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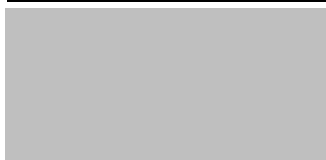
COMMISSION ON HUMAN MEDICINES

Minutes of the Videoconference Meeting held on Thursday 25<sup>th</sup> May 2023 at 09:00 via MS Teams

**Commissioners Participated**

- Professor Sir Munir Pirmohamed (Chair)
- Professor A Adler<sup>1</sup>
- Professor J Coleman
- Mrs J Cons
- Professor S Cunningham (Vice-Chair)
- Dr J Fraser
- Professor D Hunt
- Dr G Mortimore
- Professor S Padmanabhan
- Professor P M Patel
- Professor Y Perrie
- Professor R Providencia
- Dr V Raymont<sup>2</sup>
- Professor M Turner<sup>3</sup>
- Professor H Wallace<sup>4</sup>
- Professor C Weir
- Dr M Wilson

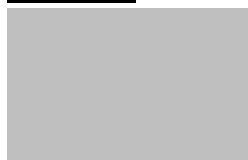
**Apologised for absence**



**Invited Experts**



**Observer**

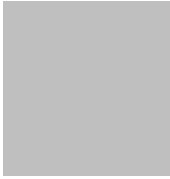


**MHRA Professional Staff Attendees**

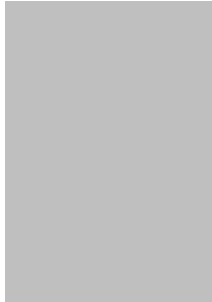
- [Redacted] - HQA
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- [Redacted] - S&S
- A Cave - Chief Safety Officer
- [Redacted] - Comms
- [Redacted] - S&S
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- [Redacted] - S&S (CHM Principal Assessor)
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- [Redacted] HQA
- [Redacted] - S&S
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- [Redacted] - S&S
- [Redacted] - HQA
- [Redacted] - HQA
- [Redacted] - Clinical Trials







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Government Legal Team<sup>9</sup>



Secretariat



-  – MHRA - NIBSC
-  – Clinical Trials
-  – S&S
-  – S&S
-  - HQA
-  – S&S



27<sup>th</sup> July 2023

- 1 Stepped out from 12:00 – 13:30
- 2 Stepped out from 13:30-14:30 & at 16:00pm
- 3 Stepped out at 12:00
- 4 joined at 10:00
- 5 joined for item 10.1
- 6. joined for item 11.1
- 7 observed for item 11.1
- 8 observed meeting on Thursday
- 9 available to join call if needed

**Key**

- HQA** = Healthcare Quality & Access Group
- S&S** = Safety & Surveillance Group
- NIBSC** = National Institute for Biological Standards & Control
- Comms** = MHRA Communications & Engagement

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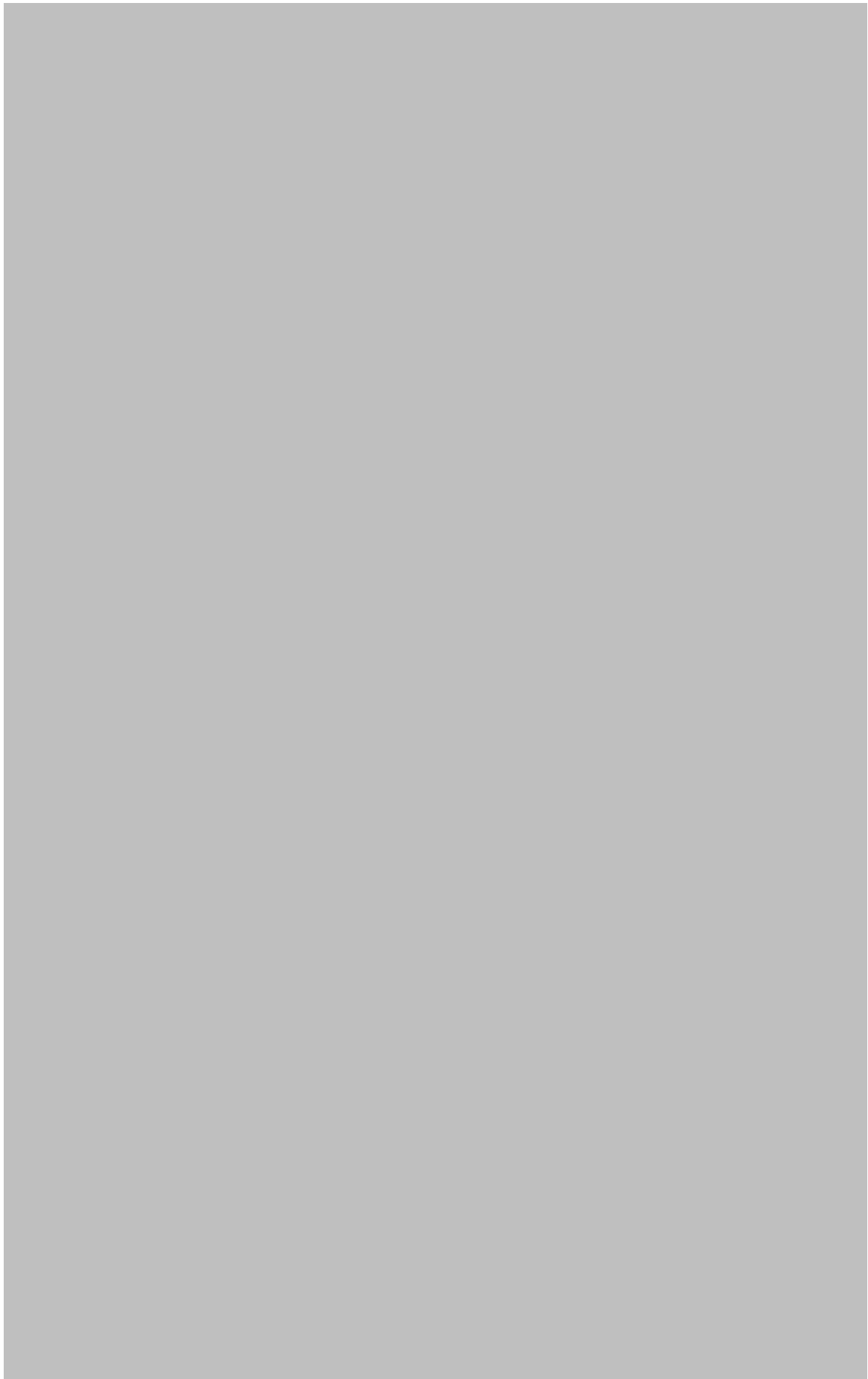
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**10. Feedback from Non-Medical Prescribing EWG 23/11/2022**

- 10.1** The Commission was presented with feedback from the Chair of the Non-Medical Prescribing Expert Working Group (EWG) at its meeting on 25 May 2023. The Non-Medical Prescribing EWG met in November 2022 to discuss non-medical prescribing with people representing biomedical scientists and clinical scientists.
- 10.2** This topic first came to the CHM in October 2021 where the CHM advised they did not support access to Patient Group Directions (PGDs) for therapeutic purposes for biomedical scientists but would be content for them to use PGD's for diagnostic purposes. The CHM was willing to consider a case for a specific range of medicines for therapeutic purposes.
- 10.3** The Commission heard that the queries that came back to the EWG were whether the CHM's decision applied to all biomedical scientists, and whether the CHM was concerned about the specific examples provided at the original presentation. It was also clarified that no examples of controlled drugs were provided and there was some misperception that biomedical scientists worked only in laboratories.
- 10.4** Meeting the stakeholders at the expert panel facilitated discussions around a few points and clarification around other points including those that came up in the previous public consultation discussed at the CHM meeting in October 2021. The Chair of the EWG summarised the discussions for the CHM and covered the clarification provided by the stakeholders on
- A) Current and evolving roles of biomedical scientists and clinical scientists.
  - B) Examples of medicinal products that biomedical scientists and clinical scientists could supply using PGDs in their current work setting and the EWG's views regarding the specific examples.
  - C) Scope of practice and the concerns of the EWG regarding the uniform availability of support systems.
  - D) The EWG's recommendations for the required structure for training and oversight and discussion on the plans for national guidance work and the work needed in this area.
  - E) The EWG's recommendations and suggestions for taking this topic forward at future discussions.
- 10.5** The Commission discussed the feedback from the EWG and endorsed the issues raised by the EWG on PGDs for therapeutic products. The Commission also agreed with the advantages identified by the EWG on PGDs of certain medicines for diagnostic use by the biomedical scientists and clinical scientists. The Commission also endorsed the EWG's views that such supply of diagnostic

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products which are usually one-off situations rather than continued treatment administration could be safely managed with appropriate training and oversight.

**10.6** For both professions (biomedical scientists and clinical scientists), the Commission supported the approval of PGD's to supply certain medicines for diagnostic use.

**10.7** However, for both professions (biomedical scientists and clinical scientists), the Commission did not support the approval of PGD's for therapeutic use at the moment.

**10.8** Before PGDs for supply of medicines for therapeutic use could be allowed, more work needs to be done and the stakeholders should come back with improved proposals. The Commission considered that compelling and well characterised examples along with an assessment of the risks and benefits would be needed from biomedical and clinical scientists showing how the ability to prescribe for therapeutic use will be safe and improve the patient journey.

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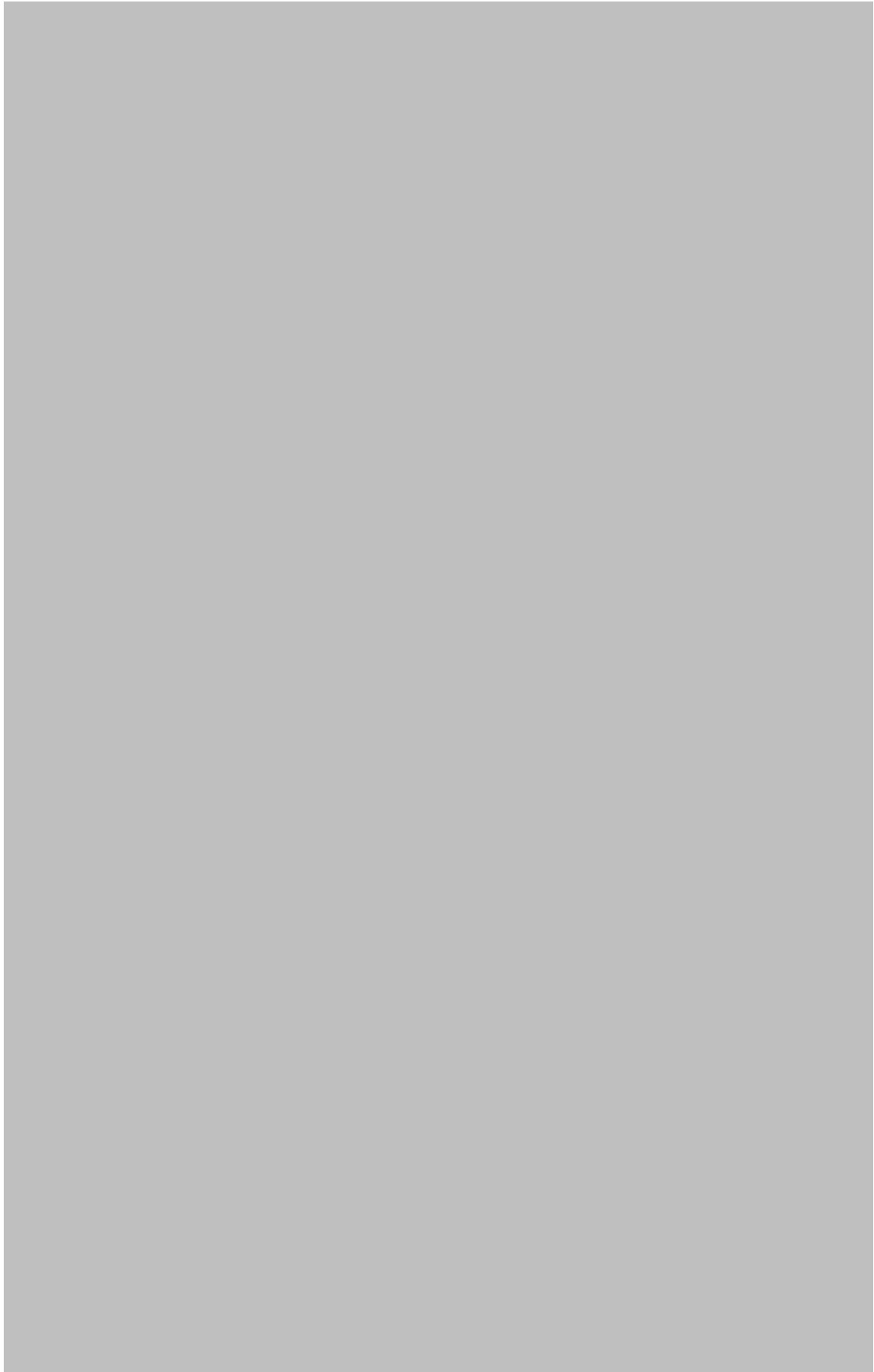
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## Annex 1

**Declaration of Interest**

Commissioners, Co-opted Member(s) appointed as Member for the day, Invited Experts and Observers adhere to the [Code of Practice for Members of the CHM](#). Following is the list of declarations submitted by members/experts; evaluation of declared interests and decision taken for the meeting held on Thursday 25<sup>th</sup> May 2023.

Key: NPNS = Non-personal non-specific, NPS = Non-personal specific, Other relevant interests

Name	Interest
Commissioners	
Professor Sir Munir Pirmohamed (Chair)	<p><b>NPNS – Sandoz / Novartis / Bayer</b></p> <ul style="list-style-type: none"> <li>Risk minimisation for disabling or long lasting ADRs with fluoroquinolones.</li> </ul> <p><b>NPNS – Sanofi</b> - they are part of the IMI initiative ARDAT</p> <ul style="list-style-type: none"> <li>Valproate – the recommendations of the Valproate Implementation Expert Working Group</li> </ul> <p>With regards to Bayer, they are part of the IMI award ARDAT (<a href="http://www.ardat.org">www.ardat.org</a>), while for Novartis, they fund research training as part of the MRC Clinical Pharmacology Training scheme (as per Sir Munir’s annual declarations).</p> <p><b>Other interest – Fluoroquinolones</b> - Professor Sir Munir Pirmohamed has agreed to be the secondary supervisor for a research project looking at the experience of FQAD/fluoroquinolones.</p> <p>The declared interests did not debar Professor Sir Munir Pirmohamed from chairing the proceedings.</p>
Professor Amanda Adler	<p><b>NPNS – Bayer</b></p> <ul style="list-style-type: none"> <li>Risk minimisation for disabling or long lasting ADRs with fluoroquinolones.</li> </ul> <p>The declared interests did not debar Professor Adler from participating in the discussion.</p>

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Professor Jamie Coleman	<p><b>NPNS – University of Birmingham.</b></p> <p>Professor Coleman is the associate medical director; however, Professor Coleman is not involved in the trial.</p> <ul style="list-style-type: none"> <li>• ALETA-001</li> </ul> <p>The declared interest did not debar Professor Coleman from participating in the discussion.</p>
Mrs Julia Cons	None
Professor Steven Cunningham	<p><b>Other Interest – Abbvie Ltd</b></p> <ul style="list-style-type: none"> <li>• Risk minimisation for disabling or long lasting ADRs with fluoroquinolones.</li> </ul> <p><b>NPNS – GlaxoSmithKline UK Limited</b> - PI for maternal RSV Vaccine Trial</p> <ul style="list-style-type: none"> <li>• Dostarlimab</li> </ul> <p><b>Other Interest – Abbvie Ltd</b> - work with US Cystic Fibrosis Foundation Data Safety Monitoring Board and allocated a role on AbbVie product DSMB)</p> <ul style="list-style-type: none"> <li>• Atogepant</li> </ul> <p><b>NPNS – Boehringer Ingelheim International GmbH</b> - Member of Trial Steering Committee and Local PI for Nintedanib in children with interstitial lung disease</p> <ul style="list-style-type: none"> <li>• Spevigon</li> </ul> <p>The declared interests did not debar Professor Cunningham from participating in the discussions.</p>
Professor Paul Dargan	Apologised for absence at this meeting
Professor David Dockrell	Apologised for absence at this meeting
Dr Jamie Fraser	None
Professor David Hunt	None
Professor David Moore	Apologised for absence at this meeting
Dr Gerri Mortimore	None
Professor Sandosh Padmanabhan	None

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Professor Poulam Patel	None
Professor Yvonne Perrie	<p><b>NPS - Cancer Research UK Formulation Unit, University of Strathclyde</b></p> <p>This unit sits within the Institute Professor Perrie is employed and whilst Professor Perrie does not line-manage the team directly or have direct involvement in their activities, she is Head of the Institute and the CRUK FU sits within the Institute buildings, budgets and her responsibility lines.</p> <ul style="list-style-type: none"> <li>• ALETA-001</li> </ul> <p>At the Chair's discretion, Professor Perrie was permitted to join the discussion and to answer specific questions from the Chair, but not volunteer any spontaneous comments.</p>
Professor Rui Providencia	None
Dr Vanessa Raymont	None
Professor Marc Turner	None
Professor Heather Wallace	None
Professor Christopher Weir	<p><b>NPNS - in University Hospital Birmingham NHS Foundation Trust.</b> Professor Weir is a co-applicant with colleagues from that institution on a programme grant funded by NIHR PGfAR for a project developing and evaluating an antimicrobial stewardship intervention in electronic prescribing systems.</p> <ul style="list-style-type: none"> <li>• ALETA-001</li> </ul> <p>The declared interest did not debar Professor Weir from participating in the discussion.</p>
Professor Anthony Williams	Apologised for absence at this meeting
Dr Martin Wilson	None
<b>Invited Experts</b>	
████████████████████	None
██████████	None
<b>Observers</b>	
██████████	None

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[REDACTED]	None
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