Statement to the Joint Oireachtas Committee on Health
Mr. Jim Breslin, Secretary General, Department of Health
16 May 2017

- I would like to thank the Committee for the opportunity for myself and Dr Tony Holohan, Chief Medical Officer of the Department of Health to meet with you this morning and to share some opening remarks.

- I would at the outset like to recall the bravery of Ms Vicky Phelan, Ms Emma Mhic Mhathúna and the loved ones of other women that have come forward in recent days. Their testimony, and their willingness to speak publically about deeply personal matters has raised very serious questions. These questions relate to how the health service engages with individuals when things go wrong and the fact that the audit results for these women were not conveyed as they should have been.

- The CervicalCheck programme was established to help prevent cervical cancer. Before it was introduced we were not making any impact on cervical cancer but following its introduction we are seeing steady reduction each year. But every time a cervical cancer is not prevented it is a tragedy. That is compounded when women who have been diagnosed with cancer are not properly informed of the results of a subsequent audit. I would particularly like to acknowledge the powerful and deeply generous nature of the advice which is given when women who have had such painful experiences encourage others to continue to participate in the programme in the interests of their health.

- These powerful testimonies place on all of us a responsibility to act to address weaknesses while sustaining the national cervical cancer screening programme in the interests of current and future generations of Irish women. The Department is committed to discharging its particular responsibility to take the necessary steps, in association with the HSE, health professionals and others, to restore the trust of women in the CervicalCheck programme, and indeed in relation to our health service more generally.
• Last week, the Government commissioned a leading UK expert, Dr Gabriel Scally, to conduct an inquiry to establish the facts and to review all aspects of CervicalCheck. We are determined to do everything we can to assist Dr Scally in his enquiries, so that we can all find out what happened and why it happened. And to make sure that we have a robust cancer screening programme for women, and that lessons are learned for the future.

• But the focus needs to be on the women most affected as well as the CervicalCheck programme. On Friday last the Government agreed a comprehensive package of health and social care measures to support the 209 women and their families who have been diagnosed with cervical cancer and whose audit result differed from their original smear test. The Government has committed to ensuring that these women and their families are supported to the fullest extent possible.

• The health and social care measures include:

  ➢ a discretionary medical card for each woman affected, or their next of kin in cases where the woman has sadly died, so that they can avail of health services, including medicines provided under the medical card scheme, free of charge;

  ➢ out-of-pocket medical costs incurred including the cost of any medicines which have been prescribed by their treating clinician;

  ➢ primary care supports, including counselling for the women affected. Also counselling services for the immediate family members of these women, including bereavement counselling where needed;

  ➢ other health and social care supports, including travel costs and childminding.
• An International Clinical Expert Review Panel is also being established as part of the Government’s investigation into CervicalCheck. The main purpose of the panel is to provide women with facts and independent expert assessment of those facts. The panel’s findings will also contribute to the overall independent assessment of the quality of the CervicalCheck programme.

• The review will consider all cases of invasive cervical cancer in Ireland since CervicalCheck was established. Women who developed cancer and who were screened by CervicalCheck will be identified and their screening histories will be examined. The expert panel will review the cases of those women who had previous screening tests prior to their diagnosis and undertake a re-examination of cytology tests. Where the expert panel opinion of cytology results differs to the original results provided by CervicalCheck, the panel will endeavour to determine, wherever possible, any failures to prevent cancer or to intervene at an earlier stage and will prepare individual reports for those affected, setting out the facts and their expert and independent assessment.

• The Government has also announced that the State Claims Agency is advancing a new initiative aimed at expediting resolution of the nine outstanding legal cases in a sensitive manner utilising mediation wherever possible.

• In addition, last week, the Minister for Health received Government approval to provide in law for mandatory open disclosure, through the forthcoming Patient Safety Bill, in respect of serious patient safety incidents. The Bill will also provide for mandatory reporting of these serious events to the appropriate regulatory authority, such as HIQA.

• Yesterday the Department published records relating to the CervicalCheck clinical audit. The information submitted by the HSE in relation to this audit in 2016 provided the Department with an understanding that this was a retrospective clinical audit undertaken for quality assurance and learning purposes and that CervicalCheck had a clear objective
to provide results to consultants in order to allow for direct communication with the women concerned. Both clinical audit and communication of the results of clinical audit to women were seen by the Department to be very worthy and valuable undertakings by the CervicalCheck programme. Clinical audit is an important means by which standards are maintained and advances made in health care.

- I believe that a reasonable approach was taken by the Department at the time based upon the information available to it. There are two ways of looking at issues – based upon the information available at the time or with hindsight. Of course had the subsequent widespread non-disclosure been escalated by CervicalCheck within the HSE and raised with the Department, this would have triggered a major concern and a much different attitude. But, based upon the information we had, we viewed the initiative taken to communicate audit findings to women in a positive light.

- However, the widespread and still unfolding distress caused by the non-disclosure of the clinical audit results to the women concerned demands serious reflection. The Scally Inquiry provides us with a mechanism to get an objective basis for introducing improvements, where these can be identified. The Department has at this stage publicly committed to engaging with the HSE on a full review of the implementation of its Open Disclosure Policy.

- As I have mentioned the Government has approved the drafting of a Patient Safety Bill by the Department. This Bill will provide a mechanism to develop and introduce standards relating to clinical audit so as to ensure that open disclosure, including roles and responsibilities for such disclosure, are fully addressed in advance of commencement of an audit. As the CervicalCheck experience shows it is important to anticipate the issues that will arise for the disclosure of clinical audit findings before commencing the process. The clinical audit standards to be introduced under the Patient Safety Bill should also entail a responsibility to record the fact that open disclosure has taken place.
• I look forward to the recommendations produced by the Scally Inquiry. The Inquiry will produce an interim report at the start of June and a final report by the end of June. The Department will be subject to this Inquiry but the Committee can be assured we will provide full support and cooperation and address any learning and recommendations as a matter of priority.

• Chairman, with your agreement, I will ask Tony Holohan to offer some additional remarks.