

## POLICY PAPER

# State/Industry Medicine Pricing Agreements, Cost Savings and Counterfactuals: the Case of Ireland

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**Abstract:** Ireland's Minister for Health claimed cumulative savings of €600 million for the 2016-2020 framework agreement with the Irish Pharmaceutical Healthcare Association. These savings are estimated using an implausible counterfactual of no agreement, since multiannual State/industry agreements are longstanding, while, since 2013, the State has powers to set medicine prices. A better counterfactual is the status quo: replicating the 2012-2015 agreement and extending its term for one year. This alternative counterfactual results in estimated cumulative savings of only €290 million. Greater transparency and more prudent choice of comparator for savings estimates would provide confidence in the estimates and more accurately demonstrate the likely savings that will be achieved.

## I INTRODUCTION

Governments have different methods of determining medicine prices for public reimbursement schemes (Kanavos *et al.*, 2011; Toumi *et al.*, 2014). One method, used for example in France and Ireland, is State/industry agreements. In the case of Ireland such multiannual agreements date back to 1969. But how

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effective are such agreements? Do they lead to lower prices/savings? If so, how should these savings be estimated? What is the relevant counterfactual? We consider these questions in relation to the most recent State/industry pricing agreement that commenced on 1 August 2016 for medicines supplied to the public health system in Ireland. The “Framework Agreement on the Supply and Pricing of Medicines” (the Agreement) will apply until 31 July 2020. Over time these State/industry agreements have become more wide-ranging, with, for example, assessments of medicines that may be high in cost or have a significant budget impact first introduced in the 2006-2010 agreement.

The Agreement, as with such earlier agreements, was negotiated by the State as the buyer, which, through the public health system, pays for a substantial share of medicines consumed in Ireland and sets the pricing patterns and rules for the remainder (McCullagh and Barry, 2016, p. 1268; Wren *et al.*, 2017, p. 201). The signatory on behalf of sellers is the Irish Pharmaceutical Health Association (IPHA), which represents manufacturers of patent-protected medicines in Ireland. The Agreement was welcomed by the Minister for Health, who stated it will result in savings of €600 million and will

*ensure that Irish patients continue to have access to new and innovative medicines and that Ireland remains in the forefront of its European peers in terms of early access to medicines in an affordable manner within available resources* (DoH, 2016, p. 1).<sup>1</sup>

The counterfactual that is used when assessing the benefits and costs of a policy can have a significant effect on the estimated net benefits. In appraising the credibility of the Minister’s €600 million savings from the Agreement, we first consider two counterfactuals: the status quo; and no agreement. We then analyse the magnitude of the savings under the Agreement using these two counterfactuals. Attention then turns to implications, conclusions and recommendations.

## II COUNTERFACTUAL

### 2.1 Status Quo and No Agreement

The **status quo** counterfactual assumes the earlier 2012-2015 agreement is replicated and the term extended by one year to 2020. In other words, the savings envisaged under the Agreement are derived by a comparison with the 2012-2015

<sup>1</sup> There were also unspecified and unquantified additional savings from “non-IPHA companies.” However, subsequently the Minister for Health put a figure of €150 million on these savings, but with no indication as to what they refer and how they were estimated (Harris, 2016). Hence we do not consider these unspecified savings further in this paper. The IPHA accounts for the vast majority of the purchases by the State of medicines supplied by the international research based pharmaceutical industry in Ireland.

agreement, the status quo. An alternative counterfactual is **no agreement**. The State would not use its powers to unilaterally set medicine prices under the Health (Pricing and Supply of Medical Goods) Act 2013 (the Health Act 2013) to mitigate the impact of no agreement. Under this counterfactual no account is taken of the ability of pharmaceutical firms to fully exploit any market power to raise price, subject only to the constraints of competition law not to charge excessive prices. A **third counterfactual** is for the State to unilaterally impose medicine prices under the Health Act 2013. Indeed, during the course of the Agreement negotiations the State threatened to do just that in May 2016, after the best offer from the IPHA was deemed unacceptable in terms of projected savings (Harris, 2016; Wall and Barton, 2016). However, the State's pricing proposals are not available nor are the likely reaction of the IPHA and its members (e.g. Court action to delay implementation, a boycott of the proposals).

## 2.2 Which Counterfactual?

The Department of Health (DoH) press release announcing the Agreement is consistent with the 2012-2015 agreement as the counterfactual. The DoH (2016, p. 1) states, for example, "*The pricing provisions in this agreement represent a significant improvement on those contained in the previous agreement.*" In the 'Notes to Editors', the press release points out the key pricing elements in the Agreement, which highlight the improvements as compared with the 2012-2015 agreement. Notwithstanding these public statements, in discussions with the DoH it was stated that the counterfactual underlying the €600 million estimate is, in fact, no agreement.<sup>2</sup> While no agreement may have been a tenable counterfactual in 1969, after almost 50 years of multiannual State/industry agreements, it is much less the case today. In analogous analysis from evaluating the competitive effects of mergers (CCPC, 2014, paragraphs 1.12-1.15) to conducting pharmacoeconomic evaluations of new medicines (NCPE, 2016), the status quo is the default counterfactual. The important question is, however, does the choice of counterfactual – status quo vs. no agreement – make any difference to the magnitude of the estimated savings due to the Agreement?

## III ESTIMATING THE SAVINGS: A MACRO VIEW

The DoH supplied estimates based on the no agreement counterfactual, which can be classified under four main headings (see Table 1):

<sup>2</sup> The IPHA (2017, pp. 6-7) claimed that the savings due to the Agreement were €785 million. We do not have access to IPHA estimates analogous to those in Table 1 and hence confine attention in this paper only to the DoH's estimates. The IPHA estimates use no agreement as the counterfactual, while the estimates refer to only IPHA members. (For a discussion of the IPHA estimates, see Mitchell, 2016). The leading categories of IPHA estimated savings, like those in Table 1, refer to annual price realignments and rebates, but with the rebates of lesser importance than annual price realignments.

- Original price of new medicines;
- Annual price realignment of existing medicines with exclusive supply;
- Price reductions for patent-expired medicines upon loss of exclusive supply, divided into non-biologic (i.e. generics) and biologic medicines (i.e. biosimilars); and,
- Rebates.

All prices are ex-factory.

**Table 1: Estimates of State/IPHA Agreement's Savings, Two Counterfactuals, No Agreement and Status Quo, Public Purchases, 2016-2020**

<i>Source of Savings (Clause of Agreement or 2012-2015 agreement)</i>	<i>Cumulative Savings 2016-2020 (€m)</i>	
	<i>Counterfactual</i>	
	<i>No Agreement<sup>a</sup></i>	<i>Status Quo<sup>b</sup></i>
Original Price of New Medicine (Clause 6 and Assessment Principles)	None	None
Annual Price Alignments on Patent-Protected and Exclusive Off-Patented Medicines (Clauses 5, 7.1.3 and 8.1.4) <sup>c</sup>	205	100
<i>Pricing of Patent-Expired, Non-Exclusive (Excluding Biologic) Medicines (Clause 7)</i>		
Existing Clause 6 (of 2012-2015 agreement)	90	–
Price Reduction Straight to 50% <sup>d</sup>	25	25
<i>Pricing of Patent-Expired, Non-Exclusive Biologic Medicines (Clause 8)</i>		
Biologics less 30%	55	55
• <i>Rebate on Sales (Clause 9)</i>		
• Clause 9 (of the 2012-2015 agreement) <sup>e</sup>	115	–
• Hospital Rebate (5.25% rising to 5.5%) <sup>f</sup>	70	70
• Extra Rebate (1.25% rising to 1.5%) <sup>f</sup>	40	40
Total	600	290

a. The counterfactual assumes no agreement between the State/IPHA and that the State does not mitigate this by employing the powers of the Health Act 2013.

b. The counterfactual is the 2012-2015 agreement extended by one year.

c. “Extended Reference Basket and Price Realignment” in the DoH documentation.

d. “Clause 7 (previous Clause 6) straight to 50 per cent” in DoH documentation. Instead of 30 per cent in Year 1 and 50 per cent in Year 2, the 50 per cent reduction occurs in Year 1 under the Agreement.

e. “PCRS Rebate” in DoH documentation. DoH confirmed that this referred to the 4 per cent rebate in the 2012-2015 agreement and continued in the Agreement.

f. The first increase occurred from 1 June 2016 to 31 July 2018; the second from 1 August 2018 to 31 July 2018.

Source: Based on information provided by the Department of Health.

The DoH estimated the savings flowing from the Agreement under the no agreement counterfactual. External consultants were hired by the DoH. The estimates were built up from assumptions, methodology and data sources concerning the growth of the medicines budget, when medicines are likely to experience loss of exclusivity, the launch date and success of competitor products and so on. These are unpublished. It is an issue we return to in Section IV.

Although the DoH estimated the savings using the no agreement counterfactual it decomposed the savings – see Table 1, column ‘Source of Savings’ – in such a way that the savings from the status quo counterfactual can also be estimated. Take ‘Rebates’ as an example. The DoH breaks the no agreement savings down into three categories. However, since ‘Clause 9 (of the 2012-2015 Agreement)’ reflects savings from the existing 2012-2015 Agreement, it can be excluded to derive the savings from the status quo counterfactual.

The differences between the two counterfactuals are dramatic: the cumulative savings relative to no agreement is €600 million, the cumulative savings relative to the status quo less than half, €290 million (Table 1).<sup>3</sup> The differences between the two counterfactuals, in terms of the individual components, are particularly striking for the annual realignment of medicines that are supplied with exclusive supply and rebates. But why are there such large differences and are they credible?

## IV ESTIMATING THE SAVINGS: A MICRO VIEW

### 4.1 Original Pricing of New Medicines

#### 4.1.1 Agreement and 2012-2015 Agreement Provisions

The initial or original pricing of new medicines under the Agreement consists of two steps. *First*, the supplier submits a maximum price to the Health Service Executive (HSE). The maximum price is either the average price across the Agreement’s 14 Nominated States in which the medicine is available or, if the medicine is not available, then the price consistent with the criteria set out in the Health Act 2013 and the Assessment Principles. The Nominated States are: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the UK. The criteria reflect value for money, cost effectiveness, budget constraints and State/industry agreements. The Agreement’s Assessment Principles set out the “*central principles and guidelines that will underpin the assessment of new medicines in Ireland which seek to be*

<sup>3</sup> Connors (2017, pp. 16-17) provides an estimate of the aggregate impact of the Agreement based on a no-policy change (NPC) counterfactual (i.e. “*in the absence of any pricing and supply agreement with the industry*”). The estimate is presented in graphical form and, insofar as one can gauge, is consistent with the €600 million DoH no agreement estimate. However, it is not entirely clear what Connors means by NPC – does it exclude the impact of all agreements with the IPHA or just the additional changes introduced by the Agreement? A detailed breakdown such as that in Table 1 is not provided. However, reference is made by Connors to a forthcoming paper in 2017 that contains more detail. This paper has, as of March 2018, not appeared.

*added to the Reimbursement List ...*” (HSE *et al.*, 2016, p. 16). These, in turn, are based on the Health Act 2013.

*Second*, the HSE decides whether or not to add the medicine to the Reimbursement List, at what price and any conditions attached to its availability based on the legislative criteria referred to above and on the pharmacoeconomic evaluations of the National Centre for Pharmacoeconomics (NCPE) (HSE *et al.*, 2016; McCullagh and Barry, 2016). Under Section 17 of the Health Act 2013 the HSE has to maintain a Reimbursement List of medicines which are eligible for patients on the various community drug schemes and in State funded hospitals. Other considerations than cost effectiveness can informally influence both the NCPE’s recommendation such as decision uncertainty (Schmitz *et al.*, 2016) and the HSE reimbursement decision such as pressure from patient groups (Gorecki, 2017b; O’Mahony and Coughlan, 2016). In some instances the HSE negotiates, under the Patient Access Scheme (PAS), commercially confidential patient access to a new medicine. The price and other conditions such as an initial free period of treatment or a price rebate are not therefore in the public domain (Brick *et al.*, 2013, p. 28; McCullagh and Barry, 2016, p. 1271-1272).<sup>4</sup>

The Agreement added five Member States to the nine Nominated States in the 2012-2015 agreement: Greece; Italy; Portugal; Sweden; and Luxembourg. The additions include some Member States that typically have lower prices (e.g. Greece). The Assessment Principles are set out in much greater detail in the Agreement than in the 2012-2015 agreement. However, in substance, there appears to be little difference between the two sets of Assessment Principles.

#### 4.1.2 Savings

No savings are reported for ‘Original Pricing of New Medicine’ for either counterfactual (Table 1). For no agreement the Health Act 2013 and the advice of the NCPE would still determine the original new medicine price. It is true that without the Agreement the maximum price submitted by the supplier would be unconstrained, but that price is not the determinant of the new medicine price. The HSE could ascertain the price of the medicine in the Member States in which it is available through access to various EU-wide datasets (e.g. Euripid), although the usefulness of such datasets is constrained by the use of the PAS.<sup>5</sup>

<sup>4</sup> The Agreement contains a ‘Decision Authority Level Table’ (HSE *et al.*, 2016, p. 24). There are two decision levels: HSE (non-leadership); and HSE Leadership. However, the decision-maker is HSE Leadership for new medicines that have a cost per QALY above €45,000, a budget impact of greater than €20 million or a budget impact between €5-20 million, together with a cost per QALY between €20,000 and €45,000. In other words, for new medicines that have the most impact on HSE expenditure, the decision-maker is the same.

<sup>5</sup> In 2016 of the leading ten General Medical Scheme medicines, by ingredient cost, with exclusive supply, none were subject to a PAS; for the High Tech Drug scheme the corresponding number was two. These two schemes are the two largest community drug schemes. Exclusive supply is defined as medicines that are patent-protected or are off-patent exclusive medicines. (For details see Gorecki, 2017a, Table 4, p. 30, Table 5, p. 31).

It is true that the Agreement adds five Member States to the list of Nominated States under the status quo counterfactual. However, this only affects the maximum supplier's submitted price and even here there are doubts that there will be any impact. Ireland is an earlier adopter of new medicines (Gorecki *et al.*, 2012, p. 42; McCullagh and Barry, 2016, p. 1269; Toumi *et al.*, 2014, p. 99).<sup>6</sup> Such medicines are initially available in higher priced Member States such as Germany or UK rather than (say) Greece. This reflects a so-called launch sequence strategy by suppliers, which is according to Toumi *et al.* (2014, p. 27, but see also pp. 31-32) "*used to delay or avoid launching new drugs in countries with lower prices ...*"

## **4.2 Annual Price Realignment of Patent-Protected and Off-Patent Exclusive Medicines**

### *4.2.1 Agreement and 2012-2015 Agreement Provisions*

The price of patent-protected medicines and off-patent exclusive medicines shall *not* increase over the term of the Agreement. The price of such medicines can only be realignment *downwards*: on 1 August 2016 and on 1 July of each subsequent year to 2019. The price for the purposes of realignment is determined by taking the average price for those Member States in which the medicine is available across the basket of 14 Nominated States as of 1 May prior to the August or July realignment.

The Agreement differs in two important respects from the 2012-2015 agreement: the increased frequency of price realignments – four (i.e. 2016, 2017, 2018, 2019) as compared to one (i.e. 2012 or 2013 depending on whether or not the medicine was introduced before or after 1 September 2006); and, the increase by five in the number of Nominated States.

### *4.2.2 Savings*

Under the no agreement counterfactual one-third of the estimated overall savings of €660 million, or €205 million, is due to the annual realignment of medicines with exclusive supply (Table 1). Under the 2012-2015 agreement counterfactual, the first annual realignment (i.e. 1 August 2016) is not attributable to the Agreement. This realignment corresponds to the 2012-2013 realignment under the 2012-2015 agreement. The magnitude of the first price realignment thus needs to be deducted from the €205 million to derive the status quo cost saving estimate.

Prior to the price realignment of 1 August 2016 under the Agreement, the price of patent-protected and off-patent exclusive medicines had not been adjusted since 2012-2013 in accordance with the 2012-2015 agreement. One way of quantifying the impact of the first price realignment is to assume that the savings of €205 million reflect price changes since 2014, given that no realignments occurred since 2012-2013. If annual realignments *had* occurred starting in 2014, terminating in

<sup>6</sup> However, the IPHA (2017) argues that this situation is changing, with Ireland no longer an early adopter.



2019, this is equivalent to annual savings of €34.2 million per annum over the six realignments (i.e. €205 million/6). However, there were no 2014 and 2015 realignments. The first realignment was in 2016, which would have reflected not only the 2016 realignment but also the forgone 2014 and 2015 realignments, or €102.5 million in total (i.e.  $3 \times €34.2$  million).<sup>7</sup> On these assumptions the Agreement's savings due to price realignment should be approximately €100 million under the status quo counterfactual.

### 4.3 Pricing of Patent-Expired, Non-Exclusive (Excluding Biologic) Medicines

#### 4.3.1 Agreement and 2012-2015 Agreement Provisions

Under Clause 7 of the Agreement medicines, excluding biologics, for which the patent has expired and for which a generic medicine is available:

- on 1 August 2016 each existing such medicine shall be reduced to 50 per cent of the original price set by the HSE for a new medicine;
- if a medicine becomes a patent-expired, non-exclusive medicine after 1 August 2016, then it shall also be reduced in price by 50 per cent of its original price.

The original price, which is defined in Clause 1 of the Agreement, is “*the ... price at which it [the medicine] was first approved for reimbursement ...*” The 50 per cent price reduction does not use the price of the medicine when the generic enters the market but rather the price of the medicine when it was first approved for reimbursement, which is likely to be a decade or more prior to the entry of the generic. Under Clause 6 of the 2012-2015 agreement, for medicines for which the patent had expired and where a generic was available, the price first fell by 30-40 per cent of the original price, before falling further to 50 per cent of the original price a year later.

#### 4.3.2 Savings

DoH attributes €115 million savings due to reductions in patent expired medicines for which a generic is available under the no agreement counterfactual to: first, existing Clause 6 of the 2012-2015 agreement, €90 million; and, second, bringing forward by one year the 50 per cent price reduction, €25 million (Table 1). Under the 2012-2015 agreement counterfactual the first component is not a saving that can be attributed to the Agreement. These reductions existed in the 2012-2015 agreement and hence were part of the status quo counterfactual.

Although the second component appears as an additional saving under the 2012-2015 counterfactual, there are grounds for questioning this conclusion. Under the Health Act 2013 the HSE sets a reference price for generic medicines which

<sup>7</sup> Such a finding is consistent with analysis of the 2006-2010 agreement where the initial price realignment was greater than the subsequent price realignment (Brick *et al.*, 2013, pp. 21-23).



have been declared interchangeable by the Health Products Regulatory Authority (HPRA, 2014). The reference price is not set by reference to the original price, but rather the price charged, *inter alia*, in other Member States (DoH, 2017a; HSE, 2013). But by how much does the price fall under reference pricing?

The results are presented in Table 2 for the 15 leading General Medical Scheme (GMS), medicines, ranked by ingredient cost in 2013, which appeared on the initial list of medicines that the DoH/HSE wished to be prioritised for interchangeability by the HPRA because they were considered as offering the greatest savings (HPRA, 2014; HSE, 2014). The GSM is traditionally the largest of the community drug schemes administered by the HSE. These 15 medicines in 2013 accounted for 18.9 per cent of GSM ingredient cost and nine of the leading 20 GSM products (HSE, 2014). The priority review was to be undertaken in the latter part of 2013 and the first quarter of 2014.

For 2005 and 2015, for the sample of 15 medicines, we estimate the average GSM cost per medicine: the total ingredient cost divided by the total number of prescriptions. We take 2005 as indicative of the original price of the medicine, when, as far as we are aware, there were no generic medicines available for each of the 15 medicines. This estimate will, of course, be biased downward as the medicine may have been available at a higher price prior to 2005. However, the earliest year in the HSE data source is 2005.

The most recent year for which the average cost of a medicine is available from the HSE data source is 2015 (HSE, 2016b). Furthermore, since the initial list of medicines to be reviewed with respect to interchangeability by the HPRA and a reference price set by the HSE would have taken place in 2013 and 2014, 2015 is the first year for which annual data would be able to capture the impact of reference pricing. The reduction in the price of interchangeable medicines with a reference price is always, without exception, more than 50 per cent of the original price (Table 2). In five of the 15 cases the decline is 80 per cent or greater; in 14 of the 15 the decline is 69 per cent or greater. In other words, under the reference pricing regime introduced under the Health Act 2013, prices of interchangeable medicines fall by more than 50 per cent. This suggests that for these medicines the provisions of the Agreement are irrelevant.

Nevertheless, there may be a class(es) of patent expired non-exclusive medicines for which the Agreement provisions are relevant and savings can be attributed. First, generic medicines considered, for medical reasons, to be unsuitable for classification as interchangeable. Second, the HSE may not request the HPRA to review all medicines and dosage forms/strengths that are suitable for classification as interchangeable. Third, there is likely to be a lag between, on the one hand, the generic being available for supply (and hence triggering the 50 per cent price reduction of the originator brand), and, on the other, the HPRA adding the active ingredient to the Interchangeable List and the HSE setting a reference price. Notwithstanding these doubts, there are enough lags and other factors to

**Table 2: Original and Reference Price, Average Ingredient Cost per Prescription, Leading 15 GMS Interchangeable Medicines,<sup>a</sup> 2005 and 2015, Ireland**

<i>INN<sup>b</sup></i>	<i>Average Ingredient Cost per Prescription, 2005 Original Price</i> (1)	<i>Average Ingredient Cost per Prescription, 2015 Reference Price</i> (2)	<i>Average Ingredient Cost Reduction<sup>c</sup> (%)</i> (3)
atorvastatin	€37.55	€4.61	87.7
esomeprazole	€41.59	€7.86	81.1
olanzapine	€117.39	€31.32	73.3
omeprazole	€49.03	€7.75	84.2
rosuvastatin	€29.95	€8.56	71.4
lansoprazole	€38.73	€6.52	83.2
quetiapine <sup>d</sup>	€60.58	€18.76	69.0
pantoprazole	€33.84	€6.52	80.7
clopidogrel	€54.45	€7.58	86.1
pravastatin	€41.55	€5.27	87.3
perindopril	€20.03	€5.98	70.1
risperidone	€63.33	€30.97	51.1
ramipril	€16.32	€3.62	77.8
valsartan	€24.06	€6.08	74.7
losartan	€27.40	€6.72	75.5

- a. The 15 leading GMS medicines, by ingredient cost, 2013, included in the initial list of medicines selected by the DoH/HSE for the HPRA to add to the list of interchangeable medicines. We were not able to find data for lercanidipine for 2005 or 2006 and hence omitted it from consideration. The HSE data source only provided data for the leading 100 medicines.
- b. International Non-proprietary Names.
- c.  $1 - ((\text{Col}(2)/\text{Col}(1)))$ .
- d. 2006 was used, since quetiapine was not listed in the data source for 2005.

Source: HPRA (2014, Table 2, p. 8); HSE (2006, Table 19.2, pp. 73-75); HSE (2007 Table 19.2, pp. 74-76); HSE (2014, Table 46, pp. 192-194); HSE (2016b, Table 42, pp. 161-163 and Table 43, pp. 164-166).

suggest that attributing €25 million to the Agreement under the status quo counterfactual is likely to be credible.

#### **4.4 Pricing of Patent-Expired, Non-Exclusive Biologic Medicines**

##### *4.4.1 Agreement and 2012-2015 Agreement Provisions*

Under Clause 8 of the Agreement, biologic medicines for which a biosimilar medicine is available:

- on 1 August 2016 shall be reduced to 80 per cent of the original price.
- after 1 August 2016 it shall be reduced “to 80 per cent of the ... price of that Biologic Medicine as of the 31<sup>st</sup> July 2016.”
- the supplier shall also pay the HSE a rebate of 12.5 per cent of the value at the reduced price, irrespective of whether or not the patent-expired non-exclusive biologic medicine became available before or after 1 August 2016.

Patent-expired, non-exclusive biologic medicines are priced, directly and indirectly, at a discount of 30 per cent to the original price or the price on 31 July 2016. Under the 2012-2015 agreement there was no provision for price reductions on biosimilars.

#### 4.4.2 Savings

DoH attribute €55 million savings due to reductions in patent expired biologic medicines for which a biosimilar is available under the no agreement counterfactual (Table 1). Given the lack of reference to biosimilars in the 2012-2015 agreement the same result holds for the status quo counterfactual. Savings of at least €55 million, at first glance, are credible. It has been estimated, for example, that over 2019-2020, six biologics will lose patent protection with sales in 2015 of €170 million: 30 per cent is €51 million (Harris, 2017; HSE, 2016a).

There are, however, serious concerns that the policy framework for the successful introduction, use and dissemination of biosimilars, in contrast to generics, is not in place. This is reflected in, for example, the extremely low market penetration of biosimilars in Ireland such as entanercept (Coyle, 2016; IMS, 2016). The DoH (2017b) issued a consultation paper on the development of a National Biosimilar Policy in August 2017. Issues considered include whether or not there should be pharmacy level substitution as occurs with generics. The consultation paper draws on the experience of the use of biosimilars in other jurisdictions: the success of the use of a biosimilar for infliximab at University Hospital Southampton;<sup>8</sup> and, in Norway and Denmark, where the infliximab biosimilar reached market penetration levels as of April 2016 in excess of 90 per cent (Welch, 2016).

### 4.5 Rebate on Sales

#### 4.5.1 Agreement and 2012-2015 Agreement Provisions

Each supplier shall provide a rebate to the HSE on the value of all medicines reimbursed by the HSE and relevant agencies including State-funded hospitals. The rebate is set at 5.25 per cent for sales between 1 June 2016 to 31 July 2018; 5.5 per cent for the period 1 August 2018 to 31 July 2020. The rebate does not apply to sales of patent expired and non-exclusive medicines, irrespective of whether or not they are biologic medicines.

<sup>8</sup> <http://pharmaphorum.com/news/uk-hospital-saving-80-000-per-month-using-biosimilar-conference/#> and <https://www.ecco-ibd.eu/index.php/publications/congress-abstract-s/abstracts-2016/item/dop029-outcomes-of-a-managed-switching-programme-changing-ibd-patients-established-on-originator-infliximab-to-biosimilar-infliximab.html>.

The rebate provisions of the Agreement marked an important break from the earlier 2012-2015 agreement in two respects: the rebate is extended to all Relevant Agencies which includes hospitals. Under the 2012-2015 agreement the rebate only applied to community drug schemes; and, the magnitude of the rebate was increased from the 4 per cent rebate in the 2012-2015 agreement. The 4 per cent rebate has been a longstanding feature of the agreements between the State and IPHA (and its earlier incarnations), first appearing in the 1969-1971 agreement.

#### 4.5.2 Savings

DoH attributes €225 million savings due to rebates on sales under the no agreement counterfactual (Table 1):

- €70 million due to the rebate on sales to hospitals of 5.25 per cent rising to 5.5 per cent;
- €40 million due to extra rebate on community drug schemes of 1.25 per cent rising to 1.5 per cent; and,
- €115 million due to the 4 per cent rebate on community drug scheme sales.

Rebates are the most important single source of savings attributed to the Agreement by DoH, accounting for more than a third of the overall figure of €600 million.

While the savings due to the extension of rebates to hospitals and the increase in the rebate on community drug schemes are clearly additional, relative to the status quo counterfactual, the same cannot be said of the 4 per cent rebate on community drug scheme sales. The 4 per cent rebate is longstanding; it is part of the 2012-2015 agreement counterfactual. In sum, the Agreement clauses relating to rebates will likely result in savings of €110 million, not €225 million, relative to the status quo counterfactual.

## V DISCUSSION

The €600 million estimate of the Agreement's savings has gained widespread acceptance.<sup>9</sup> There are few dissenters (e.g. Mitchell, 2016). Notwithstanding this acceptance, the magnitude of these savings depends critically on the counterfactual. If the status quo is selected the savings are €290 million; if no agreement, €600 million. The choice of counterfactual depends upon the purpose of the evaluation. However, the counterfactual needs to be more than just a theoretical construct. It should be credible. On this basis the relevant counterfactual is not the no agreement counterfactual (Section 2.2). The no agreement counterfactual specifically excludes

<sup>9</sup> A number of recent sources cite the Agreement in discussions of medicine costs, but do not comment on the magnitude of the claimed savings nor the underlying methodology. See, for example, Committee on the Future of Healthcare (2017, p. 100); Wren *et al.* (2017, p. 214).

the HSE unilaterally setting prices using its powers under the Health Act 2013. It seems scarcely credible that the State would accept, absent an agreement, foregoing the use of the only instrument it possessed to realise lower medicine prices. On the other hand, the 2012-2015 agreement counterfactual assumes that an agreement would have been reached, consistent with the record since 1969. The role of the Health Act 2013 is seen more in terms of strengthening the bargaining position of the State rather than as an alternative price setting mechanism. Furthermore, as noted above, the 2012-2015 agreement counterfactual is given considerable credibility since the Minister for Health in announcing the Agreement benchmarked it against the 2012-2015 agreement. In sum, given the choice between the no agreement counterfactual and the 2012-2015 agreement/status quo counterfactual, the latter is preferred.

## VI CONCLUSIONS AND RECOMMENDATIONS

Irrespective of whether the no agreement or status quo counterfactual is used to determine the Agreement savings, it is nevertheless important that the DoH publishes its assumptions (including its counterfactual), methodology and data sources underlying its estimate of the savings. The release of such information and analysis would enable legislators, policymakers and civil society to assess the credibility of the estimate and better understand which components of the agreement provided the greatest gains. Indeed, the DoH could fruitfully present the savings flowing from a number of alternative counterfactuals and variants of other key assumptions as part of a sensitivity analysis; otherwise the use of a point estimate gives the impression of a definite number with no ambiguity.

The critical policies and other actions in order to realise the savings would also need to be specified, such as the creation of a National Biosimilar Policy (Section 4.4.2). Furthermore the role played by the Agreement in lowering medicine prices as opposed to other policy instruments such as reference pricing under the Health Act 2013 would also be examined (Section 4.3.2). In other words, the areas where the Agreement played a vital role in bringing about savings would be identified.

Such an approach is consistent with the proposals of Barry (2011) who considers the issue of policymaking and the availability of research underlying important government decisions in Ireland. In the case of the assumptions underlying the Agreement, a suitable forum might be the Joint Committee on Health and Children (2015) which has already considered the issue of the cost of prescription medicines in Ireland prior to the signing of the Agreement. The Committee could examine not only the DoH estimates but also those made by Connors (2017) and the IPHA (2017).<sup>10</sup>

<sup>10</sup> These estimates are discussed in footnotes 2 and 3.

Better policy and value for money should result. Patient expectations would also be better managed. Patient advocacy groups have been relying on the DoH's €600 million savings estimate as the basis for arguing for reimbursement for new medicines (MRCG/IPPOSI, 2017, p. 6). When an earlier version of this paper was released one leading advocacy group was concerned that its demands for access to new medicines might be compromised. It called on the Government and IPHA to respond (ibid, p. 6). In sum, greater transparency and more prudent choice of comparator for savings estimates would provide confidence in the estimates and more accurately demonstrate the savings that will be achieved.

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