

Timely Patient Access To Cancer Medicines – A Collaborative Effort

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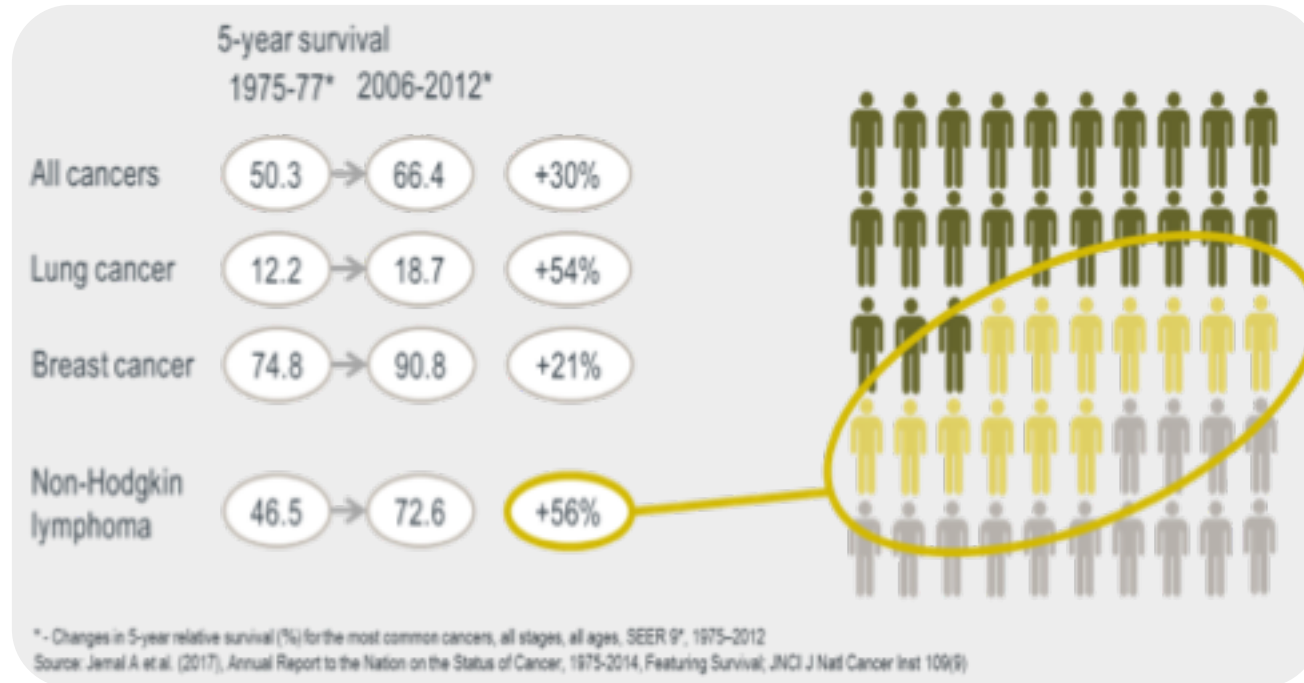
Uppsala, June 14, 2018



The Challenge – How To Reconcile Access, Affordability And Incentives For Innovation?

- «Policy makers constantly seek to reconcile access to innovative treatments with affordability, while maintaining incentives for innovation.» (OECD 2017)
- My hypothesis for this workshop discussion is
 - Timely access to innovation should be our priority
 - Price has to reflect value and should not be an access hurdle
 - To enable timely and affordable access we have to be pragmatic in the interest of patients and develop new access solutions together

We Have Made Great Progress In Treating Cancer. 7 Out Of 10 Patients With Non-Hodgkin Lymphoma Achieve 5-Year Survival

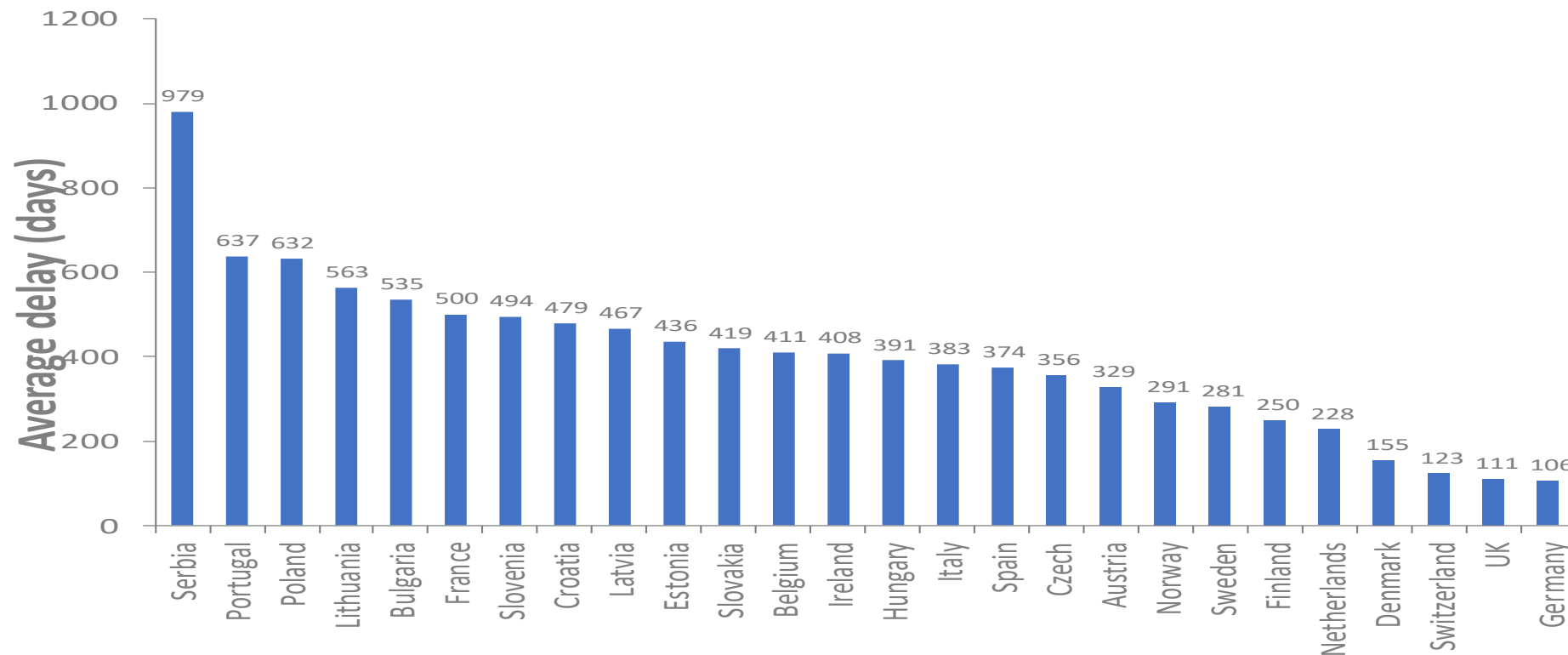


2017 Annual Report to the Nation on the Status of Cancer, 1975-2014, Featuring Survival, JNCI J Natl Cancer Inst 109(9)

Autovac



Not Everyone In Europe Can Access Treatment In Timely Manner: A Patient In Portugal Waits 6 Times Longer Than In Germany



Source: EFPIA (2018). For most countries patient access equates to granting of access to the reimbursement list, except for hospital products in FI, NO, SE where some products are not covered by the general reimbursement scheme and so the zero-delay is artificially declining the median and average.

In France, some innovative products without competitors can be made available prior to market authorisation under the system of Temporary Authorisations. As these are not taken into account in the analysis, the average for France is higher than in reality.



Countries Have Chosen Different Ways Of Creating Access



Germany grants immediate access after EMA approval and allows for «Bundling» of indications. France and the UK have specific access schemes in place such as ATU and EAMS*, respectively



Italy has created an Innovation Fund to secure timely access to innovative cancer medicines

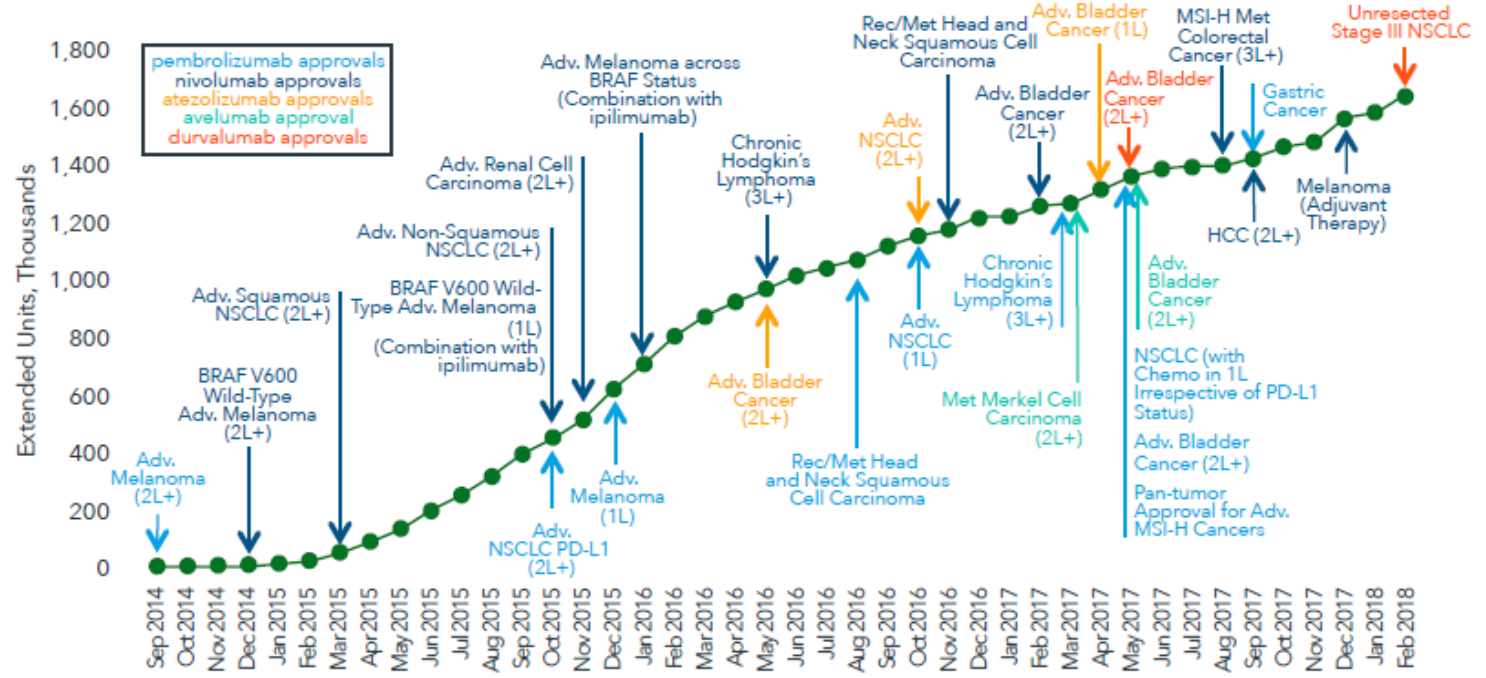


Belgium, Denmark and The Netherlands have created so-called Multi-Year-Multi-Indication Contracts to accelerate access to the various indications of the latest Immuno-Oncology medicines

* - ATU: In France, the exceptional use of pharmaceutical proprietary products that do not have MA and are not used in clinical trials is covered by obtaining a Temporary Authorisation for Use (ATU) in advance. The ATU is issued by the French National Agency for Medicines and Health Products Safety (ANSM). EAMS: The early access to medicines scheme (EAMS) aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need (<https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams>)

New Cancer Medicines Increase Complexity. Tested In Up To 30 Tumors Types, Alone Or In Combination, With Up To 5 Launches Per Year.

Chart 4: Immuno-Oncology PD-1 and PD-L1 Inhibitor Uptake in the United States

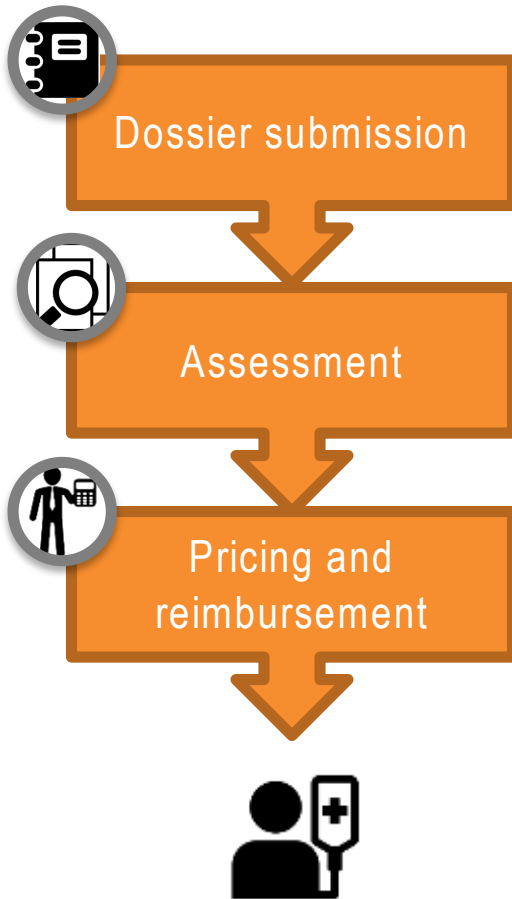


Source: U.S. FDA, IQVIA, National Sales Perspectives, Feb 2018; IQVIA Institute, Apr 2018

Source: IQVIA (2018), Global Oncology Trends. Innovation, Expansion and Disruption



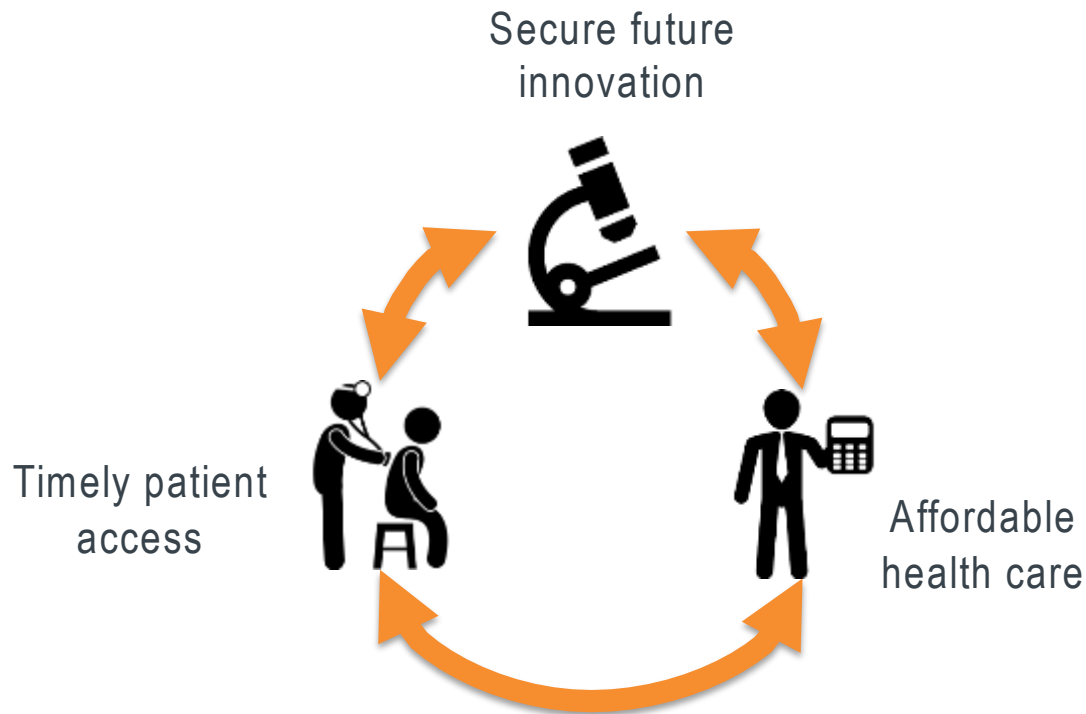
Current Pricing And Reimbursement Processes May Struggle With This New Complexity. Timely Patient Access Could Become Increasingly Difficult



x 20 indications x 3 companies = 60 dossiers, 60 assessments

Where Budget Predictability Is A Concern Multiannual Agreements Can Address Access, Affordability And Managing of Innovation In Cancer Care

Government's pharmaceutical policy objectives [1]

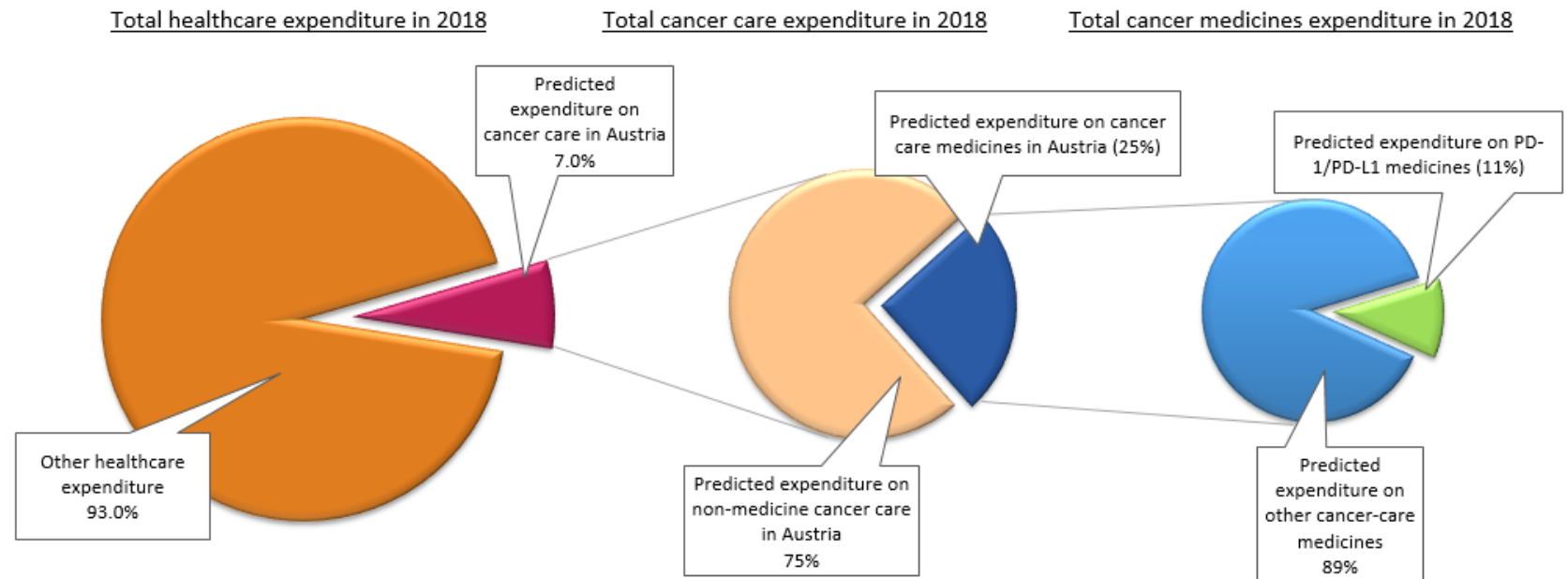


Tailored Multi-Annual Agreements

- **Time to patient access:** Agree on future coverage upfront, e.g. all indications over certain years
- **Financial predictability:** Agree on budget framework over several years
- **Effective efficiency:** reduce administrative burden of multiple renegotiations with the option to re-assess the access framework at the end of the term

We Engage With Payers And Policy Makers On Horizon Scanning Of The Health And Budget Impact Of Immuno-Oncology Medicines Over 5 Years

- Results for Austria showed that in the next 5 years I-O could lead to more than 4000 life years gained (+24%); and prevent more than 3000 adverse events (-33%)
- I-O expenditure is estimated to be less than 0.2% of total health expenditure in Austria in 2018



Timely Patient Access To Cancer Medicines Is A Collaborative Effort

- Current access processes have to be adapted to the reality of more complex treatments
- Open exchange and collaboration between innovative industry, payers and policy makers is needed
- Timely patient access is a joint effort in a world of rapidly evolving science

Annex

MSD



Fighting Cancer Requires All Stakeholders. Through Industry Associations And Stakeholders We Aim For A Consensus On Priorities In Cancer Care

- EFPIA* Oncology Platform to create a consensus on priorities in Cancer Care with multiple stakeholders
- Collaboration with patient organisations on patient involvement in HTA** and «Biomarker Literacy»
- Several projects in «Cancer Literacy» in collaboration with the Global Health Literacy Academy, patient and doctor associations



* - EFPIA: European Association of Pharmaceutical Industries and Associations (www.efpia.eu)

** - HTA: Health Technology Assessment