International Right to Know Day event 2014 - Speech by Emily O'Reilly, European Ombudsman

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Thank you Chair. I will set out, over the next few minutes, the arena of this debate from the viewpoint of the European Ombudsman. But before I do that I want to make some personal observations about the pharmaceutical industry.

I first visited the New York in 1983, just as consciousness of the emerging HIV/AIDS epidemic was reaching a peak. By that time, many friends of mine – young gay men – had left a deeply hostile atmosphere towards homosexuality in Ireland to embrace the accepting culture of the East coast . Many of them, in the late 1980's and 1990's, subsequently died from AIDS related illnesses. Thirty years later, all has changed. HIV infection has become a treatable, and may even become a curable disease. Scientific and pharmaceutical advances have made it possible to categorise HIV as a chronic illness, rather than necessarily a terminal one. Many with HIV can now, as a result, live full lives, at least in the wealthy first world.

As a child in the 1960s, my generation routinely caught measles, rubella and mumps with children dying every year as a result. To a large degree all of those diseases are now contained through vaccines.

I make these points so as not to lose sight of the profound good that developers of medicines do. Medicines save lives. Pharmaceutical companies, many of which invest billions to identify, develop and bring to market new medicines, are responsible for alleviating the suffering of countless millions. It is in the public's interest that the industry be enabled to work well and encouraged in particular to put its expertise and financial muscle to greater use in the developing world where millions still die from what are easily preventable illnesses in the first world.

But when we take medicines, or when we give medicines to our families, our children, we do so not as scientists but as trusting and largely ignorant laypeople.

If that trust is undermined, we all lose out. Most importantly, persons who become wary of taking certain medicines may put themselves, and in some cases others, at risk, as when an insufficient number take up a vaccine in a population and the relevant disease is either reawakened or never fully subdued.

Parents face this dilemma frequently. Should I trust that the vaccine prescribed to prevent my daughters getting cervical cancer in middle age will do them more good than harm? Should I trust the anti acne treatment prescribed for my son when I read of reports of

suicidal ideation or am aware of cases of young adult suicides in the course of taking the drug? When a pandemic flu scare prompts panicked public health system to rush out a vaccine, how do I know that it's completely safe? If I sense that the truth is being withheld or spun, my trust in that and other medicine will be diminished, with potential negative consequences for myself or for my family.

It would seem therefore rational to the ignorant but trusting laypeople that the information which was used to reach the conclusion that a medicine is safe and effective be subjected to extensive independent review. After all, the very nature of science, of reliable science, is that evidence, and the conclusions drawn from that evidence, will be open to review by others.

It would also seem rational that pharmaceutical companies themselves should be more than willing to build trust in their products through transparency. Trust builds the bottom line.

Scientists who work for regulators, who are entrusted with the task of verifying that medicines are safe and effective, also have an interest in transparency. They know that it is only through transparency that their work can be reviewed by their peers, and, if necessary, improved. They know that if they are prevented from being transparent, their work will be less reliable, or perceived as less reliable.

As European Ombudsman, I have a responsibility to ensure that the EU public administration acts transparently. This is particularly important in relation to those EU agencies that are entrusted to ensure that products and practices used and executed in Europe are safe. I have therefore instructed my staff to pay careful attention to the work of EU's regulatory agencies, such as the European Chemicals Agency, the European Aviation Safety Agency, the European Food Safety Agency and the European Medicines Agency, the EU agency with responsibility for evaluating the safety and efficacy of medicines before they can be placed on the market in Europe and for monitoring the effects of medicines that are already on the market.

In early September I wrote to The Food Safety, Chemicals and Aviation Safety agency to ask them about their plans to adopt transparent policies. This was inspired by EFSA's public consultation on its efforts to become an Open Science organisation and from information we had received that ECHA and EASA are also looking into this question. I suggested that Open Government Partnership initiative could be useful inspiration for their work.

It was therefore enormously encouraging that the European Medicines Agency, at the insistence of the Ombudsman, who had investigated the Agency's refusals to release information on the effects of antiobesity and antiacne drugs, and at the insistence of campaigners who had long sought greater transparency, transformed its approach to transparency in 2010. It was encouraging that the Agency began to respond positively to requests for public access to clinical study reports and even to fight, in court, attempts by some pharmaceutical companies to block the release of those reports. It was encouraging that it committed to adopting a proactive transparency policy.

I am not, in this brief address, going to deal with subsequent events other than to say that I

am continuing to examine closely whether the European Medicines Agency continues to be as committed to transparency and I look forward to Mr Rasi outlining the challenges he has faced in this area.

I have, in the last 5 months, opened three transparency investigations concerning the Agency. The first concerns public access to clinical study reports relating to an important anti-inflammatory drug. That inquiry was prompted by the settlement, reached between the Agency and the pharmaceutical company that markets that drug, which involved the pharmaceutical company dropping its court case against the Agency in return for the Agency agreeing not to disclose parts of the clinical study reports. My staff has already carried out an inspection of the Agency's file in that case and I will shortly ask the Agency to respond in writing to a series of questions .

I have also, following a complaint from a journalist, opened an inquiry relating to public access to the Agency's databases. Finally, I have opened an inquiry relating to a refusal by the Agency to give access to submissions made to it, by industry and others, on the Agency's revised proposals to make its documents available proactively.

Separately, I can inform you that once that revised proactive policy is adopted by the Agency in October, I will examine it closely to ensure that it meets the highest standards.

So with that brief overview of the role that my office is playing in this area, I will thank you for your attention and hand you back to the chair.