European Federation of Pharmaceutical Industries and Associations

Draft ☐ Final ☐

EFPIA Commitment for Cancer Care – Our Vision For Collaboration

Author: EFPIA **Date:** 10/05/2017 **Version:** Final



Briefing

1. Executive Summary

Over the last decade, major strides have been made in improving cancer outcomes in Europe. Medicines have played an essential part and contributed to significant system efficiencies that have allowed oncology expenditure to remain a constant share of health spending despite increasing incidence. Industry continues to invest in innovation and development of more targeted treatments and new modes of action, including immunotherapies and combination treatments, providing the promise of further improvement in standards of care.

However, significant disparities continue to exist in access to care and cancer outcomes in Europe.

The industry supports the EU's goal of tackling inequalities in cancer mortality amenable to healthcare, reducing the disparity between the best and worst performing Member States by 70% and resulting in an extra 200,000 people surviving at least 5 years over the next decade. Closing the gap will require action in a number of areas:

- Health spending in line with rising incidence combined with effective cancer planning, resource prioritisation and implementation of best practices
- Faster, broader and more equitable access to innovation across Europe
- Improved data infrastructure to support decision making and enable transition to more value driven payment and reward models

Industry is committed to working in partnership with our stakeholders to address these challenges. The industry recognises that affordability is an issue and is open to new pricing approaches that reflect value delivered and national circumstances (e.g. GDP/capita). It is also open to partnering in the development of necessary infrastructure and capabilities, to support new models and informed decision making.

However, in order for the above to happen there is a need for stakeholders to commit to i) support effective cancer planning, including earlier diagnosis, ii) adopt definitions of value that go beyond cost-utility and consider incremental nature of innovation and the importance of the patient perspective, iii) create frameworks that allow for flexible Pricing and Reimbursement solutions, such as outcomes-based pricing and mitigate the negative impact of External Reference Pricing.

2. Industry view on the key challenges for cancer care in Europe

Between October and December 2016, EFPIA carried out a consultation process with 15 member companies[1] to identify specific challenges that industry believes must be addressed in order to improve Cancer Care in Europe. A range of company experts were included in the consultation process to ensure a broad range of perspectives were captured, including experts in Medical Affairs, Market Access & Pricing, Global Policy and Government Affairs and the following issues were identified as key challenges:

- Mismatch between the rising burden of disease and a roughly flat spend on cancer care reflective of a sluggish economic recovery and tightening funding constraints;
- Inconsistencies in prioritisation of cancer care on the public policy agenda despite the prevailing disease burden and amplitude of future challenges;
- Readiness of healthcare systems to adjust to the rate of innovation in cancer treatment;
- Disconnect between regulatory and HTA / pricing & reimbursement procedures;
- Restrictive HTA value assessment frameworks;
- Growing disparities in care delivery and outcomes within and across countries.

While many of these challenges are not unique to cancer, growing cancer incidence and the promise of innovation support a dedicated response. Co-ordinated action is now needed by industry and other stakeholders to address these challenges, to ensure that today's patients continue to benefit from the progressive improvement in outcomes that are being made possible by current advances in medicine.

3. Tackling these challenges in an effort to improve cancer care – Industry Proposals

It is clear that the industry's main contribution to improving cancer outcomes comes from the products it successfully develops and makes available to patients. However, there is also considerable scope for the industry to work together with other stakeholders to address broader access challenges. The EFPIA Oncology Steering Group has identified three broad policy objectives:

- Value – Secure appropriate valuation of innovation in cancer therapies
- Resourcing – Ensure sufficient payer resource allocation to cancer care
- Affordability – Encourage payers to implement innovative and timely reimbursement approaches

In all of these areas, there needs to be openness on the part of stakeholders to work in a trusting and collaborative fashion with industry, and industry needs to be prepared to step up collectively on any commitments made.

Value – Secure appropriate valuation of innovation in cancer therapies

A key industry objective is to **close the widening gap and disconnect between Regulatory and HTA and P&R procedures, and specifically attitudes to value**. This requires a more progressive attitude to surrogate endpoints and the value of incremental advances that considers the patient perspective and goes beyond cost-utility, and greater consistency in evidence requirements between Regulatory,

1 Amgen, AstraZeneca, Bayer, Boehringer Ingelheim, BMS, Celgene, Ipsen, Janssen, Lilly, Merck, MSD, Novartis, Pfizer, Roche, Servier

HTA and P&R agencies. Specifically, industry advocates building on more progressive and holistic definitions of value as a way of defining and valuing oncology innovation.

With the rapid evolution in standards of care and the increased use of accelerated and adaptive pathways such as PRIME, it will become increasingly critical to assess the value and performance in real world settings. A consistent **approach for the collection and meaningful use of Real World Data (RWD) in decision-making** needs to be agreed for oncology along with a roadmap for implementation.

Resourcing – Ensure sufficient payer resource allocation to cancer care

Despite the increasing incidence, meaning that cancer is now the second largest cause death in Europe and soon be the biggest cause of disability, healthcare resources devoted to cancer care as a percentage of health spending have remained largely unchanged. Medicines innovation has helped by allowing for improved efficiency in the use of existing resources and shifting expenditure from acute to community settings. It is essential that health systems **increase absolute funding for cancer care** and **achieve maximum efficiency from existing expenditure, decommissioning procedures where appropriate**.

Effective cancer planning has an essential role to play in setting priorities and mobilising resources. Industry can work with stakeholders to ensure that effective and up-to-date cancer plans are in place, and that progress against plans is systematically assessed, improving early diagnosis and treatment outcomes. Building and collaborating on work done by other stakeholders, the industry can provide further support in **codifying and sharing best practices in cancer helping to level-up care delivery in Europe**. More specifically EFPIA should have the opportunity to play a key role in future joint action on national cancer plans, representing the shared commitment that industry has to improve cancer outcomes.

Improved horizon scanning can help policy makers better anticipate the impact of future innovation and provide for it accordingly. Where horizon scanning capabilities are under-developed, processes should be enhanced and improved to provide better visibility to payers, clinicians and commissioners of care. EFPIA's own initiative in the area is a resource that can be drawn on by policy makers, together with the initiatives of individual companies and stakeholders.

Affordability – Encourage payers to implement innovative and timely reimbursement approaches

The **development of more flexible pricing and reimbursement approaches** are vital to addressing both the challenges of recognising value in oncology, including multi-indication and combination pricing, as well as real differences in the ability to pay between Members States. As an industry we would like to advocate for a faster transition to outcomes / performance-based / pay-for-use reward and reimbursement models, as well tangible and practical access schemes that can allow for differential pricing options to address the affordability gap and the challenges presented by new technologies, such as multi-indication products and combination therapies.

It will be **critical to invest in the development of data and administrative infrastructures** that can allow for more sophisticated pricing models. The industry should be open to co-investing in making this happen, and initiatives such as Project Code are illustrative of the commitments that industry could make.

The **Innovative Medicines Initiative (IMI) and EU structural funds could provide potential financial resources to enable change** – specifically around infrastructure development.

Policies such as External Reference Pricing (ERP) can contribute to inequalities in patient access to treatment and act as a disincentive to the implementation of an outcomes-focused approach. Industry believes that **External reference pricing schemes and other current practices should be phased out** and be replaced by outcomes-focused models that can demonstrate the value that treatments deliver to national healthcare systems. Oncology could be an area where, on a pilot basis, products could be lifted out of reference pricing considerations and / or negotiated prices are maintained confidential.

Finally, industry can also play its role, together with the authorities and patient associations, in **further promoting the participation of EU patients in clinical trials**. This allows patients to access the very latest treatments where appropriate. In a number of EU markets, patients in clinical trials can account for 15%+ of all patients treated, providing a considerable subsidy of overall treatment costs.

Appendix 1: Industry Representatives

EFPIA has identified three senior oncology leaders from the project member companies to represent the industry at the roundtable event:

Amadou Diarra - Vice President, Head of Global Policy, Advocacy & Government Affairs (BMS)

Amadou joined Bristol-Myers Squibb in 1991 as market research & business development manager, Africa Division. From 1999 to 2002 he led the company's landmark philanthropic program, Secure the Future, a public-private partnership focused on care and support for women and children infected or affected by HIV/AIDS in Sub-Saharan Africa. In 2002, he was appointed general manager, Indonesia and in 2005 became general manager, Turkey. In 2008, he assumed responsibility as general manager for the Ireland & Nordic Region and was then promoted to vice president, Access Europe. Late 2010, he was appointed European vice president and general manager, UK & Ireland. During his 3 years tenure Amadou also chaired the European Works Council and sponsored the Cardiovascular and Metabolics Disease Area Committee. As a Board member of the Association of the British Pharmaceutical Industry (ABPI), Amadou chaired the Health Technology Assessment Task Force and the Reputation Strategy Group. He also represented ABPI on the All Wales Medicine Strategy Group (AWMSG).

Prior to joining Bristol-Myers Squibb, Amadou held the role of international market research manager at Laboratoire Fournier, Dijon. Amadou holds a Doctorate from the School of Pharmacy, University of Tours, France and a Masters in Business Administration from the École Supérieure de Commerce de Tours. He also completed the General Management Program delivered by the European Center for Executives Development in collaboration with INSEAD.

Amadou represents Bristol-Myers Squibb as Chair of the Pharmaceutical Research and Manufacturers of America (PhRMA) International Senior Executive Committee (ISEC) and as a Council member of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).

Cyril Titeux – Vice President of EMEA Strategy Organization (Janssen)

After qualifying as a veterinarian from the National Veterinary School of Maisons-Alfort, Cyril Titeux earned an MBA at HEC Business School before joining Eli Lilly in 1992 where he held various positions in sales, market research and marketing.

He joined Janssen-Cilag in 1997 as Product Manager. He then became Marketing Director, Sales Director and finally Business Unit Director in 2002. He left France in 2005 when he was offered the position of Global Marketing Leader in HCV. He stayed two years in the US until he was appointed Managing Director of Janssen-Cilag Austria.

He moved back to France in January 2010, appointed as President of Janssen France until January 2015. Cyril is now Vice-President of Janssen EMEA Strategy Organization. Cyril chaired Agipharm (an association which gathers the French affiliates of US pharmaceutical companies) from 2012 to 2014 and was a board member and VP of LEEM (Association of French pharmaceutical companies).

Dr Marjo Hahka-Kemppinen - Senior Director, Oncology Medical Affairs and Clinical Development International (Eli Lilly and Company)

Dr Marjo Hahka-Kemppinen is the Senior Medical Director for Oncology for Eli Lilly's international region (all countries outside North America, Japan and China). In this role, she leads the Medical Affairs and Clinical Research Organisation through all oncology compounds and pipeline development.

Dr Hahka-Kemppinen began her career at Lilly in 2002, leading the medical department in Finland. She has worked in numerous regional and country roles in Europe. Before joining Lilly, Dr Hahka-Kemppinen served as an Assistant Professor at the University of Helsinki and as a Senior Oncologist at the Oncology Department of the Helsinki University Central Hospital.

Dr Hahka-Kemppinen holds a PhD in Medicine with a specialisation in Oncology She has conducted research in the areas of melanoma, haematology and breast cancer. She has also completed an Executive MBA and is interested in improving collaboration and synergies between science and policy. This is why Dr. Hahka-Kemppinen represents the pharmaceutical industry voice at the European Commission's expert group on cancer control, where she sits on behalf of EuropaBio.