

NATIONAL APPEAL PANEL

constituted under

**THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES)
(SCOTLAND) REGULATIONS 2009 (AS AMENDED)
("the Regulations")**

DECISION

of the

CHAIR

of

THE NATIONAL APPEAL PANEL

in the Application relating to

Garrison House, 2 Clifton Street, Millport, KA28 0AZ

Applicants:	Cumbrae Community Development Company
Appellants:	Cumbrae Community Development Company
PPC Decision Issued:	15 February 2016
Panel Case Number:	NAP 52 (2016)

Decision of the Chairman of the National Appeal Panel

1. Background

- 1.1 This is an appeal against the decision of the Pharmacy Practices Committee of NHS Ayrshire and Arran ("the PPC") which was issued on 15 February 2016.
- 1.2 Cumbrae Community Development Company (the "Applicants" or "Appellants") made application for inclusion in the pharmaceutical list of NHS Ayrshire and Arran ("the Board") to provide pharmaceutical services in respect of the premises at Garrison House, 2 Clifton Street, Millport, KA28 0AZ ("the Premises") said application dated 23 November 2015 (erroneously dated 23/11/2016).
- 1.3 The PPC under delegated powers of the Board held a Hearing on 4 February 2016 and took evidence from the Applicant and interested party and considered supporting documentation and following upon which it determined that the provision of pharmaceutical services at the premises was neither necessary nor desirable in order to secure provision of pharmaceutical services in the neighbourhood in which the premises are located and accordingly refused the application.

2. Grounds of Appeal

- 2.1 The Appellants submitted a letter of appeal to the Board dated 3 March 2016, the grounds of which may be summarised as follows:-
 - 2.1.1 That "huge swathes" of the questioning of their testimony at the PCC Hearing was not minuted.
 - 2.1.2 Canon Matt McManus served as a lay member on the PPC in the current application and had also served as a lay member at the PPC Hearing which granted the licence to Cumbrae Pharmacy, the interested party in the current application. This ought to have been declared to the current PPC Panel and that Canon McManus ought to have recused himself on the basis of a conflict of interest.
 - 2.1.3 That Canon McManus was biased in the line of questioning of the Applicants during the course of the Hearing. In particular, the profitability factors discussed were necessary and apparent in order to determine a robust business plan. The Appellants also contend that Canon McManus was endeavouring to entrap the Applicants into stating that one supplier of pharmaceutical drugs was superior to another.
 - 2.1.4 The representative of the interested party, Cumbrae Pharmacy, stated that their pharmacist could not get to work on the island on only one occasion in four years. This statement was incorrect.
 - 2.1.5 The Applicants were not permitted to introduce comments regarding support of the Millport Care Home whereas the representative for Cumbrae Pharmacy was permitted to bring in statements as facts regarding the amount of medicines dispensed without being challenged by the Chair or other members of the PPC nor had the Applicants had any prior opportunity to test the veracity of the interested party's dispensing figures.
 - 2.1.6 The Applicants had raised concerns in relation to the interested party's unsuccessful attempts to interfere with the recruitment process of the Applicant's pharmacist.
 - 2.1.7 The Appellants were aware of complaints within the island community of the life threatening errors in dispensing but had not wished to go into this during the Hearing and now wished to raise the issue during the course of the appeal.

3. Summary of the Evidence

- 3.1 The evidence of the Applicants may be summarised as follows:-
 - 3.1.1 Mr Michael Bertram, for the Appellants, confirmed that they were the landlords for

Garrison House and currently lease space to the NHS for the Cumbrae Medical Centre and are familiar with the demands and standards of the Care Quality Commission. A pharmacy at the medical centre would in essence create a "one stop shop". The proposed siting of the premises would ease the pressure on the elderly.

- 3.1.2 Mr Bertram stated that the neighbourhood was the island of Cumbrae and the town of Millport which currently has two pharmacies servicing the needs of the islanders and visitors (Cumbrae or Superdrug in Largs). It was the Applicants contention that the services provided by Cumbrae Pharmacy were unsatisfactory and inadequate in that it lay a quarter of a mile approximately from the medical centre and residents were concerned as to the unsuitability of the location due to the close proximity of a busy cycle shop, and ferry bus stop (which in high season is inundated with passengers) and that the pharmacy has no available parking outside. Further, there is no bus service if the ferries are not running. There is no disabled entrance to the current pharmacy premises and the prevailing wind and weather is such that the existing pharmacy is directly in its path with no weather protection for sick patients waiting to gain access to the pharmacy.
- 3.1.3 Concerns had been raised that as the island does not have a resident pharmacist, Cumbrae Pharmacy has been required to introduce their own standard operating procedures to cover the situation of a pharmacist not in residence particularly when ferries are not running. It was Mr Bertram's view that according to the "Responsible Pharmacist Regulations 2008" that position was illegal.
- 3.1.4 The application stated that the proposal if successful would allow qualified NHS staff to offer access a full range of specified drugs, 24 hours a day, 7 days a week unlike the present pharmacy. The Applicants had commissioned a questionnaire, professionally managed and implemented, which asked the following question: "Our household would support a community pharmacy in the Garrison". The responses indicated a 72.5% approval rating of those who took part. Mr Bertram further argued that the joint consultation exercise effected with The Board supported their application for a community pharmacy to be based in the Garrison.
- 3.1.5 There are currently two pharmacies serving the island, Superdrug in Largs and Cumbrae Pharmacy. Financial viability would not be an issue as the proposed pharmacy would be replacing Superdrug giving a better service to the community.
- 3.1.6 Following questions from the interested party and the PPC, Mr Bertram stated by siting the pharmacy at the Garrison there will be closer interaction between the pharmacy and the medical practice and that it would play a greater role than Cumbrae Pharmacy. He further stated that there had been several occasions when access to medication had not been available and that the Applicants would give direct access to the proposed Garrison Pharmacy if required out of hours. The Applicants had hoped to encourage a pharmacist to live on the island thus obviating any problems of the lack of a pharmacist in the event of inclement weather and such pharmacist had already been identified. He had acknowledged that 85% of prescriptions were repeat and that for most people getting a prescription did not involve a trip to the doctor's surgery.
- 3.1.7 Mr Bertram confirmed that the Applicants had not made any formal approach to Cumbrae Pharmacy to relocate to Garrison House and that it was the Applicants' intention to employ two pharmacists. Concern was expressed that were the application to be granted that this may detrimentally affect Cumbrae Pharmacy and would this comply with the Applicants' mandate on health to which Mr Bertram responded that it would as the proposal was for a community pharmacy albeit, Mr Bertram accepted, as was Cumbrae Pharmacy; however, the proposed pharmacy would take on the role currently offered by Superdrug in Largs who were in fact supporting the application thus not affecting the status quo.
- 3.1.8 Canon McManus questioned Mr Bertram regarding the out of hours service and who, in these circumstances, would be able to access the pharmacy if not the pharmacist to which Mr Bertram responded that it was intended that the pharmacist would do so and such pharmacist would be resident upon the island were the application granted. If a doctor were present so must the pharmacist be also. Canon McManus then referred to

the delivery service in Largs and enquired as to whether the medical supplies from Superdrug were better than that available from Cumbrae Pharmacy. Mr Bertram had stated that it was nothing to do with the drugs being better but that there was a belief that the islanders did not wish to deal with Cumbrae Pharmacy an issue upon which he did not wish to elaborate. He went on to state, however, that there was a lack of a relationship between the residents and the current pharmaceutical provider and that it was patient choice not to use Cumbrae Pharmacy. Canon McManus had noted that the service offered by Superdrug in Largs where residents of Cumbrae were physically receiving and delivering medication with neither training nor insurance and whether this was an adequate service, specifically what cover the Applicants had if people delivered the wrong medication. Mr Bertram explained that the Applicants were not delivering the medication, that the collection and delivery service was NHS approved and that the Applicants' main concern was from an insurance point of view. Upon being advised by Ms Lamprell that the collection/delivery service was a non-NHS approved service Mr Bertram stated that in all the meetings the Applicants had had with the Health Board this had never been raised as a concern.

- 3.1.9 Mr Bertram explained that the application was about the island retaining its business by ensuring that profits earned on the island stayed on the island. What had been a concern was as soon as Cumbrae Pharmacy was granted a pharmacy licence the business was advertised for sale.

3.2 The evidence of Mr Brendan Semple of the interested party may be summarised as follows:-

- 3.2.1 Mr Semple concurred with the definition of the neighbourhood i.e. the Isle of Cumbrae with the only population centre being the small town of Millport, there being a single pharmacy providing services to the neighbourhood, Cumbrae Pharmacy which provides all core NHS services. There is also a prescription collection service twice daily from the surgery and home delivery if required. The pharmacy dispenses 2,200 prescriptions a month which is just above the threshold which is accepted as the "break even" point for a small pharmacy. Superdrug dispenses around 700 items per month which it is assumed is the prescription service provided to the residents of Cumbrae. Cumbrae Pharmacy is an exclusive provider of the out of hours emergency dispensing service on Cumbrae and the only provider of the eMAS service as this requires face to face contact with the patient.
- 3.2.2 Mr Semple disagreed with the Applicants' contention that the latter's proposed location would be "better" than that of Cumbrae Pharmacy, stating that as 85% of prescriptions are repeats there is no need to go to the surgery before collecting any medicine as this will be collected by the pharmacy in advance and that any modern pharmacy co-location with the surgery is of little benefit. In connection with the proposed opening hours these were regarded as unrealistic given the costs of the pharmacist and supporting staff and which would result in an on-cost of approximately £10,000 per month. In any event, the Applicant would be under no obligation to continue with the proposed hours. The Applicants' proposed services were equally unrealistic and, in any event, the Applicants would be under no obligation to provide any service which is not part of the core NHS contract.
- 3.2.3 Mr Semple then drew the PPC's attention to the joint consultation report and in particular in relation to the question as to whether there were any gaps/inadequacies in the existing provision and the substance or otherwise that the claim was made by 60 respondents who considered that there was a gap in the existing provision. The most popular reason was the distance from the surgery to the pharmacy which is 387 yards with no busy roads and on the flat. In inclement weather, the pharmacy would uplift the prescription, dispense it and deliver it. As to the "inadequacy" of their opening hours these were fully compliant with NHS Ayrshire and Arran's required hours scheme. In any event, opening hours have no relevance to a PPC hearing as any new pharmacy may adjust their opening hours once an application is granted. In response to another expressed concern, Mr Semple stated that since opening Cumbrae Pharmacy 4 years ago, there had been only one single day when a pharmacist failed to get to the island i.e. on Christmas Eve 2014 and it was agreed with the Board that the pharmacy's standing operating procedures would be sufficient to cover any emergencies on that day albeit in the event they were not required. In

this connection, they questioned the Applicant's guarantee that they would have an employee who would move to Millport. Mr Semple questioned whether the granting of the contract would secure an adequate pharmaceutical service and that Millport was not large enough to financially sustain two NHS community pharmacies. The GP's surgery generates 3,500 scripts per month, deducting care home scripts, leakage due to people going to work on the mainland and appliances, this would at a guess result in around 3,000 items. If split 50/50 that would be 1,500 items per pharmacy. No pharmacy could survive on that number per month while paying for a pharmacist and support staff and rent. He argued that it was commercially unfeasible. Thus the grant of the current application would result in the closure of either the existing pharmacy or the failure of a new pharmacy, the application could not "secure" anything. Further the application is not offering something that the existing contractor does not. He argued that the current services were adequate and the grant of the application would not only not secure an adequate pharmaceutical service but destabilise the existing service.

3.2.4 Neither Mr Bertram nor the members of the PPC posed any questions to Mr Semple.

3.2.5 Prior to the departure of the parties, the Chairman asked the parties to confirm that a fair hearing had been received and that there was nothing further to be added and that having indicated that they were so satisfied all parties left the Hearing.

4. The PPC's Decision

- 4.1 In addition to the oral evidence, the PPC had noted that they had jointly undertaken a site visit of Millport and the surrounding area considering the location of the proposed premises, the pharmacies, general medical practice and facilities and amenities within, a map showing the location of the proposed pharmacy in relation to existing pharmacies and GP surgeries within Millport and the surrounding area; an area profile report for data zone S01004508; ferry time table detailing services between Largs and Cumbrae and fares; dispensing statistics for the community pharmacies in Millport and Largs; further information including details about existing provision of pharmaceutical and medical services in and to and population figures for Millport as indicated by Scottish Neighbourhood Statistics and General Register Office Statistics; report on pharmaceutical services provided by existing pharmaceutical contractors to the neighbourhood; NHS Ayrshire and Arran Pharmaceutical Care Services Plan 2012, the Consultation Analysis report ('CAR') and all other relevant documentation .
- 4.2 The PPC summarised the Consultation Analysis Report (CAR) which expressed the views of local people who may have been affected by the application or the use of the proposed pharmacy and which had also been aimed to gauge local opinion on whether people felt access to pharmaceutical services in the area was adequate. It explained the processes of the consultation and the period over which it ran and summarised that in total 160 responses were received.
- 4.3 In considering **neighbourhood** the PPC acknowledged that there were a number of factors required to be taken into account including those resident in it, natural and physical boundaries, general amenities such as schools/shopping areas, the mixture of public and private housing, etc. and agreed along with both the Applicant and interested party that the neighbourhood should be defined as the island of Cumbrae because of the natural boundary provided by the Firth of Clyde.
- 4.4 As to **adequacy** of the existing provision of pharmaceutical services and necessity or desirability, the PPC had noted that there was one pharmacy within the neighbourhood and had equally noted the location of 4 existing pharmacies in Largs. Taking into account the prescription figures and services available at the pharmacies serving the neighbourhood, the PPC unanimously deemed that the existing pharmaceutical services were adequate. Cumbrae Pharmacy provided a prescription collection and delivery service on request and is open on bank holidays although not required to do so by the Health Board. There had been no complaints made to the Health Board concerning the pharmacy services available to the islanders but that the PPC were advised by the pharmacists on the panel that the information provided by Mr Semple that there had been no out of hours opening in the last 10 years was correct.
- 4.5 In the circumstances the decision of the PPC was unanimous that the provision of

pharmaceutical services at the premises was neither necessary nor desirable in order to secure adequate provision of pharmaceutical services within the neighbourhood in which the premises were located by persons whose names were included in the pharmaceutical list and, accordingly, the application was rejected.

5. Discussion and Reasons for Decision

- 5.1 The Regulations require to be considered in light of the objects of the scheme set out under the National Health Service (Scotland) Act 1978 and, in particular, Section 27, in that it shall be the duty of every Health Board to make arrangements as to its area for the supply to persons in that area of proper and sufficient drugs and medicines which are ordered for those persons by a medical practitioner in pursuance of his functions in the Health Service. An Application made in any case should be granted by the Board after procedures set out in Schedule 3 of the Regulations are followed, if the Board is satisfied that it is necessary or desirable to grant an Application in order to secure in the neighbourhood in which the premises are located the adequate provision by persons included on the list of the services specified in the Application. This is further extended by Regulation 5 (10) of the Regulations in that an Application shall be granted by the Board: (a) only if it is satisfied that the provision of Pharmaceutical Services at the premises named in the Application is necessary or desirable in order to secure adequate provision of pharmaceutical services in the neighbourhood in which the premises are located by persons whose names are included in the pharmaceutical list and: (b) if the boundaries of the neighbourhood within which the Applicants intend to provide pharmaceutical services falls within any part of a controlled locality, only if it is satisfied that the granting of such an application, in its opinion, would not prejudice the provision of NHS funded services in the controlled locality. For the purposes of clarification in terms of paragraph 1a of Schedule 3 of the regulations, a controlled locality is an area within a Health Board which is remote or rural in character and which is served by a dispensing doctor. This latter provision does not apply in the current circumstances.
- 5.2 In terms of paragraph 3 (i) of Schedule 3, the PPC shall have regard to the pharmaceutical services already provided in the neighbourhood of the premises, the pharmaceutical services to be provided in the neighbourhood at those premises, any information available to the PPC which, in its opinion, is relevant to the consideration of the Application, the CAR, the Pharmaceutical Care Services Plan and the likely long-term sustainability of the pharmaceutical services to be provided by the applicants.
- 5.3 The grounds of appeal are limited to areas where the PPC has erred in law in its application of the provisions of the Regulations, that there has been a procedural defect in the way the Application has been considered, that there has been a failure by the PPC to properly narrate the facts or reasons upon which their determination of the Application is based, or there has been a failure to explain the application by the PPC of the provisions of the Regulations to those facts.
- 5.4 The principal point of the PPC's decision is whether or not it has exercised its judgement fairly and given adequate reasons for it and that it does not otherwise offend against the grounds of appeal set out in Schedule 3, paragraph 5 (2A) and (2B). It is relevant to note that the PPC comprises pharmacists and lay members who may be expected to understand the issues involved on the evidence before it. It is an expert tribunal. Equally, it must be understood that the PPC's decision must be intelligible and it must be adequate. It must enable the reader to understand why the matter was decided as it was and what conclusions were reached on the principal issues and its reasoning does not give rise to any substantial doubt that it had erred in law. Such adverse inference will not readily be drawn.
- 5.5 The Appellants have contended that "huge swathes" of questioning of their testimony made to the PPC hearing was not minuted and a request had been made to The Board for a full transcript and tapes of the hearing to which the Appellants had received a response from The Board stating that "we have sought advice on this matter from NHS National Services who supplied the secretarial services to the hearing and they have advised that as the report of the meeting has been signed off by the Chair of the Pharmacy Practice Committee as a true record of the hearing and covers the salient and relevant matters of the discussion, then the secretary's notes cannot be requested. No stenographer was at the hearing and the hearing was not recorded on tape or any other audio device. I can also advise that it is neither normal practice that hearings are recorded or that verbatim minutes are provided." I can add nothing

further to this statement. Once the minutes have been signed off by the Chair of the meeting, then that is an end of the matter. The Appellants have not stated in what respects aspects of their testimony have been omitted.

- 5.6 The Appellants have contended that Canon McManus was biased in his line of questioning of the Applicants. They cite the issue of profitability factors discussed which if anything were necessary and apparent in order to show a robust business plan. The Appellants state that the line of questioning appeared to be based on either trying to "entrap" the Applicants into stating that one supplier of pharmaceutical drugs was superior to another or some other motive which would have come to light only if CCDC had agreed that Superdrug supply was superior. The Appellants prayed in aid the case of *GPC -v- Z.Hussain (GPhC Reg.No.204, p 753) [2015]*. The reference to this "authority" is mistaken. This was a case that appeared before the Fitness to Practice Panel of the General Pharmaceutical Council where Mrs Hussain had been caught on camera in a BBC investigation supplying a prescription drug without prescription. In the course of her preliminary plea to the Fitness to Practice Panel, she alleged entrapment. There is little point in going into the detail of this case, suffice to say that any suggestion of entrapment or an abuse of process was rejected by the Panel who directed that the entry of her name be removed from the Register. On her appeal to the High Court earlier this year that removal was upheld. There is nothing offensive in the questions raised by Canon McManus which were effected during the proper course of examination albeit that it might have been regarded by the Appellants as firm. Canon McManus had asked Mr Bertram whether "the medication from Superdrug was always better than that available a few yards from Garrison House". Mr Bertram responded to that enquiry. The discussion on profitability appeared fair and Mr Bertram had been given the opportunity to respond to it. Accordingly, on the basis of the Minutes there appears to be no justification for the allegation that Canon McManus was biased on this issue.
- 5.7 The Appellants state that as Canon McManus served as a lay panel member at the first application made by Mr James Semple for a licence which was subsequently granted to Cumbræ Pharmacy, he ought to have declared this to the PPC Panel and recused himself on the basis of a conflict of interest. The Appellants quote a number of authorities in support of their contention. The leading authority of *Porter -v- MacGill & Another [2002]* states that the standard of bias is to be assessed against the fair minded and informed observer and the test of bias is whether there is a *real possibility* of bias. Since then the House of Lords (now Supreme Court) have considered this formulation in the context of asylum law where a patent bias was alleged: *Helow -v- Secretary of State for the Home Department [2008]*. In that case it was alleged that there was a perception of bias in the consideration of a claim for refugee status by a Palestinian applicant by Lady Cosgrove. She subscribed to a Jewish legal chronicle that contained articles that were hostile to Palestinians. Lord Hope stated in that case "...the observer who is fair minded is the sort of person who always reserves judgment on every point until he has seen and fully understood both sides of the argument. He is not unduly sensitive or suspicious (as was observed in *Johnson -v- Johnson*). His approach must not be confused with that of the person who brought the complaint. The "real possibility" test is that there is this measure of detachment. The assumptions that the complainer makes (in this case the Appellant) are not to be attributed to the observer unless they can be justified objectively. ...He knows that fairness requires that a Judge must be, and must be seen to be unbiased. ...Then there is the attribute that the observer is "informed". He makes the point that before he takes a balanced approach to any information he is given, he will take the trouble to inform himself in all matters that are relevant. He is the sort of person who takes the trouble to read the text of an article as well as the headline. He is able to put whatever he has read or seen into its overall social, political or geographical context. He is fair minded, so he will appreciate that the context forms an important part of the material which he must consider before passing judgment." Lord Hope concluded in this case that there was no "basis upon which the observer would conclude that there was a reasonable possibility that the Judge was biased". There is no suggestion by the Appellants that Canon McManus had a personal interest in the matter in the sense of his having a personal interest in the determination of the application. The fact that he had sat on a previous panel which found in favour of the then Applicant can not possibly justify a recusal or, for that matter, a declaration of interest. The circumstances obtaining at the time of the first application were entirely different to those of the current application. The appellants have not sufficiently articulated any reason as to why Canon McManus was conflicted and thereby biased other than the fact that he had sat on a

previous application involving the interested party in this case . It does not follow that he was biased in the current application . Furthermore, no objection was taken by the Applicants at the time and if they had so objected, the Chair would have been within his rights to refuse to consider such objection.

- 5.8 The Appellants queried the evidence given by the interested party that there was only one occasion in four years where the pharmacist could not get to work and other issues which, frankly, are not a matter for this forum and it is not possible to hear any further evidence at this stage. The remit of the National Appeal Panel is, stated above, limited to those set out in Schedule 3, paragraphs 5 (2A) and (2B). All other grounds of appeal not referred to above are regarded as either *de minimis* or irrelevant in that they are not a matter of concern to this jurisdiction
- 5.9 In the circumstances it is found that the Appellants' letter of appeal discloses no reasonable grounds.

(sgd) JMD Graham

**J. Michael D. Graham
Interim Chair
National Appeal Panel
6 June 2016**