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Mr Roderic O'Gorman TD
Minister for Children, Equality, Disability, Integration and Youth
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23 March 2021

Re: Commission of Investigation into Mother and Baby Homes and certain related matters

Dear Minister,

I am writing to you in response to your letter of 12 March 2021 to the Chief Executive of GSK, Emma Walmsley.

We deeply sympathise with all the former residents of mother and baby homes in Ireland. The Commission of Investigation's report makes for distressing reading and sheds light on the hardship and suffering of innocent women and children. We hope that the publication of the report and the ameliorative steps that are being taken in light of the report's recommendations will help former residents and their families.

As a company, we fully supported the work of the Commission. As the report notes, we carried out searches of our archives for any relevant documents held regarding The Wellcome Foundation Limited and Glaxo Limited – both legacy companies of GSK – and we sought to address, to the best of our ability, the Commission's requests for information regarding clinical trials conducted in the relevant institutions during the period 1934-1973. We provided the Commission with copies of the documents that were identified.

However, records from so long ago are inevitably incomplete. Unfortunately, there are also no living witnesses remaining who were involved in the running of the clinical trials that we could speak to about the events of that time. As a result, it is very difficult to fully understand or comment on events which occurred so many decades ago.

The records we shared with the Commission showed that the trials were conducted by a number of experienced medical researchers. These included the late Professor Patrick Meenan, Professor of Medical Microbiology at University College Dublin (UCD) and head of the university's National Virus Reference Laboratory; the late Dr Irene Hillary, a public health practitioner and lecturer in medical microbiology at UCD; the late Dr Victoria Coffey, a paediatrician, medical researcher and lecturer at Trinity College Dublin; and the late Dr Margaret Dunleavy, a medical researcher and public health doctor specialising in childhood immunisation.

While the trials involved products under development by Glaxo and Wellcome, these independent researchers, as the individuals conducting the trials, were personally responsible for ensuring that they

were carried out with the licenses, permits, permissions and consents required under Irish law and practice at the time. We are disappointed to read the findings in the report that, based on the available evidence, there were failings in fulfilling those responsibilities, particularly in the context of seeking and/or receiving appropriate consents.

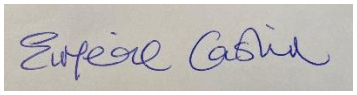
Despite this, each of the trials described in the report was bona fide and undertaken for the purpose of legitimate medical and scientific investigation into improvements to essential childhood vaccines and, in one trial, infant milk products. Importantly, the report concluded no adverse injuries were experienced by children involved in these trials.

It is also very important to state that the failings with regard to consent and documentation identified in the report do not reflect how clinical studies are conducted today. In today's clinical studies, participants or their parents/guardians must give their informed consent to participate after being told about the study, its potential benefits and its potential risks. Withdrawal from a clinical study remains the right of all participants.

We appreciate the overwhelming public reaction to the report's publication and the calls for institutions to reflect on their response. While the findings of the Commission's report are extremely upsetting, they do not question Wellcome or Glaxo's responsibilities and duties in developing, manufacturing and supplying vaccines for the purposes described above. For this reason, we do not propose to pay reparations in response to the issues raised in the report.

We are, however, aware that many former residents are understandably seeking to access their personal information on these events. As the holders of records from these clinical trials, we've reflected on how we may be able to improve and expedite the way we share personal information with former residents. To this end, we propose to set up a dedicated and confidential information service to assist in responding to questions from former residents and their families. We are keen to work with your department to explore how best to enable this in line with government plans and we would welcome the opportunity to discuss this proposal further. We hope this would go some way to support those who are searching for more information and transparency relating to their personal experience or that of their families.

Yours sincerely,



Eimear Caslin

General Manager

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