IPPOSI recommendations for the re-negotiation of the IPHA-Dept-of-Health-HSE agreement

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ACCESS TO INNOVATIVE MEDICINES

FOR PATIENTS IN IRELAND

DIALOGUE **TRANSPARENCY** **EVIDENCE**

Ireland has faced, and learnt from, the unprecedented challenges brought about by the global COVID-19 pandemic.

To meet future social, economic and health challenges together - partners must approach the re-negotiation of the IPHA-DoH-HSE agreement with maximum co-operation, creativity, and courage.

We believe that dialogue, transparency and evidence should be the guiding principles for guiding future policy and decision-making around access to new health innovations. The implementation of these principles require health managers, companies, and patients to agree a new approach to how we prioritise health, to ensure that access to medicines with demonstrable clinical efficacy is not unduly delayed, limited, or denied.

We believe that medicines assessment and reimbursement in Ireland must improve from pre-COVID levels. Access cannot take a back seat while we live with COVID or while we recover from COVID. The health needs and rights of patients with chronic and/or rare conditions must be met and protected – and all negotiating partners have a shared responsibility to make this a reality.

Dr Derick Mitchell, IPPOSI Chief Executive

DIALOGUE **TRANSPARENCY** **EVIDENCE**

The Irish Platform for Patient Organisations, Science & Industry – IPPOSI - *is a multi-stakeholder platform involving patient, science and industry representatives. Patient members set the agenda, and work with science and industry members to identify areas of consensus. Access to medicines is a long-standing and shared concern. The recommendations made in this paper reflect the ideas and views of our patient members.*

During the lifetime of the extended IPHA agreement[1] (2016-2020), the health sector in Ireland has broadly embraced the theory of patient-centricity; creating several opportunities for greater public and patient involvement, including across the medicines assessment and reimbursement process.

In negotiating the next agreement, IPPOSI invites both the Government and IPHA to consider the recommendations outlined below which have been drafted by our patient organisation members, as well as the summary report from our September 2020 digital discussion around the experience of patient involvement in the medicines assessment and reimbursement process and the challenge of ensuring sustainable access to medicines.

We believe that a commitment must be made to include all perspectives from the earliest possible stages, and particularly those of the patient, in order to arrive at a well-negotiated, mutually acceptable agreement where responsibilities and commitments are clearly understood and subject to ongoing compliance and performance monitoring.

[1] The current framework agreement between the Irish Government (represented by the DoH, DPER and HSE) and the international originator biopharmaceutical industry in Ireland, (represented by the Irish Pharmaceutical Healthcare Association -IPHA) expired on 31 July 2020. In light of the ongoing COVID-19 pandemic, the decision was taken to extend the existing agreement until 2021. Negotiations around the new agreement are underway.

Recommendations to the Irish Government ('the State'):

1.1. We encourage the State to be informed and mindful of the **patient perspective** in any discussions or negotiations with IPHA around access to medicines. The State should consider inviting patients to observe the future rounds of negotiations. Without this equal and ongoing access to the items up for discussion, patients are unlikely to be able to feed into new solutions in a meaningful way. Patients are open to sign the relevant documents to facilitate their involvement and to protect confidentiality for commercially sensitive issues.

1.2. We encourage the State to become familiar with the recommendations set forth in the *Charter for Patient Involvement in Medicines Assessment and Reimbursement*, signed by 36 Irish patient organisations in 2019, as well as the *IPPOSI-HRCI 'Drug Iceberg' reports* (2017, 2018), and to clearly incorporate requirements for **more public and patient involvement (PPI) across the medicines development lifecycle** within any new agreement reached with IPHA. We acknowledge some important initial steps taken by the National Centre for Pharmacoeconomics (NCPE) and the HSE[2], but much remains to be done in terms of increasing the number of PPI opportunities, strengthening the role of the PPI representatives, and reviewing the experience of the PPI representatives who have been involved to date.

1.3. We encourage the State to undertake a **full review of the 2016-2020 agreement**, in consultation with patients and companies. The State should guarantee that any and all **savings accrued** are made publicly known and

[2] In 2018, the HSE included two patient representatives in the membership of the Rare Disease Technical Review Committee – a mechanism established to support a more detailed assessment of medicines for unmet need within the rare disease patient community. In the same year, two patient representatives were added to the HSE Drugs Committee – the mechanism responsible for recommending reimbursement to the HSE Senior Leadership and/or Minister of Health. Within the NCPE, a Stakeholder Engagement Lead for Rare Diseases was appointed, a collaboration was established with IPPOSI to deliver a patient education module on health technology assessment, and a public consultation was opened to fine-tune the patient submission process.

are reinvested into future new medicines budgets not subsumed into the general health budget. More broadly speaking, while we recognise that the health budget faces unprecedented challenges, we underline that zero-growth budgets for new medicines – like those experienced in the HSE 2020 Service Plan – are not realistic or responsible.

1.4. We encourage the State to develop a **National Medicines Strategy** to outline how medicines will be sustainably funded over the next five-to-ten years to reassure Irish patients that a situation will not occur where the majority of new medicines become inaccessible on the public system. In particular, the State should have a strategy for funding public access to advanced therapy medicinal products (ATMPs).

1.5. We encourage the State to provide **greater transparency** around *how* (as distinct from, *what*) prices are agreed with Industry. We acknowledge that calling for *the actual price* of each and every medicine to be made public may be unrealistic, but the same cannot be said of the *method of price setting*. Both patients and tax-payers must know, and be involved in determining, the approaches and processes used for setting the prices of new medicines.

1.6. We encourage the State to ensure that **public investments** in medicines research and development are clearly traceable (investments include direct funding, but also the use of public sector personnel and state-funded universities and research centres). The public investment data captured must inform any pricing negotiations, and going forward, we invite the State to make greater use of conditionality agreements when making investment decisions. A record of public investments should be published annually in the interests of transparency.

1.7. We encourage the State to put in place the digital infrastructure needed to capture data on **health outcomes** in the medium-to-long term. Health outcomes for patients must be the guiding factor in determining access to medicines decisions in the future. The State and Industry will need to develop infrastructure to capture the real-world data and evidence needed to measure the effectiveness of medicines *post*-reimbursement. Public, or public-private investment in digital health solutions, including patient registries, may be needed to ensure that this data can be collected, stored and used appropriately. We should aim to arrive at a point where all medicines can be assessed objectively against clinical and patient-centered outcomes, and disinvestments made accordingly.

1.8. We encourage the State to establish specific mechanisms for assessing and approving the reimbursement of **rare disease medicines and high-tech medicines.** The State should require review by the **Technical Review Committee for Rare Disease Medicines** in all instances where a new rare disease medicine has not been positively assessed for reimbursement, so that recommendations issued by the HSE Drugs Group can benefit from rare disease expert clinical and patient perspectives – before final consideration by the HSE Senior Leadership Team or Department of Health.

1.9. We encourage the State to ensure that rare disease patient organisations and groups are supported (perhaps via funding allocated to the National Rare Disease Office) in preparing patient submissions for new medicines applying for reimbursement, to ensure that the "lived experience" of these patients is considered during the assessment process. We draw your attention to the EURORIDIS 2018 report "Breaking the Access Deadlock to Leave No One Behind".

1.10. We encourage the State to incorporate the practice of considering the **evidence provided by patients** – who are experts by (lived) experience – into the assessment and reimbursement process. Patient evidence must be considered both by the NCPE and by the HSE during the various stages of the process. Currently, patient evidence is often simply appended to various reports, rather than seen as an integral part of the available body of evidence. Formal feedback outlining how the patient evidence was considered in arriving at the final reimbursement decision must be shared with the patient community.

1.11. We encourage the State to acknowledge the special unmet need of specific patient communities, and to establish a **national programme for early or managed access** to new medicines (not yet approved for reimbursement) but where clinical effectiveness is clearly demonstrable. Patients should not have to rely exclusively on individual clinicians directly requesting access from companies. The State should also seek to collect real-world data through early or managed access programmes to inform a final assessment and reimbursement decision.

1.12. We encourage the State to reserve the right to legislate on the improved use of **generics and biosimilars** where it is safe to do so, and to address any contractual obstacles. The State should publish the progress made under the Medicines Management Programme (MMP).

1.13. We encourage the State to invite patient representatives to join the governance structures of the to-be-established **National Medicines Agency** (as announced in the June 2020 programme for government) to allow for patient perspectives to inform national prescribing and medicines reimbursement approaches. As little is known about the proposed role to be played by this agency, and we encourage patient perspectives to also inform the early design process. We ask that a timeframe

for the establishment of the National Medicines Agency be provided to all stakeholders.

1.14. We encourage the State to participate fully in the development of **common health policy** (such as the EU Pharmaceutical Strategy) and of **joint European initiatives** (such as BeNeLuxA, Valleta Declaration) in the access to medicines space. Of particular note, the State should advocate for (and make greater avail of) opportunities to work with EU Member States on the clinical effectiveness of new medicines, including the possibility of reviewing health technology assessment reports from other EU Member States during the Irish assessment and reimbursement process. The State should aim to secure learnings from the first BeNeLuxA joint assessment.

Recommendations to the Irish Pharmaceutical Healthcare Association (IPHA):

2.1. We call on IPHA to explore all possibilities for reaching a **fair and realistic agreement** with the State to implement the recommendations from patients as listed above.

2.2. We call on IPHA to discourage its members from adopting marketing approaches which may **preferentially launch** new medicines in higher-income countries first which can result in an inflated average external reference price. Such practices are unethical and leave some patient communities waiting much longer than their European peers to access life-changing or life-saving medicines.

2.3. We call on IPHA to discourage its members from **withdrawing medicines** from the Irish market purely for commercial reasons. Patients rely on innovative treatments to manage their conditions – some treatments offer patients additional benefits or greater tolerability than

others – their health should not be used as leverage in a legal or economic battle over supply or pricing.

2.4. We specifically call on IPHA to encourage their members to guarantee that patients participating in **compassionate use** programmes and successful clinical trials, have access to the medicine for the duration of their lifetime or condition, even (and especially) when a medicine has been denied approval for reimbursement by the State.

Recommendations to the Irish Government and to the Irish Pharmaceutical Healthcare Association (IPHA):

3.1. We encourage the State and Industry to prepare **public information material** detailing the specific benefits accrued to each stakeholder as a result of the new IPHA/State agreement. Materials should be co-produced with patients to ensure readability and utility. It is important that the public understand the value of medicines, the approach to funding new medicines, and the budget allocated to secure access to new medicines as a percentage of the total budget.

3.2. We encourage the State and Industry to adhere to **stricter timeframes in completing the post-HTA process**. The current post-HTA process for new medicines is protracted and frustrating for all involved – the State, Industry and Patients. The 2016-2020 agreement proposed that the State (HSE) endeavour to advise Industry of the recommendations of the HSE Drugs Group within 14 days of the Drug Group recommendation. It also proposes that the HSE Leadership Team endeavour to make a decision on the HSE Drugs Group recommendation within 45 days. The State and Industry must do everything within their power to make sure that negotiations which ensue within these timeframes are efficient, genuine, and constructive.

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