

OFFICE OF THE ADVISORY COMMITTEE ON BUSINESS APPOINTMENTS

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BUSINESS APPOINTMENT APPLICATION: Dr lan Hudson

The Committee has been asked to consider an application from Dr Ian Hudson, CEO of Medicines and Healthcare Regulatory Service (MHRA). Dr Hudson retired from his post at MHRA in September 2019 and wishes to take up a role at the Bill & Melinda Gates Foundation (the Foundation).

MHRA is an executive agency of the Department of Health and Social Care (DHSC). MHRA is responsible for the regulation of medicines, devices, blood, biological standards, and research services using anonymised healthcare data.

The Bill & Melinda Gates Foundation (the Foundation) describes itself as helping all people lead healthy, productive lives. In developing countries, it focuses on improving people's health and giving them the chance to lift themselves out of hunger and extreme poverty. It describes its Global Health division as seeking innovative, ambitious, and scalable solutions to address health problems that have a major impact in developing countries.

Dr Hudson informed the Committee he has been offered the role of Senior Advisor, Regulatory Affairs, Integrated Development, Global Health. This was following an application for an advertised post and will be a full time, paid role. Dr Hudson said it will focus on Low and Middle-Income countries (LMIC); and working on project work in a number of areas (new drugs for Malaria, drugs for Neglected Diseases, Maternal and Child Health as well as regulatory system strengthening).

Dr Hudson explained the Foundation provides grants to organisations to facilitate its objectives in strengthening global health. In that capacity, the role may include some contact with the government as the Foundation provides grants to organisations that are able to support its aim of supporting healthcare in LMICs. Dr Hudson confirmed that MHRA has been **in receipt** of some grant funding from the Foundation; and it is possible that MHRA might be able to bid for more grants in the future, given the world renown expertise of their

work. He notes other parts of the UK Government and health service may also have relevant expertise that can help in this regard.

In addition, Dr Hudson stated 'the ethos of the Foundation is improving healthcare in developing countries. One which I am sure the UK Government fully supports. My current organisation, the MHRA, is a globally recognised organisation with very specialist and in some cases unique competencies and therefore it is not surprising that we are in receipt of grants from the Foundation for very specialist work. In my Senior Adviser role, I would therefore want to be able to approach UK expertise, and am sure UK Government organisations would want, to be able to participate in this work and be in receipt of Gates funding, in relation to projects I will manage or advise on. I would hope therefore that this could be agreed without any restriction in relation to contact with UK Governmental bodies.'

Dr Hudson provided the following details of grants of which he has varied exposure and involvement in whilst at MHRA:

- a. For the National Institute for Biological Standards and Control (NIBSC) work in 2016/17. The Director of the NIBSC (part of the MHRA) was responsible for this. Dr Hudson said he had no involvement in the delivery; day to day work; or the application for funding.
- b. For strengthening Pharmacovigilance systems in September 2017 (\$1.3m). Dr Hudson said, though he does not manage this on a day to day basis, he discussed the possibility of MHRA's involvement in this work and subsequently the Pharmacovigilance team prepared the bid and managed the work. He met staff from the Foundation on a number of occasions to discuss the progress of this work, together with relevant staff from MHRA's pharmacovigilance team.
- c. For pharmacokinetic modelling in pregnancy in July 2019 (\$318,670). Dr Hudson was aware of MHRA's bid and supportive of it but has not directly been involved in its preparation or any aspect of it. MHRA's Director of its Licensing Division is directly responsible.

Dr Hudson informed the Committee that due to MHRA's work on building pharmacovigilance (PV) systems in developing countries, DHSC together with MHRA colleagues were invited to the Foundation's offices in Seattle in April 2019, where he spoke about MHRA's work. Officials from the Foundation have also visited MHRA to discuss progress in relation to the work they are doing for them in accordance with the PV strengthening grant.

Dr Hudson also noted that he worked with an employee of the Foundation on the Prime Minister's Dementia Challenge (set up by David Cameron). He also met with other employees of the Foundation who visited the Agency in relation to other projects, or at international forums he is part of.

Dr Hudson said the regulatory work of MHRA has a bearing on how medicines are developed, and that some of the regulatory system strengthening work they have done around the world has been, or is being, funded by the Foundation. However, this work will

not have had any bearing on policy (either from MHRA of DHSC) that could affect the Foundation. He also noted that if MHRA had not done the work funded by the Foundation, others would have received the funding to carry it out.

DHSC were consulted on this application and it confirmed the details of Dr Hudson's application. In addition, DHSC noted:

- the Foundation have also provided MHRA with resources to assist in the development and promotion of spontaneous reporting schemes in LMICs; and grants for the preparation of re-agents for use in LMICs.
- there are other Departmental links with the Foundation e.g. on anti-microbial resistance or dementia but these are similarly about the Foundation's part in funding DHSC programmes (not grants from DHSC to them); and not issues handled by MHRA or involving Dr Hudson.
- MHRA and DHSC has provided no funding to the Foundation.
- there has been no opportunity for Dr Hudson to be influenced in his current role as CEO of MHRA, with the hope of future employment.
- the Chair of MHRA, Sir Mike Rawlins, and DHSC do not consider the Foundation '...has anything to gain by this appointment beyond Ian Hudson's personal experience and skills.'
- DHSC has no reservations about this appointment.
- DHSC recommended a restriction on any lobbying of UK government on behalf of the Foundation; and that he be reminded he may not use privileged information gained in his time at the MHRA for the benefit of his new employer.

The Committee's consideration

The Committee¹ agreed with DHSC that there is no particular risk of impropriety in this application. Although Dr Hudson has had some official dealings with the Foundation and worked with them on projects, it is MHRA that has benefitted from the Foundation's funding, on matters aligned to MHRA's work. Further, Dr Hudson applied for an advertised role. Therefore, it cannot reasonably be perceived this offer of employment is a reward for decisions he took in office to the benefit of the Foundation.

The Committee noted that, as he will be working on Global Health, there may be cross over with the work of MHRA, DHSC and wider government, including further applications from the UK Government for funding from his future employer. The Committee considered that routine contact with the UK Government in line with the role as described above would not

¹ This application for advice was considered by Sir Alex Allan; Jonathan Baume; Baroness Angela Browning; Lord Michael German; Lord Larry Whitty and John Wood. Dr Susan Liautaud and Richard Thomas were unavailable.

be improper, as the risk of unfair advantage to the Foundation is low, given the restrictions below. However, it noted that whether or not Dr Hudson should be involved in any future funding discussions is a matter for the Foundation. Although MHRA and DHSC may be seen to benefit from that relationship, the Government's Business Appointment Rules are concerned with preventing an unfair advantage being conferred to his employer.

As with all officials operating at Dr Hudson's level - as CEO at MHRA, there are inherent risks relating to his access to privileged information, and his contacts within government. The Committee considered the ban on drawing on privileged information and the ban on lobbying government that applies to officials under the Government's Business Appointment Rules sufficiently mitigates these risks.

Under the Government's Business Appointment Rules, the Prime Minister has accepted the Committee's advice that this appointment be subject to the following conditions:

- he should not draw on (disclose or use for the benefit of himself or the organisation to which this advice refers) any privileged information available to him from his time in Crown service;
- for two years from his last day in Crown service he should not become personally involved in lobbying the UK Government on behalf of the Bill & Melinda Gates Foundation, its partners or subsidiaries. Nor should he make use, directly or indirectly, of his contacts in Government and/or Crown service to secure funding or influence policy on behalf of the Bill & Melinda Gates Foundation, its partners or subsidiaries. This does not preclude routine contact on matters relating to his duties as Senior Advisor, Regulatory Affairs, Integrated Development, Global Health.

By 'privileged information' we mean official information to which a Minister or Crown servant has had access as a consequence of his or her office or employment and which has not been made publicly available. Applicants are also reminded that they may be subject to other duties of confidentiality, whether under the Official Secrets Act or otherwise.

The Business Appointment Rules explain that the restriction on lobbying means that the former Crown servant/Minister "should not engage in communication with Government (Ministers, civil servants, including special advisers, and other relevant officials/public office holders) – wherever it takes place - with a view to influencing a Government decision, policy or contract award/grant in relation to their own interests or the interests of the organisation by which they are employed, or to whom they are contracted or with which they hold office."

I should be grateful if you would ensure that we are informed as soon as Dr Hudson takes up this position, or if it is announced that he will do so (I enclose a form for this purpose). We shall otherwise not be able to deal with any enquiries, since we do not release information about appointments which have not been taken up or announced, and this could lead to a false assumption being made about whether he had complied with the Rules.

I should also be grateful if you would ask that Dr Hudson informs us if he proposes to extend or otherwise change the nature of his role as, depending on the circumstances, it may be necessary for him to make a fresh application.

Once this appointment has been publicly announced or taken up, we will publish this letter on the Committee's website, and where appropriate, refer to it in the relevant annual report.

Yours sincerely

Tiffany Amusu
Committee Secretariat

