IPHA Agreement - One Year On

June 22nd 2017

Agenda

- Market Overview
- 2016 Framework Agreement
  - Pricing & Reimbursement Process review
  - Concluding Remarks
- Discussion

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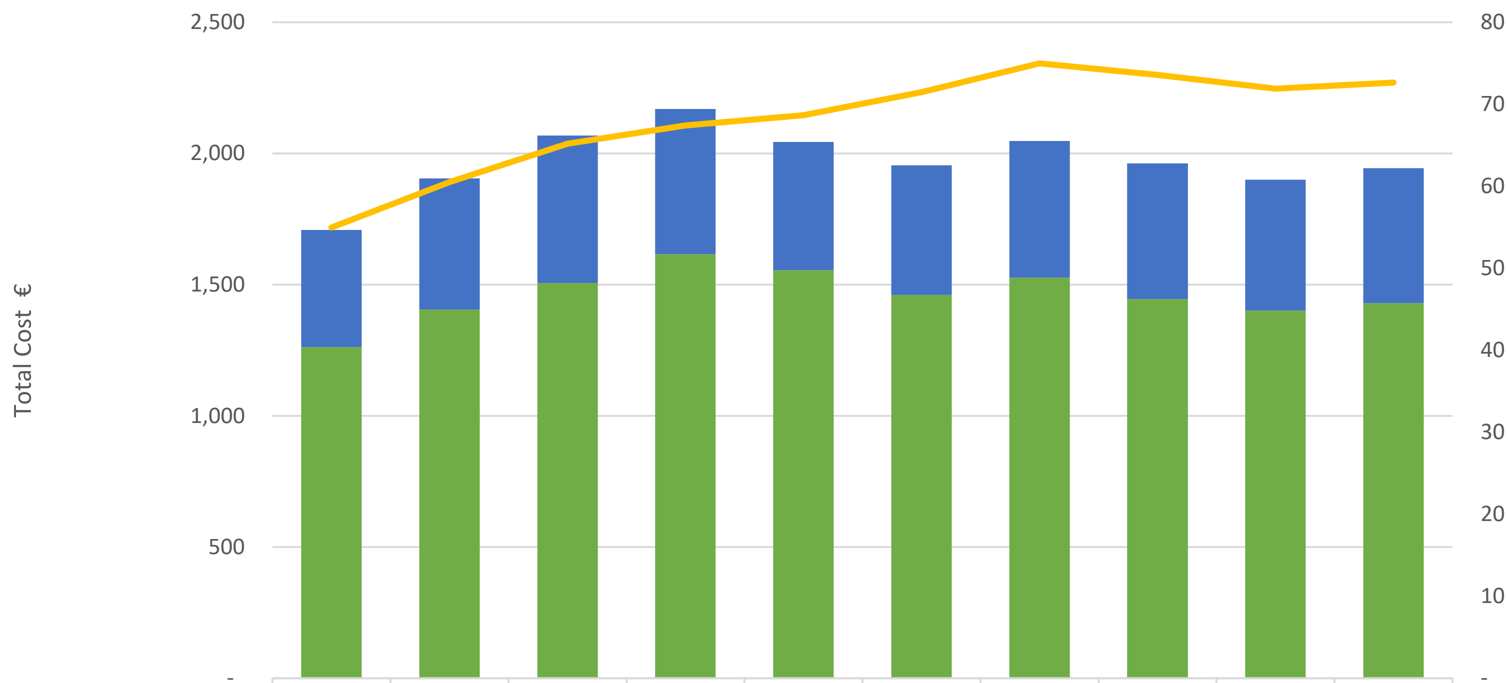
The IPHA Agreements have generated headroom for more treatments for Irish patients

The dynamics have changed over time more treatments for less money
Ingredient cost increased by 13.2% but the volume has increased 32.1%

Primary Care Medicines Analysis - Cost and Volume 2006 to 2015



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Distribution Fees €	446	500	562	554	490	494	521	517	499	515
Ingredient cost €	1,262	1,404	1,506	1,615	1,554	1,460	1,527	1,445	1,400	1,428
Volume (items)	55	60	65	67	69	71	75	74	72	73

Source: PCRS Statistical Analysis of Claims and Payments

Irish Pharmaceutical Market 2015 & 2016

Source: IMS Health; prices at ex-manufacturer price

Irish Retail Pharmaceutical Market 2013 to 2017 by top ATC classes

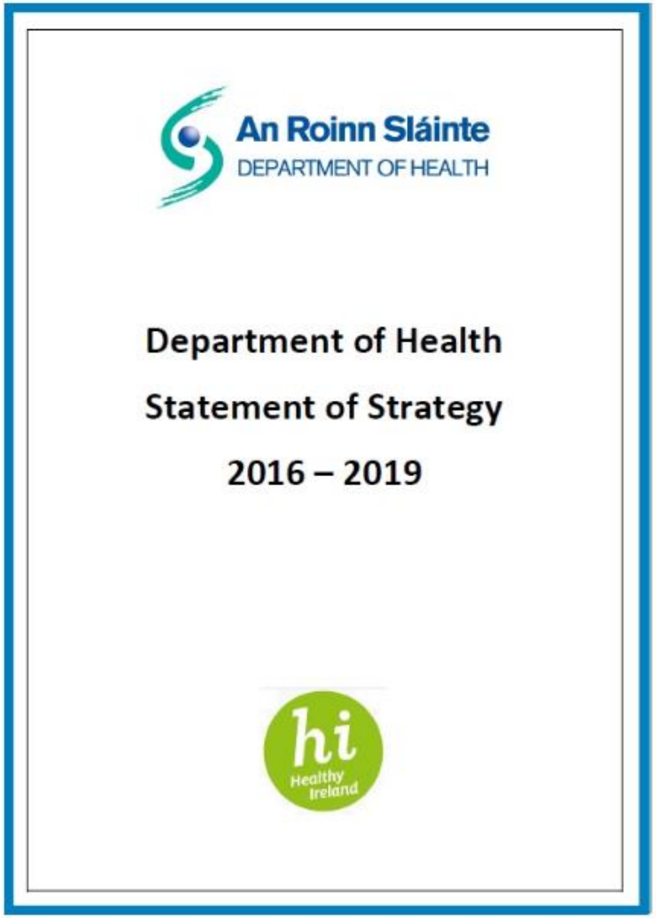
	MAT/ MAY/13	MAT/ MAY/14	MAT/ MAY/15	MAT/ MAY/16	MAT/ MAY/17	17 vs 13
PRESCRIPTION BOUND	**1,285**	**1,225**	**1,208**	**1,277**	**1,295**	**0.8%**
L4B ANTI-TNF PRODUCTS	114	125	139	158	167	45.9%
N3A ANTI-EPILEPTICS	68	64	70	73	65	-5.1%
N7A MULTIPLE SCLEROSIS PRODS	25	32	37	46	49	95.4%
L1H PROTEIN KINASE INH A-NEO	24	27	29	35	44	82.5%
R3F B2-AGON+CORTICOIDS COMBS	51	48	47	47	41	-19.5%
C10A CHOLEST&TRIGLY.REGULATOR	101	67	44	40	41	-59.9%
L4X OTHER IMMUNOSUPPRESSANTS	22	22	22	28	37	66.0%
A2B ANTIULCERANTS	79	62	44	31	33	-58.5%
N6A ANTIDEPRESS.& MOOD STAB.	59	60	50	38	31	-48.0%
B1F DIRECT FACTOR XA INHIBS	2	6	13	23	30	1532.4%
N5A ANTIPSYCHOTICS	48	44	35	33	27	-43.4%
A10C HUMAN INSULIN+ANALOGUES	22	22	23	24	23	2.3%
L2B CYTO HORMONE ANTAGONISTS	10	13	15	21	22	126.3%
L4C INTERLEUKIN INHIBITORS	3	4	7	11	22	650.6%
N2A NARCOTIC ANALGESICS	21	20	21	23	22	5.0%
Total Displayed (15)	649	614	597	629	653	0.5%
Total Others (251)	635	612	611	648	642	1.1%
UNITS	**78**	**79**	**82**	**86**	**88**	**12.1%**

Source: IMS Health; prices at ex-manufacturer price

DoH Mission Statement

To improve the health and wellbeing of people in Ireland by:

- keeping people healthy;
- providing the healthcare people need;
- delivering high quality services; and
- **getting best value from health system resources.**


An Roinn Sláinte
DEPARTMENT OF HEALTH

Department of Health

Statement of Strategy

2016 – 2019

hi
Healthy Ireland

DoH Policy on Medicines

Securing Cost-Effective Access to Medicines for People

- **Medicines play a key role** in improving the health of people in Ireland. Securing timely access to medicines at an **affordable price**, in particular innovative medicines offering **enhanced health outcomes** is a key priority. Securing the cost effective and economic provision of medicines for the health service is vital to **free up resources for continued investment** in new and innovative medicines.
- The Department will continue to progress a number of initiatives to ensure the cost-effective provision of medicines**, including the implementation of the new 4-year Framework Agreement with the Irish Pharmaceutical Healthcare Association on the pricing and supply of medicines**.
- **Action:** Ensure the most cost-effective provision of medicines for patients through procurement, pricing and prescribing measures.

2016 Framework Agreement

IPHA commitments

Pricing & Reimbursement Process Review

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IPHA members have honoured their commitments

- Clause 5.2 Price Realignments
- Clause 7.1 LoE Small molecule
- Clause 8.1 LoE Biologics
- Clause 9.1 Rebate 5.25%
- Clause 9.4 Hospital Rebate data

Value of the Agreement

Clause	Totals from each clause	% of Total
5	317,108,352	40.4%
7	112,102,702	14.3%
8	104,104,613	13.3%
9	251,312,500	32.0%
	784,628,167	

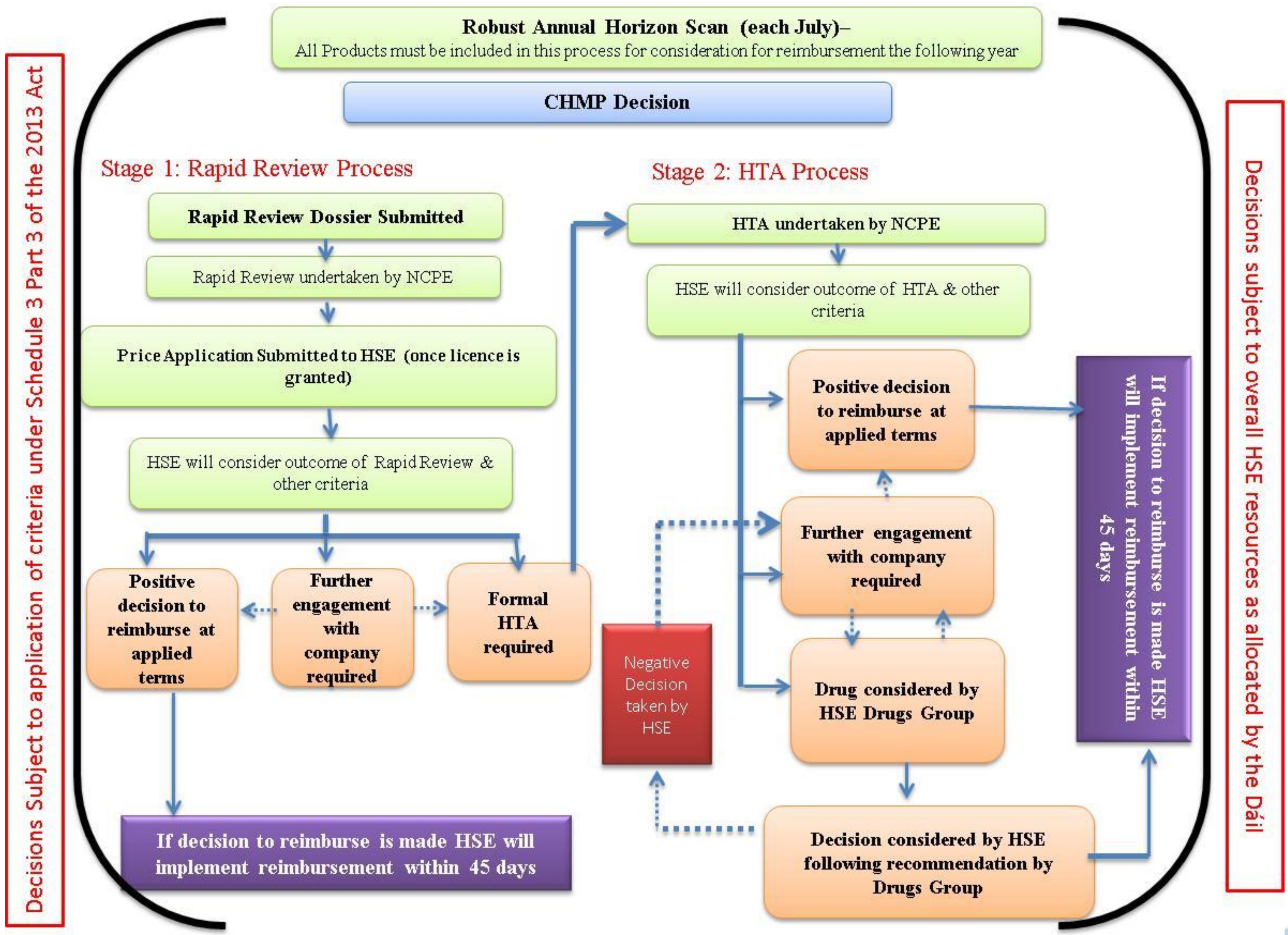
Year	Totals from each clause	% of Total
2016	140,221,435	17.9%
2017	188,590,419	24.0%
2018	201,576,384	25.7%
2019	254,239,928	32.4%
	784,628,167	

Actual Value of the Agreement 2016

August to December

• Realignment	
– Retail	24,416,500
– Hospital	8,897,233
– Total	33,313,733
• Loss of exclusivity	2,603,572
• Rebates	
– Retail (Jun-Dec)	26,942,416
– Hospital (Jun- Dec)	5,400,000
Total Savings Delivered 2016	**68,259,721**
(Annualised)	*(141,645,674)*

New Medicines – Assessment Process



Who makes the decision?

- The HSE is empowered to make the decision under the Health (Pricing & Supply of Medical Goods) Act, 2013
- **CPU** initiate the process & negotiate prices
- **NCPE** complete the RR/HTA
- **NCCP** advise for cancer products
- **HSE Drugs Group** reviews all medicines and makes recommendations
- **HSE Senior Leadership Team** takes the reimbursement decision
- **DoH** for non-budgeted items ???

Products reimbursed Aug 16 to May 17

- The State has added 21 IPHA products to the reimbursement list Aug 2016 to May 2017
  - 11 of these are existing molecules or line extensions with no budget impact.
- In relation to the 10 new molecules/products, the net budget impact is of the order of €17m on an annualized basis
  - 3 products account for €14.5m of this
- There have been 6 non-IPHA products (excluding Orkambi)
- There have been 60 generic/biosimilar products
  - 46 on CDS and 14 on High Tech
- There were 36 Parallel trade products approved

New Medicines – Decision Authority

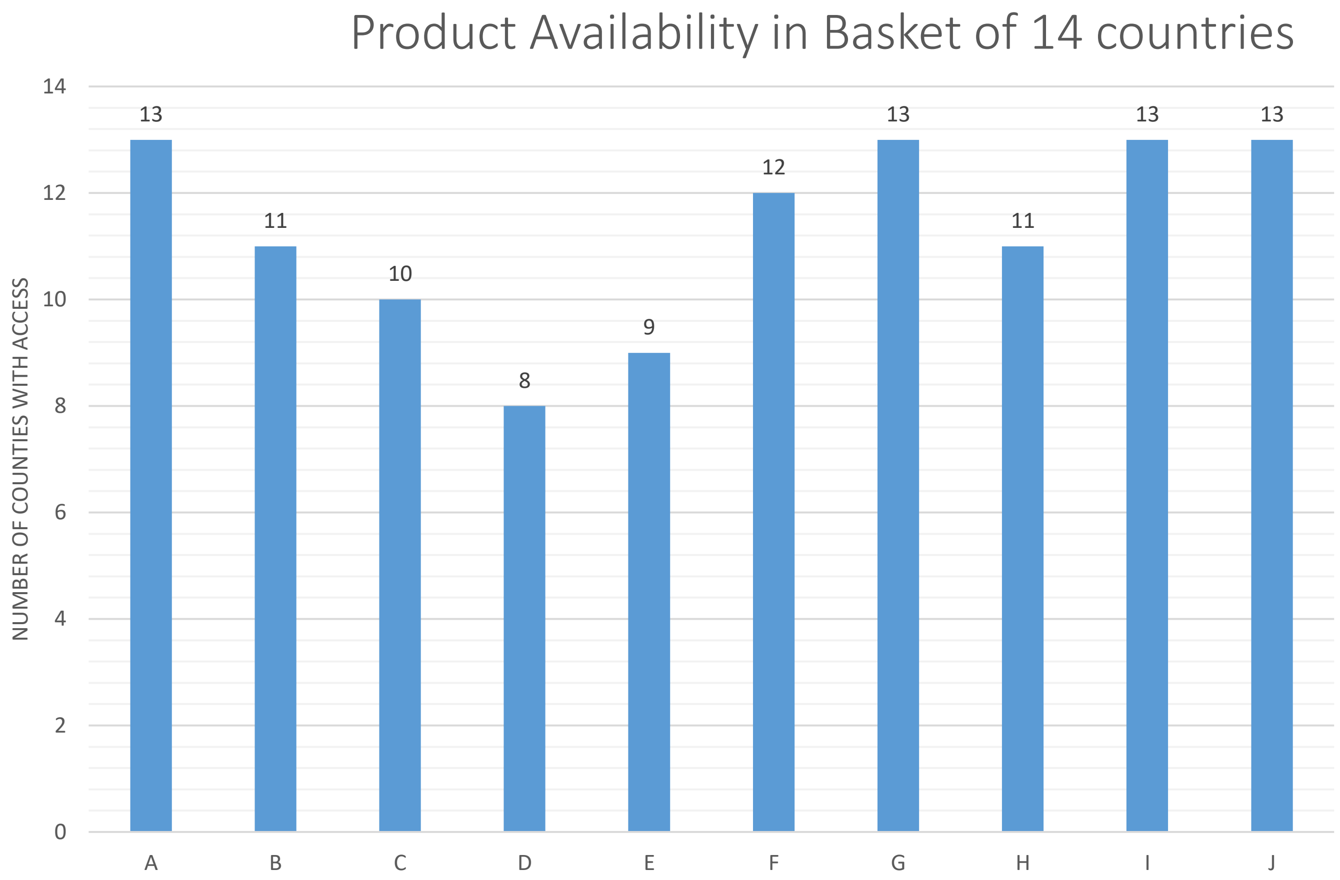
Decision Authority Level Table*

		QALY Threshold as Per NCPE Assessment		
		Up to €20,000	Up to €45,000	Above €45,000
Net Budget Impact as per NCPE Assessment for each drug	Budget Neutral - €5m#	HSE (non – leadership)	HSE (non – leadership)	HSE Leadership
	> €5m - <€20m#	HSE (non – leadership)	HSE Leadership	HSE Leadership
	> €20m	HSE Leadership	HSE Leadership	HSE Leadership

*It will be a matter for the HSE to decide each year on the decision authority level in line with the Health Act 2004. The HSE reserves the right for all drugs to be considered by Leadership

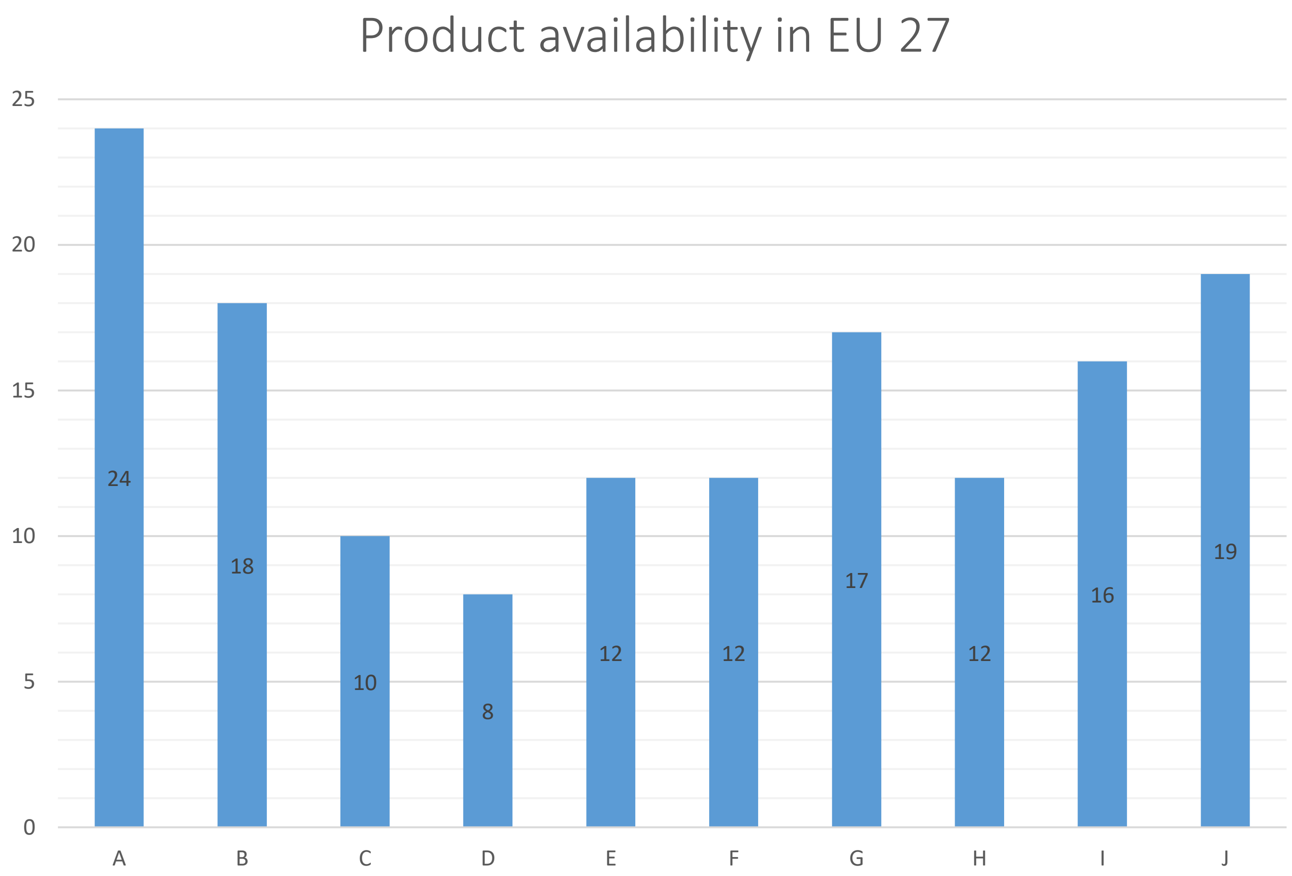
Budget Impact for each drug: This is based on the NCPE estimated net budget impact over 5 years but is subject to a gross budget impact of less than €30m for those categories denoted by #.

Overview Reimbursement Status



- On average the products are in 11 of the 14 countries

Overview Reimbursement Status



- On average the products are in 15 of the 27 countries

EFPIA Patient WAIT indicator – Rate of availability in 2016

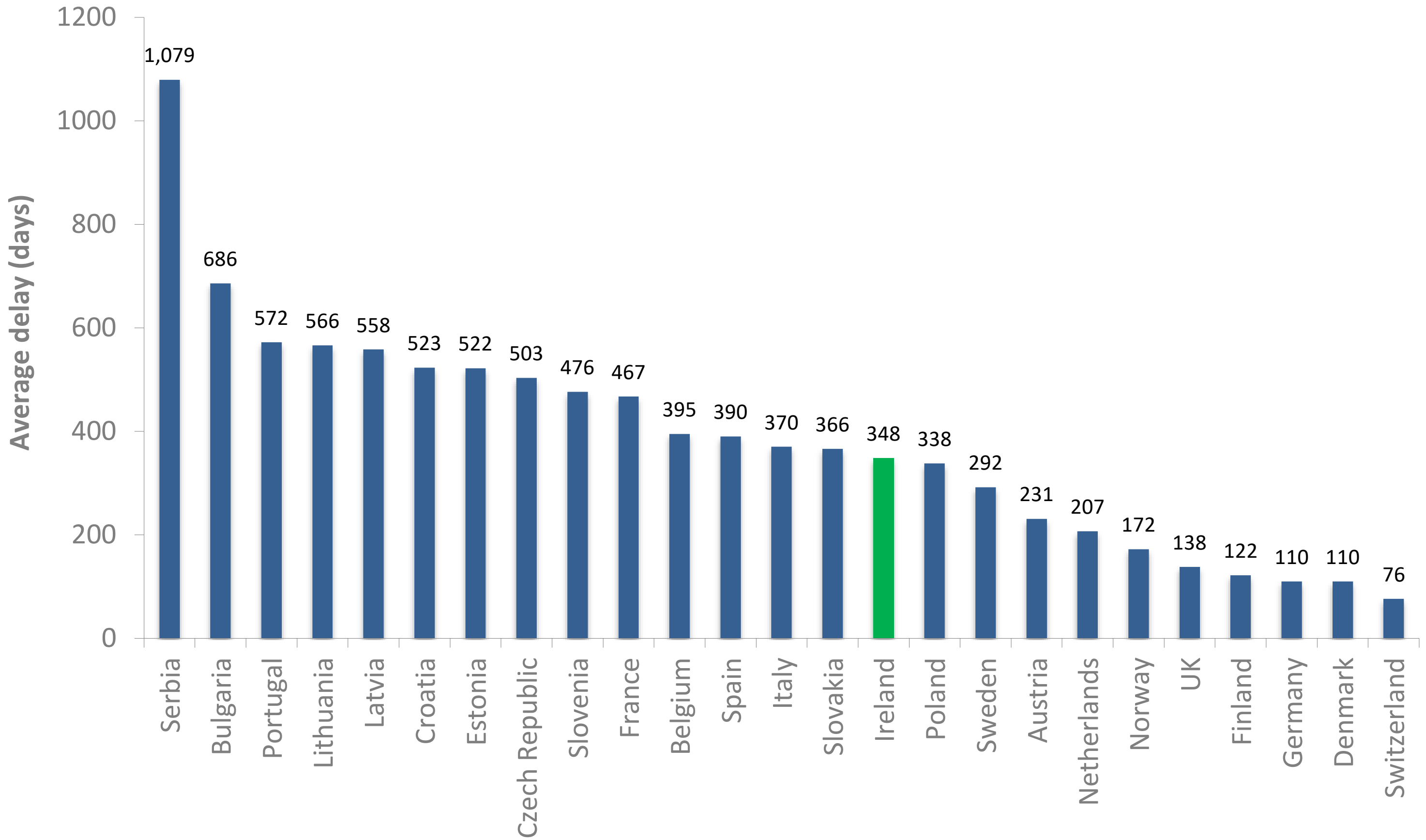
The rate of availability, measured by the number of medicines available to patients in European countries as of 2016: for most countries this is the point at which the product gains access to the reimbursement list.

efpia

Notes: Poland - 4 products only available on the private market

www.efpia.eu

EFPIA WAIT – average delays 2013-15



- On average the delay was almost one year

Free the IPHA Ten!!!

	RR start date	HTA outcome	Day since RR	Days since HTA
A	01/10/2014	16/11/2016	994	217
B	05/01/2015	17/12/2015	898	552
C	07/12/2015	19/10/2016	562	245
D	11/05/2016	25/01/2017	406	147
E	19/04/2016	05/01/2017	428	167
F	24/02/2015	29/04/2016	848	418
G	12/09/2014	13/11/2015	1013	586
H	12/08/2015	12/10/2016	679	252
I	28/05/2015	18/03/2016	755	460
J	06/11/2015	08/07/2016	593	348
			718	**339**

- Currently the delay is almost two years
- It is taking just over one year to complete the pharmacoeconomic evaluation and almost a further year for the negotiation phase

Concluding Remarks

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Current Challenges

- HTA specific
  - Early/immature data
  - Uncertainty – requests for model updates
  - NCPE resourcing
- Negotiation Process
  - BUDGET IMPACT
  - Multiple indications
  - Combination pricing
  - Transparency, communication
  - Multiple steps/reviews/hurdles
  - Referral to the DoH

IPHA activities

- The HSE committed to applying the terms of the Agreement from January 2017
- IPHA has been tracking the progress of individual products since then
- IPHA has had 4 meetings with the HSE in 2017
- Members have been contacted individually for regular updates
- Of the 14 post HTA products being tracked only four have been reimbursed
  - Only one of these was subject to a HTA
- Various correspondence with HSE & DoH
- Upcoming Biannual Oversight meeting

Questions & Discussion