Bridge the Gap campaign's response to the draft Health Care and Associated Professions (Indemnity Arrangements) Order 2013

1. We have considered the draft Health Care and Associated Professions (Indemnity Cover) Order 2013 [the 2013 Order] and raise matters herein in relation to the drafting, and the effectiveness of the 2013 Order in achieving transposition of Directive 2011/24/EU into UK law. We have specialist expertise in the area of the law pertaining to the provision of dental care in the UK and have largely confined our analysis of the 2013 Order to its impact in this area

2. We have considered in detail the following questions:

Question I Does the 2013 Order give effect to the Directive's requirements in respect of indemnity arrangements?

Question II Does the 2013 Order give effect to the Directive's requirements in respect of communication of indemnity arrangement information to patients?

Question III Are there areas of drafting of the 2013 Order which could be amended to improve accuracy?

Question IV Are there areas of drafting of the 2013 Order which could be made more consistent or more effective?

3. We submit that there may be an opportunity to improve clarity and effectiveness of the drafting of the order, in both procedural and substantive areas, and make suggestions as to where and how changes may be made. We note our concerns that, in the absence of amendment of the draft order, we are of the opinion that there may be a risk that UK government will fail to transpose the relevant Directive effectively and therefore that there may be a risk of infraction proceedings being initiated in respect of any such failure.

4. Our analysis of the specific requirements of Directive 2011/24/EU [The Directive] is set out below, and the sections of draft order are considered

Question I Does the 2013 Order give effect to the Directive's requirements in respect of indemnity arrangements?

Requirements of indemnity arrangements imposed by the Directive.

5. Mechanisms of patient protection and for seeking remedies should be appropriate to the nature and extent of the risk (Preamble 24)

6. It is the Member States which must ensure that mechanisms for the protection of patients and for seeking remedies in the event of harm appropriate to the nature and extent of the risk (Preamble 24)

7. A system of professional liability cover must be in place for treatment (Article 4(2)(d))

8. It is the Member State of treatment which must ensure that the system of professional liability which is in place for treatment is appropriate to the nature and extent of the risk (Article 4(2)(d))

BTG commentary on the effectiveness of the 2013 Order in satisfying the Directive Requirements regarding indemnity arrangements.

9. Part 2 of the 2013 Order requires at section 26A (1) that a registered dentist must have in force an indemnity arrangement which, "provides appropriate cover for practising as such".

10. "Appropriate cover" is defined within the 2013 Order at section 26A (3) as meaning cover, "as such which is appropriate, having regard to the nature and extent of the risks of practising"

11. It is inferred that the 2013 Order has been drafted in accordance with the Government's Guiding Principles for EU Legislation finalised in 2011 and in particular it is noted that a "copy-out" approach of the phrase, "nature and extent of the risk" has been adopted in relation to the drafting of the definition of appropriate indemnity arrangement

12. Part 2 of the 2013 Order does not provide an express power for the General Dental Council to determine what amounts to appropriate cover having regard to the nature and extent of the risks of the individual's practice as a dental practitioner

13. The explanation for the absence of provision of such a express power to the General Dental Council is set out in the DH consultation paper on the 2013 Order which states, at page 14 paragraph 37, that, inter alia, it is the view of the Department that responsibility should be on healthcare professionals themselves to ensure that indemnity arrangements are appropriate to the nature and extent of the risk that may be encountered.

14. However, by contrast, the Directive expressly indicates that it is the responsibility of the individual Member State, rather than the individual healthcare provider, to ensure that the system of professional liability which is in place for treatment is appropriate to the nature and extent of the risk.

15. The DH consultation paper on the 2013 Order also states, at page 14 paragraph 37, that, inter alia, it is the view of the Department that healthcare professionals are "best placed" to make the assessment as to whether or not their individual indemnity arrangements are appropriate.

16. However it is the view of Bridge the Gap that the purpose of the Directive, and the imposition of a statutory requirement for indemnity arrangements, is to ensure the safety of patients, and the availability of remedy to patients in the event of harm. It is submitted that it is individual Regulators, expressly charged with the protection of patients, and not individual healthcare professionals, who are "best placed" to determine which minimum or core features of indemnity arrangements are essential to ensure the safety of patients and availability of redress. It should be noted that there is a significant risk that individual healthcare practitioners' choice of indemnity arrangement may be determined by criteria other than patient protection, including cost.

17. The DH consultation paper on the 2013 Order also states, at page 14 paragraph 37, that, inter alia, it is the view of the Department that it would be disproportionate to require the professional regulatory bodies to assess whether or not the individual indemnity arrangements of health care professionals were appropriate.

18. However it is noted that Part 2 paragraph 3 of the 2013 Order amends section 18 of the Dentists Act to require, as part of the procedure for registration, that those wishing to be registered as dental practitioners must produce or send to the Registrar documents conferring or evidencing that there is or will be in force in relation to the potential registrant, "appropriate cover under an indemnity arrangement".

19. Additionally Part 2 of the 2013 Order in relation to section 26A (4)(a)-(c) allows for the Regulator to make rules in connection with information regarding indemnity arrangements to be provided by the healthcare professional seeking registration, seeking restoration on the register or seeking retention on the register.

20. It is submitted that for the proposed amendment of section 18 by the 2013 Order to be effective, and/or for the rule-making capacity conferred by Section 26A (4)(a)-(c) to be effective, upon receipt of the relevant documents or information, in each case the Registrar must engage in an assessment of the supplied documentation or information to ensure that the documents or information do amount to evidence of the potential registrant's appropriate cover under an indemnity arrangement.

21. Accordingly whereas the Department describes any requirement upon the professional regulatory bodies to assess whether or not the individual indemnity arrangements of health care professionals are appropriate, as "disproportionate", nevertheless Part 2 of the 2013 Order creates precisely such an obligation, albeit by implication, upon the dental Regulator.

22. We are concerned that there is no evidence that the Department recognises that the Order creates such an obligation upon the dental Regulator.

23. It is submitted that at a minimum, the discharge of the obligation imposed upon the Regulator by Part 2 of the 2013 Order would require consideration by the Regulator of whether or not the documents or information supplied were prima facie evidence of the potential registrant's appropriate cover under an indemnity arrangement.

24. It is submitted that the minimum or core relevant information amounting to prima facie evidence of the potential registrant's appropriate cover under an indemnity arrangement which the Regulator must consider in order to discharge its obligations under Part 2 would include the identity of the commercial organisation providing the cover, the existence and size of any excess, the limit of indemnity, the period of cover and the risks covered.

25. Accordingly because the 2013 Order itself creates obligations upon the Regulator to undertake a consideration of what may amount to "appropriate cover under an indemnity arrangement", it is submitted that it would not be disproportionate for professional regulatory bodies to be provided with an express power to provide detailed guidance to regulated healthcare professionals as to what minimum or core elements should be present in an indemnity arrangement so as to avoid a finding that indemnity cover was inappropriate. In effect this power would result in publication of the criteria which the Regulator was using to discharge its obligations in Part 2 para 3 and under section 26A as guidance. Such guidance would not require detailed consideration of each regulated healthcare professionals circumstances, but would allow scope for application of the guidance by healthcare professionals to their specific practice risk, and tend to increase compliance rate by healthcare professionals.

26. The DH consultation paper on the 2013 Order posits, at page 17 paragraph 48 that there may be circumstances where an individual healthcare professional obtains an indemnity arrangement which is inappropriate to the scale of risk of the individual's practice. The Department expresses the view that in such circumstances, the Regulator should have the power to decide whether or not such activity should amount to impaired fitness to practise and the further power to take action if appropriate.

27. However as currently drafted Part 2 of the 2013 Order contains no express power for the Regulator to determine whether or not an individual health care professional's indemnity arrangement amounts to inappropriate cover nor does the 2013 Order provide a power for the Regulator to act thereafter. It is submitted therefore if the Regulator was to make such a determination in such

circumstances, as the Department suggests it should, that there would be a significant risk that the Regulator would be acting ultra vires.

28. In conclusion it is submitted that Part 2 of the 2013 Order, as drafted, risks failing to implement EU policy and legal obligations in that there is a failure to ensure that indemnity arrangements under the Order would be appropriate to the nature and extent of the risk

29. It is recommended that Part 2 of the 2013 Order be redrafted for clarity to provide the Regulator with the express power to determine whether or not a particular indemnity arrangement amounts to appropriate cover.

30. It is recommended that Part 2 of the 2013 Order be redrafted to incorporate the provision of an power for the Regulator to provide guidance as to minimum or core elements which should be present in an indemnity arrangement so as to satisfy the ‘copy-out’ Part 2 test at section 26A (3).

31. It is recommended that Part 2 of the 2013 Order be redrafted to provide a power for the Regulator to take action insofar as any particular indemnity arrangement is found to fail to amount to appropriate cover.

Question II Does the 2013 Order give effect to the Directive's requirements in respect of communication of indemnity arrangement information to patients?

Requirements of Communication of indemnity arrangement information to patients imposed by the Directive.

32. Safety information should be supplied upon request to enable patients to make an informed choice (Preamble 20)

33. Healthcare providers are the persons who should provide patients with information on request (Preamble 20)

34. The relevant information must be provided to individual patients (Article 4(2)(b))

35. The relevant information must be specific to individual patients to enable the individual patients to make an informed choice about treatment (Article 4(2)(b))

36. Inter alia, the information provided to individual patients must be clear (Article 4(2)(b))

37. The specific and relevant information to the individual patient must include treatment option information, treatment price, individual healthcare provider registration status and individual healthcare provider professional liability cover information (Article 4(2)(b))

38. It is individual healthcare providers who must provide the relevant information (Article 4(2)(b))

BTG commentary on the effectiveness of the 2013 Order in satisfying the Directive Requirements regarding Communication of indemnity arrangement information to patients

39. We note that Part 2 of the 2013 Order is silent regarding the communication of information to individual patients by healthcare professionals despite the express requirement within the Directive that Member States ensure that they do so.

40. The explanation for the absence of a requirement to communicate information of indemnity arrangements to individual patients on the part of individual healthcare professionals is set out in the DH consultation paper on the 2013 Order which states, at page 9 paragraph 11, that it is the view of the Department that once the 2013 Order is in force, the public record of the registration of an individual healthcare professional will be sufficient to

confirm the possession of appropriate indemnity arrangements by the registered healthcare professional.

41. However the Directive expressly requires not only the communication by an individual health care professional to an individual patient of information regarding both the professional's registration status but also and separately information regarding the professional's indemnity arrangement

42. Further the Directive places the communication of information regarding the professional's indemnity arrangement in the context of the information supplied by the healthcare professional to the patient to enable the individual patient to make an informed choice about treatment, alongside information about treatment options and cost. The Directive clearly envisages that in such a context the informed patient will require specific information which will allow a choice to be made not only between treatment options but also between healthcare professionals to provide the treatment.

43. The Directive states that information about indemnity arrangements of individual healthcare professionals must be clear. It is submitted that implied indemnity by reference to un-ratified adherence on the part of the individual healthcare professional to the sections in Part 2 of the 2013 Order does not amount to communication of clear information to the patient by the professional of his or her indemnity arrangement.

44. It is submitted that specific features of different indemnity arrangements held by individual healthcare professionals, such as the identity of the commercial organisation providing the cover, the existence and size of any excess, the limit of indemnity, the period of cover and the risks covered are relevant to the choice of healthcare professional made by the individual patient. We note that the Directive requires that patients be provided with such information in precisely the same way that patients are able to access information regarding the public liability insurance product which their healthcare professional has purchased to protect patients in, for example, accessing the building in which healthcare is provided.

45. In conclusion it is submitted that Part 2 of the 2013 Order, as drafted, falls short of implementation of EU policy and legal obligations in that there is a failure to ensure transposition of the Directive's communication requirements in respect of indemnity arrangements to patients by healthcare professionals

46. Part 2 of the 2013 Order could be redrafted to incorporate the provision of an obligation upon individual healthcare professionals to communicate clear details of their indemnity arrangements to patients in accordance with the requirements of the Directive.

47. In the alternative, we suggest that communication of indemnity arrangement information by healthcare professionals could be achieved directly by information recorded on the Regulator's public record of the individual healthcare professional.

48. It is submitted that for the operation of amendment of section 18 by the 2013 Order to be effective, and/or for the rule-making capacity conferred by Section 26A (4)(a)-(c) to be effective, the Regulator will necessarily have assessed and recorded minimum or core relevant information amounting to prima facie evidence of the potential registrant's appropriate cover under an indemnity arrangement which the Regulator must consider in order to discharge its obligations under Part 2 – see above at paragraphs18-24. This information will include the identity of the commercial organisation providing the indemnity cover, the existence and size of any excess, the limit of indemnity, the period of cover and the risks covered.

49. It is submitted that the requirements of the Directive could be satisfied at negligible additional cost if the 2013 Order was redrafted to provide the Regulator with the power to place the minimum or core relevant information regarding healthcare professionals' indemnity cover on public record.

Question III Are there areas of drafting of the 2013 Order which could be amended to improve accuracy?

50. The 2013 Order Schedule 1 Part 2 (4) refers to the substitution of section 26A insurance for dental practitioners with section 26A indemnity arrangements

51. The General Dental Council is empowered to make rules by virtue of the operation of the Dentists Act 1984

52. The Dentists Act 1984 was amended by the operation of the Dentists Act 1984 (Amendment) Order 2005 [The 2005 Order]

53. Article 16 of the 2005 Order provided for detailed requirements to be inserted into the Dentists Act 1984 in the form of section 26A in relation to professional liability cover for registered dentists

54. The 2005 Order was made on 19th July 2005 but restricted to certain articles only. Article 16 was not expressly among the articles which came into force on the making of the 2005 Order

55. Article1 (4) allowed for those provisions of the 2005 Order which conferred powers enabling rules and regulations to be made by the General Dental Council to come into force on the day of the making of the 2005 Order

56. Article 1 (5) allowed for the Secretary of State to specify the dates on which other provisions of the 2005 Order would come into force, and Article 1(7) provided for publication of the same in the London Gazette

57. A review of the London Gazette indicates that the DH gave notice of provisions of the 2005 Order coming into force on the following dates:

i. 19.08.05
ii. 05.05.06
iii. 21.07.06
iv. 01.02.08
v. 18.07.08
vi. 01.05.09
vii. 28.01.11

58. Article 16 of the 2005 Order was not specified as coming into force in the above notices

59. Save for in relation to subsections 26A(6) and 26A(8) which may be interpreted as conferring powers on the GDC, it is submitted that s26A has not been inserted into the Dentists Act 1984

60. Schedule 1 Part 2 (4) of the 2013 Order is therefore inaccurately drafted in that the new section 26A is not a substitute section but rather is a new amendment of the Dentists Act 1984.

61. Redrafting of Schedule 1 Part 2 (4) of the 2013 Order is advised. Please be advised that the same inaccuracy may apply to Schedule 1 Part 2 (5) of the 2013 Order in relation to registered dental care professionals.

Question IV Are there areas of drafting of the 2013 Order which could be made more consistent or more effective?

62. Parts 1 through 8 of Schedule 1 of the 2013 Order confer comparable powers on the relevant healthcare regulator in each healthcare sector.

63. For example in Part 1, the General Medical Council is empowered in section 44C (4) in terms that, "The General Council may make regulations in connection with the information to be provided to the Registrar…"

64. In Part 3, section 10A (4) the Optical Council is empowered in similar terms, as is the General Osteopathic Council in Part 4 section 37 (4), and so on.

65. However drafting of the relevant sections of Part 2 of the 2013 Order as pertaining to amendments to the Dentists Act 1984 is inconsistent with, and lacks the clarity of the drafting elsewhere in the 2013 Order

66. Part 2 section 26A (4) states, 'Rules may make provision in connection with the information to be provided to the Registrar…

67. It is submitted that Part 2 section 26A (4) lacks clarity as drafted, fails in its intention to grant the required power to the General Dental Council to make rules and should be redrafted in line with the clear drafting in Parts 1, 3, 4 and so on

68. Similar lack of clarity in drafting is present at Part 2 section 26A (5), and Part 2 section 26A (6), and both of these sections of Part 2 should be redrafted in line with the clear drafting in Parts 1, 3, 4 and so on

69. Similar lack of clarity in drafting is present at Part 2 section 36L (4), (5), and Part 2 section 36L (6), and these sections of Part 2 should be redrafted in line with the clear drafting in Parts 1, 3, 4 and so on

70. Note as an aside that section Part 5 section 37 (4) in relation to amendments to the Chiropracters Act 1994 is drafted to include an element of the incomprehensibility of Part 2 section 26A (4) drafting,

71. Part 5 section 37 (4) reads, "The General Council may make by rules make provision in connection with…"

72. Although drafting of Part 5 section 37 (4) is probably sufficient to render the subsection effective, nevertheless clarity and drafting consistency require that Part 5 section 37 (4) be redrafted in line with the clear drafting elsewhere in the Order in Parts 1, 3, 4 and so on, and also in line with Part 5 section 37 (6) and Part 5 section 37 (7) which are both clear and consistent with each other.