Executive Summary

The Irish health care system is under severe budgetary pressure. Pharmaceutical expenditure is no exception. During the 2000s Ireland experienced one of the highest annual growth rates in pharmaceutical expenditure of any OECD country. In 2009 Ireland spent more on pharmaceuticals per capita than any other OECD country (with the exception of the US, Canada and Greece).

The onset of the financial crisis has seen a number of austerity budgets, which will continue to at least 2015. Public expenditure is being tightened. Households, whose incomes are being squeezed, are likely to be asked to make greater out-of-pocket contributions towards pharmaceuticals. Budget 2012, for example, raises the monthly threshold for the Drugs Payment Scheme by €12 to €132 and retains the 50c charge per prescription item for medical card patients, which was introduced in October 2010.

One way of alleviating the pressure on government and household budgets arising from expenditure on pharmaceutical products is to address the following questions:

- Can the pharmaceutical delivery system be improved?
- Can better value for money be achieved?

The purpose of this report is to examine these issues, by analysing policy in relation to the major participants in the pharmaceutical delivery system including the manufacturer, wholesaler, pharmacist, prescriber and the Health Service Executive (HSE).

In designing ways of achieving better value for money, the proposals in this report are based on evolution, rather than revolution. In part this approach has been driven by the observation that variation within health care systems is much greater than between them. Thus by reforming the current model of pharmaceutical delivery, better value for money can be realised, while at the same time the costs and unintended consequences of large changes can be prevented. This minimises the chances that there will be an adverse impact on security of supply.

In Ireland much valuable research has already been conducted and policy reform introduced. The prices of new pharmaceuticals and those that no longer have patent protection have been significantly reduced. Wholesale mark-ups have been halved. Pharmacist mark-ups have been reduced for the State schemes, although the extent to which this has influenced the cash paying patient is unclear. Nevertheless, despite

these undoubted improvements more can and should be done. Relatively little attention has been devoted to the demand side in terms of, for example, examining the role of prescribers.

Prices of *new pharmaceuticals,* subject to patent protection, could be reduced further by setting the ex-factory price with reference to the lowest priced comparator Member State. An examination of data for the last number of years suggests that prices would decline by 20 to 25 per cent if such an approach were adopted. Measures should also be taken to ensure that when a new pharmaceutical is introduced it does not displace, for particular uses, equally effective but lower priced alternatives. It should be confined to those indications for which it provides value for money. Economic evaluation of new interventions is crucial in this regard. Risk-sharing arrangements between the HSE and individual pharmaceutical firms are proposed to address this issue.

Parallel imports of new products – pharmaceuticals that are imported to Ireland from another Member State where the price is lower and without the authorisation of the patent owner – is legal. Indeed, it is an imperative of the EU single market. These lower price parallel imports are important, in some instances accounting for as much as 20 to 25 per cent of the sales of leading new pharmaceuticals in Ireland. However, consistent with experience in other Member States, these lower prices are not reflected – except to a small degree – in either the price that the HSE or the cash paying patient is charged. This needs to change if expenditure is to be reduced and value for money obtained. The HSE and the cash paying patient should share in the benefits of lower price parallel imports. It is proposed that, initially at least, the difference between the price of the parallel imported product and the price charged by the patent owner in Ireland should be shared 50:50 between the parallel importer and the HSE/cash paying patient.

Once patent protection for a pharmaceutical expires, in particular for high volume products, generic competitors supply *interchangeable products* at a lower price. This increased competition should benefit both the HSE and the cash paying patient. These benefits are likely to increase as a series of blockbuster pharmaceuticals lose patent protection in the near future. However, at the moment there are barriers that prevent full realisation of the benefits from competition. A series of proposals are made to correct this situation. Interchangeability will be determined by an expert body, such as the Irish Medicines Board. For high volume interchangeable pharmaceuticals the price should be set by competitive tendering. The HSE and the cash paying patient should only pay the lowest price for an interchangeable product. For higher priced interchangeable products – typically the brand name – to be paid for by the HSE the prescriber should specify the reason and write in their own hand

'no substitution' on the prescription. This will provide useful feedback to the HSE and the agency charged with determining interchangeability. These ideas, it is anticipated, will inform the debate concerning forthcoming legislation on reference pricing and generic substitution.

The *wholesale function* is an important bridge between the manufacturer and the pharmacist. The evidence suggests that there is vigorous competition between the three full-line wholesalers. The market appears to work well. While it is the case that the current recession and HSE policy moves have placed wholesalers under financial pressure, this is insufficient reason to change the wholesalers' current business model. Many other sectors are experiencing falling profits and demand. However, there are some issues that might raise concerns over the Direct to Pharmacy (DTP) distribution model. Under this model the brand name manufacturer sets the quality standards for the wholesale function (e.g. frequency of deliveries) and pays the distributor a fixed distribution fee. DTP has limited but rising penetration in Ireland. Nevertheless, we recommend that the HSE actively monitor the importance and service levels offered by DTP brand name manufacturers. If the service levels fall below acceptable levels to the HSE, then minimum quality standards should be set.

The *pharmacy market* is marked by a lack of information available to patients on not only pharmaceutical prices, mark-ups and dispensing fees, but also the services supplied by pharmacists. These services have been expanding with the administration of the seasonal influenza vaccine and the dispensing of emergency hormonal contraception. In other professions such as dentistry and medicine in Ireland, as well as pharmacy in other jurisdictions, patients are provided with information that assists them in deciding which provider to choose. The same should apply for pharmacy in Ireland. Dispensing fees, services offered and mark-ups should be posted in pharmacies, and pharmacists should have the option of using media to disseminate such information. New forms of retailing such as the internet should – under the appropriate regulatory conditions – be considered by the HSE, perhaps on a trial basis. The result should be a more competitive, efficient and vibrant pharmacy sector that is more responsive to patient preferences and needs.

The *prescriber,* typically the family doctor, acts on the patient's behalf in making decisions concerning the appropriate course of treatment in addressing the patient's condition. This may involve selection of a pharmaceutical. The report suggests that in writing a prescription that the international non-proprietary name – atorvastatin, rather than Liptor, fluoxetine rather than Prozac – be used by the prescriber. In other words, the prescriber selects a particular pharmaceutical rather than a particular supplier or brand. There are likely to be exceptions, as discussed in the report, such as that referred to above in the discussion of no-substitution prescriptions. Proposals

are also made concerning the development of protocols and clinical guidelines so that the quality of prescribing will be improved. At the present time the HSE is providing tools whereby prescribers can compare their prescribing patterns for selected products with their peers. These proposals take the debate a stage further.

As with any set of recommendations, resource costs are an issue, particularly in a time of fiscal austerity. However, because the proposed changes are incremental and build on what has already gone before, the costs of implementation are likely to be minimal. The agreements between the State and the pharmaceutical firms are due to expire in 2012; the legislation to implement reference pricing and generic substitution is expected to be introduced in 2012. Many of the measures to liberalise pharmacy could be accommodated within the existing legislative framework. However, other policy changes may require legislation, but a considerable amount can be achieved by refining current policy.

While these recommendations and proposals are likely to improve the efficiency and effectiveness of the pharmaceutical market, they are not likely to be the last word. Apart from the fact that new problems may arise or that the report may have inadequately specified a problem, the participants in the pharmaceutical delivery system are likely to react to the proposals in ways that prevent the intended outcome of a particular recommendation. Hence the Health Service Executive and the Department of Health need to maintain constant vigilance of the system and, where appropriate, to take action to achieve publicly stated and agreed objectives.

The recommendations contained in this report are designed to ensure that taxpayers get better value for money from the €1.9 billion public pharmaceutical budget, but also that the cash paying patients benefits too. They are also designed to ensure that patients, irrespective of whether or not the State pays for the pharmaceutical, receive safe and effective pharmaceuticals without interruption to supply.