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Dear Raj,

Government Response to Independent Report; Finding a Path for the Cure for Dementia

As the Ministers responsible for dementia and drug devlopment policy respectively, we are writing to extend our personal gratitude for the time and expertise you have given to the Department of Health over the last eighteen months in leading work to help shape an innovative approach to accelerating drug development for dementia. Dementia remains an immense challenge. Over 47 million people already live with this life shattering disease worldwide, with the number expected to rise to over 75 million over the next fifteen years. By 2030, it is estimated the cost of caring for people with dementia worldwide could rise to US \$2 trillion.

In 2013 the UK Government made it a priority to tackle this global challenge through our presidency of the G8. Alongside our global partners we made a commitment to finding a disease-modifying therapy or cure for dementia by 2025. The Integrated Development initiative was therefore established in order to assess what work could be undertaken in the regulatory space to create a better environment for dementia drug development, guided by your knowledge and experience.

With your leadership we have been able to bring together regulators from ten jurisdictions in an unprecedented manner, allowing them to work together voluntarily on identifying opportunities for improvement. This work has already facilitated increased collaboration amongst regulatory agencies, and will continue to make a real difference in dementia drug development. It will also act as an incentive to encourage investment and research to take place, working alongside other UK initiatives such as the Dementia Discovery Fund.

There is consensus amongst our stakeholders that this work should carry on, and should be appropriately supported in the future. We know that regulators too are keen to ensure this work continues, and is linked to other innovative initiatives, including international research networks. The UK Government will continue to have a role in the facilitation and promotion of this work.

The outputs of this ground breaking initiative could also go beyond the scope of tackling dementia alone. For example, we are sure that the Office for Life Sciences will explore the potential for making use of this learning within the Accelerated Access Review.

The Department welcomed the publication of your independent report in July this year, building on the recommendations which you shared with us at the first World Health Organisation (WHO) Global Ministerial Conference on Global Action on Dementia. We acknowledge your 'actions for change' and the direction that you consider the international community needs to move in to improve the dementia drug pathway. These actions build on the Integrated Development work of the UK Department of Health to date, and will provide a core component of the next steps in our global effort.

The Department of Health has therefore been working with an advisory group of key stakeholders to explore how policy devleopment can align to, and be informed by, your recommended actions for change.

Your report highlights the limitations of the current scientific knowledge around dementia, and makes clear that the challenges in dementia drug development cannot be solved through regulatory measures alone. We and international partners are actively promoting research that will increase knowledge of the science around dementia.

We also welcome the steps that are being taken by our global partners in this area. It is noted that The EU Joint Programme – Neurodegenerative Disease Research (JPND) and the US National Institute on Ageing already share common objectives and will take initial steps to work in closer alignment. These are conversations for the relevant national research agencies and related bodies to progress. Through our support for the WHO Observatory on Dementia the Department of Health will stay connected to ongoing collaboration in dementia research on a global level.

Your report also highlights the difficulties that exist around data sharing and assessment of clinical evidence. This is a complex topic, however we are aware that there is increasing collaboration on this matter, and that our partners finding innovative ways to work together.



Finally, we are interested in your idea of an international platform of dementia experts, able to advise along the process of finding potential cures for dementia. We are currently working with key stakeholders to explore how this could integrate with UK dementia research strategy.

We have welcomed this opportunity to explore your recommendations with stakeholders and organisations, and to open up opportunities for future alignment and collaboration. We attach a response, which summarises our conversations to date.

In the coming months we will continue to work on the implementation plan for the Prime Minister's Challenge on Dementia to 2020, it will take into account your report and will outline the next steps for the UK, and will be publish in the New Year. We will also be working closely with partners who have agreed to explore your 'actions for change' to ensure we develop a sustainable strategy and approach for the future. We would very much welcome your involvement in these discussions and we know that Jon Rouse and his team are working closely with you to discuss this in more detail.

Yours sincerely,

JANE ELLISON MP

GEORGE FREEMAN MP