Access to Medicines Ireland – Opening Statement

We are very grateful for the invitation to attend today and we very much welcome this opportunity to address the topic of fair and equitable access to medicines.

My name is Kieran Harkin and I am a GP based in Dublin, Robbie Lawlor has HIV and is an advocate for persons with HIV globally while Ciara Conlan is a doctor based in St. James’s Hospital.

We are all founder members of Access to Medicines Ireland (AMI), a group of medical professionals, patients and concerned members of the public campaigning to ensure that medicines are made accessible at a fair price and that medical research and innovation is directed at areas of greatest global health need. We are a membership group of Comhlámh, a registered charity, which is an organisation of development workers.

Members of the Joint Oireachtas Committee on Health will be aware that health systems across the world are faced with the challenge of delivering safe and effective care within the context of limited budgets. This is certainly the case in Ireland, with our growing and ageing population.

This challenge is compounded by spiralling medicine costs and the ever-increasing demand for access to new, high-tech and innovative medicines for patients in need.

It is clear that unless addressed, the current system of medicines development and commercialisation will continue to heap financial pressure on already strained health systems with consequent pressure on governments to reimburse medicines at any price. It will also continue to deny patients access to essential medicines.

Members of the Committee will be familiar with examples of problems of access to medicines in Ireland and in particular access to ‘Orphan Drugs’ which are drugs developed for the treatment of conditions that affect less than 5 per 10,000 population,

In 2017, following a long public campaign, the Irish Government approved reimbursement of Orkambi although two years later many European countries including the UK have withheld approval for reimbursement because of high prices.

Other examples of drugs to receive media attention in recent times include Spinraza to treat infantile spinal muscular atrophy; Pembro, a drug to treat certain forms of cancer and Respreeza, used to treat certain types of lung emphysema.

However it is when high prices are attached to drugs used to treat more common diseases that the greatest economic challenge arises.

New Hepatitis C treatment drugs were introduced to Ireland in 2014 with a list price of €46,000. Due to the estimated 50,000 patients in need of treatment at this time this carried an estimated budget impact of €2.25 billion.
Fortunately a number of similar drugs came on the market in 2015 and the monopoly was therefore weakened with a subsequent drop in price.

The difficulties we currently face will appear minimal when compared with new cancer treatments, such as CAR T-cell treatments coming on to the Irish market (currently in US). Impressive results have been reported in clinical trials but they are expensive with a price tag of €450,000 per patient.

The fundamental problem of the current model is that a 20 year period of market exclusivity - a monopoly granted as the reward for successful R&D - during which time pharmaceutical companies set prices with a focus on extracting the maximum amount that a buyer is willing to pay for a medicine.

In contrast, the pharmaceutical company will be able to negotiate a deal with any number of countries at the same time and can thus readily put pressure on governments unwilling to pay.

While the pharmaceutical industry might claim that high prices are essential to encourage innovation, a recent WHO report (10) on cancer drugs concludes ‘Concerns that lower cancer medicine prices might impair future R&D seem misplaced because evidence suggests that (a) prices of cancer medicines bear little or no relationship with R&D costs; (b) financial returns of cancer medicines are high; (c) potential impact on revenue due to lower prices could be offset by higher volume, especially when the marginal cost of production is low’; and (d) governments and the non-profit-making sector have made substantial contributions to the R&D of medicines through direct funding and other incentives'

In addition we know that the Pharmaceutical industry spends only 8% of their global sales on R&D (1), equivalent to approximately half their marketing expenditure (2)

Other problems with the current R&D model are;

- **Lack of financial transparency** to justify prices with industry citing ‘commercial sensitivity’.
- R&D is directed towards projects which are likely to **maximise shareholder profit** as opposed to public health gain. Hence a plethora of ‘me too’ drugs of limited therapeutic advantage and an absence of research into new antibiotics to address the problem of antimicrobial resistance.
- **‘Silo’ based research** with companies working on similar projects in isolation from each other with duplication of research missed opportunities for shared learning
- **High expenditure on marketing** (1)
- **High senior management salary** costs (CEO of Biogen €12 million ‘compensation costs’ 2017)
- **Huge (30%) public investment** in R&D is funded globally from public sources (3) without public return (paying twice for a drug!)
We recognise the efforts of the Irish Government to try to contend with this issue. They have introduced Reference Pricing and Generic Substitution, negotiated deals at a national level with the IPHA and have entered the BeneLuxA pact at an EU level, all in an effort to ensure and improve access…...and this has delivered some savings and promises to deliver more. In February 2018 this committee has issued a report on evaluation orphan drugs and a bill is currently being moved in the Dáil to try and address some of the associated difficulties.

We commend the Irish government on joining the BeNeLuxA initiative and believe that this initiative will strengthen Ireland’s strategic position when negotiating the pharmaceutical industry.

In Britain (4), Canada (5) and the Netherlands (6) we have seen Parliamentary Health Committees work to advance the case for an improved system. We have seen the Italian Government propose a resolution (attached) to the WHA (May 2019) seeking to improve transparency of pricing, R&D and production costs including public sources of funding.

**Recommendations**

*Public funding* should be directed preferentially towards projects that are needs-driven, demonstrate transparency, and are likely to result in an affordable end product with funder input to drug price (8)

*Alternative incentives for R&D* should include up front government funding in the form of grants and prizes. All medicines developed as a result would be ‘patent free’ and be manufactured generically at affordable prices. Such models have led to successful R&D by Public Private partnerships such as DNDi. Ultimately an EU grouping or an global organisation such as the WHO R&D observatory needs to be established as suggested by the UN High Level Panel on Access to Medicines (9)

*Support Italian resolution* on Transparency to WHA * (letter and draft resolution attached) that would give the World Health Organization an “authoritative mandate to strengthen WHO’s technical work” on transparency of both R&D costs and drug prices, Grillo wrote in a letter to World Health Organization Director General Tedros Adhanom Ghebreyesus. Dated February 1, have been making the rounds among governments and civil society groups.

*Consider the use of WTO TRIP’s exceptions* such as compulsory licencing for certain drugs- eg Spinraza? UK parliament in February discussed compulsory licence for Orkambi - this has put pressure on vertex the company prior to further negotiations this month. Within recent weeks the Swiss government have been petitioned to issue a compulsory licence for a Roche’s cancer treatment drug Perjeta.

*Inter governmental and inter agency support* We believe a better system is possible but will only be delivered by parliaments recognising the problem and working together to find a solution. Governments need to work collectively in order to successfully negotiate with global industry.
Conclusion

In conclusion we believe that the current R&D model is unsustainable and that it has the potential to bankrupt health care systems while failing to advance public health. At present we have an industry driven model whose key objective is shareholder profit.

We believe that radical reform of the drugs R&D model is required and that Governments must take direction of the system and place public health and patient welfare at the centre of the process. We believe such a model can be created with greater equity and cost efficiency when driven by public interest.

We would like to quote Professor Mariana Mazzucato in her editorial in the British Medical Journal (7) ‘The first important step to reaching a better deal is for governments to realise that they have the power to actively shape and create markets, and not just remain on the sidelines fixing broken ones, especially in the area of health that is heavily subsidised by the public’. This resonates with recommendation 10 of this committees report on Evaluating Orphan Drugs in February 2018. ‘The Committee recommends that the State and the HSE has some role in innovation, in collaboration with university structure. It is the Committee’s view that unless the State has some involvement over the R&D element of the orphan drug and high tech phenomenon we will constantly be on the back foot with regard to funding. The Committee affirms the need for a sustainable, affordable and perhaps even novel model of funding’.

We believe the Joint Oireachtas Committee on Health, is uniquely placed to take a lead in this area in pursuing reform of the medicines R&D model.

We would like to thank the committee for granting us this opportunity to share our perspective.

We would also like to take this opportunity to invite all members of the Oireachtas to the 3rd annual conference on Access to Medicines Organised by AMI to be held in the Royal College of Surgeons on April 16th. Many Irish and international experts will speak and the conference is hosted in partnership with RCSI, Irish Forum for Global Health and Medicins Sans Frontieres.

This submission was informed from many sources, in particular the following three reports;

- **UN High-Level Panel** on Access to Medicines
- **Lives on the edge, Time to align medical R&D with peoples health needs. Medicins Sans Frontieres.**
- **The People’s Prescription: Re-imagining health innovation to deliver public value** Mariana Mazzucato 2018
References


Ref 2 Swanson A. Big pharmaceutical companies are spending far more on marketing than research. [Online] Reuters. 11 February 2015 [cited 2016 Apr 22]. Available from https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/


Ref 5 Report of the Canadian Standing Committee on Health: TOWARDS OPEN SCIENCE: PROMOTING INNOVATION IN PHARMACEUTICAL RESEARCH AND DEVELOPMENT AND ACCESS TO AFFORDABLE MEDICATIONS BOTH IN CANADA AND ABROAD.


Ref 7 High cost of new drugs Why government must negotiate a better deal for publicly funded research BMJ 2016;354:i4136 doi: 10.1136/bmj.i4136

Ref 8 Public return on public investment: Ensuring sustainable societal impact of EU-funded biomedical research & innovation CIVIL SOCIETY’S PROPOSAL FOR HORIZON EUROPE, THE NEXT EU RESEARCH FRAMEWORK PROGRAMME
