Neutral Citation Number: [2017] EWHC 3232 (Admin)

Case No: CO/1394/2017

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 12 December 2017

Before :

MRS JUSTICE LANG DBE

- -

Between :

THE QUEEN
on the application of

(1) HANNAH BEETY
(2) SABINE VON TOERNE
(3) SUSAN SPENDER
(4) ELEANOR MISKIN-GARSIDE — **Claimants**

- and -

NURSING AND MIDWIFERY COUNCIL — **Defendant**

(1) INDEPENDENT MIDWIVES UK
(2) LUCINA LIMITED — **Interested Parties**

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- -

Kieron Beal QC and Jessica Boyd (instructed by **Deighton Pierce Glynn**) for the **Claimants**
Timothy Dutton CBE QC and Chloe Carpenter (instructed by **CMS Camerson McKenna Nabarro Olswang LLP**) for the **Defendant**
The **Interested Parties** were not represented

Hearing dates: 18 & 19 October and 15 November 2017

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Approved Judgment

Mrs Justice Lang:

Introduction

1. The Claimants applied for judicial review of the decision of the Registrar of the Nursing and Midwifery Council ("the NMC"), dated 20 December 2016, that the indemnity arrangement providing cover to members of Independent Midwives UK ("IMUK") by Lucina Ltd ("Lucina") was not "appropriate" for the purposes of article 12A of the Nursing and Midwifery Order 2001 ("the NMC Order"), and their registration with the NMC.

2. The NMC is the statutory regulator of nurses and midwives in the UK, established as a body corporate under article 3(1) of the NMC Order. Its principal functions are to establish and maintain professional standards for nurses and midwives (article 3(2)). Its overarching objective is the protection of the public (article 3(4)).

3. EU Directive 2011/24 ("the Directive") requires each member state to put in place appropriate professional liability insurance, or a similar arrangement, for medical treatment provided on its territory. The Directive was implemented in the UK by the Health Care and Associated Professions (Indemnity Arrangements) Order 2014. It amended the NMC Order to add a new requirement for nurses and midwives to have indemnity arrangements in place.

4. Article 12A(1) of the NMC Order provides that a practising registrant must have "an indemnity arrangement which provides appropriate cover". Paragraph (3) defines "appropriate cover" for a nurse or midwife as "cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such". A registrant who fails to comply with this requirement may be refused registration or removed from the register or may be subject to a charge of impairment of fitness to practise by reason of misconduct.

5. The First, Second and Third Claimants were independent midwives and members of IMUK. I shall refer to them as "the midwife Claimants". IMUK was a membership organisation, run by a board of members. It was created in 2008 and as at March 2017, it had 80 members. Members paid an annual membership fee (£900 in the first year and £400 per year thereafter[1]). Membership of IMUK was only open to midwives who were providing midwifery services in the capacity of a self-employed sole trader (though they might also supplement their earnings by working part-time for the NHS and/or other organisations).

6. The midwife Claimants were members of Lucina, and the Lucina scheme. Lucina was a not-for-profit private company wholly owned by its members, who had to be members of IMUK. Members of IMUK and Lucina were eligible to join Lucina's discretionary professional indemnity scheme ("the Lucina scheme"). There was an annual subscription fee of £750, plus £400 per birth attended. It provided member midwives with indemnity cover against damages arising from successful negligence claims made against them, in their capacity as sole traders. Cover was provided for ante-natal, intrapartum (i.e. care during labour) and post-natal care. It was not an

[1] As at August 2017

insurance policy, and so there was no contractual obligation to meet a claim. Under rule 4.1 of the Scheme Rules, benefits were paid at the "sole and absolute discretion of the Board", and were expressly limited by reference to the total funds available to the scheme. Aside from that, there was no financial limit on the benefits payable.

7. In the light of the decision of the Registrar that the cover provided by the Lucina scheme was not appropriate, IMUK members, including the midwife Claimants, were informed that they would be removed from the NMC register by 10 January 2017 unless they provided a signed declaration that they would not rely upon the Lucina scheme for any aspect of their practice which involved attending women in childbirth (as opposed to pre-natal and post-natal care), and that they had appropriate alternative cover in place. All members of IMUK gave the signed declaration.

8. The midwife Claimants had the option of not signing the declaration and appealing against removal from the register. On appeal to the Registrations Appeal Panel, they would have been entitled to a full merits review, unlike a claim for judicial review, which is limited to a review of the lawfulness of the Registrar's decision. Thus, they could have called evidence in support of their contention that the Registrar's decision was factually, as well as legally, wrong. The midwife Claimants stated that they did not wish to take the risk of removal, fearing for their livelihoods. Though as the NMC pointed out, any appeal would have operated as a stay of the removal decision.

9. Permission to apply for judicial review was given by King J. on the papers in an order dated 4 May 2017, despite the NMC's submission that permission to apply for judicial review should be refused because the Claimants had a suitable alternative remedy by way of statutory appeal.

10. The Fourth Claimant was a former client of an independent midwife who wished to use independent midwifery services again in the future if she became pregnant. It was rightly questioned whether she had a sufficient interest to bring the claim, but the Defendant did not pursue the point once permission was granted.

History

11. The Claimants made witness statements, and in support of their claim, witness statements were filed by Ms Tomkins, Chair and Chief Executive of IMUK and sole subscriber of Lucina; Mr Graham, managing director of Lucina; Baroness Cumberledge, patron of IMUK; Ms Schiller, Chief Executive of Birthrights; and Ms Warwick, Chief Executive of the Royal College of Midwives. On behalf of the Defendant, witness statements were filed by Ms Smith, Registrar and Chief Executive of the NMC; Ms Padley, General Counsel of the NMC; Ms Hilken, Acting Head of Policy and Legislation in the NMC's Registration and Revalidation Directorate; and Mr Critchlow, an actuary and independent expert in insurance from OLA plc. A substantial amount of documentary material was also adduced in evidence. It included reports from Mr Critchlow and Miller Associates, both commissioned by the NMC, and reports from BWCI and Marcuson Consulting, commissioned by Lucina.

Pre 2009

12. Until 1994 the Royal College of Midwives provided an indemnity arrangement for all of its members, including independent midwives practising on a self-employed basis outside the NHS. In 1994, it withdrew its indemnity arrangement for self-employed independent midwives, following a full consultation with its members, as a result of the significant increase in the cost of the cover.

13. Between 1994 and 2002 self-employed independent midwives were covered by professional indemnity insurance obtained from the Medical Defence Union.

14. Between 2002 and 30 June 2014 self-employed independent midwives were unable to obtain professional indemnity insurance but had legal expenses insurance.

15. In 2003 the NMC Code was amended to recommend that independent midwives should hold indemnity cover, and to require them to advise their clients if they did not have cover in place.

16. According to a Department of Health Impact Assessment (dated 1.1.12), in 2005 harm was caused to a mother and baby by an independent midwife, resulting in permanent disability for the child and reconstructive surgery for the mother. The midwife had not informed her client that she had no cover, and she did not have sufficient assets to pay compensation.

17. At some stage between 2004 and 2009 (there were conflicting dates in the evidence before me), the Department of Health made a policy decision to introduce a requirement for mandatory indemnity cover for all health professionals. However, concerns were expressed that the market would be unable to offer cover for some groups of self-employed registered healthcare professionals.

2009

The Finlay Scott report

18. In 2009 the Secretary of State for Health commissioned an independent review led by Mr Finlay Scott, former Chief Executive of the General Medical Council. It recommended that making insurance or indemnity a condition of registration for health professionals was the most cost-effective and proportionate means of achieving the Government's stated policy objective that all healthcare professionals must have indemnity cover. The review also stated that there were groups of self-employed professionals who could not obtain insurance or indemnity in the market, and an affordable solution should be facilitated for them.

2010

19. In December 2010 the Government confirmed its intention to proceed to introduce legislation requiring all registered healthcare professionals to hold mandatory indemnity cover, without facilitating a solution to the problem identified in the Finlay Scott report.

2011

20. On 9 March 2011 the European Union Directive 2011/24/EU was passed, introducing a mandatory requirement for all EU healthcare professionals to have professional liability insurance or a similar arrangement in place.

The Flaxman report

21. The NMC and the Royal College of Midwives jointly commissioned Flaxman Partners Ltd to prepare a report setting out the feasibility of a model for supporting the continuity of independent midwifery. In September 2011 Flaxman Partners Ltd produced a report called "The Feasibility and Insurability of Independent Midwifery in England", which concluded that independent midwives could only viably secure insurance by becoming an employee of a social enterprise or corporate structure entity regulated by the Care Quality Commission.

2012 – NHSLA "Ten Years of Maternity Claims"

22. In October 2012, the NHS Litigation Authority ("NHSLA") published "Ten Years of Maternity Claims, An Analysis of NHS Litigation Authority Data" (hereinafter referred to as "the NHSLA study"). The Introduction stated:

> "Maternity claims account for the highest value, and the second highest number, of claims under the Clinical Negligence Scheme for Trusts (CNST), a risk pooling scheme for NHS organisations managed by the NHSLA. By the end of March 2011, more than 13,000 obstetrics and gynaecology claims, with a total estimated value in excess of £5.2 billion, had been notified to the NHSLA under the CNST since it started in 1995…."

23. The report set out the findings of a study into 5,087 claims on the NHSLA's database between 2000 and 2010. During a similar time period there were 5.5 million births in England, so less than 0.1% of these births had become the subject of an NHS claim. However, the total value of this small percentage of claims was extremely high: £3.1 billion. Of these claims, about 37% did not succeed.

24. The ten most frequent types of claims, out of 21 categories, were those relating to the management of labour (14.05%); caesarean section (13.24%); cerebral palsy (10.65%); perineal trauma (8.66%); antenatal care (7.68%); stillbirth (4.93%); shoulder dystocia (4.91%); CTG interpretation (5.89%); antenatal investigations (7.68%) and retained swabs (3.65%).

25. The ten most expensive types of claim, out of 21 categories, together with the value expressed as a percentage of the total value of the claims, were as follows:

    i) Cerebral palsy: £1,263,581,324; 40.52%.

    ii) CTG interpretation: £466,393,771; 14.95%.

iii) Management of labour: £424,039,651; 13.60%.

iv) Caesarean section: £216,167,223; 6.93%.

v) Antenatal investigations: £149,986,770; 4.81%.

vi) Antenatal care: £144,811,665; 4.64%.

vii) Shoulder dystocia: £103,520,832; 3.32%.

viii) Uterine rupture: £103,264,627; 3.31%

ix) Operative vaginal delivery: £93,659,223; 3.00%

x) Perineal trauma: £31,202,836; 1.00%

26. The NHSLA study helpfully indicated the nature of the risks, and the number and size of claims, but as it did not distinguish between negligence on the part of midwives and other medical professionals, it did not provide evidence of claims against midwives as a group. Moreover it was based on NHS hospital maternity care, so it included surgical procedures, interventions such as forceps, drugs to induce labour, and CTG monitoring which independent midwives, who only attended home births, and favoured low-intervention care, would not be involved in.

2013

27. On 22 February 2013 the Department of Health issued a consultation document on the proposed UK legislation.

28. At this time, IMUK decided to pursue a self-insure solution. It proposed setting up a protected cell named "Lucina" within a Protected Cell Company named Windward Insurance PCC Ltd, to be registered in Guernsey. In 2013, IMUK made an application to the Guernsey regulator for a licence to form the Lucina captive cell.

29. In 2013, IMUK approached the Department of Health for £10 million in funding for this solution. It stated that without government funding, the Lucina cell would only have sufficient assets in the initial period to offer £100,000 cover per claim, with an annual aggregate of £500,000, though it hoped to increase the cover in due course to a target of £3 million by means of "reinsurance mechanisms". Since it was possible that much larger claims could be made, IMUK asked for Government funding to enable it to increase the cover per claim to £3 million. IMUK argued that the existence of private midwifery services reduced demand on NHS services, and so represented a saving to the Government.

2014

30. The Government refused to provide the £10 million funding requested by IMUK. A briefing published by the Department of Health on 6 March 2014 stated that it had received independent advice that the business model proposed by IMUK was

"unlikely to be successful in providing long-term protection for patients". It concluded:

> "Alternative solutions for independent midwives to get affordable indemnity insurance are available, such as setting up social enterprises. These mean that no independent midwife will be left unable to work. Independent midwives in some areas of the country have already formed organisations such as social enterprises and small and medium sized businesses to buy the insurance. These organisations, such as Neighbourhood Midwives … and One to One Midwives … mean midwives can have their independence and offer mothers and babies safe, quality care which is covered by compensation should anything go wrong."

31. Details of the earlier Lucina project and the failed application for Government funding were not disclosed to the NMC when it was considering its decision on the adequacy of the current Lucina scheme.

32. On 17 July 2014 the NMC Order was amended to introduce the new article 12A requiring registrants to have an indemnity arrangement which provided appropriate cover.

NMC Guidance 2014

33. In July 2014 the NMC issued a document entitled "Professional Indemnity arrangement: A new requirement for registration". It explained that whilst the majority of registrants would be covered by their employers' schemes, self-employed registrants would need to obtain their own cover, either as part of a membership of a professional body or from a commercial provider. It was made clear that registrants would have to make a declaration that they had obtained cover, and they could be subject to compliance checks. In answer to the question "what is appropriate cover?" it stated as follows:

> "Appropriate cover is an indemnity arrangement which is appropriate to your role and scope of practice and its risks. The cover must be intended to be sufficient to meet an award of damages if a successful claim is made against you.
>
> Determining what appropriate cover is for you will be influenced by:
>
> - what your job involves and where you work;
>
> - who you provide care to and the level of care you provide;
>
> - the risks involved with your practice.
>
> We are unable to advise you about the level of cover that you need. We consider that you are in the best position to determine, with your indemnity provider, what level of cover is

> appropriate for your practice. You should seek advice as appropriate from your professional body, trade union or insurer to inform your decision….
>
> If you have made your own professional indemnity arrangements, you should make sure that you understand how your cover will work. For example, most indemnity insurance will be offered on a 'claims-made' basis, This means that the cover would need to be in place both when the event causing the claim occurred and when the claim was made (which may be years later). This also includes understanding any requirements to disclose relevant information to your indemnity provider which would influence a provider's decision whether or not to offer cover."

34. In July 2014, IMUK took out an insurance policy with Elite Insurance ("Elite") on behalf of its members which provided cover of only £400,000 per claim.

35. The Royal College of Nursing offered an indemnity arrangement to self-employed midwives for ante-natal and post-natal care, but not intrapartum care.

36. In late July 2014 concerns were raised with the NMC by UK Birth Centres that independent midwives who were members of IMUK had failed to comply with the new statutory requirement to have in place an appropriate indemnity arrangement. The NMC began an investigation. Agents for Elite wrote to the NMC in January 2015 stating that, having conducted the necessary reviews and assessments, they were satisfied that it was an appropriate policy. Before the NMC had reached any conclusion on the appropriateness of the Elite scheme, IMUK decided not to renew the policy because of the high cost of the premiums.

2015

Lucina scheme

37. On 13 July 2015, IMUK entered into an indemnity scheme on behalf of its members with Lucina. On 9 July 2015 Lucina Ltd was incorporated as a company limited by guarantee with Ms Tomkins, chair of IMUK, as subscriber, in the sum of £1. The directors were Mr Donald Graham and Ms Jacqueline Holman. Mr Graham was the husband of an IMUK member. He was appointed managing-director of Lucina, and drew no salary. Lucina's business address was the home address of Mr Graham and his wife. Mr Graham stepped in to help IMUK find an insurance solution because his wife was an independent midwife and he was aware of the difficulties which independent midwives had in obtaining cover.

38. Mr Graham qualified as an accountant in 1982 and held positions as head of tax in several large businesses prior to his retirement in 2015. His experience in insurance came from his work on insurance when employed by Avis car rental, and from acting as director for two captive insurance companies, one of which he set up. He did not have a career or qualifications in insurance. He had no professional experience in the health sector.

39. The other director, Ms Holman, was a former business colleague of Mr Graham's with a background as a company secretary and head of insurance. She was a non-executive director and according to Mr Graham, he did all the day-to-day work.

Lucina scheme rules and policy

40. The "Lucina Ltd IMUK Discretionary Scheme Rules" provided that the purpose of the scheme was to provide members of IMUK with professional indemnity cover. The rules provided, inter alia:

> "**4. Benefits under the scheme**
>
> 4.1 Discretion of the Board
>
> All benefits available to Members under the scheme shall be given in the sole and absolute discretion of the Board whose decision in these matters shall be final and binding. These Rules shall not, under any circumstances, be construed to imply that any contract of insurance exists between the Member and the Board or that the benefits of the Scheme are not discretionary. Subject to the total funds available to the Scheme and the discretion of the Board, [and with the exception of any Gap benefit claim] there shall be no limit to the financial benefits available under the Scheme in respect of any one claim.
>
> 4.2 Coverage of Scheme
>
> The liabilities covered by the scheme are any liabilities in tort owed by a Member to a third party in respect of or consequent upon personal injury or loss arising out of or in connection with any breach, after the Membership date, of a duty of care owed by that Member to any client or their baby with whom they have had a Contract for care and treatment, in consequence of any act or omission to act on the part of the Member in connection with any part of their Midwifery Practice.
>
> …
>
> 4.4 Claims Made Basis
>
> Subject to the overriding discretion of the Board benefits (other than GAP benefits which shall be provided in such manner and in such circumstances as the Board shall determine) shall be provided on a Claims incurred basis.
>
> This means that in order to receive benefits in respect of a Claim the Member must have been a Member at the time of the incident giving rise to the Claim occurred and be a Member or Past Member at the time the Claim is made and have paid all

contributions due whether in respect of the Contract under which the Claim arose or otherwise.

4.5 Legal fees

The Board may also at its absolute discretion provide funds to make payments for Legal fees.

4.6 Past Member Benefits

The Board may exercise its discretion in favour of a Past Member or their estate but only in respect of Claims arising from events which occurred during the period in which they were a Member of the Scheme and which arise in respect of a Contract entered into when they were a Member of the Scheme.

This benefit will only be available where prior to leaving the scheme the leaving Member has notified the Board in writing in the approved format that they wish to be considered for this benefit and have paid any required contribution.

…

4.8 "Gap" Benefits

The Board may exercise its discretion in favour of a Member or past Member where a Claim arises in respect of a Contract entered into before commencement of this scheme and which but for the timing of the Claim would have been eligible for indemnification under the Member's Prior Insurance Arrangements. [Benefits under this section shall be limited to £400,000 per Claim inclusive of Legal fees].

…

4.10 Limits to Benefits

The Board may refuse to provide financial benefits to any Member if they are in breach of these Rules or the rules of membership of IMUK including any subsidiary rules as laid out in The IMUK Handbook (the IMUK rules).

In exercising its discretion the Board will also consider the extent to which the Member complied with IMUK clinical risk management guidance in place at the time of the incident and the extent to which in the Board's opinion any non-compliance with that guidance may have contributed to the alleged negligence.

…

6. Member's contributions

> 6.1 Funding of the Scheme
>
> The Scheme shall be funded by contributions made by the Members. The level of contributions shall be determined annually by the Board and shall be in three parts:-
>
> An annual contribution payable on [July 14 2015] and annually thereafter on November 1 in each year starting in 2016.
>
> An additional contribution payable within 7 days of signing each Contract to provide Intrapartum Care.
>
> A single contribution payable immediately prior to leaving the scheme where a Member wishes to be eligible for Past Members benefits …"

41. At some stage Lucina adopted a risk management policy, informed by an advisory committee of IMUK members. It provided, inter alia:

    i) bookings after 39 weeks gestation or planned breech and twin births or extension of the 8 week post-natal period would only be allowed with prior permission, and additional safety procedures could be required;

    ii) members were strongly advised to arrange for a second midwife to be present at all home births;

    iii) members had to comply with IMUK rules of membership, including registration with the NMC and compliance with the NMC Code of Conduct; maintaining up to date skills and being aware of current evidence based practice and guidelines.

42. On 12 August 2015 Ms Tomkins sent an email to the NMC in the following terms:

> "… our members' new indemnity arrangements have no financial cap on the level of claims that can be met…
>
> IMUK members are now covered via an indemnity arrangement which is essentially similar to the Clinical Negligence Scheme for Trusts ("CNST") which is administered by the NHSLA and which covers registrants working in the NHS. As you are aware the NMC has approved the CNST arrangements as appropriate.
>
> Like the CNST the new IMUK arrangement is not an insurance based scheme but an "Indemnity arrangement" under s 12(b) of the order. It follows that there is no policy but rather, like the CNST, cover under the rules of the new arrangements are governed by scheme rules…as you will see, like the CNST, cover under the rules of the new arrangement has no cap on the level of award that can be paid out… the scheme under which our members are indemnified is run by a company that is totally independent of IMUK, with a Board of Directors none

> of whom is an IMUK member and which exercises its powers quite independently of IMUK…"

The email attached a copy of Scheme rules and the rules applicable to the CNST.

43. On 11 September 2015 the NMC sent a letter to Ms Tomkins of IMUK:

> "Thank you for your email dated 4 September 2015 and your confirmation that you are urgently seeking the required information. We are concerned that this information is not readily available. For your convenience I repeat the information that [the NMC] have requested in relation to the funding of your indemnity arrangement below:
>
> - The funding arrangements that exist to ensure that there is an adequate pool of funding;
> - The extent of the liability of members – are they joint and severally liable or is the scheme underwritten by an insurance policy;
> - The current and expected pool of funding for the arrangement; and
> - How the indemnity arrangement will pay out, should there be a claim against a member.
>
> As you are aware it is the professional responsibility of nurses and midwives to ensure that they have in place an indemnity arrangement providing appropriate cover for the nature and the risks of their practice. In order for you to have determined that this cover is appropriate, you would need to have access to the above information. Therefore we are not assured that appropriate indemnity arrangements are in place…
>
> We have examined the Companies House documentation of Lucina Ltd, the company that you have stated as providing your indemnity arrangement. We note that you are listed in the certificate of incorporation as providing the guarantee of £1. Having had sight of this, we are extremely troubled that you are neither able to provide information regarding the funding for this indemnity arrangement nor are you able to control the timescales for the provision of this information.
>
> As you have advised that you are unable to provide a date by which you can forward the requested information and given the seriousness and the urgency of this issue, we are writing to the director of Lucina Ltd, Mr Donald Michael Graham, asking for information about the indemnity arrangements…

> … we did have concerns about your previous arrangements [with Elite] and those concerns were around the level of cover provided and exclusions…
>
> … In terms of your current arrangements our concern is in relation to the availability of funding to meet liabilities…."

44. On 11 September 2015 the NMC sent a letter to Mr Graham, seeking the following information:

    i) The funding arrangements that exist to ensure that there is an adequate pool of funding;

    ii) The extent of the liability of members – are they joint and severally liable or is the scheme underwritten by an insurance policy;

    iii) The current and expected pool of funding for the arrangements; and

    iv) How the indemnity arrangement will pay out, should there be a claim against a member.

45. On 21 September 2015 Mr Graham sent a letter to the NMC stating:

> "… We have established the Scheme as a discretionary indemnity arrangement and such discretion distinguishes the Scheme from an insurance provider. However, we consider that the standards used by the insurance industry to assess capital strength of firms can provide a useful benchmark against which to test the capital adequacy of the Scheme.
>
> On that basis we have prepared a detailed model against which we have tested the Scheme's capital strength. In developing this model we have sought input from actuaries and have amended the model as necessary in light of their comments. As a result the board considers that this model is an appropriate tool for measuring the capital adequacy of the Scheme.
>
> We have looked at the forthcoming "Solvency 2" requirements for insurance firms in determining the capital requirements of the Scheme. The Solvency 2 regulations set out two measures of capital adequacy for insurers… SCR… [and] … MCR….The Lucina board fully supports the intent of Solvency 2 which is to ensure as far as reasonable practical companies are adequately funded to meet expected liabilities… In light of the nature of clinical negligence claims we have applied a standard that assess the Scheme's ability to respond over a longer period than required by Solvency 2. Further, we have set a level of confidence requirement which is higher than the MCR applying under the Solvency 2 regime as we consider this to be prudent given the long tail nature of clinical negligence claims….

> …each member of the IMUK discretionary scheme is liable to make contributions to the scheme as set out in Article 6 of the scheme rules. For the period October 21, 2016 these contributions have been set at the following levels:-
>
> Annual contribution: £1000 (all members of the Scheme)
>
> Intrapartum contribution: £400 (per Intrapartum contract)
>
> Past member benefit: £1500 (for past members of IMUK)
>
> The board has the power to alter these amounts on an annual basis …
>
> … the Scheme's capital position currently exceeds the threshold requirements based on our actuarial models and so there is no insurance policy in place. The Scheme's directors will keep the capital position of the Scheme under careful review and will take such action as is considered necessary to maintain an adequate level of capital…"

46. The annual contribution figure of £1,000 referred to in the letter of 21 September 2015 was altered at some point – the correct figure was £750.

47. On or about 25 September 2015, there was a meeting between representatives of IMUK, Baroness Cumberledge, Mr Graham, and officers of the NMC.

48. On 6 October 2015 the NMC sent a letter to Ms Tomkins, of IMUK:

> "….1. Does Lucina Ltd have any other assets in addition to the contributions listed in section 6.1 of the Scheme rules which could be used to provide the indemnity under the Scheme? If yes, please provide details.
>
> 2. Please provide the pro forma financial statement, business plan and full details of the model including any supporting actuarial analysis/ assumptions and data used by Lucina Ltd.
>
> 3. Please provide clarification regarding the circumstances or criteria that would be used in determining the discretions of the Board in determining the financial benefits under the Scheme as stated in sections 4.1 and 4.9 of the Scheme rules…
>
> We will also be providing a copy of this request to Don Graham, Director of Lucina, who also agreed to provide any necessary further information…"

BWCI report

49. On 7 October 2015 a report of the BWCI headed "Independent Midwives (UK) Ltd. Review of the Reasonableness of Claims Modelling Method and Assumptions" was

published. It was not disclosed to the NMC until 26 February 2016. The report contained the following points:

> "1.1 I have been requested by the Directors of [IMUK] to undertake an independent review of the reasonableness of the methodology and assumptions used to model future maternity claims…
>
> 2.1… the purpose of this report is to review the reasonableness of the methodology and assumptions used to model future maternity claims in a spreadsheet produced by IMUK. IMUK is considering establishing a mutual company based in Guernsey ("the Mutual") that will provide a discretionary indemnity for its members…
>
> 3.6. Claim rate and Amounts "….The rate of claims appears reasonable based on the data as modified and discussed in Section 3.5 above. The rate of claims is assumed to be very low so any increase could be challenging to manage…"
>
> 4.1 "…. There is a risk that the Mutual may not be able to meet all future claim payments in certain scenarios. In the event that a claim is reported that exceeds available assets, the Directors would need to decide whether to restrict the amount eventually settled having regard to their discretionary powers. Such a judgment could only be made at the time. However, there is a potential adverse impact on the Mutual's reputation if any claims cannot be met in full (and potentially an adverse impact on the relevant midwife if cover is insufficient…"
>
> 4.3.1. Base Case Scenario… The base case scenario phasing is set at 0.25 for all claim sizes… I am content that this assumption is reasonable. However, it does not allow for the random effect of claims occurring more frequently in certain periods…
>
> 4.4.3 Financial assumptions. I have reviewed the membership and subscription assumptions and these appear reasonable. However, I note that although the model allows for new members into IMUK, it does not allow for members leaving. In effect the growth in membership is assumed to be net of leavers. We do not have any data to determine whether this growth rate is reasonable…
>
> 5.1.1. Base case scenario
>
> The model shows that under the base case scenario, the Mutual would not hold enough assets to meet liabilities in year 6 (assuming a high claims phasing factor of 0.1)….

> 5.1.2. Downside 1…. The model shows that under the "Downside 1" scenario the Mutual would not hold enough assets to meet liabilities in year 5 (assuming a high claims phasing factor of 0.1)…
>
> 5.1.3 Downside 2…. The model shows that under the "Downside 2" scenario the Mutual would not hold enough assets to meet liabilities in year 6 (assuming a high claims phasing factor of 0.1)…
>
> 5.1.4 Risk of Early Reporting and Settlement.
>
> Unless the phasing factor is 0.1, the model does not include the possibility of a large claim being paid (within the above £1m claim bands) before year 19 of the 20 year projection period.
>
> There is a risk that claims are reported and/or settled more quickly than is assumed by the model. In many scenarios, while the model shows that the Mutual would hold enough reserves to pay a claim at the assumed settlement date, there is often insufficient funds to meet the reserves at the reported date, particularly for larger claims.
>
> Under the base case scenario, if a medium or large claim (greater than £750,000 say) were to be reported and settled within the first five years in addition to the claims projected within the model, the Mutual is unlikely to be able to meet its subsequent liabilities in full… The Mutual would remain solvent as the Directors would retain the discretionary power to decline or reduce claims. However, as considered in Section 4.1, there may be adverse reputational impacts should the Mutual not be able to pay a claim in full…
>
> 5.2 Summary….
>
> There are scenarios in which claims incurred at an early stage could exceed the resources of the Mutual at that time (even if the model projects that the claim could be met from future cashflow). I recommend that IMUK consider carefully how such a scenario would be managed and investigate whether it would be possible to reinsure or otherwise mitigate such a risk at an affordable cost…."

50. On 17 October 2015 Mr Graham of Lucina sent a letter to the NMC stating:

> "1) In addition to the funds that are accumulating from members' contributions, Lucina also holds personal guarantees for £500,000 which it can draw against should the need arise. We are also in the process of putting in place an insurance policy that will give Lucina cover against claims up to £2

> million. A proposal has been developed by our brokers and is currently with a number of underwriters for consideration…
>
> …..
>
> In the meantime we attach a 5 year forecast pro-forma income and expenditure account, cash flow statement and balance sheet which are based on the output of the model.
>
> ….."

51. The letter attached the 5 year forecast pro-forma income and expenditure account, cash flow statement and balance sheet. These showed that for year commencing 1 July 2015 the total assets of Lucina were £294,126 in cash, plus undrawn guarantees of £500,000.

52. The Projected net assets were:

    i) Year commencing 1 July 2015: £294,126

    ii) Year commencing 1 July 2016: £616,927

    iii) Year commencing 1 July 2017: £970,459

    iv) Year commencing 1 July 2018: £1,356,499

    v) Year commencing 1 July 2019: £1,777,039

    Plus undrawn guarantees £500,000.

    These figures were based on the assumption that membership would rise by 4 each year (6 new members and 2 members leaving) and that no funds were reserved for claims or paid out.

53. On 20 November 2015 the NMC sent a letter to Mr Graham:

> "…1….Please confirm your current subscription paying membership numbers. Please also confirm that they align with the financial projections for year 1.
>
> 2. The Guarantees… please provide information regarding…
>
> - Details of the parties providing the guarantees
> - Detailed information of the financial resources available to the guarantors
> - Details of the terms and conditions of the guarantee- a copy of any agreement if possible
> - Please explain why the guarantees are not recognised in the Lucina Ltd scheme rules…

> 3. Additional insurance cover. You referred, in your letter of the 17 October, to searching for insurance protection up to a limit of GBP 2 million. Please confirm whether or not this insurance will act as an indemnity to Lucina Ltd and please provide details of the cover, including scope and limits of cover. Please also confirm the amount of the premium and how that will be paid.
>
> 4… Please confirm whether the "downside" scenarios [in the model] include catastrophic claims against any member of Lucina. Please also confirm how you would handle a claim that could not be covered by Lucina's financial resources…"

54. On 4 December 2015 Mr Graham sent a letter to the NMC stating:

> "1. The Financial Projections of Lucina. We confirm that the results of the period July 14, 2015 to 31 October 2015 are broadly in line with our expectations…
>
> 2. The Guarantees. We have referred this question to our lawyers for advice as to what information we can provide within our contractual obligations to maintain confidentiality.
>
> 3. Additional insurance cover… Discussions are still ongoing with potential underwriters and at the time of writing no commercial terms have been agreed. You will understand that bespoke insurance of this nature can take some time to arrange.
>
> 4. Insurance cover in relation to a claim that could not be covered by Lucina's financial resources.
>
> a) Modelling. We confirm that all scenarios modelled, including the downside scenarios, include the possibility of catastrophic awards of damages. We would also remind you that our modelling shows Lucina meeting all awards in full in all scenarios and that the modelling does not include either the Guarantees or the Additional Insurance Cover both of which will therefore provide additional comfort that all awards will be met…
>
> As previously advised, based on the modelling we have undertaken the Lucina board considers that the possibility of an award of damages arising that Lucina would be unable to settle is remote. We are not prepared to enter into speculation as to what actions the board might take in a future hypothetical scenario that all our modelling indicates has a very low probability of arising."

2016

55. On 2 February 2016 the NMC sent Mr Graham a further letter asking for confirmation of the number of current subscription paying members and the value of the eligible assets held by Lucina. The letter also asked for details of the guarantees, the additional insurance cover and actuarial advice received.

56. On 18 February 2016 Mr Graham sent a letter in reply to the NMC which included the following points:

    i) As at 31.12.15 Lucina had 73 members. Not all provided intrapartum care. Some provided only ante natal and post natal care. 57 members had paid additional contributions for intrapartum care covering 203 clients.

    ii) He had received the necessary consents from the 2 guarantors and had asked them to write to the NMC direct.

    iii) The negotiations relating to insurance were ongoing. The insurers he had approached needed to carry out an assessment of the extent of the risks associated with independent midwifery. One offer of cover had been received but as it might not represent good value, other quotes were being sought. However, additional insurance was not needed as Lucina was sufficiently capitalised without it.

    iv) Lucina had asked its actuaries to prepare a calculation of the risk capital that Lucina should carry were it an insurance company using the standard model developed by the Prudential Regulatory Authority for this purpose as part of the Solvency II regulatory framework. The drafts received showed that Lucina was comfortably capitalised beyond the statutorily imposed levels that would apply to insurers.

    v) In response to the NMC's concern about high value awards in cases of catastrophic injury, he set out in an appendix a "High value claim risk analysis", based on the findings in the NHSLA study. He had concluded that the risk of a successful cerebral palsy claim against independent midwives was considerably less than in the NHS because of their practice of non-intervention. In such cases, NHS practitioners had been found to be negligent in the administration of drugs to induce labour; the use of forceps; or failure to carry out adequate CTG monitoring, but independent midwives did not use these methods. He estimated that the likelihood of Lucina receiving a claim in excess of £1 million was no more than 1 in 50,000 births attended. As the NHS data showed an average settlement period of 8.47 years, Lucina would have the opportunity to increase its capital before paying out any awards.

57. On 18 February 2016 BWCI sent a letter to Mr Graham headed "Solvency Capital Requirements ("SCR") Projections for Lucina Ltd" up to 30 June 2019 based upon revised projected figures provided by Lucina. The calculations now included personal guarantees in the sum of £500,000, as eligible capital, for the entire period up to 30 June 2019, but scaled down to a maximum of £230,094, so as not to exceed 50% of the SCR, in accordance with regulatory requirements. BWCI stated that it was possible that the actual SCR could be above or below the figures shown. On the

figures shown, the SCR would not be met before 30 June 2017. The figures assumed significant annual increases in the assets (based on investment of subscription income) and the claims reserve, and relatively small discounts for risks.

58. On 20 February 2016 Mr Graham sent an email to the NMC attaching a guarantee for £250,000 he had signed in favour of Lucina. The guarantee was dated 12 February 2016 and expired on 31 October 2017. The email also attached a statement of his personal assets, principally his home (equity of about £590,000) and his personal pension fund (£120,000 net of tax). It stated that he also had preserved benefits in two occupational health schemes which would generate a comfortable level of pension in retirement. Contrary to the earlier assurances that there were two guarantors and a total guarantee in the sum of £500,000, there was only one guarantor (Mr Graham himself), whose guarantee of £250,000 only extended from 12 February 2016 to 31 October 2017.

Miller Insurance Services report

59. The NMC commissioned Miller Insurance Services LLP to prepare a report on indemnity arrangements for NMC registrants. On 27 April 2016 the Miller report was sent to the NMC. It reviewed damages awards for maternity claims, not just from the NHSLA scheme, but also from published litigation and settlement results. There had been multi-million pound awards for catastrophic brain damage from lack of oxygen during labour and from untreated hypoglycaemia. Awards in the region of £575,000 and £850,000 were made for shoulder dystocia. The report noted that maternity wards were more likely to be handling high risk births than independent midwives at home, but that in some cases, the potential for a delay in transfer to an obstetric unit meant that home-birthing midwives were at risk of being the primary focus for malpractice claims.

60. In respect of the Lucina scheme, the Miller report concluded that in the event of a claim it was possible that Lucina could quickly exhaust its assets and it might have to exercise its discretion to restrict payments or call on its guarantees, said to be in the sum of £500,000. Although the letter of 17 October 2015 referred to a search for additional insurance protection in the sum of £2 million, no policy was in place. In considering what protection would be provided in the event of an unexpected catastrophic claim which could arise at any time, it concluded that the Lucina scheme was unlikely to have sufficient resources to provide appropriate indemnity to its members.

Registrar's provisional decision

61. On 2 August 2016 the Registrar made a provisional decision that the Lucina scheme did not provide appropriate cover for independent midwives whose midwifery practice included attending women in childbirth. The decision was detailed (running to 11 pages) and its conclusions were as follows:

> "Conclusions

52 I consider that "appropriate cover" under an indemnity arrangement means not only that the terms of the cover must be adequate but also that the provider must have access to adequate financial resources to pay the indemnity (damages), not just on paper but also in reality. Otherwise, public protection and public confidence would be jeopardised.

53 Midwifery practice, including attending a woman in childbirth, involves all the risks associated with childbirth (including the small risk that a catastrophic injury including cerebral palsy could occur), and any indemnity arrangement must reflect this.

54 IMUK has analysed that nature and extent of the risk associated with the practice of their members and has accepted that there is a very small risk that IMUK members may incur liabilities for catastrophic claims relating to cerebral palsy and uterine rupture, as well as for less devastating injuries.

55 While the chances of a successful claim for catastrophic injury are low, the cost of meeting such a claim is likely to be very substantial: paragraphs 23-28 above.

56 In light of this, it is important that Lucina can call on substantial resources. The information provided to date does not provide adequate assurance in this regard.

57 Firstly, Lucina's financial projections prepared for the NMC in October 2015 are unsatisfactory in several respects.

57.1 They assume growth in membership (and therefore financial growth) until 2019, apparently without any proper explanation and without allowing for the possibility of departures.

57.2 They explicitly assume that nothing will be paid out to cover claims over the entire five year period in respect of any of its members. This seems unduly optimistic and raises unanswered questions about what protection would be provided to IMUK members in the event of an unexpected substantial claim, which could arise at any time.

57.3 They rely on guarantees, said to be worth £500,000, without information about the identity of the guarantors, their financial strength or the terms of the guarantees, making it impossible to assess their value.

58 Secondly, even on the basis of Lucina's own financial projections, which include the guarantees, the scheme will not have sufficient resources to meet the average cost of a single catastrophic claim for cerebral palsy until July 2019.

> 59 Thirdly, the commentary provided by Lucina's own insurance expert, BWCI, suggests that the scheme is unlikely to hold enough assets fully to meet liabilities that may be incurred by its members in years 5 and/or 6, and makes a positive recommendation for IMUK to investigate whether it would be possible to reinsure or otherwise mitigate such a risk at an affordable cost.
>
> 60 Finally, Lucina itself has said it is in the process of putting in place an insurance policy that will provide the scheme with additional cover to meet negligence claims for up to £2 million, but so far the NMC has not had any confirmation that this has actually been done.
>
> 61 In addition, there is no assurance that cover will be maintained after departure from the scheme.
>
> 62 For these reasons, I have made a provisional decision based upon all the evidence available to me, that the Lucina scheme does not provide appropriate cover for IMUK midwives whose practice includes attending women in childbirth.
>
> 63 I have also provisionally decided to treat this as a registration issue rather that an FTP (misconduct) matter.
>
> 64 I emphasise that none of this has any immediate or inevitable effect on the right of IMUK midwives to practise, and I have not yet made any decision about the registration of any individual midwives. If my final decision turns out to be that the Lucina scheme is appropriate, there will be no impact on registration.
>
> 65 I will be sending this provisional decision to IMUK to give it an opportunity to respond to my concerns within 28 days, and provide the necessary assurance that the scheme provides appropriate cover. I will then proceed to make a final decision. Given its potential significance, I will also be sending a copy of this provisional decision to all current IMUK members, who are also welcome to comment within the same timeframe. They might, for example, wish to make specific points about the scope and characteristics of their individual practices/cover."

62. The Registrar initially asked for any responses to the provisional decision within 28 days. She extended the deadline to 23 September 2016, in response to a request from IMUK for an extension to 1 October 2016, stating that this was a balance between the need for public protection and considerations of individual fairness.

63. On 20 September 2016 Ms Tomkins sent a letter to the Registrar, attaching a copy of the provisional decision with IMUK's and Lucina's comments written onto it. The comments stated, inter alia, that:

i) The Registrar had not properly considered or taken into account the evidence provided from Mr Graham and BWCI. BWCI's calculations based on the Solvency II model showed that Lucina was adequately capitalised and the Miller report stated that analysis drawn on Solvency II guidelines would be a reasonable benchmark to use.

ii) The instructions given to those preparing the Miller report were insufficient, and the report was incomplete.

iii) The extended definition of "attendance" in rule 2 of the Nursing and Midwifery Council (Midwives) Rules 2012 did not apply for the purposes of indemnity provision in article 12A of the NMC Order.

iv) The Registrar failed to consider properly the specific nature of independent midwifery, as opposed to midwifery in general, and therefore did not conduct a sufficient investigation into the nature and extent of the risks of practice as an independent midwife.

v) The data in the NHSLA study covered all claims against member health trusts and did not distinguish between negligence on the part of midwives, and other health professionals. Therefore using the data without adjustment gave a wholly misleading view.

vi) The negligence that caused the cerebral palsy in the case of *Robshaw* was misuse of drugs to induce or augment labour combined with a failure properly to monitor the effects of those drugs. A Swedish research project found that in 86% of cases where negligence of a midwife was found, it arose out of misuse of such drugs coupled with a failure to monitor their effects. Independent midwives do not use such drugs.

vii) The length of time typically taken for complex high value claims to be settled, and the use of periodical payments, reduced the likelihood of Lucina being faced with a substantial cash settlement during its early years.

viii) The NHSLA had recently reduced the premiums of One to One Midwives, an independent provider of midwifery led services that operated a continuity of care model, on the basis that the risks associated with its work were substantially lower than in the NHS.

ix) No indemnity provider could hold sufficient financial resources to meet all possible claims that might arise. Indemnifiers operate on the basis that they hold sufficient assets to cover the awards that appear likely to arise based on statistical analysis. Even though Lucina was not subject to the Solvency II regime, it had adopted the Solvency II risk limits as a benchmark, and satisfied it.

x) The modelling carried out for Lucina showed all claims being paid in full for all scenarios (including catastrophic claims) without the need for guarantees or additional insurance cover.

xi) There had been 5 claims made against IMUK members from 1994 to date, and the combined settlement figure was expected to be less than £700,000, at worst.

xii) Details of one guarantor, Mr Graham, had been provided. The other person who had agreed to provide a guarantee declined to do so, following the NMC's demand for personal financial information.

xiii) "We would also remind you that Lucina advised you in the letter of 18 February 2016 that they had received a proposal for a layer of insurance but that, given the small reduction in the overall risk profile of the company that the layer would have provided, they concluded that the commercial terms offered were not sufficiently attractive. They also advised you that they remain, via their broker, in contact with the insurance market and should a more attractive proposal emerge they would consider it. However, they do not consider that obtaining such an insurance layer is essential and …neither the detailed modelling nor the Solvency II calculations performed by their actuaries assume that any such policy is in place."

xiv) Overall, the decision was unreasonable and the manner in which the inquiry had been conducted was inappropriate. The evidence had not been properly considered or taken into account.

xv) The Registrar did not have jurisdiction to determine whether cover was appropriate; that was a matter for each registrant to assess, as stated in the NMC guidance issued in 2014. However, if the NMC was to be the arbiter of what constituted an appropriate level of financial resources then it had to provide clear and objective guidance on how such a figure is to be calculated.

64. On 10 October 2016 the Registrar sent a letter to Ms Tomkins inviting Lucina and IMUK delegates to a meeting with the NMC representatives. At the meeting, an actuarial expert instructed by the NMC would "view Lucina's risk model and ask questions both about the model itself and the risk assumptions used to build it".

65. On 11 October 2016, Basi & Basi Financial Planning Ltd sent a letter to Mr Graham reporting on their efforts to source investment funds for Lucina. Out of four expressions of interest, they had identified as most suitable a Russian national wishing to move to the UK under the Tier 1 Investor Visa program who would be able to provide funds of up to £2.25 million to invest into the model on the basis of providing the fund with a level of indemnity. However all potential investors required confirmation that the current NMC investigation had concluded satisfactorily.

66. On 25 October 2016, the NMC instructed Mr Critchlow of OAC plc to provide an independent expert report.

Meeting of 3 November 2016

67. On 3 November 2016, a meeting took place between Ms Padley and Ms Hilken of the NMC, Mr Critchlow, Mr Graham of Lucina and Ms Tomkins and Ms Chaubert of IMUK. The meeting was recorded and transcribed. The IMUK representatives described the work of an independent midwife, setting out their view that, because of the continuity of care provided and effective communication with the mother, giving her responsibility for the choices to be made, the risk of a claim for negligence was greatly reduced, in comparison to an NHS delivery. During a home birth, in the event of a "red flag" e.g. bleeding, unstable foetal heart rate, the midwife will call an ambulance and, if the mother consented, she would be transferred to hospital.

68. Prior to the meeting, Mr Graham circulated a written summary of the methodology and assumptions behind the models. At the meeting, Mr Graham gave an oral presentation, supported by power point slides, of Lucina's modelling: the claims data module and the financial data module which both fed into a claims modelling module (the static model), and the 'Monte Carlo' simulation which generated random values/numbers. He explained that he was using the Solvency II standard formula to calculate the solvency capital ratio. The static model indicated that Lucina would meet all awards as they fell due. The Monte Carlo model indicated a failure rate of less than half a percent over 20 years. He was closely questioned by Mr Critchlow, and in my view, the exchanges between them demonstrated that Mr Critchlow understood what Mr Graham was saying. After the meeting, Mr Graham provided his power point presentation slides and details of the models on a memory stick to the NMC and Mr Critchlow.

69. Concerns about Lucina's funding were raised at the meeting. Mr Critchlow questioned IMUK about the ability or willingness of Lucina members (then 84 in number) to pay additional contributions to meet a multi-million pound claim. Ms Chaubert said she believed they would pay, and membership was increasing.

70. Ms Padley asked about the sole guarantee provided by Mr Graham, whether it was backed by liquid assets, or depended upon his home being sold or his mortgage or other borrowing being increased. Mr Graham said that he had some liquid assets, referring to his pension fund, cash and shares. I note that the cash and shares were not referred to in his schedule. As to the ability to raise the balance of the guarantee from his home, he said he would be able to apply for equity release. I note that no details were given as to the amount which a lender would allow him to take by way of equity release. Mr Graham confirmed that the other potential guarantor had withdrawn when asked by the NMC to confirm how he would meet the guarantee from his assets.

71. When asked whether steps could be taken to obtain further funding for Lucina, Mr Graham said that he would not be able to get an investor to put capital into the business whilst there was a risk that the NMC would find the cover inappropriate.

72. As to the attempts to obtain insurance, Mr Graham agreed to request information from the brokers about the insurance applications made and send it on to the NMC.

73. On the claims history, IMUK and Mr Graham confirmed orally the information given in the response to the provisional decision, namely, that on a worst case scenario, previous claims would amount to a value of about £700,000. Between 2003 and

2014, when IMUK midwives only had a legal expenses policy, four claims were notified. One claim failed. Two claims were settled but Mr Graham did not know the exact awards; he believed one was settled for about £22,000 and the other for between £100,000 and £200,000. The fourth claim was ongoing, and "the worst estimate provision would be about £500,000". In 2014 a further claim was made under the Elite policy, which was believed to be weak, and worth about £20,000 at worst.

74. Mr Graham sent a follow-up email on 24 November 2016 stating that the fourth claim "had not materialised" and therefore could be removed from the list. This reduced the number of successful claims to two, which he valued at £200,000, with one unresolved claim, which had not been issued, valued at £20,000. I note that none of the claims history, including lack of claims, was confirmed in written evidence from insurers or parties involved.

75. Mr Graham also sent a letter dated 15 November 2016 from Lucina's brokers, BGi.UK Insurance, which stated that:

> "… most insurers have midwifery as a big "No" on their registers so even when we find a willing underwriter we then have to delve into their reinsurance arrangements….. the recent withdrawal of a potential but substantial claim has improved the claims experience considerably… We are continuing with our strategy of approaching only a couple of insurers at a time. One insurer … has shown renewed interest…I have suggested that they might like to write a line rather than 100% of the risk if this provides them with a greater degree of comfort…"

76. On 25 November 2016, Ms Hilken emailed Ms Tomkins and Mr Graham to inform them that Mr Critchlow's report was expected by 28 November and that any comments from them would be required shortly thereafter, so that the Registrar's decision could be notified to them by mid-December if at all possible. The Critchlow report was emailed to them on 30 November and they were asked to provide their comments, if any, by 9 December 2016.

Critchlow report

77. In his report dated 30 November 2016, Mr Critchlow summarised his conclusions as follows:

> "**Claims data**
>
> 21. In respect of claims data, I have identified a number of issues with how the data has been used within the Lucina Model. As such the Lucina Model does not, in my opinion, provide a reasonable or reliable basis to assess the likely financial impact of claims that may be made against members of IMUK. Accordingly I do not believe that it would be appropriate for the Registrar to rely on the outputs from the Lucina Model when considering whether the indemnity

arrangement is appropriate having regard to the nature and extent of the risks facing IMUK members.

Risk assumptions

22. In respect of the assumptions and sensitivity tests used within the Lucina Model and the Lucina Monte Carlo Simulation Model, the results do not, in my opinion, provide a reasonable or reliable basis to assess the likely or variable financial impact of claims that may be made against members of IMUK. This reinforces my opinion that I do not believe that it would be appropriate for the Registrar to rely on the outputs from the Lucina Model when considering whether the indemnity arrangement is appropriate having regard to the nature and extent of the risks facing IMUK members.

Risk Management

23. The Lucina Scheme is a discretionary arrangement and as such is not classified as an insurance company. This means that it is not required to meet the regulatory requirements such as Solvency II that those companies face. However Solvency II would provide a sound and rational basis by which the risks inherent within the Lucina Scheme can be assessed and can be used to consider the financial resources that may be needed to support those risks. Without such an analysis it is difficult to see how Lucina can reasonably consider the extent to which the Lucina Scheme members provides of IMUK with appropriate cover against liabilities which may be incurred.

24. I have reviewed the evidence presented by Lucina that they meet the various requirements of Solvency II. Whilst some aspects have been met, for example by meeting the Solvency Capital Requirement ("SCR") as set out in the BWCI reports (but only from 2017), this is merely one aspect of the regime. Further requirements exist to ensure that firms capture adequately the nature and extent of the risks within their business. These further requirements are:

i. Ensuring the firm has a minimum level of capital in the business (the Minimum Capital Requirement ("MCR");

ii. to test the appropriateness of the methodology used to calculate the SCR for the specific characteristics of that business;

iii. undertake additional scenario tests, as part of its risk management framework, to test what situations would lead to the failure of the business (a so called "reverse stress test"); and

> iv. firms to accrue for claims as they are incurred rather than as they need to be settled.
>
> 25. I have not seen any evidence that Lucina have considered these additional matters in any part of their risk management framework or process.
>
> 26. To gain further insight into the risks underlying the Lucina Scheme I have tested Lucina's assertion that they meet the 99½% confidence level test by reference to the likelihood of a claim being made over the next 12 months. I estimate that, using Lucina's own estimate of the risk factors attaching to a Cerebral Palsy claim for example (and I have noted in paragraph 58 why I believe these to be underestimates) then there is approximately a 1% chance (1 in 100) that a claim might arise over the next 12 months which is likely to cost around £6.09m to settle. Based on the evidence presented in Lucina's financial projection model, Lucina's assets are expected to be around £3.4m after 8 years which is well short of the possible £6.09m settlement cost. As such I conclude that the Lucina Scheme fails to satisfy the 99½% confidence level test."

78. On 6 December 2016, Mr Graham emailed Ms Hilken asking for an extension of time until 16 January 2017 to comment on Mr Critchlow's report, so that he could carry out further detailed analysis and modelling with the assistance of "our actuaries". Ms Hilken replied on 8 December 2016 saying that the NMC did not agree that further time was required, as the information which Mr Critchlow was commenting on had been provided by Mr Graham in the first place, and it was based on Mr Graham's own modelling.

79. On 15 December 2016, Mr Graham sent a document headed "First Interim Response to OAC Review of Lucina Scheme" which identified a "number of significant errors" in Mr Critchlow's report, detailed over more than 20 pages. In summary, it alleged that he had misunderstood how the linear model and the Monte Carlo model operated. He had also misunderstood the risk factors in the "maternity care pathway". Its conclusions were, therefore, unreliable and the report was not fit for purpose. The review pointed out that Lucina never stated that it had met all the requirements of Solvency II, but it used the solvency capital requirement as a benchmark.

80. Mr Critchlow provided the NMC with advice on the "First Interim Response" in a note dated 16 December 2016.

The Registrar's decision

81. The Registrar issued her final decision on 20 December 2016. Her conclusions were as follows:

> "**My conclusions**

54 Having considered all of the information carefully, I have concluded that Lucina does not have available to it sufficient financial resource to meet its liabilities, having regard to the nature and extent of the risks. This was a conclusion which I had reached previously on a provisional basis on 4 August 2016 on the information available to me at the time. Since that date, despite extensive representations from Lucina and IMUK, I have not received the assurance I needed to conclude that the Lucina scheme provides appropriate cover to IMUK members having regard to the nature and extent of the risks.

55 I note that:

55.1 Lucina's financial projections have not significantly altered from those which were sent to the NMC in 2015;

55.2 The "undrawn guarantees" which are part of its financial assets are lower than I had assumed at the time of my provisional decision. They amount to £250,000 and not £500,000;

55.3 It has not secured any additional financial assurance by way of either additional capital funding or re-insurance.

56 I note further that:

56.1 As IMUK and Lucina agree, IMUK midwifery practice involves all of the risks associated with childbirth, including the small risk that a catastrophic injury such as cerebral palsy could occur;

56.2 Such a claim will if proved prompt a very high award of damages; the average being around £2.2 million, whilst the highest UK award for a maternity-related cerebral palsy claim so far is £14.6 million (*James Robshaw v United Lincolnshire Hospitals NHS Trust* [2015] EWHC 923 (QB) 1 April 2015);

56.3 Since 2003 IMUK has been notified of four smaller personal injury claims, and on behalf of IMUK members three such claims have settled or are in the process of being settled, at a total cost of around £700,000[2];

56.4 Although IMUK and Lucina have asserted that Lucina has a 99.5% level of assurance that their risks will

[2] The figure of £700,000 was provided by IMUK but subsequently reduced to £200,000. It was altered in the re-consideration letter sent by the Registrar on 27.1.2017. The Registrar considered whether the reduction made any difference to her conclusions, and decided that it did not.

be covered, this is not a view which is shared by Mr Critchlow, an independent actuary with significant experience in dealing with smaller insurers, who has examined the detailed information provided by Lucina. Using Lucina's own estimate of the risk factors involved, their own estimate that IMUK members perform approximately 630 births per year, and the evidence presented in their own financial projection model, Mr Critchlow has reasonably stated that the chance of a cerebral palsy claim over a 12 month period, is approximately 1%.

56.5 Mr Critchlow has calculated that if a cerebral palsy claim were made over a 12 month period, assuming 630 births a year it would have a cost of £6.09 million;

56.6 Lucina's own financial projections, which have not significantly altered from those which were sent to the NMC in 2015, show that their funds over an eight year period are likely to be no more that £3.4 million;

56.7 Lucina's own actuaries, BWCI, have commented that the Lucina scheme is unlikely to hold enough assets fully to meet liabilities which may be incurred by its members in years 5 and 6;

56.8 It is evident from the transcript of the meeting on 3 November 2016 and information provided by Lucina, that Lucina has investigated the possibility of re-insurance, but has decided that it would not be prepared to pay the financial premiums that would be required to obtain an appropriate level of cover.

Decisions

Deferment of my decision

57 I have carefully considered IMUK and Lucina's request that I defer my decision as to whether the Lucina scheme provides appropriate cover for IMUK midwives. I have concluded that it would not be appropriate for me to defer my decision, for the following reasons:

57.1 The NMC has had concerns about the appropriateness of the indemnity cover provided by IMUK to its members, since July 2014. The investigation into the appropriateness of the cover provided by the Lucina scheme dates from mid-2015;

57.2 As I have noted above, it is for the individual registrant to satisfy me, when asked to do so, that an

appropriate level of cover is in place, and justify their decision as to the scope and level of that cover;

57.3 I consider that IMUK, acting on behalf of its members and Lucina have now been afforded a full opportunity to explain how they consider that the Lucina scheme provides cover against liabilities which may be incurred in practice as an independent midwife, having regard to the nature and extent of the risks. They have provided detailed information in relation to Lucina's indemnity model, and have sought to assert that despite its low reserves, Lucina will be able to meet any claims successfully brought against IMUK member. However, based on Lucina's own financial and risk assumptions, and using standard statistical techniques, an independent insurance expert, Mr Critchlow of OAC, has stated that he does not consider that Lucina's assertion that it meets an appropriate level of assurance that their risks will be covered can be relied upon;

57.4 I do not consider that the conclusions I have reached above, namely that Lucina does not have sufficient financial resource to cover its liabilities having regard to the nature and extent of the risks, are likely to materially alter by the provision of further actuarial material. The point remains that, if IMUK were to receive a high value claim (such as a cerebral palsy claim) tomorrow at average cost, then using Lucina's own assumptions regarding the claims settlement period, asset growth and claims inflation, they would have insufficient resources to meet the claim at the point it became due for payment.

58 In my opinion, the NMC has conducted a thorough investigation and followed a procedurally fair process in investigating its concerns with regard to indemnity cover provided by IMUK for its members. These are concerns which the NMC has had for some considerable time. In my provisional decision of 4 August 2016, I expressed the provisional view that, on the information before me, I did not consider that the cover provided by the Lucina scheme was appropriate. Despite the information provided by IMUK and Lucina since that date, I remain of that view. Moreover, the debate between Lucina and Mr Critchlow principally concerns modelling and predictions as to risk. These is no real dispute as to what assets Lucina currently has or is likely to have. Reduced to essentials it is common ground that Lucina has currently a low asset base and has not strengthened its position with guarantees beyond one of £250,000, nor does it have insurance or re-insurance. My concern that Lucina has insufficient resources so as to satisfy me that appropriate cover

> is in place is founded upon these fundamentals and the matters set out in paragraphs 54-56 as I am not satisfied that, if a claim for catastrophic or serious injury were made Lucina would have sufficient resources to meet the claim. Lucina may debate with Mr Critchlow what may or may not happen in future, but given Lucina's low assets I am not satisfied that it will be able to meet a claim for catastrophic injury, or other claims of serious injury.
>
> 59 Further, I have had to consider the public interest. IMUK and Lucina have been given ample opportunity to meet the concerns set out in my provisional decision. Those concerns have not been met. This in turn means that members of the public attended upon by IMUK midwives are in a position where they cannot be confident that the indemnity arrangement will have the resources needed to meet liabilities for injury should they arise. This is contrary to the public interest and the objective of Article 12A.
>
> *Decisions on appropriateness of cover and registration*
>
> 60 For the reasons above, I have decided that the Lucina scheme does not provide "appropriate cover" as required by Article 12A of the Order.
>
> 61 In the circumstances, practising IMUK midwives relying on the Lucina scheme as their indemnity arrangement for any aspect of their practice which involves attending women in childbirth, will be removed from the register unless they provide a signed declaration to the NMC by 10 January 2016 that they will not rely on Lucina for any such aspect of their practice, and confirm that they have appropriate alternative cover in place to satisfy the requirements of Article 12A(1).
>
> 62 I have decided that removal is a proportionate course of action, bearing in mind the risk to the public. In reaching this decision I have taken into consideration that any midwife who is subject to removal has a right of appeal under Article 37 of the Order."

Reconsideration by the Registrar on 27 January 2017

82. On 6 January 2017, Mr Graham sent a report by Mr Marcuson of Marcuson Consulting Ltd to the NMC. Mr Marcuson criticised Mr Critchlow for failing to appreciate the differences between the linear model and the Monte Carlo model. Mr Marcuson also made the following points:

i) The Monte Carlo model was capable of generating claims with an amount greater than £10,000,000 and incorporating these losses in its evaluation of Lucina's financial position.

ii) Lucina's cover was a "claims-made" indemnity product and so claims incidence would be lower in the early years of the scheme. This effect was particularly pronounced where, as with cerebral palsy claims, the delay in reporting claims was significant. This had not been taken into account by Mr Critchlow. Therefore the 0.92% chance of a cerebral palsy claim arising over the next 12 months calculated by Mr Critchlow, should be reduced to approximately 0.2%. This would increase over time, only reaching 0.92% in several years' time when the Lucina scheme had matured.

iii) The analysis by Mr Critchlow showing £10.7 million liability over the next year in paragraph 109 of his report was incorrect. He had failed to multiply the probability of a claim arising in each of the four claim bands in the linear model and instead simply added the total value of the claims. The probability of a claim arising in each of the bands over one year was effectively zero (0.000012%).

iv) The chances of there being a total claim above £6.1 million in the next 12 months was 0.1% and not 0.92% as Mr Critchlow had calculated.

83. Mr Critchlow responded to the Marcuson report and his advice to the NMC was incorporated into memoranda to the Registrar dated 20 and 23 January 2017.

84. Correspondence was sent to the NMC by IMUK, the Claimants' solicitors and others raising concerns about the Registrar's decision. In response to a request to re-consider her decision, the Registrar sent a letter dated 27 January 2017 stating:

> "I consider, having read Mr Graham's email of 9 January 2017 and Mr Marcuson's letter of 6 January 2017 as well as Mr Critchlow's comments on these documents, that neither document addresses the fundamental concerns I expressed in the Decision; namely, that the Lucina scheme has available insufficient financial resources to meet liabilities arising out of a claim for catastrophic injury upon which it might have to pay out within an eight year period.
>
> I note the core area of dispute between Lucina and Mr Critchlow is in relation to the size of that risk during the next 12 months. As has been made clear by Mr Critchlow in his report of 30 November 2016 however, it is precisely because of the challenges of producing a reliable estimate of the actual size of that risk that the other requirements of the Solvency II regime are so significant in this case. Mr Critchlow explained in paragraphs 133 – 148 of his report that the smaller the indemnity arrangement and number of expected claims, the greater the uncertainty that exists in terms of the number of claims which might be incurred and the expected ultimate cost. He gave his opinion that smaller schemes such as the Lucina

scheme need to recognise the risk that they will have a claim made against them, even though the likelihood of such an event happening may be remote; and they must have sufficient funds in place to ensure that they can meet the costs of the claim. He stated that in order to give a sufficiently high degree of confidence that Lucina will have sufficient funds to pay claims as they fall due, they would need to assess and answer the questions listed at paragraph 117 and 163-165 of his report. Mr Critchlow stated that there is no evidence that Lucina has addressed or answered these questions, and that accordingly it would not be appropriate for the Registrar to reply on the outputs of the Lucina model. Mr Critchlow set out in paragraph 174 of his report the arrangements which he considered necessary for Lucina to take in order to provide IMUK members with an appropriate level of cover. These include securing reinsurance or additional funding to enable them to meet a high value claim. I note from the transcript of the meeting between IMUK, Lucina and the NMC on 3 November 2016 that Lucina accepts that the cost of such a claim could be in the region of £12.5 million.

There is nothing in the Marcuson report to indicate that Lucina have asked themselves the fundamental question of whether they have sufficient funds to pay out (in 5-8 years' time) on a high value claim which they might be notified about tomorrow, as they would be expected to do under the Solvency II regime, in order to give them the 99.5 percent confidence level they profess to have. I also note that it is common ground that Lucina currently has a low asset base and has not strengthened its position with guarantees beyond one of £250,000 provided by Mr Graham, Managing Director of Lucina Ltd, himself. In particular, it has not secured any additional financial assurance by way of either additional capital funding or re-insurance, so as to provide the necessary assurance that it would be able to pay out on a high value claim within the next 5-8 years.

My fundamental concern about the Lucina scheme is that it does not have available to it sufficient financial resource[s] to meet its liabilities, having regard to the nature and extent of the risks. The Marcuson report does not provide any new evidence that the resources that will be available to Lucina over the next 10 years or beyond are higher than those presented by Lucina. In my view, this evidence and indeed any new modelling that is now undertaken by Lucina, does not change the underlying point that, if IMUK did in fact receive a cerebral palsy-related claim (or similar catastrophic injury claim) tomorrow, then using Lucina's own assumptions of claims settlement period, asset growth and claims inflation, they would have insufficient resources to meet the claim at the point it became due for payment.

It follows that I do not consider that anything in the further actuarial evidence provided on behalf of Lucina causes me to alter my previous decision as to the sufficiency of the indemnity cover provided by the Lucina scheme.

…

I should inform IMUK or Lucina of the level of assets required

DPG have asserted that it is my duty as Registrar to inform IMUK and Lucina of the level of assets I require Lucina to hold in order to be satisfied that IMUK midwives have appropriate indemnity cover. …

As I have stated, I consider it necessary for any indemnity provider to ensure that it has sufficient resources to meet claims which may be made against members when they fall due for payment. It is the indemnifier who must take steps to ensure that it has sufficient financial resources, whether by increasing its capital or by obtaining appropriate reinsurance, to ensure that it is able to meet (at a minimum) the cost of paying for a single large claim. As Mr Critchlow explained at paragraph 144 of his report, securing such reinsurance or such funding must be done in advance of needing the funding, since if a large claim has already been made, no reinsurer will be willing to take on the liability, and no investor will be willing to invest. In the absence of any evidence that Lucina has taken these steps, I do not consider that the scheme provides appropriate cover for IMUK midwives, having regard to the nature and extent of the risks.

The Decision has not taken into account an adjusted past claims figure

DPG informed me that the figure of £700,000 cited at paragraph 56.3 of the Decision as the approximate figure for settlement of past claims is incorrect, and that I have not taken into account the adjusted figure of £200,000 given to us after the meeting of 3 November 2016.

I note that Lucina emailed us on 24 November 2016 to say that the figure for past claims and number of claims settled against IMUK which Mr Graham provided us with during the meeting of 3 November 2016 was incorrect; that the number of claims was in fact three and the figure £200,000. I have no reason to doubt this information (although I note that the Marcuson report also refers to four claims rather than three) and I accept that this correction was not reflected in the Decision.

Be that as it may, I have asked myself whether if the correct figure is £200,000 rather than £700,000, this make any

difference to my Decision. I have reached the firm conclusion that it does not. When assessing whether Lucina will have sufficient resources to meet claims which may be made against IMUK members, I was not assuming that past claims in any way affected Lucina's available resources. I was also aware that Lucina's own risk modelling is not predicated on IMUK claims history, but on the NHSLA data, and that this was clearly reflected in Mr Critchlow's report.

I do not consider therefore that the adjustment to the settlement figure caused any error in my conclusions about Lucina's available assets or the Decision as a whole. My Decision is unaffected by the settlement error.

The Decision is flawed due to an error in Mr Critchlow's report

DPG solicitors contend that the Decision is flawed because of the reliance placed on paragraphs 106-109 of Mr Critchlow's report. In particular, they contend that I have failed to properly consider Lucina's submissions that Mr Critchlow used a historic claims factor of 2 when testing Lucina's assumptions, whereas at paragraph 57 of his report he cited 1.47 as a more accurate historic claims inflation figure; and that had Mr Critchlow used a 1.47 factor this would have produced a lower future cost of claims figure that the £6.09 million figure cited.

As Mr Critchlow made clear in his report, his purposes at paragraphs 106 - 109 was to test Lucina's own assumptions, using their own data, in the absence of evidence that they had appropriately stress-tested their model in such a way as to meet Solvency II requirements. It was for this reason that he used the historic claims inflation figure used by Lucina in its own modelling. Whilst it is correct that Mr Critchlow stated, at paragraph 57 of his report, that the historic claims factor has been overstated and that a factor of 1.47 would be more accurate, he has also pointed out at various points (for example at paragraph 80) that the future claims inflation date [rate] should be raised from the minimum level of 3.4 percent to a level for up to 6 per cent. It is further clear from Mr Critchlow's report as a whole, that any overstatement by Lucina in relation to historic claims merely offsets the understatement of average claims value. This is fully explained at paragraphs 150 - 153 of Mr Critchlow's report.

Further, Mr Critchlow has since confirmed (see Annex 1) that the point which he was seeking to make was that the risk faced by Lucina is not trivial, and that in order to be able to show that they have the 99.5 percent confidence level which they assert, he would expect them to carry out some or all of the steps set out at paragraph 117 of the report. This is in my view

> abundantly clear from the report as a whole and is also reflected in the Decision, which clearly states that my fundamental concern is that Lucina has available insufficient resource to meet a high value claim which might be incurred within the next twelve months, at the point at which it fell due for payment.
>
> I therefore do not consider that the Decision is flawed due to such reliance as I placed on paragraphs 106-109 of Mr Critchlow's report….."

Grounds for judicial review

85. The Claimants' pleaded grounds in the Statement of Facts and Grounds were as follows:

(1)Error of law

86. The Registrar of the NMC misapplied the statutory test in article 12A(1) and (3) of the NMC Order 2001 by failing to take proper account of the "nature and extent of the risks of practising". The Registrar wrongly directed herself that the capital funds had to be such as to cover entirely the costs of the largest claim which might be brought against a registrant, even though the probability of that risk was extremely small. The Registrar required a level of confidence and capitalisation in excess of that required by the Solvency II regime, which although not binding, was taken into account as an appropriate benchmark.

(2)Breach of EU rights and Human Rights Act 1998

87. The Second Claimant, who was a German national, was exercising her rights under Articles 49 and 56 of the Treaty on the Functioning of the European Union ("TFEU") and Articles 15 and 16 of the EU Charter on Fundamental Rights ("the Charter") to pursue self-employed activities in the UK. The First and Third Claimants were exercising their EU rights to offer services to other EU nationals in the UK. Those rights were infringed by the NMC's decision which prevented them from pursuing their self-employed practices.

88. Their self-employed practices were possessions protected by Article 1, Protocol 1 ("A1P1") of the European Convention on Human Rights ("ECHR").

89. The Fourth Claimant had been denied access to independent healthcare services, in breach of article 35 of the Charter.

90. Whilst the NMC was entitled to require indemnity cover to be in place, the Registrar's decision was disproportionate because it imposed unduly stringent conditions which had the effect of shutting down self-employed midwifery services, without considering alternatives. The Registrar failed to consider the nature and extent of the risks of the midwife Claimants' practices and failed to provide guidance on the amount of indemnity cover required.

(3)Failure to take account of material considerations and/or errors of fact

91. The Registrar failed to take into account relevant considerations when making her decision and/or made errors of fact. She relied upon the assessment made by an independent expert commissioned by the NMC (Mr Christopher Critchlow), which was inadequate and flawed. She failed to give Lucina time to produce an expert report before making her final decision, and subsequently engaged only cursorily with a report submitted on its behalf by an independent expert, Mr Alex Marcuson.

92. The Claimants' skeleton argument departed significantly from the pleaded grounds. It was not accompanied by any application to amend the grounds. It comprised only two grounds:

    i) **Error of law and Wednesbury unreasonableness**. This ground included the matters pleaded in the original ground 1. It added a detailed critique of the competing evidence available to the Registrar, from Lucina and Mr Critchlow, criticising the Registrar's analysis and conclusions. It developed submissions previously made under ground 3. In conclusion, it made the wide-ranging submission that the decision was vitiated by "error of law and/or a failure to undertake adequate enquiry and/or to take relevant considerations into account and/or a fundamental error of analysis and/or is unreasonable".

    ii) **Infringement of TFEU, the Charter and A1P1**. This ground repeated the original ground 2, as pleaded in the Statement of Facts and Grounds. It added a submission that the NMC failed to comply with the EU principle of equality, since it has allowed registrants to continue to rely upon the indemnity scheme offered by the Royal College of Nursing, which capped the level of cover per claim at £3 million.

93. Mr Dutton QC's complaints about the late changes in the presentation of the Claimants' case were justified. However, I decided to allow the Claimants to rely upon their additional grounds, as they were closely related to the pleaded grounds, and the NMC had adequately addressed them in its skeleton argument. I concluded it was in the interests of both the Claimants and the Defendant for all the issues raised to be considered and decided at this hearing, in the hope of achieving a resolution to this contentious case. I have therefore treated the grounds in the skeleton argument as the Claimants' pleaded case, in place of the grounds originally pleaded in the Statement of Facts and Grounds.

Legal framework

94. Article 3 of the NMC Order sets out its functions and objectives:

> "3.— The Nursing and Midwifery Council and its Committees
>
> …
>
> (2) The principal functions of the Council shall be to establish from time to time standards of education, training, conduct and

> performance for nurses and midwives and to ensure the maintenance of those standards.
>
> (3) The Council shall have such other functions as are conferred on it by this Order or as may be provided by the Privy Council by order.
>
> [(4) The over-arching objective of the Council in exercising its functions is the protection of the public.
>
> (4A) The pursuit by the Council of its over-arching objective involves the pursuit of the following objectives—
>
> (a) to protect, promote and maintain the health, safety and wellbeing of the public;
>
> (b) to promote and maintain public confidence in the professions regulated under this Order; and
>
> (c) to promote and maintain proper professional standards and conduct for members of those professions.
>
> [(5) In exercising its functions, the Council shall—
>
> (a) have proper regard for—
>
> (i) the interests of persons using or needing the services of registrants in the United Kingdom, and
>
> (ii) any differing interests of different categories of registrants; …"

95. The Registrar is appointed pursuant to article 4.

96. Under article 5, the NMC must establish and maintain a register of qualified nurses and midwives. Article 9 provides that a person seeking admission to the register must satisfy the specified conditions, which include at sub-paragraph (2)(aa):

> "satisfies the Registrar that there is in force in relation to the applicant, or there will be as necessary for the purpose of complying with article 12A, appropriate cover under an indemnity arrangement."

Article 10(2) makes similar provision for persons seeking to renew registration or applying for re-admission.

97. Article 12A(1) of the NMC Order provides:

> "12A.— Indemnity arrangements

(1) Each practising registrant must have in force in relation to that registrant an indemnity arrangement which provides appropriate cover for practising as such.

(2) For the purposes of this article, an "indemnity arrangement" may comprise—

(a) a policy of insurance;

(b) an arrangement made for the purposes of indemnifying a person;

(c) a combination of the two.

(3) For the purposes of this article, "appropriate cover", in relation to practice as a registered nurse or midwife, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such.

(4) The Council may make rules in connection with the information to be provided to the Registrar—

(a) by or in respect of a person applying for registration (including an application for restoration or readmission) for the purpose of determining whether or not the Registrar is satisfied that if the person is registered, there will be in force in relation to that person by the time that person begins to practise, an indemnity arrangement which provides appropriate cover;

(b) by or in respect of a person applying for renewal of their registration for the purpose of determining whether or not the Registrar is satisfied that if the person's registration is renewed, there will be in force in relation to that person by the time that person resumes practice, an indemnity arrangement which provides appropriate cover; and

(c) by or in respect of a registrant for the purposes of determining whether at any time there is in force in relation to the registrant an indemnity arrangement which provides appropriate cover.

(5) Rules made under paragraph (4) may require information to be provided—

(a) at the request of the Registrar; or

(b) on such dates or at such intervals as the Registrar may determine, either generally or in relation to individual registrants or registrants of a particular description.

> (6) The Council may also make rules requiring a registrant to inform the Registrar if there ceases to be in force in relation to that registrant appropriate cover under an indemnity arrangement.
>
> (7) The Council may also make rules requiring a registrant to provide the Registrar with such information as is necessary for the purpose of satisfying the Registrar that there is or will be in force in relation to that registrant appropriate cover provided under an indemnity arrangement by an employer.
>
> [(7A) For the purposes of verifying that information, the Registrar may disclose to any person information relating to a person's indemnity arrangement which is provided to the Council by virtue of rules made under paragraph (4) or (7).]
>
> (8) If a registrant is in breach of paragraph (1)—
>
> (a) the Registrar may remove that person from the register; or
>
> (b) the person's fitness to practise may be treated for the purposes of article 22(1)(a)(i) as being impaired by reason of misconduct, and the Registrar may accordingly refer the matter to persons appointed by it under article 22(5)(b)(i) (where rules under article 23 provide) or to a Practice Committee under article 22(5)(b)(ii).
>
> (9) If an applicant breaches rules under paragraph (4), or there is a breach of rules under that paragraph in respect of the applicant the Registrar may refuse the applicant's application for—
>
> (a) admission (or readmission) to the register;
>
> (b) restoration to the register; or
>
> (c) renewal.
>
> (10) If a registrant breaches rules under paragraph (4)(b) or (c), that person's fitness to practise may be treated for the purposes of article 22(1)(a)(i) as being impaired by reason of misconduct, and the Registrar may accordingly refer the matter to persons appointed by it under article 22(5)(b)(i) (where rules under article 23 provide) or to a Practice Committee under article 22(5)(b)(ii). …"

98. The requirements for nurses and midwives to have indemnity arrangements in place were introduced by amendments made by the Health Care and Associated Professions (Indemnity Arrangements) Order 2014, which implemented the EU Cross-border Healthcare Directive 2011/24 into UK law. Article 4(2)(d) of the Directive provides:

> "1. …

> The Member State of treatment shall ensure that:
>
> … (d) systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory."

99. The Directive does not provide any definitions of the terms used in article 4(2)(d).

100. Since article 12A of the NMC Order implements the terms of an EU Directive, decisions taken pursuant to it must conform with the general principles of EU law and respect EU treaty rights set out in the TFEU and the Charter: Case 5/88 *Wachauf v Germany* [1989] E.C.R. 2609, CJEU at [19]; and Case C-260/89 *ERT* [1991] ECR I-2925, CJEU at [42].

The Solvency II regime

101. The Solvency II regime is contained in Directive 2009/138/EC. It applies to insurance companies with gross premium income above €5 million. The regime did not apply to Lucina, because it was a wholly discretionary indemnity scheme which falls below the income threshold. However, Lucina relied on the Solvency II regime as a benchmark in its representations to the NMC, and therefore a brief explanation of the regime is required.

102. Solvency II was intended to harmonise the insurance laws of Member States in order to facilitate the take up of insurance and ensure consistent protection for policy-holders across the EU.

103. It comprises three main pillars: (1) tests for consistent calculation of insurance liabilities and risk-based calculation of capital; (2) a supervisory review process; and (3) reporting and transparency requirements.

104. The first main pillar calculates insurance liabilities and whether the company has the required level of capital to meet the risks, assessed according to tests set out in the Directive. There are two main requirements: the Solvency Capital Requirement ("SCR") and the Minimum Capital Requirement ("MCR").

105. Recital (64) of the Solvency II Directive defines the purpose behind the SCR as follows:

> "In order to promote good risk management and align regulatory capital requirements with industry practices, the Solvency Capital Requirement should be determined as the economic capital to be held by insurance and reinsurance undertakings in order to ensure that ruin occurs no more often than once in every 200 cases or, alternatively, that those undertakings will still be in a position, with a probability of at least 99.5 %, to meet their obligations to policy holders and beneficiaries over the following 12 months. That economic

> capital should be calculated on the basis of the true risk profile of those undertakings, taking account of the impact of possible risk-mitigation techniques, as well as diversification effects."

106. The purpose behind the MCR is set out in recital (70) as follows:

> "The Minimum Capital Requirement should ensure a minimum level below which the amount of financial resources should not fall. It is necessary that that level be calculated in accordance with a simple formula, which is subject to a defined floor and cap based on the risk-based Solvency Capital Requirement in order to allow for an escalating ladder of supervisory intervention, and that it is based on the data which can be audited."

107. Rules on the calculation of the SCR and MCR are set out in Articles 101 and 129 of the Directive.

Conclusions

108. The Registrar is a statutory officer who has responsibility for discharging the statutory powers and duties of the NMC, pursuant to the NMC Order. In order to remain on the register, the midwife Claimants had to satisfy the Registrar that they had an indemnity arrangement which provided appropriate cover for their practice (articles 9, 10(2) and 12A of the NMC Order).

109. Despite the real difficulties which self-employed independent midwives face in obtaining appropriate cover, the Registrar was required to treat the protection of the public as her overarching objective in the exercise of her functions under these provisions, by virtue of article 3(4). Article 3(4A) provides that protection of the public involves, inter alia protecting, promoting and maintaining the health, safety and well-being of the public. Although childbirth is a natural occurrence, it still carries with it high risks of harm to child and mother, as the NHS Study demonstrated. The range of risks may be reduced in the types of birth attended by independent midwives, but the risk of serious harm is not eliminated. The substantial sums of damages which have been awarded reflect the fact that some of the personal injuries which are suffered at birth leave children with permanent physical and mental disabilities, as a result of which they may be unable to earn a living and may require a life time of care.

110. Where a health professional providing maternity care does not have an indemnity arrangement which provides appropriate cover, the harm to the parents and child is compounded because they will receive little or no compensation to assist with the costs of care etc. The Department of Health, when assessing the requirement for mandatory indemnity arrangements, cited a case in 2005 where harm was caused to a mother and child by an independent midwife, resulting in permanent disability for the child and reconstructive surgery for the mother. The midwife had not informed her client that she had no cover, and as she had no assets, any attempt to seek redress in court would not have resulted in compensation to mother or child. I note that this case would not be counted as a successful claim against an independent midwife if the

client decided that it was not worth pursuing a defendant who was uninsured. Cases such as this led the Department of Health to conclude that mandatory indemnity cover for health professionals ought to be introduced, even prior to EU Directive 2011/24.

111. In deciding whether or not the midwife Claimants had "appropriate cover for practising", the Registrar had to apply the statutory test in article 12A(3) of the NMC Order:

> "(3) For the purposes of this article, "appropriate cover", in relation to practice as a registered nurse or midwife, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such."

112. This is a broad statutory test which requires an exercise of judgment on the part of the Registrar. Her conclusions could only be found to be unlawful on public law grounds (including proportionality). The Claimants' attempts to insert their own conditions or criteria into the statutory test, and then criticise the Registrar for not applying them, were misconceived since those conditions or criteria were not to be found in the domestic legislation or the Directive. In this difficult case, the Registrar had to assess a number of competing opinions, which were necessarily based on incomplete and uncertain evidence. After giving careful consideration to her decision, I did not consider that it disclosed any error of law.

113. The Claimants submitted that the Registrar failed to consider or understand the evidence given by Mr Graham, and BWCI, and "proceeded on the basis of a fundamental misunderstanding as to what constitutes "appropriate" indemnity cover ….that indemnity cover cannot be appropriate unless it is adequate to meet any claim, whenever arising, regardless of the degree of risk that it will arise" (Skeleton argument paragraph 8).

114. In my judgment, this submission was far too sweeping and it mischaracterised the Registrar's careful approach. The Registrar plainly did consider both the nature and the extent of the risks of the practices, as required by the statutory test. She accepted that the risk of a high-value claim was very low but nonetheless it was real, not theoretical. Importantly, she found that the nature of the risk was very severe. She found that Lucina did not currently have recourse to sufficient assets or reinsurance to pay one large claim, or even several smaller claims, and therefore the cover was not appropriate to meet the liabilities that might be incurred.

115. On the evidence before the Registrar, this was a reasonable conclusion. Lucina was a new scheme which had only come into existence in 2015. It was a tiny operation, run solely by Mr Graham, a retired businessman and accountant, from his home. It was not subject to any external regulatory supervision. He had created the scheme because he was aware, through his wife who was a member of IMUK, of the difficulties that independent self-employed midwives were facing in obtaining appropriate cover. As described earlier in my judgment, it had been widely recognised for years that independent self-employed midwives were unable to obtain appropriate cover from professional bodies or commercial insurers because there was a claims history of multi-million pound awards arising from negligence in maternity care in the NHS, and "the number of individuals is too small to enable the risk to be pooled and spread

in a way that produces an affordable premium" (Finlay Scott report, paragraph 141). The Royal College of Midwives withdrew indemnity cover from independent self-employed midwives in 1994; the Medical Defence Union no longer provided cover after 2002; the Royal College of Nursing provided antenatal and postnatal cover, but not the higher risk intrapartum cover. The Flaxman review commissioned by the NMC and the Royal College of Midwives in 2011 concluded that independent self-employed midwives could only viably secure insurance by becoming an employee of a social enterprise or corporate structure entity. In my view, there was a legitimate need to scrutinise closely Lucina's assertion that it could provide appropriate cover for self-employed midwives, given that so many other providers had decided that they could not do so.

116. Lucina was set up without any capital investment. It was a company limited by guarantee in the sum of £1. Its only source of income was the subscriptions paid by its members – a small cohort of midwives. Its projected net assets in the early years of operation were very modest: in the year commencing 1 July 2015 - £294,126; in the year commencing 1 July 2016 - £616,927; in the year commencing 1 July 2017 - £970,459. The increase year by year was based upon a net increase of 4 members and income earned from investing previous years' subscriptions. Significantly, these projections assumed that no funds were reserved for claims or paid out. The BWCI report, submitted by Lucina, expressed doubts about the sufficiency of Lucina's assets to meet liabilities in the early years.

117. During its investigation, the NMC asked Lucina if it could obtain additional insurance cover. Mr Graham said he was searching for insurance protection in the region of £2 million. The letter from its brokers stated that most insurers would not insure midwives. In the event, the only offer made was rejected by Lucina as the premiums were too costly.

118. During the investigation, Lucina repeatedly stated that two persons had offered guarantees totalling £500,000. However, when asked to provide copies of the guarantees, and the assets backing them, Lucina could only put forward one guarantee in the sum of £250,000, from Mr Graham himself. The assets backing the guarantee were his family home and his pension fund.

119. Mr Graham had not managed to secure any investment into the scheme from third parties, despite efforts to do so.

120. A mutual indemnity fund, with a large pool of members of high net worth, such as the Bar Mutual Indemnity Fund (which is subject to the Solvency II regime), could realistically raise funds to meet an unanticipated high level of claims by increasing the annual membership contribution from its members. However, it was doubtful whether the small pool of self-employed independent midwives would be willing or able to increase their membership contributions to meet a multi-million pound claim.

121. Under rule 4 of the scheme rules, Lucina was an entirely discretionary indemnity scheme, and it was not under any contractual obligation to meet claims made by members. Although it did not set any limit to the amount payable on a claim, it stated that this was "subject to the total funds available to the Scheme". This may be contrasted, for example, with the Bar Mutual scheme which enters into an insurance contract with members, under which the scheme will meet eligible claims made. Mr

Graham, in his fourth witness statement (paragraphs 23 and 43) considered that the wholly discretionary nature of the scheme was an advantage, as it meant that Lucina would not become insolvent in the event that a valid claim was made which it could not meet. It also meant that it did not have to comply with the accounting requirement to create a full reserve at the point of receipt of a claim. However, from the perspective of a regulator, that would mean that a baby or mother would be left without compensation, which would not meet the objective of protecting the public.

122. Ms Tomkins, in her letter of 12 August 2015, compared the Lucina scheme to the CNST administered by the NHSLA which had been approved by the NMC as appropriate. However, the essential difference between the two schemes was that the CNST was much larger and better funded than Lucina, and in the last resort, would be able to draw on Treasury funds to meet claims.

123. The risk of a high value claim arising in the early years of the Lucina scheme has recently been illustrated by the claim made by Complainant A. Mr Graham stated in his first witness statement that, on 7 February 2017, he received a letter from Irwin Mitchell solicitors enquiring about the Lucina scheme as they had been instructed to investigate the possibility of making a claim against two IMUK midwives in relation to a baby injured at birth in October 2015. Allegations of negligence against the two midwives were subsequently referred to the NMC's Fitness to Practice Directorate. The potential claim related to a baby who was delivered by two IMUK midwives in October 2015. He was born with a catastrophic brain injury which has left him severely disabled.

124. Lucina was seeking to limit any indemnity cover to £400,000 in respect of both midwife members on the basis of rule 4.8 of the Lucina scheme (the contract pre-dated the commencement of the scheme). If that was a correct interpretation of the Lucina rules, the payment would represent only a small fraction of the likely award if the claim succeeded, leaving the baby and parents uncompensated.

125. Mr Beal QC repeatedly criticised the NMC as misguided for not accepting the assumptions and modelling presented by Mr Graham, and his conclusion that the scheme provided appropriate cover. However, the Registrar was entitled to prefer the evidence of Mr Critchlow, the independent actuary instructed by the NMC, to that of Mr Graham, and it was not irrational for her to do so. Mr Critchlow's doubts about the scheme were also supported by Miller Insurance Services LLP who prepared an independent report for the NMC. It was important to bear in mind that this was a claim for judicial review, not a merits trial at which the court could decide which of the competing expert evidence was to be preferred. The midwife Claimants had the option of a merits appeal against the Registrar's decision to the Registrations Appeal Panel, but elected not to pursue that route.

126. Mr Critchlow considered that Mr Graham's evidence that Lucina could meet its liabilities with a 99.5% confidence level in accordance with the SCR in Solvency II could not be relied upon because its modelling was unreliable. In his report, Mr Critchlow reviewed Lucina's linear model and made the following criticisms:

    i) The linear model did not make explicit allowance for the impact of delays in reporting claims in determining the expected incidence rate per birth. This

understatement in incidence rates per birth could be 30% to 40%, possibly higher.

ii) In calculating the incidence rate per birth, the linear model used the entire population of births as the divisor, even though some of those births would not apply to IMUK members. The effect of this exclusion potentially would increase the incidence rate per birth used within the linear model by as much as 67%.

iii) The methodology used by the linear model to calculate an average claim value ignored the impact that settled claims had on the calculation. Mr Critchlow estimated that the average claim value could be understated by around 38%.

iv) Allowance for historic claims inflation was likely to be overstated by around 36% which partially offset the understatements above. However, even after taking this into account, as a result of the facts above the incidence rate per birth should be approximately doubled.

v) The approach taken by the linear model to the timing of claim payments, and splitting the analysis by banding category, meant that there is likely to be such a material distortion in timing of when claims might be expected to be incurred that it invalidated its use in any cash flow or balance sheet analysis of the possible liabilities the Lucina scheme might be expected to bear.

vi) The linear model had not been subject to sufficient stress testing.

vii) The lack of qualitative as opposed to quantitative analysis carried out by Lucina meant that the linear model should not be relied upon.

127. Mr Critchlow considered that most of the issues set out above were not addressed in the Monte Carlo model either, other than that the Monte Carlo model did not use the timing/banding category approach, which he accepted. Further, whilst the Monte Carlo Model was used to seek to model what a random series of claims might look like, Mr Critchlow had not seen any evidence base which supported the inputs into the Monte Carlo model such as the variability in claim costs and delay in claim settlement. Even if the inputs to the Monte Carlo model could be relied upon, it had not been subject to sufficient stress testing or any reverse stress testing or other qualitative analysis.

128. Taking Lucina's own figures, Mr Critchlow calculated that the risk of a successful cerebral palsy claim being incurred from a birth in any 12 month period was 0.92%. This was low but higher than 0.5%. Lucina's own figures stated that the average cost of a cerebral palsy claim was £2.2 million and as at 8 years from Lucina's incorporation would be £6.09 million (taking into account inflation). Lucina's own projections were that it would hold only £3.4 million 8 years from its incorporation. Therefore, if a successful cerebral palsy claim were made in respect of an incident (birth) in a 12 month period (of which there was on Lucina's figures a chance of 0.92%) and if that claim was of average cost, Lucina would not have the assets to be able to meet that claim either at the date the claim was made or on the date Lucina assumed it would fall for settlement (8 years from the birth event).

129. The allegation that Mr Critchlow failed properly to review or understand the Monte Carlo model was unsustainable. Mr Critchlow had the benefit of attending a meeting on 3 November 2016 when Mr Graham gave an extensive presentation on the Lucina scheme and modelling. Mr Critchlow asked Mr Graham detailed questions, and in my view it was apparent from the transcript that he had a good understanding of the issues. Mr Critchlow was able to refresh his memory from the transcript when preparing his report. Mr Critchlow also had Mr Graham's presentation slides. He also considered Lucina's claims modelling documentation; the Workbook on the linear model; and the Workbook on the "Monte Carlo" simulation model. He did not review the calculations underlying the "Monte Carlo" model, because this would have taken 7 to 10 days and in his professional opinion, it was not necessary to do so. I consider that was a legitimate view to adopt.

130. In support of its case that it met the SCR requirements in Solvency II, Lucina had relied upon the letter from BWCI dated 18 February 2016 but it only showed the SCR ratio in Solvency II met from 30 June 2017 onwards and not met as at 2016, when the decision was made.

131. Neither Mr Critchlow nor the Registrar adopted the erroneous view that Lucina was governed by Solvency II. However, given Lucina's reliance upon its compliance with one aspect of the Solvency II regime, it was reasonable to consider the extent to which it complied with other aspects, such as the MCR, testing the appropriateness of the methodology, reverse stress testing and accruing for claims as they are incurred. The SCR had been calculated on the basis that these other requirements, including a gross premium income above €5 million, were in place.

132. Mr Critchlow provided a cogent analysis of the risks associated with a small membership scheme at paragraphs 133 to 148 of his report. Generally, with a larger insurance company or scheme it was possible to predict with a reasonably high degree of accuracy the range of claim costs that might be expected to be incurred each year. The smaller the arrangement and the smaller number of expected claims, the greater the uncertainty in terms of the number of claims that might be incurred and the expected ultimate cost. Smaller schemes needed to recognise the risk that they will have a claim made against them, even though the likelihood of that event may be remote, and have sufficient funds in place to meet the costs of that claim. Quite how much capital a firm needed was a matter of judgment but it would generally start off as a minimum at the cost of paying for at least one large claim. Small insurers sometimes dealt with this by obtaining reinsurance or additional financing. Securing reinsurance or additional financing should be done in advance of needing the funding, because if a large claim had already been made then no reinsurer would be willing to take the liability and no investor would be willing to invest.

133. In my judgment, the Registrar conducted a proper investigation and in reaching her conclusions, she assessed the evidence with care, and took into account all relevant considerations. Having concluded that the cover provided by Lucina was not appropriate, she went on to consider what steps to take. She decided that IMUK midwives relying upon the Lucina scheme for any aspect of intrapartum care (not ante-natal or post-natal care) would be removed from the register unless they provided a signed declaration to the NMC by 10 January 2017 that they would not rely on Lucina for any such aspect of their practice, and confirm that they had alternative

cover in place. She expressly applied the test of proportionality, stating at paragraph 62:

> "I have decided that removal is an appropriate course of action, bearing in mind the risk to the public. In reaching this decision I have taken into consideration that any midwife who is subject to removal has a right of appeal under Article 37 of the Order."

134. In my judgment, this was a proportionate and lawful step for the Registrar to take, bearing in mind the risk to the public of the midwives continuing to practise on a self-employed basis with inappropriate cover. She limited the scope of the declaration to higher risk intrapartum maternity care, enabling midwives still to rely upon the Lucina scheme for lower risk ante-natal and post-natal care. I consider below the issue of proportionality in the context of alleged infringements of EU law.

135. The Claimants alleged that the Registrar gave insufficient weight to the likely risks to public health that emanated from her decision, given the acknowledged benefits of independent midwifery and the increased prevalence and risk of "free birthing". However, it was not open to the Registrar, under the terms of the statutory scheme, to dis-apply the requirement of appropriate cover to one sector of midwives, no matter how valued they were. Appropriate indemnity cover was a mandatory requirement for all healthcare professionals. The Registrar was entitled to decide that they could not continue to practise in the high risk area of intrapartum maternity care without appropriate cover, because of the risk to the public.

136. In my judgment, the Claimants' submission that the Registrar was required to inform IMUK members of the precise level of cover which she would find to be appropriate was based upon a misunderstanding of the statutory scheme. Article 9(2)(aa) of the NMC Order made it a condition of registration that a member "satisfies the Registrar that there is in force …appropriate cover under an indemnity arrangement". There was no obligation on the Registrar to provide guidance to registrants on the appropriate level of cover for their individual practices. The Registrar gave clear reasons for her conclusions that the Lucina scheme did not have sufficient resources to cover its liabilities, having regard to the nature and extent of the risks. It must have been obvious to IMUK and Lucina, both during the course of the investigation and after the provisional decision, that it would be prudent to obtain additional funding, by way of additional insurance, guarantees or investment.

137. During the NMC's investigation, IMUK and Lucina repeatedly criticised the NMC for procedural failings e.g. a failure to give them sufficient time to respond, a failure to give them sufficient time to present further information or to obtain further funding.

138. In my judgment, the NMC conducted a thorough and fair investigation, which gave IMUK and Lucina sufficient time to respond to the concerns raised. IMUK must have been well aware of the difficulties in establishing an appropriate scheme before it was set up in July 2015, since in 2013 it had attempted a similar project, when it sought £10 million funding from the government on the basis that the Lucina cell would have insufficient assets to meet claims in the early years. The NMC's investigation into the indemnity cover held by IMUK members began in July 2014, in connection with its previous cover from Elite. There was a lengthy period between August 2015 when IMUK notified the NMC of the Lucina scheme and the NMC's investigation into the

Lucina scheme began, before the NMC made its provisional decision in August 2016. IMUK and Lucina were given ample opportunities to present their case, and at the same time they could have tried to secure further funding for Lucina, by way of investment, reinsurance and guarantees. The NMC was thorough and persistent in pressing Mr Graham for the required information. It instructed Miller Insurance Services LLP as experts to prepare a report. It had careful regard to the report and letter produced on behalf of Lucina by BWCI.

139. In my view, it was helpful to IMUK and Lucina to receive a detailed provisional decision on 2 August 2016, as this gave them time to address the NMC's concerns about the claims risks, and Lucina's limited assets, before its final decision on 20 December 2016. The NMC engaged with the issues raised by IMUK and Lucina, instructing another expert and holding a meeting on 3 November 2016 at which Mr Graham and IMUK were able to present the scheme to Mr Critchlow and senior NMC officers, and answer their questions.

140. In her final decision, the Registrar addressed IMUK and Lucina's request for a deferral, at paragraph 57, explaining that the NMC had been concerned since July 2014 about the appropriateness of the indemnity cover provided by IMUK to its members. In her view they had had sufficient time to respond to the issues raised, and that further actuarial evidence was not going to materially alter the basis of her decision. It was not in the public interest to leave members of the public in a position where they could not be confident that the indemnity cover was insufficient to meet liabilities for injury should they arise. In my judgment, this was a reasonable and proportionate stance for the NMC to adopt.

141. Nevertheless, the Registrar did permit IMUK and Lucina and their solicitors to make further representations on the final decision, including submission of a report from a new expert, Mr Marcuson. The Registrar duly considered the representations and evidence. In my judgment, the Registrar's reasoned reconsideration adequately addressed the issues raised and she was entitled to conclude that her decision remained the same.

Rights under EU law

142. Article 49 TFEU guarantees the right to freedom of establishment, including the right for a national of one member state to exercise a right of self-employment in another member state. Freedom of establishment includes the right to take up and pursue activities as self-employed persons.

143. Article 56 TFEU prohibits restrictions on the freedom to provide services in another member state.

144. It was common ground that these rights could not be applied to situations which are purely internal to a Member State.

145. Article 15 of the Charter protects the freedom to pursue a chosen occupation, to work, and to provide services in any member state.

146. Article 16 of the Charter recognises the "freedom to conduct a business in accordance with Union law and national laws and practices".

147. Article 35 of the Charter provides a right of access to preventive healthcare and the right to benefit from medical treatment under the conditions established by national law and practice.

148. Article 52(1) of the Charter provides:

> "Any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others."

149. Limitations on the rights set out above must satisfy the principle of proportionality. Proportionality is a fundamental principle of EU law. The CJEU set out the test to be applied by the courts in Case C-331/88 *FEDESA* [1990] ECR I-4023, [1991] 1 CMLR 507, at [13]:

> "The court has consistently held that the principle of proportionality is one of the general principles of Community law. By virtue of that principle, the lawfulness of the prohibition of an economic activity is subject to the condition that the prohibitory measures are appropriate and necessary in order to achieve the objectives legitimately pursued by the legislation in question; when there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued."

150. This test has been approved by UK domestic courts applying EU law, which have held that the least restrictive measure test is an integral part of assessing proportionality (see *Gaughran v Chief Constable of the Police Service of Northern Ireland* [2015] UKSC 29; [2015] 39 BHRC 698, per Lord Kerr at [77]-[79]; *R (Lumsdon) v Legal Services Board* [2015] UKSC 41; [2016] AC 697, SC per Lords Reed and Toulson at [23]-[26] and [33]-[39]).

151. There was a dispute between the parties as to whether there had been any restriction on the rights of IMUK members to establish self-employed businesses or offer services. I am prepared to assume, for the purpose of this claim, that the requirement to hold appropriate indemnity cover restricts the ability to exercise those rights. However, it is a legal requirement under the Directive and the NMC Order. Therefore the Registrar was under a legal duty to ensure that all registrants had appropriate indemnity cover. She could not make an exception for IMUK members, no matter how highly valued their services.

152. The Claimants submitted that the Registrar's decision that they could not rely on the Lucina scheme as appropriate indemnity cover for intrapartum maternity care was

disproportionate because it prevented them from pursuing their midwifery practices. However, I agree with the Defendant that this was an exaggeration. Midwives practise outside the NHS in the private sector in a number of different ways. For example, they may be self-employed sole traders; they may work in partnership with other midwives in social enterprises or employee-owned organisations; and they may be employed by private providers such as the UKBC. Midwives working in social enterprises or employee-owned organisations have been able to obtain indemnity cover. So too have private providers who employ midwives.

153. IMUK members argued that only they could be described as "independent" midwives because they provided a complete maternity care "package", covering ante-natal, intrapartum (labour) and post-natal care. Delivery was midwife-led, at the client's home. They provided continuity of care, which was client-led, and they offered clients the choice of a natural birth at home, avoiding drugs and intervention, where safe to do so.

154. However, many of these services (including continuity of care) were also provided by midwives operating in other parts of the private sector. They would be able to provide such services to the Fourth Claimant, if she became pregnant again.

155. Moreover, even before the decision in this case, some IMUK members combined self-employed and employed work in the private sector. For example, the Third Claimant and Ms Chaubert of IMUK were employed by the private maternity provider, UKBC. Some also worked in the NHS e.g. the Second Claimant carried out bank shifts for St George's Hospital.

156. After the decision, contingency arrangements were made. Some NHS trusts offered bank contracts to IMUK midwives so that they could continue to care for existing clients, with the benefit of NHS indemnity cover. The UKBC offered to allow any IMUK midwife to transfer to UKBC with an existing client, for a fee, thus gaining the benefit of UKBC's indemnity cover.

157. I accept that the Registrar's decision prevented the midwife Claimants from continuing to provide intrapartum maternity care unless or until they could obtain appropriate indemnity cover, as the Lucina scheme could no longer be relied upon for this purpose. This did impact adversely on their existing practices and clients. However, I consider that this was justified on proportionality grounds, bearing in mind the risk to the public of the midwives continuing to practise on a self-employed basis with inappropriate cover. It was proportionate to limit the scope of the restriction to higher risk intrapartum maternity care, enabling midwives still to rely upon the Lucina scheme for lower risk ante-natal and post-natal care or under the Royal College of Nursing indemnity scheme.

158. The Claimants also submitted that the Registrar's decision infringed their property rights under A1P1. I accept the Defendant's submission that A1P1 was not engaged because of the well-established principle that a self-employed professional has no tradeable goodwill that amounts to a possession within the meaning of A1P1. For example, a self-employed barrister has no goodwill in his practice within the meaning of A1P1 (see *R (Nicholds) v Security Industry Authority* [2007] 1 WLR 2067 [72] to [76] endorsed by the House of Lords in *R (Countryside Alliance and others) v Attorney General* [2008] 1 AC 719 [21]; *R (Malik) v Waltham Forest* [2007] 1 WLR

2092 [40]; *Malik v United Kingdom* 2370/08 [2012] ECHR 438 [96], [110]); *Lumsdon v Legal Services Board* [2014] EWHC 28 (Admin) at [120] to [127]). Although some of the midwife Claimants traded under "brand names", for example, the Second Claimant traded with Ms Tomkins under the name "London Birth Practice", their position was indistinguishable from that of barristers who trade from a set of chambers with a brand name.

159. But even if I am wrong, and A1P1 was engaged, I consider that the interference with their property rights was justified and proportionate, applying the *Bank Mellat* test, conveniently set out by the Divisional Court in *Lumsdon* at [130]. The reasons are those already explained at paragraphs 133 – 134 and 152 - 157 above.

160. The Claimants submitted that the NMC had failed to comply with the EU principle of equality since it had allowed practitioners under the Royal College of Nursing scheme to continue, even though the level of cover per claim was capped at £3 million, had not been subject to investigation. In my view, there was no evidence that IMUK members had been unfairly singled out for investigation – the investigation was prompted by concerns about IMUK members' cover raised with the NMC by UKBC. The Registrar has not made any finding in respect of the Royal College of Nursing scheme. In any event, that scheme was clearly distinguishable from the Lucina scheme because it expressly excluded from the scope of the indemnity cover self-employed midwives providing intrapartum care because of the high risks involved.

161. For the reasons set out above, I do not consider that the Claimants have established any unlawfulness on the part of the NMC and so the claim is dismissed.