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RESEARCH REPORT

Value of Medicines in Ireland

A new perspective on the macroeconomic impact of wealth and health

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List of Abbreviations

ATC	Anatomical Therapeutic Chemical
CVDs	Cardiovascular Diseases
CSO	Central Statistics Office
DALY	Disability-Adjusted Life Years
EU	European Union
GDP	Gross Domestic Product
GNI	Gross National Income
GNI*	Gross National Income Modified
NCD	Non-Communicable Diseases
PYLL	Potential Years of Life Lost
ROI	Return on Investment
SDGs	Sustainable Development Goals
WHO	World Health Organization
YLD	Years Lived with Disability
YLL	Years of Life Lost

Executive Summary

Medicines are some of the most powerful tools in helping people live longer, healthier, and more productive lives. Medicines help people avoid disability, are related to lower death rates, improved quality of life, and potentially lead to lower treatment costs. Innovative medicines in Ireland have contributed to higher life expectancy – an improvement of over a third in the last seventy years. Patients with chronic diseases such as cancer, diabetes and Alzheimer live better, more normal lives with less severe symptoms. Deaths from cardiovascular diseases, such as stroke and heart disease – the leading cause of death in Ireland – have been reduced by nearly half. It is not feasible to put an exact value on innovations such as medicines. However, we can quantify the value of medicines to patients and to society by capturing improvements in Years of Life Lost (YLLs) and Years Lived with Disability (YLDs), and the resulting economic benefits. Apart from the quantifiable gains in healthy life years and the economy, the pharmaceutical industry helps to reduce both health inequalities and rates of illnesses.

In this study, we investigated and analysed the value of medicines in Ireland. We focused on three disease areas with a high burden in Ireland: cardiovascular diseases, cancer, and respiratory diseases. These diseases affect a significant proportion of the Irish population, cause high disease burden and are often fatal in the absence of medicines. This analysis estimated the impact of new drug launches through the associated effects on YLLs and YLDs for the period 2005 to 2025. We translated these health benefits into economic gains as every life year gained is potentially associated with increased productivity. Increased productivity is linked to greater output generated by a firm, industry, or country for the same level of input. Therefore, increased productivity allows for higher revenues, and subsequently generate higher Gross Domestic Product (GDP). To our knowledge, this is the first study quantifying this benefit in an Irish context.

Our analyses showed that from 2005 through 2025, the **cumulative effect of new drugs in Ireland translates to a decrease of 1.4 million in Years of Life Lost**, and **93,000 in Years Lived with Disability.** That is, YLL combined with YLD would be about 1.5 million higher without drug launches than with drug launches.

This results in a **total potential savings of €51.7 billion** in monetary terms, which represents:

- **24% of total GNI***
- **2.2 times health expenditures**
- the **productivity of 598,000 employees**

in Ireland in 2019,

and the average annual socioeconomic benefit of the new drug launches, estimated at **€2.5 billion,** is **more than the State's pharmaceutical spending of €2.2 billion in 2019.**

Furthermore, the savings, or socioeconomic benefit, of €51.7 billion is equivalent to:

- **22% of 20-year health expenditure**
- **44% of 20-year education expenditure**
- **And it would cover the 20-year budget of 7 hospitals the size of St. James in Dublin.**

The socioeconomic **benefit per capita** for the period 2005-2025 is **€11,000**, which represents **1/3 of the average GNI* per capita** for the respective period.

The Return on Investment (ROI) analysis showed that **for every additional Euro** of pharmaceutical expenditure in these three disease areas, **3.8 additional Euros would be added to the Irish economy until 2025.** As expected, medicines for cardiovascular diseases contributed most to these economic gains (€25.8 billion), followed by cancer (€16.8 billion), and respiratory diseases (€9.1 billion) (Figure 1). It should be noted that the quantified benefits are a fraction of the total likely benefits associated with medicines. New, more effective medicines not only improve physical health but also affect psychosocial health of patients and ease the burden of caregivers, aspects our analysis has not quantified.

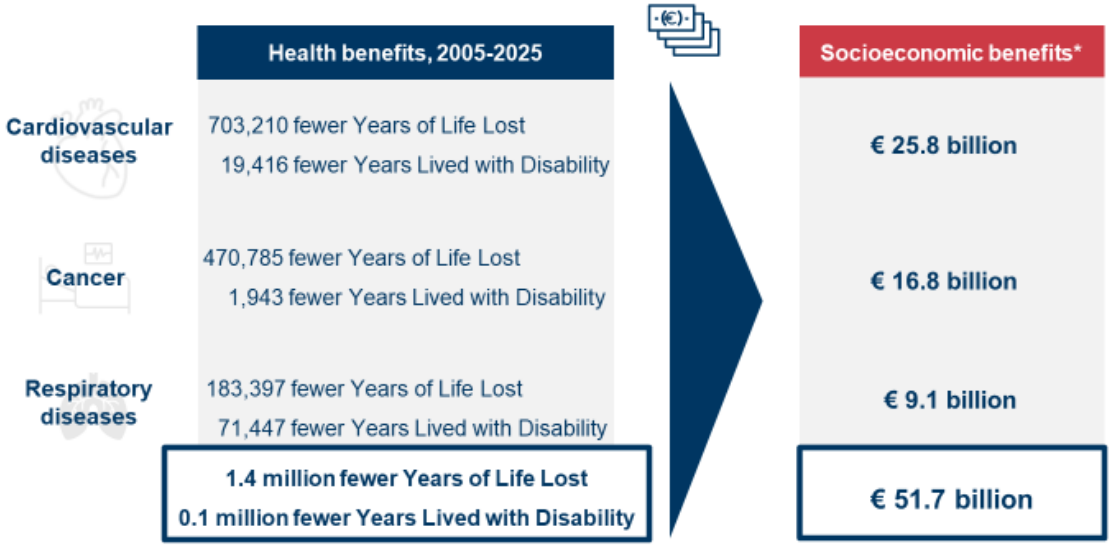

Figure 1: The health and socioeconomic benefits of new drug launches in cardiovascular diseases, cancer, respiratory diseases.

This study aims to help raise awareness and interest among stakeholders regarding the value of medicines and the link between better health and the economy.

The healthcare sector and in particular the pharmaceutical industry represent the backbone of the Irish economy and are a major source of growth and employment. **Despite the considerable Irish activity in the pharmaceutical sector at a European and international level, Ireland is falling behind in terms of access to medicines in relation to other western European countries,** according to EFPIA Patients W.A.I.T. Indicator 2019 survey[1]. **Therefore, an increase in the access to and availability of medicines to the Irish population will safeguard Ireland's human capital and will increase its productivity.** In addition, when population productivity increases, and as a result the State's GDP increases, the health budget can be increased to a certain level. A rise in the health budget could be invested in better health again and could lead to a healthier and more productive population leading once more to incremental GDP, or wealth.

The results presented in this report support **the case for continued investments in medicines and medical innovation** and demonstrate the **benefits associated with such investments,** both from a population health perspective and the economy. **Investment in medicines should be perceived as a driver for wealth, growth, employment, and better health rather than a cost factor.** Further analysis could i) compare the socioeconomic benefits of individual medicines

[1] IQVIA, EFPIA Patients W.A.I.T. Indicator 2019 Survey. 2020 May.

against the standard of care (according to the “Social Impact of Medical Innovations” methodology[2]), ii) compare the socioeconomic benefits of medicines against their costs, and iii) compare benefits and costs of other health investments.

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1 Introduction

Population health has improved globally over the past several decades and life expectancy at birth has lengthened significantly (1). The all-cause number of potential years of life lost per 100,000 population declined by 11% between 2010 and 2016 and by about 30% between 2000 and 2016 (2).

The pharmaceutical industry has delivered tremendous progress in recent decades and have allowed us to prevent and manage diseases more effectively. Innovations in medicines have improved survival and the quality of life of patients and have changed the nature of diseases such as cancer (3). Although other factors have also contributed, life expectancy has been increasing, primarily because of the development of effective and innovative medicines (4). Beyond that, medicines not only create direct health benefits for the population, but also drive productivity gains in the economy and the society (5). Medicines keep workers healthy, reduce impairment and reduce or prevent disability and/or premature death (6,7). In other words, innovative medicines are linked to human capital and lead to productivity growth.

New medicines and other health technologies have revolutionized medical practice and these advances have contributed to economic and social development, by building healthier and more productive societies. Yet, innovations in medicines need to continue, as non-communicable diseases (NCDs) such as some respiratory diseases, cardiovascular diseases, diabetes, chronic obstructive pulmonary disease, and neoplasms continue to be the leading cause of death, disease and disability around the globe. With growing incidences, they put increasing strain on population's health, health systems, economic development, and the well-being of large parts of the population.

The overall objective of this study is to support the necessity of medicines and their importance not just for population health and individual health gains, but also for the economic health of Ireland.

The total population of Ireland is approximately 4.98 million (8). The Gross National Income (GNI) at current market prices in 2019 was €275.5 billion, representing a 7.0 % increase since 2018 (€ 257.5 billion) (9). In Ireland, given the specifics of its

economy, GNI* is used rather than GNI. GNI* is an indicator that uses GNI and adjust for:

- factor income of redomiciled companies
- depreciation on R&D service imports and trade in IP
- depreciation on aircraft leasing

to exclude globalization effects.

Health expenditures increased by 6 % between 2018 and 2019 (10) and by 19 % between 2014 and 2018 (11). In 2019 the health expenditure was €23.8 billion, and in 2018 it was €22.5 billion. In both years, health expenditures represented approximately the 11% of the GNI* (10,11). In 2017 and 2016, health expenditures represented 12.2 % and 12.8 % of the GNI* respectively, reflecting a decline in healthcare expenditures as percentages of the total GNI* (11).

The health status of the Irish people has improved over the last decades. Life expectancy has lengthened significantly, and population health has improved. According to the Central Statistics Office (CSO), life expectancy at birth for males rose by 23 years, from 57 years in 1926 to 80 years by 2015 (12). On the other hand, the increase among women was slightly larger at 26 years, from 58 years in 1926 to 84 years by 2015 (12). The Irish male life expectancy was ranked 8th within Europe in 2016 (79.6 years), while the Irish female life expectancy was ranked 15th (83.4 years) (12).

Considering which diseases have the biggest impact on life expectancy, respiratory diseases, cardiovascular diseases and malignant neoplasms (cancer) make up the largest proportion of all mortality in Ireland, accounting for 12, 29 and 31 %, respectively (13) (Figure 2):

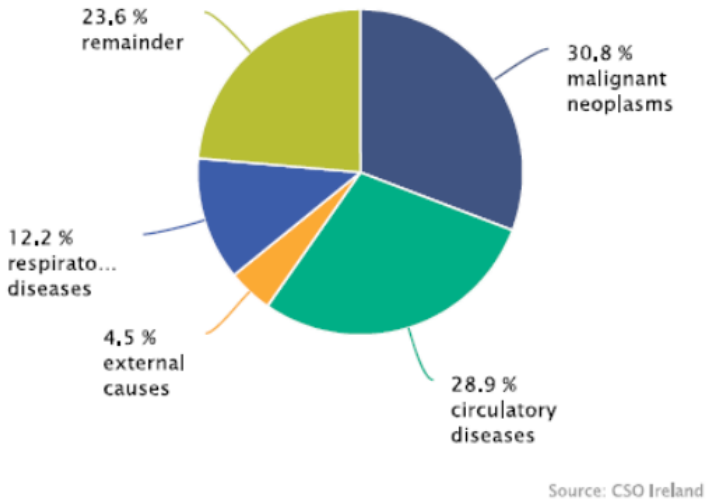

Figure 2: Principal causes of death 2019

As with many economies around the world, the Irish economy, and the potential investment of Ireland as a business location is dependent on the availability of human capital and a skilled workforce. An increase in the access to and availability of medicines will safeguard Ireland's human capital and productivity. Recognizing this fact is crucial to ensure continued access and availability of medicines in Ireland.

This analysis estimated the impact of new drug launches through the associated effects on YLL and YLD for the period 2005 to 2025. We translated these health benefits into economic gains as every life year gained and lived with no disability is potentially associated with increased productivity. Increased productivity is linked to greater output generated by a firm, industry, or country for the same level of input. Therefore, increased productivity allows for higher revenues, and subsequently generate higher GDP. To our knowledge, this is the first study quantifying this benefit in an Irish context.

Our study aims to assess econometrically to what extent medical innovation could reduce the disease burden. Based on the argument that better and effective medicines are linked with improved human health and productive human capital, we attempt to highlight the value of medicines in Ireland. Hence, the purpose of our study is to instill a new understanding and mindset around the value of medicines for the Irish economy and society. This study helps frame and answer policy questions around the necessity of medicines and the importance of medicines in

Ireland. We focus on three disease areas – cardiovascular diseases, cancer, and respiratory diseases. Assessing health and socioeconomic benefits within a disease area will provide evidence on which types of policies are viable and establish whether investments in health in general, and in the management of chronic conditions in particular, are likely to provide returns on investment sufficient to justify continued resource allocation.

2 Methodological approach

In our analysis, we used data from various sources including the Institute for Health Metrics and Evaluation (IHME), the Irish Central Statistics Office (CSO), IQVIA's drug launch data supplied by IPHA, and evidence from the current literature having conducted a thorough search in databases such as PubMed and Google Scholar. From IHME, we collected disease specific prevalence, incidence, YLL, and YLD. We gathered the modified Gross National Income (GNI*) and population estimates from the CSO (Figure 3).

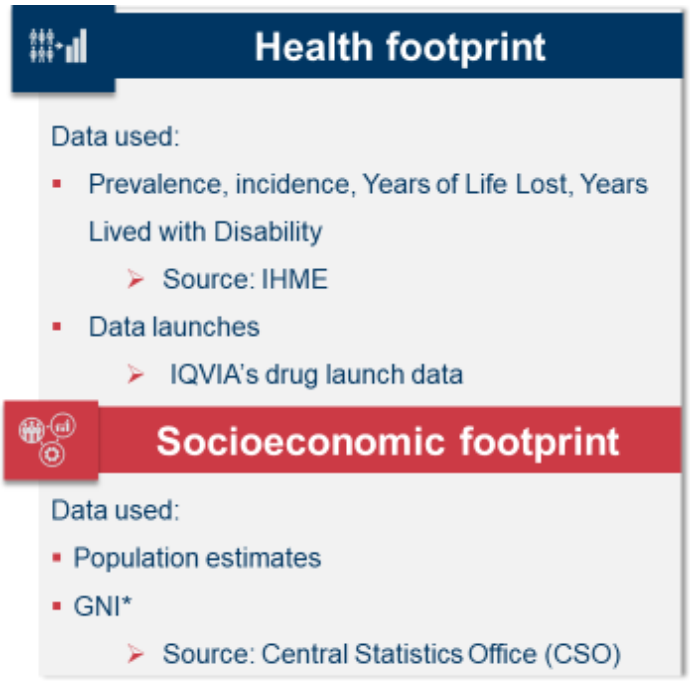

Figure 3: Data sources

Disease areas were identified using IHME defined areas:

- Cardiovascular disease was identified as Cardiovascular Diseases including all subcategories.
- Malignant neoplasms (cancer) include all subcategories except for the benign neoplasms, therefore we deducted subcategories referring to benign neoplasms to derive the values utilized in our analysis.
- Chronic Respiratory Diseases was combined with Respiratory Infections and Tuberculosis.

The following ATC3 codes were included in our analysis:

- **Medicines for Cardiovascular Diseases**: B01A, B01B, B01C, B01D, B01E, B01F, B02A, C01B, C01C, C01D, C01E, C01X, C02A, C03A, C04A, C07A, C07B, C08A, C09A, C09B, C09C, C09D, C09X, C10A, C10B, C10C, C11A. Antithrombotic drugs were included.
- **Antineoplastic (cancer) medicines**: A04A, B03C, L01A, L01B, L01C, L01D, L01F, L01G, L01H, L01J, L01X, L02A, L02B, L03A. Medicines for supportive care were included.
- **Medicines for Respiratory diseases**: R01A, R01B, R03A, R03C, R03D, R03F, R03H, R03J, R03K, R03L, R03M, R03X, R05C, R06A, R07A, R07X.

In our analysis we have included all medicines independently of their legal basis, i.e., originators, generics, biosimilars. We have excluded all duplicates based on the distribution channel while we have not excluded the different products having the same active ingredient as we consider that this increases the access to treatment of the patients.

Our main outcomes were Years of Life Lost (YLLs) and Years Lived with Disability (YLDs). Simply, YLL is defined as number of potential years lost due to death and YLD is defined as number of years lived with disability due to a disease. Mathematically, the outcomes are defined as follows:

YLL/person = Life expectancy in Ireland – age at death (e.g., 84 – 50 = 34 YLL)

YLD/person = prevalence of disease x disability weight

Using robust standard error regression analyses, we correlated cumulative drug launches with outcomes including age-standardized YLLs and YLDs. We ran separate regressions for each condition and outcome. We did not have individual level data, however, we set gender variable as our panel variable to derive average fixed effects between gender. Our right-hand side variable of interest was new launches post-2004 (last 15 years) (interaction of all brand drugs, generics, and biosimilars and time period).

We specified separate models as follows:

$$Log\ of\ Y = \alpha + \beta 1*CUM\_Launches + \beta 2*POST + \beta 3*CUM\_Launches\ x\ POST + e$$

where Log of Y is either log of YLL (rate per 100,000) or log of YLD (rate per 100,000) (separate model), CUM_Launches are cumulative launches (average cumulative

effect of drug launches), POST is a dichotomous variable equalling 1 if time period is >2004 (2005 through 2019), else 0 (controls for secular trends over time), CUM_Launches x POST is the variable of interest that shows the impact of all drug launches in the last 15 years in our data, and e is the error term. The r-squared[3] of our models ranged from 0.51 (YLL, neoplasm) to 0.95 (YLD, respiratory disease) indicating a relatively good fit (minimal error term). We also conducted omitted variable bias test and with the exception of YLD, respiratory disease ($p = 0.0002$), we were unable to reject the null hypothesis that the model has no omitted variables.

Our model shows the cumulative impact of the launch of drugs for a disease on the burden of that disease. However, the model does not capture possible spillover effects (externalities) of the drugs on the burden of other diseases. That is, the relative impacts with other diseases are not captured and the spillovers may be either positive or negative. We use drug launch data in Ireland, which indicates that patients *could* have been treated with a specific drug, not necessarily that patients *were* treated with that drug. Further, we identified drugs using the Anatomical Therapeutic Chemical (ATC) Classification codes to identify and place launched drugs into disease categories. This way of identification likely ignores multiple indications that many drugs have (the identification method and having only launch data also makes it difficult to account for off-label use of drugs).

Our objective is to show the change in YLLs and YLDs in the absence of drug launches over time. We use our key estimates ($\beta 1$ and $\beta 3$) from our model to derive the marginal effect of drug launches on our outcomes of interest. To create a counterfactual effect (absence of drug launches), we take the exponentiated inverse of the key estimates weighted by drug launch over years. For example, in 2019, there were 397 unique products available in the cardiovascular disease area. Multiplying this by our estimate (-0.00106) gives us a weighted estimate of -0.42126. Exponentiated inverse of the weighted estimate equals, $1/\exp(-0.42126) = 1.524$. That is, in the absence of drug launch, cardiovascular YLLs would be about 1.53 times higher than what they are in 2019.

We finally forecast rate of YLL and YLD to 2025. We use vector autoregressive (VAR) modelling with relevant lags. The model is a multivariate time-series regression of each dependent variable on lags of itself. We conducted this modelling

[3] A model with a higher r-squared is considered a good fit. R-square shows by how much the explanatory variables (right-hand side variables) explain the variability in the dependent variable (left-hand side variables). Example, r-squared value of 0.8 indicates that the explanatory variables explain 80 % of variability in the dependent variable.

in STATA v12 (StataCorp LLC). The forecasted rates per 100,000 persons was converted into absolute YLLs or YLDs using the total population in Ireland (absolute YLLs = (YLL rate/100,000) x population).

We multiplied the difference between the status quo scenario (a world with drug launches) and the counterfactual scenario (a world in the absence of drug launches) (Figure 4), with the GNI* per capita to derive the economic impact of each year (2005 through 2025).

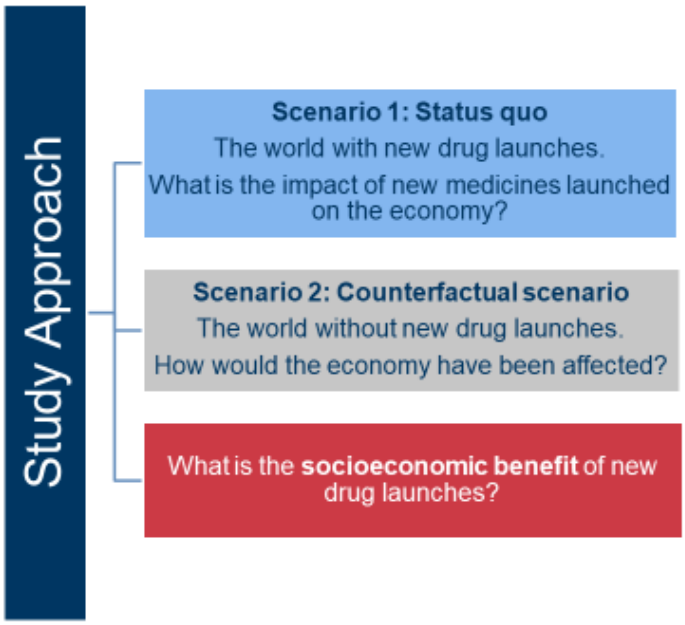

Figure 4: Study approach and modelling scenarios

To analyze the potential gain to economic welfare due to the drug launches in the chosen therapeutic areas, we calculated the Return on Investment (ROI). By measuring the ROI, the profitability of an investment in health is evaluated. ROI can be simply defined as the monetary value gain for every additional Euro spent. ROI is a metric that relates the incremental benefits due to medical innovations with the value invested from the health care system. In other words, the potential socioeconomic benefit due to a healthier population due to drug launches i.e., the Social impact is set in relation to the amount spent by the healthcare system.

Data on pharmaceutical expenditures was calculated using the wholesale data on the ATC codes mentioned above over the years 2005-2020 and then multiplied by the per year average for the twenty years. Launches since 2015 were discounted

by 37% per NCPE data and the IPHA advised discounting rate (14,15). Next, the value of rebate payments to the state spending was applied, calculated across 4% of retail sales from 2005 to 2016 then moving to 5.25% and then to 5.5% as per the industry agreements; 2016 also included a hospital level rebate.

3 Results

3.1 Cardiovascular Diseases

Cardiovascular diseases (CVDs) are the most common NCDs and leading cause of deaths worldwide. In 2017, about 18 million deaths worldwide were attributed to cardiovascular diseases (16). In Europe, CVDs accounted for 32 % of all deaths, and 45 % of all NCD deaths. Coronary heart disease and cerebrovascular disease are the deadliest, accounting for 1.8 and 1.0 million deaths, respectively (17). Although approximately three-fifths of cardiovascular disease related deaths are among the older population (ages 75 and over), a large proportion of the economically active people die from CVD too (17).

CVD incidence rates (per 100,000 persons) in Ireland have decreased in the last 20 years from 926 in 1990 to 809 in 2019 while the prevalence has increased from 8.30% in 1990 to 8.67 % in 2019. CVDs are considered a leading cause of death accounting for almost one third (32 %) of all deaths in 2019 (18). Rising prevalence, and declining incidence in combination with declines in mortality means that people are living longer with the disease. Lengthier duration of disease could be to an extent attributed to the medicines.

In Ireland, CVD events were associated with 424 working days lost per 1,000 population in 2003 (19). Additionally, CVD events cost the EU healthcare system approximately €105 billion or about 12 % of the total healthcare expenditure in 2003 while CVD related deaths were associated with a total loss of about 2.2 million working-years (19).

Our study shows that the cumulative impact of drug launches in the period 2005-2019 is associated with YLL gains of about 306,013 and these gains are expected to increase to over 397,197 in the period 2020-2025 (Figure 5). Our forecast indicates that if drug launches continue to take place with a similar trend, we expect a great impact on YLLs from 2020 until 2025 in YLLs, however this impact appears

to be progressive throughout the years (see Appendix 1). Perhaps this may be since recent drugs in this area are more effective than older drugs and generally more efficacious, and safer drugs are expected to be launched.

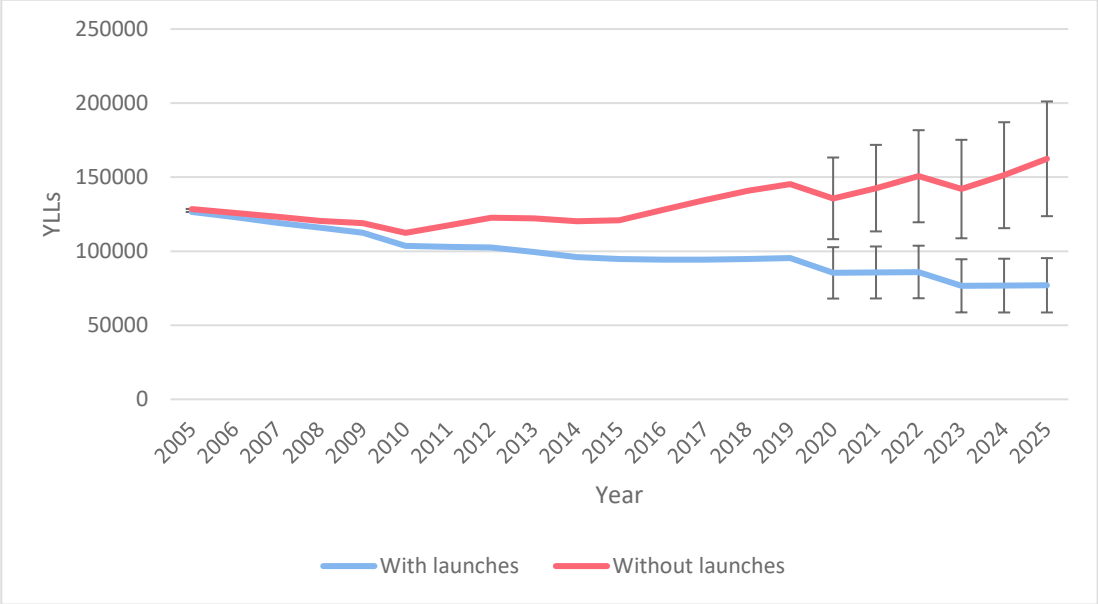

Figure 5: Cardiovascular Diseases, Years of Life Lost, 2005-2025, with and without drug launches

We also note that there is a rather steep increase in the number of YLLs in the counterfactual scenario with no drug launches while YLLs with drug launches have decreased over time.

Similarly, YLDs with drug launches have increased at a slower pace over last many years and the increases are likely to remain flat in the next 5 years. Our results also demonstrate that in 2025, the YLDs in the counterfactual scenario with no drug launches are 19 % higher than YLDs with drug launches, suggesting that the quality of life among people with CVD might be relatively higher even in presence of their disease (Figure 6, see also Appendix 2).

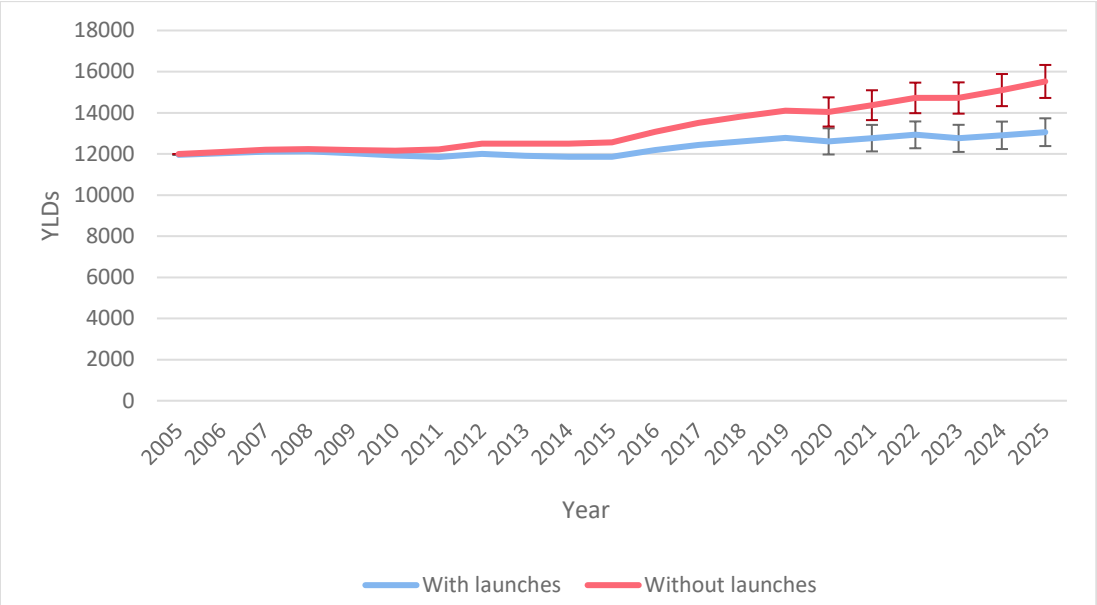

Figure 6: Cardiovascular Diseases, Years Lived with Disability, 2005-2025, with and without drug launches.

The above gains in YLLs and YLDs result in substantial socioeconomic gains of €25.1 billion and €694.4 million respectively, totaling **€25.8 billion for the study period (2005-2025).** This is almost **three times the GDP of the Midland region** (20), and **more than the State's health expenditures** in 2018 (10).

We projected that new cardiovascular disease medicines will contribute €13 billion for the Irish economy over the years 2021-2025 (Figure 7).

Figure 7: Projected benefits for the period 2021-2025.

3.2 Cancer

Cancer incidence and mortality is rapidly growing worldwide and ranks in the top two leading causes of death in several countries. The increased cancer burden is mainly due to aging and growth of population, but also linked with socioeconomic factors (21). According to the WHO, in 2018 cancer was responsible for 9.6 million deaths (22). Lung cancer is the most frequently diagnosed cancer type (11.6 % of all cases) and the leading cause of death attributable to cancer (18.4 %) (21).

The cancer incidence rate in Ireland has continuously increased from 1990 (434 per 100,000) to 2019 (588 per 100,000) (18), while prevalence almost doubled rising from 1.4 % in 1990 to 2.6 % in 2019. According to the Annual Report of the 2019 National Cancer Registry of Ireland, the prevalence of all cancer was 180,550 cases in 2017 corresponding to about 4 % of the Irish population (23).

Mortality due to cancer increased from 24 % in 1990 to 32 % in 2019(18).
The literature suggests that the cancer related premature mortality costs are significant and expected to increase over time (24). In Europe, over 40 % of the diagnosed patients are of working age (25). When people exit the workforce, either temporarily or permanently, it represents a loss in productivity and/or output. Thus, cancer related events/deaths have wider socioeconomic effects.

According to a recent economic impact study, in Ireland the productivity losses due to all invasive cancers between 2011 and 2030 accounted for a total of €73 billion, and €13 billion of these could be attributed to paid work and €60 billion to unpaid activities (e.g., household production) (25).

The number of YLLs during the study period remained stable with launches of new drugs at about 137,000 YLLs in 2025, while without drug launches, this number would have been considerably higher by an additional 56,000 YLLs in the year 2025 (Figure 8, see also Appendix 3).

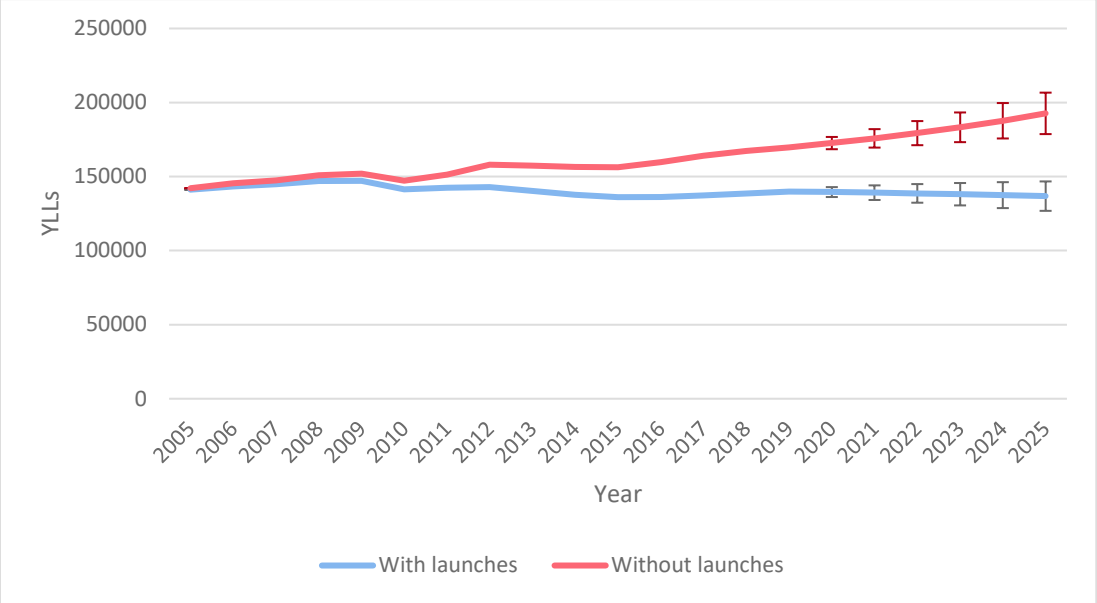

Figure 8: Cancer, Years of Life Lost, 2005-2025, with and without drug launches

The number of YLDs has been gradually rising during the entire study period and we found no statistical difference between the two scenarios (with and without drug launches), although numerically the resulting number of YLDs in 2025 without new drug launches is larger (9,810 vs 10,047) (Figure 9, see also Appendix 4).

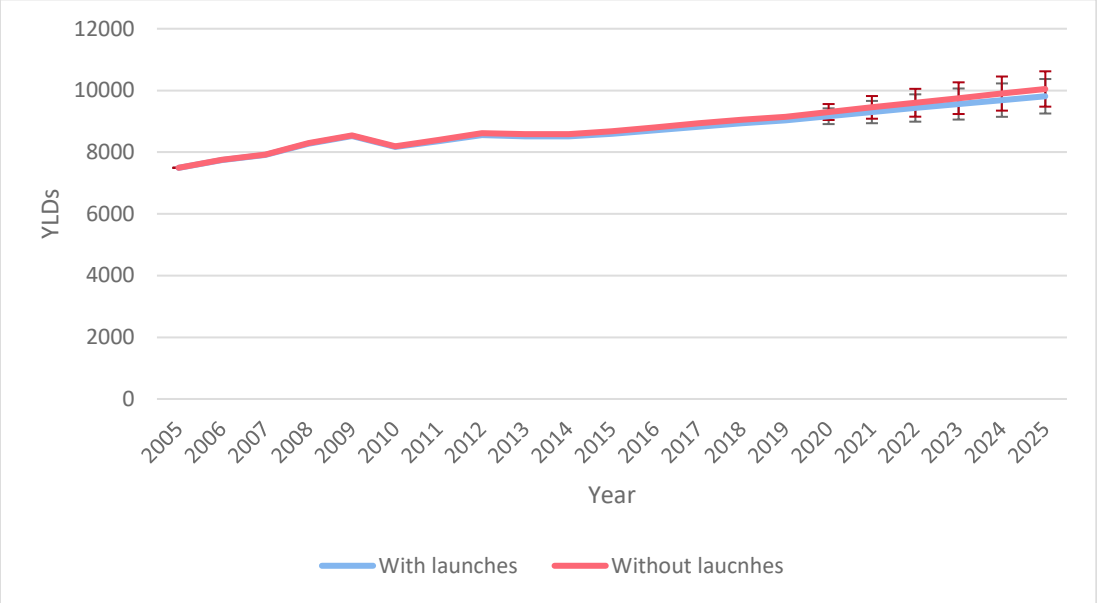

Figure 9: Cancer, Years Lived with Disability, 2005-2025, with and without drug launches.

The above gains in YLLs and YLDs result in important socioeconomic gains of €16.7 billion and €69.2 million respectively, totaling **€16.8 billion for the study period**. This is **equal to the GDP of the South East region** (20) and **75% of total health expenditures** in 2018 (10).

We projected that new cancer medicines will contribute €8.4 billion for the Irish economy over the years 2021-2025 (Figure 10).

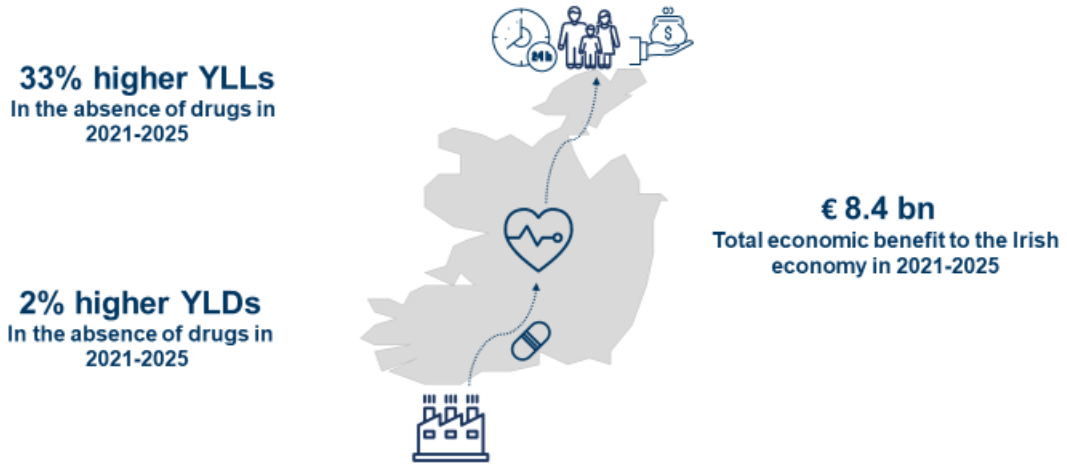

Figure 10: Projected benefits for the period 2021-2025.

3.3 Respiratory Diseases

Irrespective of the current Covid-19 Pandemic Respiratory diseases refer to a range of conditions with different causes (i.e., genetic factors, environmental factors, smoking, occupational exposure) (26). The worldwide incidence rate in 2017 was 233,000 per 100,000[4] (18). Although the incidence rate in Ireland has slightly declined from 1990 to 2019 (from 275,294 to 258,797 per 100,000), also followed by a decline in prevalence (from 33 % to 24 %), mortality rates remain high at 12.2 % to 13.3 %, depending on the source (13,18). O'Connor et al. (26) reported a 15 % increase in the absolute number of people who died from respiratory diseases between the years 2007 and 2016. This makes respiratory diseases together with cardiovascular diseases and cancer as one of the three leading causes of death in Ireland (26).

As shown by an economic impact study, the total cost of respiratory diseases in the European Union is approximately €380 billion per year (27).

Therefore, despite the decline in incidence and prevalence, respiratory diseases account for a considerable impact on the Irish society and economy, and, as

[4] There are times when IHME incidence estimates can exceed population numbers for certain diseases/conditions and locations. This occurs where certain diseases/conditions are highly prevalent and acute incidence of the disease/condition can occur multiple times each year in individuals – so each episode is counted as a discrete case of incidence. Respiratory infections are one example of this.

demonstrated by the results of our study that follow, this impact would have been much higher without the beneficial effect of the launch of new medicines.

In respiratory diseases and during the entire study period, we observe in YLLs an important and early separation of the two curves demonstrating a substantial effect of the drug launches on the lives saved. The result for the year 2025 is that, without drug launches, 21,550 more Life Years would have been lost (Figure 11, see also Appendix 5).

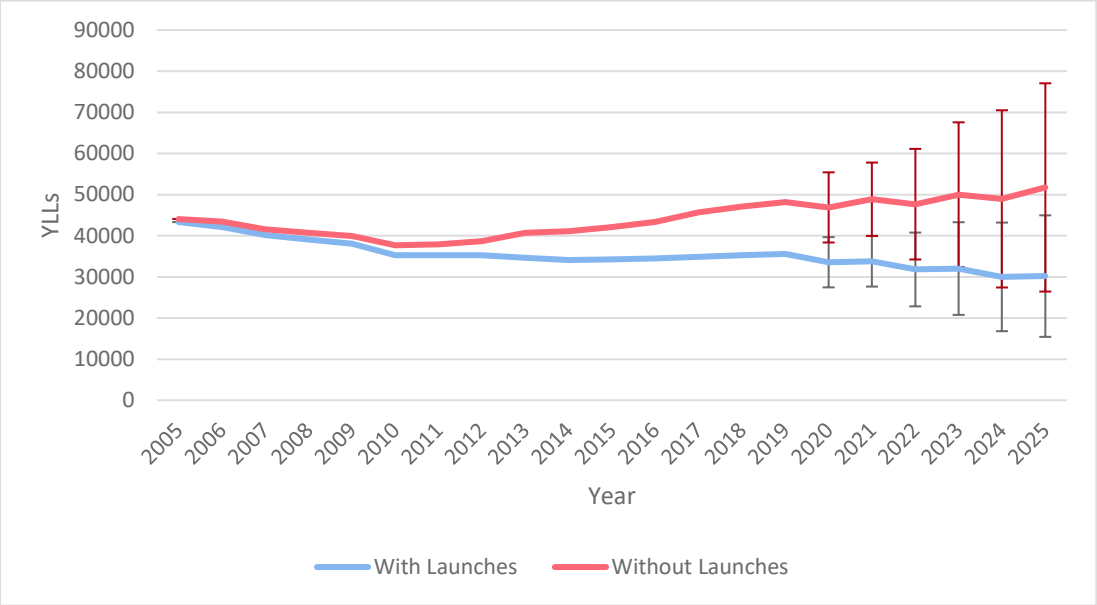

Figure 11: Respiratory Diseases, Years of Life Lost, 2005-2025, with and without drug launches

The same pattern is observed for the YLDs since there is an early separation of the curves maintaining stable the number of YLDs with new launches while, in their absence, there would be a net and significant increase of patient's disability with 8,800 additional YLDs in 2025 (Figure 12, see also Appendix 6).

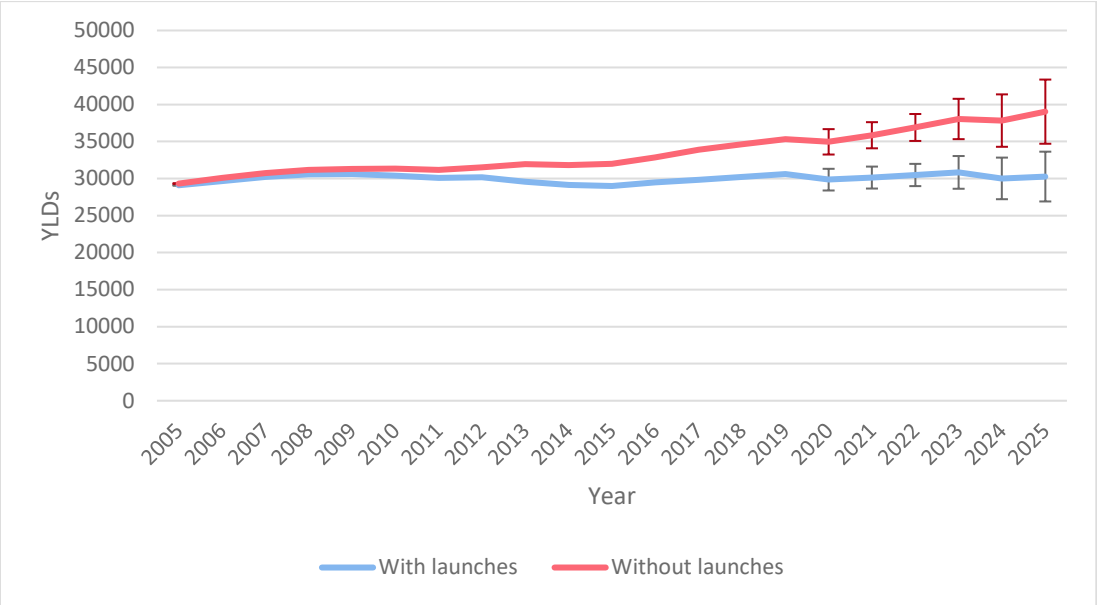

Figure 12: Respiratory Diseases, Years Lived with Disability, 2005-2025, with and without drug launches.

The above gains in YLLs and YLDs result in socioeconomic gains of €6.5 billion and €2.5 billion respectively, totaling **€9.1 billion for the study period (2005-2025).** This number is **comparable to the GDP of the Border region** (20), and almost **two-fifths of total health expenditures** in 2018 (10).

We projected that new cancer medicines will contribute €4.6 billion for the Irish economy over the years 2021-2025 (Figure 13).

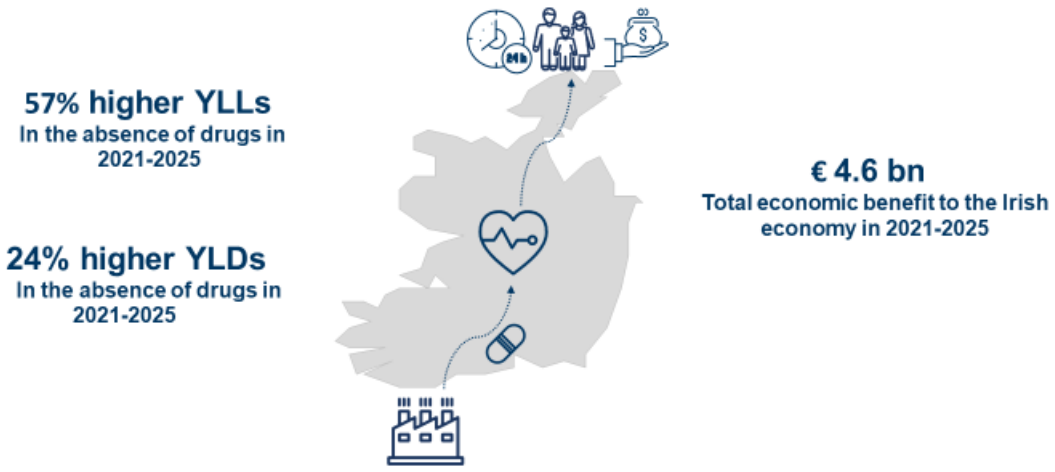

Figure 13: Projected benefits for the period 2021-2025.

3.4 Overall gains (YLLs, YLDs, S/E benefit)

The cumulative effect of new drug launches in the three disease areas with the highest mortality rates in Ireland for the study period (2005-2025), can be summarized in the following Table.

	CVD	Cancer	Respiratory Diseases	TOTAL
YLLs	703,210	470,785	183,398	**1,357,393**
YLDs	19,416	1,943	71,447	**92,806**
Socioeconomic benefit (€)	25,790,408,339	16,815,787,957	9,101,437,578	**51,707,633,874**

Table 1: Effect of new drug launches

Overall, 1.4 million YLLs and **93,000 YLDs** h**ave been avoided because of new drug launches.** This results in a very substantial impact, or **socioeconomic benefit, of €51.7 billion**, which is almost **24% of total Irish GNI*** (9) and **2.2 times the health expenditures in 2019** (10). This economic gain is also equivalent to the GNI* produced by **598,000 employees** (24% of the total labour force) in Ireland in 2019 (28). Additionally, the average annual socioeconomic benefit of new drug launches in these three disease areas, estimated at **€2.5 bn,** is **more than the 2019 pharmaceutical expenditure**, which is approximately €2.2 bn (29).

When comparing our estimate to a 20-year period (which is in line with the time period under investigation), the **socioeconomic benefit of new medicines, €51.7 billion,** is equivalent to almost **22% of the 20-year health expenditure** and **44% of the 20-year education expenditure** (30)**,** while it could also cover the **20-year budget of 7 hospitals** the size of St. James in Dublin (31).

The impact of medicines on CVDs is greater compared to cancer and respiratory diseases. This could be explained not only by the highest prevalence rates of CVDs, but also by the fact that during the last 15 years more products were introduced in this area.

In the following graph, we present the economic outcomes associated with the two scenarios examined (Figure 14).

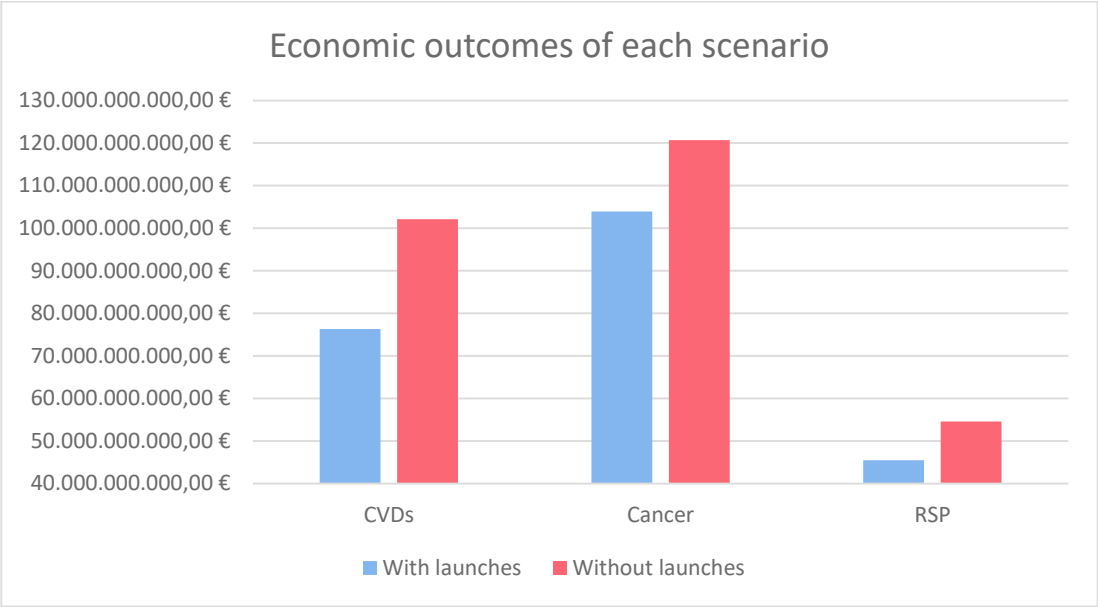

Figure 14: Economic outcomes of each scenario.

3.5 Return on Investment (ROI)

An ROI result above 1 indicates that monetary health benefits are higher than the costs incurred upon the healthcare sector. In Ireland, the spending on these disease areas includes spending by both the State and the private sector. From a macroeconomic perspective, new drug launches in the three disease categories (cardiovascular diseases, cancer, respiratory diseases) create € 3.8 of potential welfare for each additional €1 of pharmaceutical expenditures. Our results also showed a 20-fold increase of the ratio of benefit/pharma expend per capita within 15 years, while expenditure has increased only by 1.26 over the same period. The following graph shows the relationship between the cumulative drug launches and the ratio of socioeconomic benefits and pharmaceutical expenditures (Figure 15).

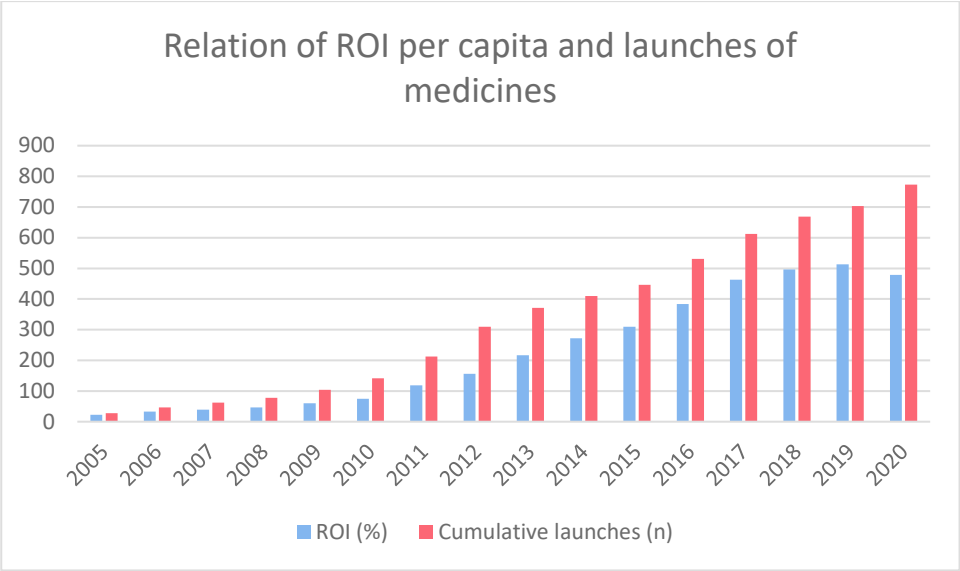

Figure 15: Relation of ROI per capita (%) and drug launches

3.6 Prevalence – Incidence – Duration of Disease

The effect of an intervention on the health of a population and its effect on the course of a disease could be observed through the prevalence, the incidence, and the duration of the disease. We therefore analyse the above measures for each disease separately, while for the respiratory diseases we split the measures into chronic (such as asthma and COPD) and infectious since the duration of disease of these two sub-entities is not the same.

- In cardiovascular diseases, we observe a decline in the prevalence and incidence rates per 100,000 persons, albeit the rates decline differentially between the two measures. As a result, we see a slight rise in the duration of the disease (Figure 16).

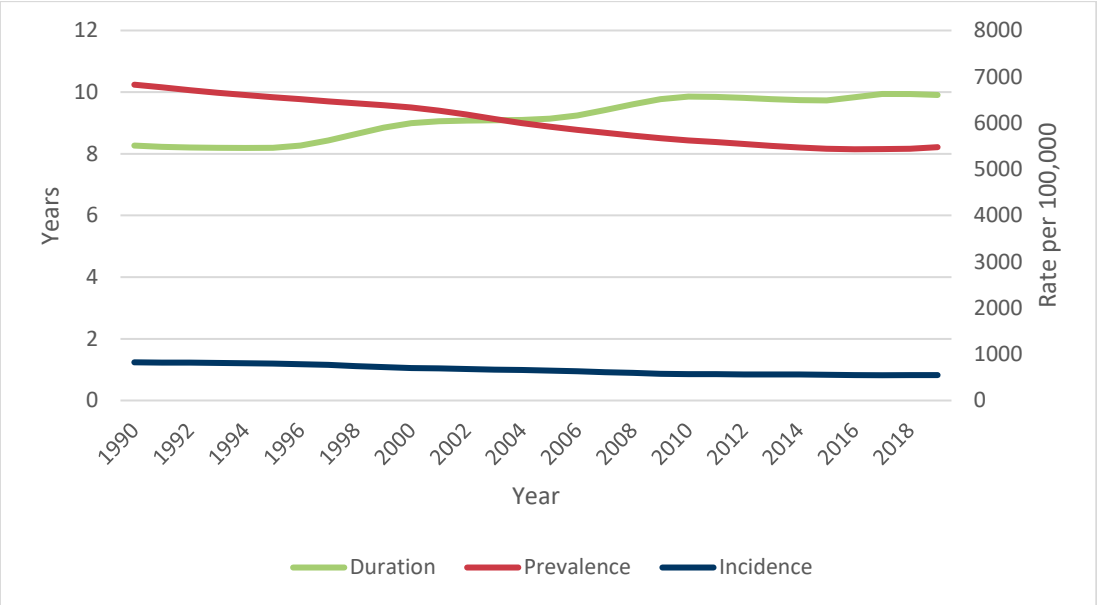

Figure 16: Cardiovascular Diseases, Duration, Prevalence, Incidence

- In cancer, the incidence has remained relatively stable while prevalence and duration of the disease demonstrate a constant rise, although with a stabilizing trend in the last 10 years. This could suggest that treatments are associated with patients' extended survival (Figure 17).

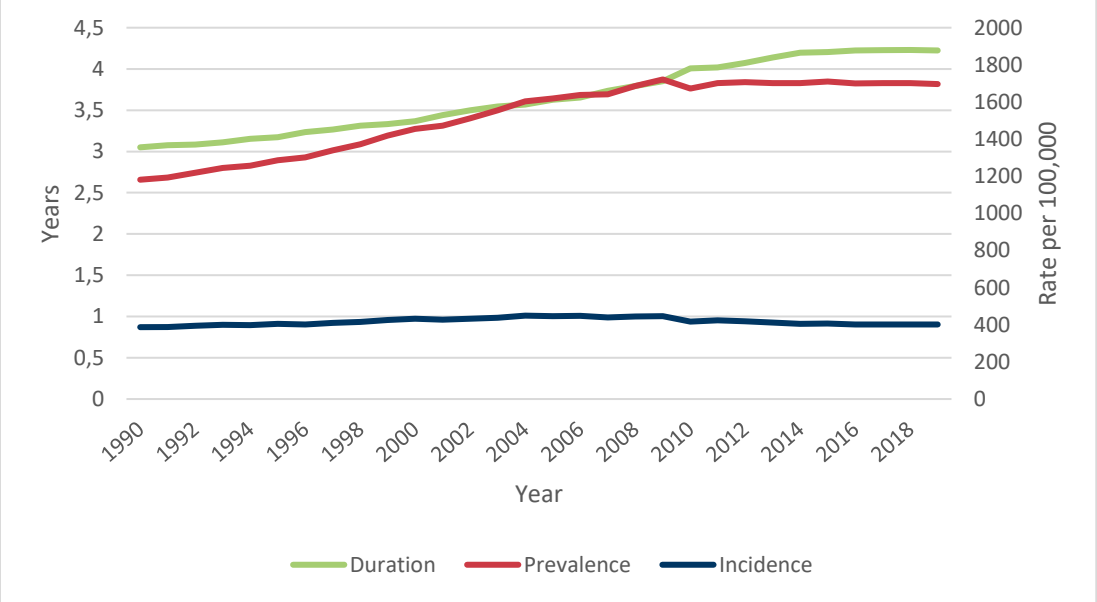

Figure 17: Cancer, Duration, Prevalence, and Incidence

- Finally, for the respiratory diseases, we observe two different patterns:
    - The duration and the prevalence of the chronic respiratory diseases considerably decline while the incidence remains stable, suggesting an increasing effectiveness of the medicines (Figure 18).

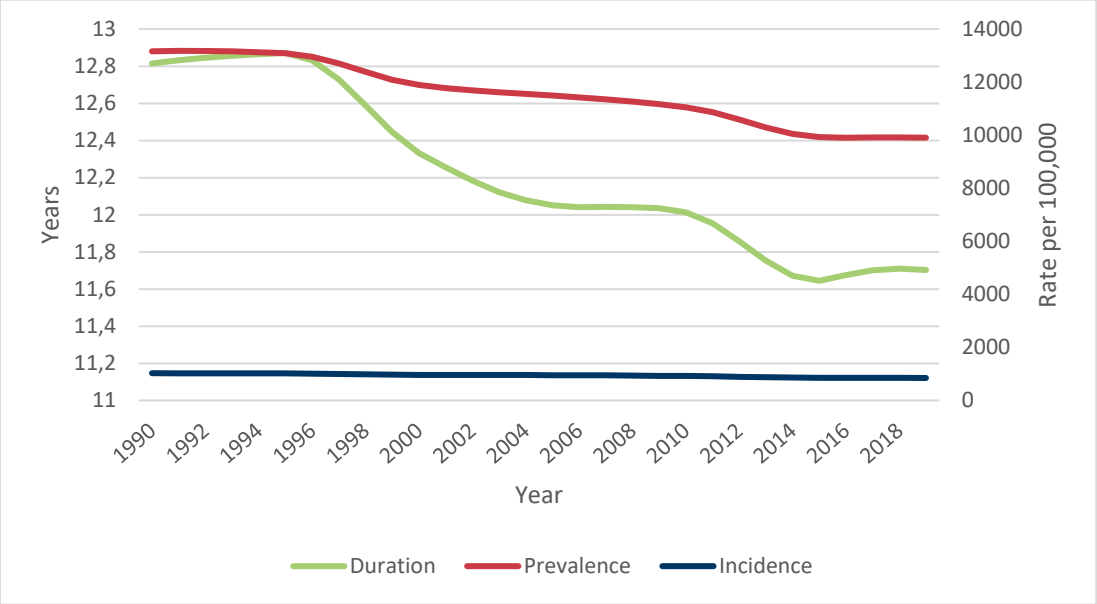

Figure 18: Chronic Respiratory Diseases, Duration, Prevalence and Incidence

- Prevalence of respiratory infections decreased considerably while incidence remain relatively stable, suggesting a decrease in the duration of disease and a faster cure associated with medicines (Figure 19).

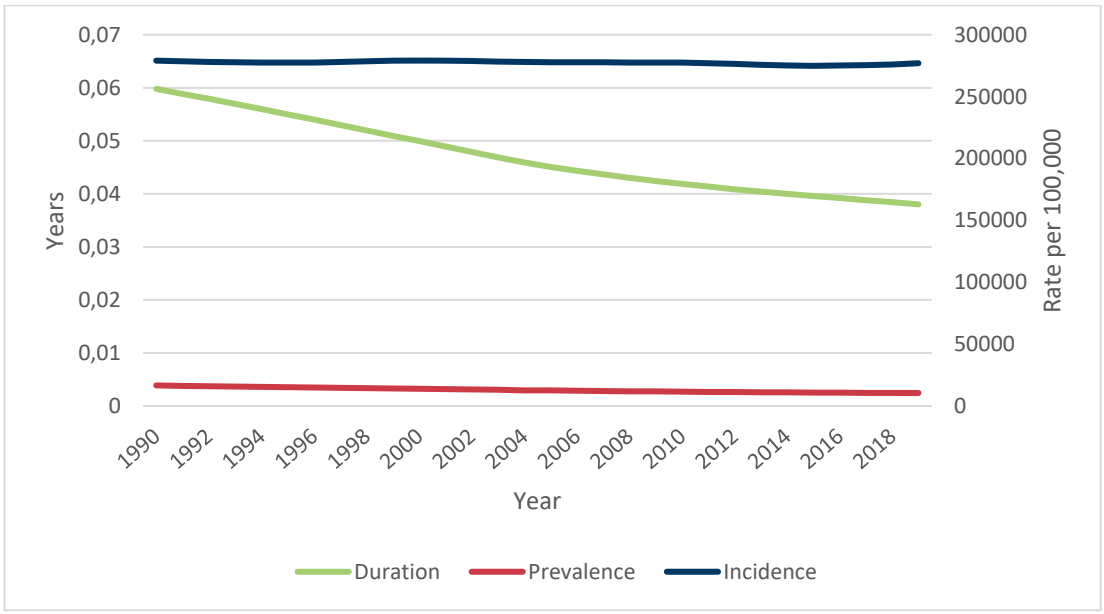

Figure 19: Respiratory Infections and Tuberculosis, Duration, Prevalence, and Incidence

4 Discussion

According to the WHO “health is a state of physical, mental, and social well-being, not merely the absence of disease or infirmity” (32). In order to achieve this, there are multiple determinants, including personal, environmental and social initiatives to prevent diseases, and even health care services. Within the latter, medication is a resource of great relevance. Its impact can be enhanced by the ability of health professionals to provide timely diagnosis, a correct prescription and medicines working properly, as well as patients completing their treatment correctly.

In this report, we present the socioeconomic benefits associated with the value of medicines among three disease areas: cardiovascular diseases, cancer, and respiratory diseases. To the best of our knowledge, this is the first study estimating the value of medicines in the three disease areas in Ireland. We acknowledge that selecting disease categories rather than specific diseases may lead to broader assumptions but given the scope and the aim of the study, three disease areas affecting a relatively large proportion of the Irish society in terms of mortality, were selected. This study employed a research design to measure the impact of drug launches on mortality and disability. We focused retrospectively on drug launches in the last 15 years and look forward 5 years to 2025. The results indicate that new drug launches are positively associated with economic benefits to the Irish economy. That is, substantial amounts of loss in productivity and unpaid activities (implied in our analysis) could be avoided. This assumes a collective continued commitment with efforts by the government, the private sector, academic, health institutions and the regulatory authority.

The healthcare sector and in particular the pharmaceutical industry is of an important economic significance. The pharmaceutical industry represents a key asset for the Irish economy and is a major source of growth and employment. It is one of the most competitive sectors in Ireland and the European Union (EU). In relation to other small size countries, as well as compared to other sectors, the industry presence in Ireland is quite significant. The number of pharmaceutical manufacturing sites is continuously growing. The industry represents 62% of Ireland’s exports and it occupies over 45,000 employees. Thus, Ireland has a robust and competitive national pharmaceutical industry.

While playing a crucial role in fostering growth and competitiveness, the presence of a viable pharmaceutical industry also contributes to health and quality of life of the population by providing new and effective medicines to an increasing number of patients. However, the funding of new medicines seems to be insufficient. Despite the considerable Irish activity in the pharmaceutical sector at a European and international level, Ireland is falling behind in terms of access to medicines in relation to other western European countries, according to EFPIA Patients W.A.I.T. Indicator 2019 survey (33). This is known as the “innovation paradox”.

- “Time to availability” (or length of delay) refers to the period between EMA marketing authorization and patient access to medicine. In Ireland, the mean “time to availability” is 521 days, ranking Ireland 19th out of 34 countries and noticeably behind Germany (127 days) and Denmark (154 days), ranking 1st and 2nd respectively.
- The “rate of availability” refers to the number of authorized medicines that are available to patients in European countries through reimbursement. 45 % of products are available to the Irish population, slightly lower than the European average (49 %), and considerably lower than Germany and Denmark (85 % and 84 % respectively).

As discussed above, this study demonstrates the economic benefits in terms of gain in years of life lost (YLLs) and years lived on disability (YLDs). Research has shown that medical innovation improves human health, having wider social effects such as labour productivity and improved workforce. Therefore, **an increase in the access to and availability of medicines to the Irish population will safeguard Ireland’s human capital and will increase its productivity.** In addition, when population productivity increases, and as a result the State’s GDP increases, the health budget can be increased to a certain level. A rise in the health budget could be invested in better health again and could lead to a healthier and more productive population leading once more to incremental GDP, or wealth.

Investing in new medicines due to demographic changes (increased life expectancy) is crucial. According to ESRI projections, demand of prescription medicines is expected to rise between 34 % and 38 % in 2030 compared to 2015 (34). **To tackle unmet needs of the Irish population, and to secure positive health outcomes, innovations from the pharmaceutical industry, as well as increased patient access, is required.**

Despite the above-mentioned impact of medicines on population health, since 2019, investments in medicines may be insufficient given the population needs. Anecdotally, these decisions could be political in nature rather than pragmatic. Reduced investments could further burden the population health and the economy.

Our findings – that new drugs reduce the number of YLL and the number of YLD – suggest that people live longer and with improved disease management. We would expect approximately 1.4 million YLLs and over 90,000 YLDs in the absence of new launches for the three disease areas. Improved survival while reducing the severity of diseases (disability caused by disease) consequently is associated with increased workforce and productivity (the improvement in quality of the workforce also). Our approach shows the health and social benefits at a macroeconomic scale. The total economic gains due to the availability of new medicines are € 48.4 billion in terms of YLLs and €3.3 billion in terms of YLDs. Furthermore, reducing the health burden of chronic conditions, is likely to reduce the pressure on the Irish healthcare system.

Previous research has already demonstrated the value of medicines in tackling diseases, such as cardiovascular diseases and cancer. Although existing literature shows a similar trend regarding the benefit of new launches, robust comparison of our findings is not possible due to several differences between the studies. A study by Lichtenberg et al (35), reported that without new launches between 2006-2010, we would expect 8.28 million additional YLLs. This number refers to 19 types of cancer in 36 countries, including Ireland, therefore reasonably the estimate is much higher than ours – unfortunately, the Irish estimate is not reported separately. In a study conducted in Switzerland (36), the reported number of years of life gained due to pharmaceutical innovation for cancer in 2012, is slightly higher than our estimate for the respective year (17,092 vs 15,199) and is referring to the ages before 75.

Another study (7), analysed the impact of new launches for 66 diseases in 27 countries – including Ireland. The findings imply that in a counterfactual scenario without drug launches, YLLs before the age of 85 would have been 2.16 times higher in 2013. Our findings indicate that, in 2013, in the absence of new launches, YLLs would have been 1.23, 1.12 and 1.18 times higher for cardiovascular diseases, cancer and respiratory diseases, respectively. This difference may be attributed to the larger sample size analysed in that study. Further, possible differences between the countries (e.g., demographic differences, life expectancy, lifestyle, availability, and access to medicines) might be responsible for this difference.

Our study not only confirms previous results on the positive impact of new medicines on population's health, but also shows the benefits at a macroeconomic level. Based on these findings, **investment in medicines should be perceived as a driver for wealth, growth, employment, and better health rather than a cost factor**. Therefore, this study supports the investment and continued access to medicines.

Health expenditures have been discussed politically only as a cost and not as an investment in sustainable development and growth. For years, governments have aimed to keep costs down. The COVID-19 pandemic has made apparent that investments in health are crucial for a resilient health system that can ensure access of the vulnerable to diagnostics and treatment. Substantial investments in health are essential to set up a defense plan against future pandemics. However, they are equally important to achieve the Sustainable Development Goals (SDGs), in particular SDG 3 "to ensure healthy lives and promote well-being for all at all ages". Consequently, a **paradigm shift is needed to recognize health as an investment and driver for sustainable wealth, growth, and health in the State**.

One country in which this paradigm shift has already occurred is Germany, as evidenced by the National Health Account framework (37) that was collaboratively developed between the Ministries of Health, Ministry of Economics, and WifOR (38) , and as acknowledged by the World Health Organization (39,40). Furthermore, we believe that this has and will increasingly enable the uptake of the socioeconomic perspective in the analysis and assessment of therapeutic areas and medicines (41–46).

We would like to acknowledge certain assumptions and limitations of the study. The disease areas chosen in this study are quite broad and as a result, we lose some degree of variability. This could (statistically) affect the correlation of drug launches and the outcomes of interest (e.g., YLL rate per 100,000). Nevertheless, the chosen disease areas serve well the interest of the study with a focus on policymakers and other stakeholders. To derive productivity impact for years lived on disability, we assume a 100% work productive capability. That is, we do not apply a productive impairment for someone living on disability. Additionally, we do not take into account the impact years lived with disabilities may have on early retirement and the associated indirect economic impacts.

We acknowledge that other health investments such as medical devices, access to primary and acute care, infrastructure etc. play a substantial role in improving the health of Irish citizens. However, in this study we are not factoring in these

investments and their possible contribution to health, and therefore to the reduction of mortality and morbidity. Additionally, each patient's lifestyle may contribute to the reduced or increased health status. However, capturing the potential differences in patient's lifestyles and this contribution to mortality and/or morbidity was beyond of the scope of this study.

5 Conclusion

In this study, we assessed econometrically the association of new drug launches with reductions in disease burden in Ireland. We investigated three disease areas making up the largest proportion among all-cause mortality in Ireland. These include cardiovascular diseases, cancer, and respiratory diseases.

This **interdisciplinary, evidence-based study** highlights the importance of medicines innovation in both health and macroeconomic terms:

- **The pharmaceutical industry in Ireland is of an economic significance** (e.g., job creation, exports, GDP contribution). Ireland is an important pharmaceutical player in terms of both development and manufacturing, not only at a European but also at an international level.

- The pharmaceutical industry and medicines innovation improve the lives of millions of Irish people through their contribution to health. Our estimates indicate that **if no drugs had been launched in the last 15 years, the numbers of Years of Life Lost and Years Lived with Disability would have been considerably higher (1.4 million in YLLs**, and **93,000 in YLDs).** Generally, drugs seem to have a greater impact on mortality than on disability. Also, we observed that the impact is larger for cardiovascular diseases, compared to cancer and respiratory diseases.

- The **total economic gains of drug innovation** within the last 15 years with a projection until 2025 were calculated to be **€ 51.7 billion**. **These savings can be invested in the Irish economy and enable better health for the future.** The estimated gains are roughly equivalent to:
  - **22% of 20-year health expenditure**
  - **44% of 20-year education expenditure**
  - **And it would cover the 20-year budget of 7 hospitals the size of St. James in Dublin.**

- **New drug launches** in the three disease categories (cardiovascular diseases, cancer, respiratory diseases) **create € 3.8 of potential welfare for each additional € 1 of pharmaceutical expenditure**.

- An urgent challenge for the Irish government is the investment in new medicines. Despite the significant economic and public health impact of medicines, **funding of new medicines has been delayed and seems to be insufficient.** Ireland is **falling behind in terms of access to medicines** in relation to other western European countries. Notably, in Ireland the mean length of delay in access to medicines is 521 days, placing Ireland 19th out of 34 countries (33).

- **The State and the pharmaceutical industry have a common responsibility to provide the Irish population with the same treatment options and access as their European counterparts**. Close collaboration and partnerships are necessary to promote public health and economic development.

Our study shows the value medicines bring to both patients and society, and therefore supports investment into new drugs and underscores the need to improve timely patient access to medicines.

Political implications

We hope that this study helps to create a new perspective on health – away from a cost factor and towards health and medicines innovation as investments that drive sustainable wealth, growth, employment, and better health. Macroeconomic evaluations should be considered in future decision making in the State. Such evaluations can help support future evidence-based health strategies with additional and new key performance indicators about the outcome of health investments. In the next decade, the importance of macroeconomic health benefits in terms of GNI, GNI* and GDP contribution generated by the launch of new medicines will obtain an even greater importance. We hope that the results of this study will enrich the dialogue in Ireland and abroad and highlight the importance of wise investments in health, and particularly in the pharmaceutical sector, despite increasing pressure on public budgets.

Appendices

Appendix 1 - Table 2: Total gains in YLLs – CVD

Year	Years Life Gained (number)	Years Life Gained (%)	Economic Benefits
2005	2,029.60	2%	€ 58,645,729
2006	2,771.24	2%	€ 80,545,589
2007	3,986.02	3%	€ 116,515,239
2008	4,515.99	4%	€ 133,532,269
2009	6,626.28	6%	€ 200,305,700
2010	8,817.69	9%	€ 254,233,228
2011	14,362.89	14%	€ 405,490,642
2012	20,120.15	20%	€ 554,820,791
2013	22,847.34	23%	€ 681,010,189
2014	24,215.34	25%	€ 780,778,512
2015	26,165.51	28%	€ 910,955,962
2016	33,448.99	35%	€ 1,240,871,689
2017	40,148.51	43%	€ 1,514,351,046
2018	46,037.75	49%	€ 1,765,765,906
2019	49,920.09	52%	€ 1,947,527,952
2020	50,321.77	59%	€ 1,807,424,210
2021	56,942.47	66%	€ 2,031,116,989
2022	64,644.33	75%	€ 2,313,464,729
2023	65,353.40	85%	€ 2,358,806,051
2024	74,539.67	97%	€ 2,740,624,590
2025	85,395.75	111%	€ 3,199,154,714
TOTAL GAIN	703,210.80	34%	€ 25,095,941,727

Appendix 2 - Table 3: Total gains in YLDs – CVD

Year	Difference in YLDs (number)	Difference in YLDs (%)	Economic Benefits
2005	44.20	0%	€ 1,277,074
2006	62.36	1%	€ 1,812,530
2007	92.76	1%	€ 2,711,329
2008	107.90	1%	€ 3,190,402
2009	160.98	1%	€ 4,866,297
2010	228.22	2%	€ 6,580,022
2011	364.18	3%	€ 10,281,480
2012	509.46	4%	€ 14,048,636
2013	585.35	5%	€ 17,447,468
2014	635.14	5%	€ 20,479,041
2015	691.03	6%	€ 24,058,337
2016	888.92	7%	€ 32,976,690
2017	1,066.04	9%	€ 40,209,705
2018	1,212.47	10%	€ 46,503,994
2019	1,311.98	10%	€ 51,183,976
2020	1,430.52	11%	€ 51,380,313
2021	1,602.02	13%	€ 57,143,311
2022	1,795.19	14%	€ 64,245,672
2023	1,961.58	15%	€ 70,799,629
2024	2,198.88	17%	€ 80,847,094
2025	2,467.08	19%	€ 92,423,609
TOTAL GAIN	19,416.26	8%	€ 694,466,612

Appendix 3 - Table 4: Total gains in YLL – cancer

Year	Life Years Gained (Number)	Life Years Gained (%)	Economic Benefits
2005	1,005.04	1%	€ 29,040,763
2006	2,048.63	1%	€ 59,542,917
2007	2,721.14	2%	€ 79,541,522
2008	3,962.83	3%	€ 117,175,910
2009	4,772.65	3%	€ 144,272,316
2010	5,888.75	4%	€ 169,785,490
2011	8,859.98	6%	€ 250,133,383
2012	15,198.77	11%	€ 419,111,787
2013	17,012.47	12%	€ 507,090,116
2014	18,768.69	14%	€ 605,161,585
2015	20,195.48	15%	€ 703,108,549
2016	23,446.54	17%	€ 869,806,273
2017	26,656.82	19%	€ 1,005,461,629
2018	28,684.53	21%	€ 1,100,187,673
2019	29,838.69	21%	€ 1,164,094,159
2020	33,071.17	24%	€ 1,187,828,616
2021	36,672.11	26%	€ 1,308,080,693
2022	40,690.55	29%	€ 1,456,216,695
2023	45,184.51	33%	€ 1,630,848,245
2024	50,222.15	37%	€ 1,846,534,258
2025	55,883.76	41%	€ 2,093,555,935
TOTAL GAIN	470,785.24	16%	€ 16,746,578,514

Appendix 4 - Table 5: Total gains in YLD – cancer

Year	Difference in YLDs (Number)	Difference in YLDs (%)	Economic Benefits
2005	3.69	0%	€ 106,678
2006	7.64	0%	€ 221,996
2007	10.24	0%	€ 299,435
2008	15.31	0%	€ 452,710
2009	18.92	0%	€ 571,919
2010	23.17	0%	€ 668,059
2011	35.08	0%	€ 990,494
2012	60.31	1%	€ 1,662,949
2013	67.90	1%	€ 2,023,931
2014	75.79	1%	€ 2,443,819
2015	82.99	1%	€ 2,889,295
2016	96.57	1%	€ 3,582,363
2017	109.37	1%	€ 4,125,466
2018	117.46	1%	€ 4,505,111
2019	122.03	1%	€ 4,760,682
2020	136.37	1%	€ 4,898,211
2021	152.33	2%	€ 5,433,590
2022	170.08	2%	€ 6,086,645
2023	189.82	2%	€ 6,851,024
2024	211.77	2%	€ 7,786,322
2025	236.20	2%	€ 8,848,744
TOTAL GAIN	1,943.05	1%	€ 69,209,443

Appendix 5 - Table 6: Total gains in YLL – respiratory disease

Year	Years Life Gained (Number)	Years Life Gained (%)	Economic Benefits
2005	755.15	2%	€ 21,820,193
2006	1,329.19	3%	€ 38,632,701
2007	1,412.53	4%	€ 41,289,673
2008	1,655.16	4%	€ 48,941,124
2009	1,885.43	5%	€ 56,994,453
2010	2,395.02	7%	€ 69,053,525
2011	2,653.66	8%	€ 74,917,737
2012	3,450.03	10%	€ 95,135,845
2013	6,108.96	18%	€ 182,089,676
2014	6,995.01	21%	€ 225,541,129
2015	7,890.39	23%	€ 274,705,170
2016	8,841.14	26%	€ 327,983,509
2017	10,798.24	31%	€ 407,295,998
2018	11,872.11	34%	€ 455,351,608
2019	12,635.95	36%	€ 492,965,247
2020	13,330.99	40%	€ 478,813,532
2021	15,042.65	44%	€ 536,565,697
2022	15,868.98	50%	€ 567,912,431
2023	17,963.50	56%	€ 648,358,315
2024	18,960.14	63%	€ 697,113,824
2025	21,553.56	71%	€ 807,454,478
TOTAL GAIN	183,397.79	25%	€ 6,548,935,866

Appendix 6 - Table 7: Total gains in YLD – respiratory disease

Year	Difference in YLDs (Number)	Difference in YLDs (%)	Economic Benefits
2005	238.14	1%	€ 6,881,253
2006	438.52	1%	€ 12,745,395
2007	496.98	2%	€ 14,527,365
2008	604.28	2%	€ 17,867,817
2009	706.52	2%	€ 21,357,332
2010	957.05	3%	€ 27,593,746
2011	1,048.86	3%	€ 29,611,302
2012	1,358.27	5%	€ 37,454,746
2013	2,356.68	8%	€ 70,245,632
2014	2,683.78	9%	€ 86,533,540
2015	2,981.10	10%	€ 103,787,364
2016	3,353.07	11%	€ 124,390,212
2017	4,046.47	14%	€ 152,627,675
2018	4,435.54	15%	€ 170,124,082
2019	4,722.11	15%	€ 184,223,422
2020	5,105.86	17%	€ 183,389,006
2021	5,715.59	19%	€ 203,872,916
2022	6,416.65	21%	€ 229,636,582
2023	7,210.87	23%	€ 260,262,527
2024	7,807.33	26%	€ 287,054,667
2025	8,763.79	29%	€ 328,315,132
TOTAL GAIN	71,447.47	11%	€ 2,552,501,712

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