither Mr. Stenson's report nor his evidence to the court fundamentally impact on the assessment of the proportionality of the sanction.
69. There was never a suggestion of other wrongdoing, nor any deficiency in the general standard operating procedures on, *inter alia*, the dispensing of high-tech medications (SOP's) in the applicant's pharmacy. The applicant's work in updating and stress testing the SOP's is welcome, but does not address the central issue in this case: for a period of eight months, high tech medication was dispensed without prescription to the two patients and at no stage during this time did the applicant call up or look at the relevant prescription.
70. The Council cannot be criticised for not specifically referring to Mr. Stenson's report in its decision on sanction. The court accepts that the first report was incomplete and difficult to interpret in many respects and that it was reasonable for the Council not to afford significant weight to it. The position before the court was different and I have given careful consideration to whether Mr. Stenson's second report, demonstrating that this is the only lapse in good practice by the applicant, renders the sanction of two months' suspension too harsh. In my view it does not. That the applicant has otherwise acted in accordance with good practice and continues to do so, does not alter the seriousness of the conduct in issue in these proceedings.

Failure to afford leniency and to give appropriate weight to other mitigatory factors

71. A sanctioning body must consider sanctions of lesser severity before considering the more severe sanctions available to it. Such a body is under an obligation to assist the practitioner with as much leniency as possible. The applicant maintains that the Council failed to respect this principle and failed to give appropriate weight to mitigating factors.
72. This submission in relation to an absence of leniency cannot succeed. The PCC's decision, which the Council endorsed, referred specifically to the PSI's guidance on sanction which sets out the obligation to assist practitioners with as much leniency as possible. Furthermore, this requirement was adverted to in the advice of the legal assessors before both the PCC and the Council.
73. It cannot realistically be argued that the PCC or the Council failed to have regard to the submissions made on behalf of the applicant in relation to mitigation. In this respect, it is important to emphasise that there is a distinction between the present case and Dowling. In Dowling, the PCC, which made findings of misconduct, had recommended that the practitioners be censured. However, the Nursing Board subsequently decided to impose the far more severe sanction of erasure. In such circumstances, the Nursing Board could not rely upon the reasons outlined in the PCC report for the selected sanction and it was thus incumbent upon it to fully explain why the more harsh sanction was selected. It was in this context that Ní Raifeartaigh J. was critical of the generalised manner in which the Nursing Board dealt with the mitigating factors which had been argued before it. The same cannot be said in this case. The PCC report set out in full each of the applicant's submissions on mitigation, dealt fully with each of these mitigatory factors and explained their relevance in the context of the recommended sanction. The PCC report was adopted

by the Council. It cannot be said that there was a generalised approach to mitigation or a failure to engage with the applicant's submissions.

74. In all the circumstances and being fully conscious of the obligation to assist the applicant with as much leniency as possible, the court must conclude that the sanction imposed in this case is reasonable and that the Council carried out a correct calibration of the conduct, the purpose of sanction and the mitigating factors. Although I have considerable sympathy for the applicant, who has demonstrated remorse and more importantly insight which, without doubt, will henceforth be reflected in all aspects of his practice, the court is not prepared to cancel the sanction imposed.
75. In light of the fact that the applicant has not been successful in his application to cancel the sanction imposed by the Council, the respondent is presumptively entitled to its costs of the proceedings subject to any case which the applicant may wish to make to the contrary. If the applicant intends to argue for a different conclusion in relation to costs, he is at liberty to furnish by email to the registrar (copied to the solicitor for the respondent) within 14 days from the date of delivery of this judgment his submissions to that effect, in which case the respondent will have a period of 14 days thereafter in which to furnish replying submissions (to be copied to the applicant's solicitors), following which I will issue a written ruling on costs.