The Value of Personalised Medicines for healthcare systems in Europe

Considering enablers to the adoption of Personalised Medicines in Europe

Anthony Barron, Associate Principal
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Background to this study

- The European Biopharmaceutical Enterprises (EBE), and the European Federation of Pharmaceutical Industries and Associations (EFPIA) has asked Charles River Associates (CRA) to conduct an evidence-based analysis of the value of personalised medicines (PM).

- In particular, the objectives are to:
  - Characterise and measure the benefit of PM to patients, society and healthcare systems
  - Identify the key enablers to the adoption of PM but also the main barriers that impede the development of PM in Europe from an economic and access perspective
  - Elaborate strategic recommendations for decision-makers to overcome these barriers and incentivise the development and adoption of PM in Europe
This considered a range of PM technologies

- We define PM as any technology that aims to improve the prevention, diagnosis and treatment of diseases by using patients’ individual characteristics to identify the most appropriate care.

- Broadly classified into two categories:
  - **Targeted therapies**: These are therapies that act on specific molecular targets associated with a disease. These targets can arise from specific mutations associated with the disease or protein-expression targets within biological pathways.
  - **Individualised therapies**: This includes modified T-cell therapies and gene therapies, which are considered ATMPs. These technologies are specifically targeted at an individual patient.

- PM refers to a process by which genetic information is used to evaluate patients at risk of developing particular diseases, or who have mutations which can be targeted by specific medicines. This includes next generation sequencing (NGS), assays for specific mutations, and gene expression profiles which characterise sections of an individual’s genome.
Four tumour types were selected as cases studies to develop a fact-based landscape analysis

- CRA selected case studies in consultation with the EBE/EFPIA steering group

<table>
<thead>
<tr>
<th>Products / targets</th>
<th>Non-small cell lung cancer</th>
<th>Breast cancer</th>
<th>Ovarian cancer</th>
<th>Melanoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Multiple specific mutations (ALK+, ROS+, EGFR) plus protein-expression targets (PD1)</td>
<td>• Germline and somatic mutation-targeted therapies • Potential usage of advanced diagnostics (e.g. Oncotype) separate from treatments</td>
<td>• Introduction of PARP inhibitors • Use of diagnostics in screening programs for BRCA mutations</td>
<td>• Introduction of BRAF inhibitors (and later BRAF / MEK inhibitors) • Use of tumour mutation testing for treatment decision-making</td>
<td></td>
</tr>
<tr>
<td>• Companion and complementary diagnostics</td>
<td></td>
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</tr>
</tbody>
</table>

To investigate the environment for each case study we chose a subset of European markets to examine in detail

Countries were selected on the basis that they:
- represent different regions of Europe
- represent different reimbursement mechanism and approach to HTA
- have some level of policy activity and prioritisation for PM
- have sufficient treatment infrastructure to enable adoption of PM

- CRA conducted a set of interviews with external stakeholders to fill evidence gaps and gather different perspectives in each country (n=19)

After reviewing a range of options we agreed to focus the case studies only on oncology reflecting that this is the therapy area with the most examples to-date
The benefits of PM can be classified into three main categories:

<table>
<thead>
<tr>
<th>Delivering better treatments for patients</th>
<th>Delivering benefits to healthcare systems and society</th>
<th>More efficient development of novel medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved efficacy i.e. patient more likely to receive a medicine delivering a clinical benefit</td>
<td>Prevention and prediction of disease</td>
<td>More effective clinical trials</td>
</tr>
<tr>
<td>Improvement in overall survival</td>
<td>Improvement in patient management of diseases</td>
<td>Efficient clinical trials and reduction in cost</td>
</tr>
<tr>
<td>Reduced adverse events</td>
<td>Prevention or delay of more expensive care costs and allowing scarce healthcare resources to be using most efficiently</td>
<td>More ethical clinical trials</td>
</tr>
<tr>
<td></td>
<td>Reduces hospitalisation</td>
<td></td>
</tr>
</tbody>
</table>

- Improved efficacy: Patient more likely to receive a medicine delivering a clinical benefit.
- Improvement in overall survival.
- Reduced adverse events.
- Prevention and prediction of disease.
- Improvement in patient management of diseases.
- Prevention or delay of more expensive care costs and allowing scarce healthcare resources to be using most efficiently.
- Reduces hospitalisation.
- More effective clinical trials.
- Efficient clinical trials and reduction in cost.
- More ethical clinical trials.
PM offers many possible treatment options to facilitate earlier treatment or prevention protocols

- Molecular analysis can determine precisely which sub-phenotype of a disease a person has, or whether they are susceptible to medicine toxicities, to help guide treatment choices. This shifts the emphasis in treatment from reaction to prevention.

- This has the potential to lower overall healthcare costs through early-detection, prevention, accurate risk assessments and efficiencies in care delivery.

**Early identification of Familial Hypercholesterolemia (FH) through genetic testing has led to significant savings in healthcare costs – in the UK estimated savings to the NHS are £6.9 million per year.**

- In France, INCa allocated an additional €1.7M to regional genetics centres across the country for EGFR testing. This resulted in substantial increase EGFR screening in patients:
  - INCa concluded that this additional investment in EGFR testing would save €69 million to the French health insurance by identifying patients who harboured the EGFR mutation.

![Number of lung cancer patients screened for EGFR mutations in France](image)

<table>
<thead>
<tr>
<th>Year</th>
<th>Patients identified</th>
<th>Patients screened</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>2067</td>
<td>275</td>
</tr>
<tr>
<td>2009</td>
<td>1735</td>
<td>2139</td>
</tr>
<tr>
<td>2010</td>
<td>20750</td>
<td>21995</td>
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<td>2011</td>
<td>23339</td>
<td>23358</td>
</tr>
<tr>
<td>2012</td>
<td>24558</td>
<td></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Cost of screening</th>
<th>€0.1 M</th>
<th>€0.3 M</th>
<th>€1.7 M</th>
<th>€2.1 M</th>
<th>€2.1 M</th>
<th>€2.2 M</th>
<th>€2.5 M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment savings</td>
<td>€5.2 M</td>
<td>€11.0 M</td>
<td>€69.5 M</td>
<td>€85.6 M</td>
<td>€90.7 M</td>
<td>€96.3 M</td>
<td>€101.3 M</td>
</tr>
</tbody>
</table>

**Notes:** * Treatment savings account for the spared cost of gefitinib treatment by only targeting patients more likely to respond to EGFR inhibitors.

Source: CRA analysis of WIN Consortium

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¹ Marks D (2002); ² Nowak, F. (2012)
Better patient management is associated with savings to healthcare systems and society

Case Study: NSCLC

- Treatment algorithms for NSCLC have changed dramatically over the last few years, following the approval of the first generation of targeted therapies

- PM is associated with more savings to society compared to standard chemotherapy in terms of increased productivity and decreased social benefits paid to patients who are able to work in France, Germany, Italy, and Spain

- Mean incremental savings to society per patient receiving bevacizumab plus chemotherapy treatment ranged from €2,277 in Italy to €4,461 in Germany

Source: Lister et al (2012)
We also considered some the environmental factors that affect the development and adoption of PM in Europe:

- Recognition of personalised medicine as a policy priority
  - Approach to disease profiling versus whole genome sequencing

- The care environment
  - Organisation and coordination of care

- Access to diagnostics and testing infrastructure
  - Testing landscape

- Access to personalised medicines
  - Value assessment, reimbursement, speed of access

Conclusions and policy recommendations: The environment for Personalised Medicine

The benefits of Personalised Medicines

Introduction
There are a mix of approaches to prioritising PM in terms of health care policy across EU markets

- The clear benefit of having PM strategies in addition to national cancer plans (NCPs), is to allow for a forward-looking perspective on the value of genomics to healthcare systems; to support the testing infrastructure towards the development of whole genome sequencing (WGS) and its applicability to other conditions outside oncology.

- Countries have adopted different approaches to implementation, however plans have common elements:
  - Denmark has implemented NCPs from an early stage relative to other European countries; the first plan was published in 2000. In 2017 Denmark opened a national genome centre for personalised medicine which will serve as a hub for integrating genomic data.
  - England was the first to launch a dedicated program to whole genome sequencing in Europe. NHS England is supporting the integration of genomics into its services though setting up a new national network of Genomic Laboratory Hubs (GLHs) by November 2018.
  - France initially invested centrally in molecular diagnostics and infrastructure as part of its NCP, with the development the French National Cancer Institute (INCa) in 2004. In 2016, France announced the “France Médecine Génomique 2025” program.

<table>
<thead>
<tr>
<th>Country</th>
<th>Policy prioritisation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denmark</td>
<td></td>
<td>• Key focus within National Cancer Plans</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Recent National strategy for PM (2017-2020)</td>
</tr>
<tr>
<td>England</td>
<td></td>
<td>• PM strategy through NHS England</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Focus of increased integration of genomics and diagnostics into the NHS</td>
</tr>
<tr>
<td>Estonia</td>
<td></td>
<td>• PM program (2016–2020) managed by the Ministry of Social Affairs</td>
</tr>
<tr>
<td>France</td>
<td></td>
<td>• Key focus within National Cancer Plans</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Recent investment in genomic and PM program (2016)</td>
</tr>
<tr>
<td>Germany</td>
<td></td>
<td>• National plan on PM that focusses on new priorities for government funding</td>
</tr>
<tr>
<td>Italy</td>
<td></td>
<td>• PM included within agenda for sustainable healthcare</td>
</tr>
<tr>
<td>The Netherlands</td>
<td></td>
<td>• Government acknowledges PM in Medicines Plan and is included in the research agenda for sustainable health</td>
</tr>
<tr>
<td>Poland</td>
<td></td>
<td>• No specific plan on PM</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Access to diagnostics included as an objective in the National Cancer Plan</td>
</tr>
</tbody>
</table>

Notes: Green – High (dedicated national plan on PM); Amber – Medium (inclusion of PM in health strategies or national cancer plans); Red – Low (no policies on PM)
Centralising and increasing coordination of care is important, but should not limit PM as it is incorporated into standard of care

- Countries have varying degrees of centralisation of cancer care:
  - **Centralisation by tumour type**
    In Denmark, national cancer patient pathways results in centralisation of treatment to specialised centres. Whereas in the Netherlands the degree of centralisation varies, e.g. EGFR+ NSCLC is not centralised, resulting in variation to treatment approach
  - **‘Hub-and-spoke’ delivery of cancer care**
    In England, patients benefit from a cancer management strategy formulated by a multidisciplinary team (MDT) found across cancer units in general hospitals, with specialist MDTs located in larger specialised hospitals
  - **Accredited hospital networks**
    INCa coordinates cancer institutions across regions to support consistency and multidisciplinary team have also been introduced in France. A similar model is being implemented in Poland
  - **Concentration of expertise and infrastructure investment** in specific centres support the availability of specialised testing units to identify patients. This is particularly important for rare cancers that require specialist diagnosis
  - There is evidence demonstrating that centralising rare cancer care to specialist centres of excellence improves outcomes for patients. Similarly, studies have also suggested that centralisation may be associated with increased cost effectiveness of PM

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The adoption of technologies by laboratories and the factors influencing this varies depending on the technology

- The lab’s decision to adopt a particular test may be dependent on the reimbursement regime for diagnostics locally. For example, if NGS panels are reimbursed and single gene tests are not, this will lead to greater use of NGS.
  - While usage of NGS systems is increasing, this varies by country. approximately 17% of MolDx labs in Europe have an NGS machine and, of those not currently running NGS, another 21% plan to acquire it in the next 5 years.\(^1\)

- Despite the importance of testing, there is currently no standard metric or central public data-set which shows usage of diagnostic tests in Europe with geographical breakdown, either in terms of biomarker testing performed by laboratories or in terms of the sales of commercial test kits and equipment.

- Additionally, the degree to which diagnostics are subject to a value assessment and the degree to which they are integrated with the assessment of associated therapies varies across Europe:
  - The evaluation of diagnostics (including the impact on costs) is integrated into the NICE appraisal of PM.

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\(^{1}\) Whitten C M et al (2016)
The funding model should take into account infrastructure investment and the need to encourage competition between diagnostic providers

- There are wide variation in per capita expenditure on in vitro diagnostics (IVD) across selected countries in Europe.
- Disease-specific funding has enabled diagnostic services to be funded as part of broader efforts to improve oncology care, this has allowed for infrastructure investment and high levels of access.
  - In France, there is good access to lab based testing services but appears to be limited access for specific diagnostic kits.
- In other markets, testing services are integrated into hospital budgets and are expected to be covered through a Diagnosis-related group (DRG)-type funding.
  - HER2 breast cancer diagnostic testing in Poland is predominantly the responsibility of pathology laboratories in hospitals. This creates challenges for new tests.
- Until now, investment in CDx was linked to the value of an individual medicine. Therefore access to testing could be supported by the manufacturer. England has many examples of this.
  - As testing moves away from direct associations to particular products, and towards panel sequencing, individual manufacturer funding becomes no longer justified.

The benefits of Personalised Medicines

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  - As testing moves away from direct associations to particular products, and towards panel sequencing, individual manufacturer funding becomes no longer justified.
Access to PM is restricted when countries adopt more formal HTA

- Generally, the EU5, Scandinavian and Benelux markets grant greater access to innovative therapies, whereas Central and Eastern European markets such as Poland are more likely to restrict access to manage budget impact.

- In England, access to personalised cancer treatments has been problematic due to challenges in meeting required cost-effectiveness thresholds to achieve positive NICE recommendations. In these cases, patient access schemes and the Cancer Drugs Fund have been important programmes in facilitating access.

- Countries like the Netherlands which are more pragmatic about using available evidence, or facilitating the collection of RWE through registries have better access to novel treatments.

- Payer perceptions of products with CDx or specific biomarkers are generally more positive than of those without such biomarkers.

- Clinical guidelines play a different role in different EU markets; in England, guidelines are integrated into HTA, whereas in consensus driven markets such as Denmark, clinical guideline development is crucial for the introduction of novel therapies.

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Reimbursement status of PM across case study markets

<table>
<thead>
<tr>
<th>Indication</th>
<th>Class</th>
<th>Drug</th>
<th>DK</th>
<th>EN</th>
<th>FR</th>
<th>NL</th>
<th>PL</th>
</tr>
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<tbody>
<tr>
<td>Breast cancer</td>
<td>HER2+</td>
<td>Trastuzumab</td>
<td>🟢</td>
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<td>✓</td>
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<td>✓</td>
</tr>
<tr>
<td></td>
<td>HER2+</td>
<td>Lapatinib</td>
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<td>✓</td>
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<tr>
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<td>HER2+</td>
<td>Pertuzumab</td>
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<tr>
<td></td>
<td>HER2+</td>
<td>Ado-Trastuzumab emtansine</td>
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<td>✓</td>
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<tr>
<td>Melanoma</td>
<td>BRAF+</td>
<td>Vemurafenib</td>
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<td>Trametinib</td>
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<tr>
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<td>CTLA-4</td>
<td>Ipilimumab</td>
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<tr>
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<td>ALK+</td>
<td>Crizotinib</td>
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<td>Alectinib</td>
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<td>✓</td>
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<td>Ovarian cancer</td>
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<td>Bevacizumab</td>
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<tr>
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<td>PARP</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Notes: Green – Full reimbursement; Amber – Reimbursed with restrictions; Red – Limited / no reimbursement

Source: CRA analysis
Delays to access and updating treatment guidelines to reflect innovative treatments are clearly a challenge for PM.

- The Netherlands and Denmark (that exempted products from HTA) have faster access, providing access within 1 month following approval.
- All countries made a reimbursement decision within 1 year of approval. England and Poland took the longest, and there was a further 2 year delay to incorporate novel PM for Melanoma into treatment guidelines.
- The delay in updating treatment guidelines in Poland meant vemurafenib could only be available through compassionate use or clinical trial programs.
- The use of pembrolizumab in melanoma was the first product to be launched through the UK’s Early Access to Medicines Scheme (EAMS), providing over 500 UK patients with early access. NICE have committed to start the HTA process in parallel with the MA review; earlier NICE assessment of EAMS-approved products is expected to shorten delays to reimbursement.
- Indeed draft NICE guidance for pembrolizumab within 5 weeks of EMA approval. Though NICE is yet to update melanoma treatment guidelines to reflect pembrolizumab.

**Melanoma: vemurafenib**
- EMA Approval: Feb 2012
- England: Mar 12, Dec 12, Feb 13, Mar 14
- France: Oct 12, Jan 13, Feb 13, Aug 15
- The Netherlands and Denmark: Feb 12, Mar 12, Dec 12, Mar 13, Aug 13

**Melanoma: pembrolizumab**
- EMA Approval: Jul 2015
- England: Sep 15, Aug 16
- France: Oct 15, Mar 16, Jul 16
- The Netherlands and Denmark: Oct 15, Jan 17

The benefits of Personalised Medicines
- Introduction
- Methodology
- The environment for Personalised Medicine
- Conclusions and policy recommendations
Tackling delays to reimbursement of new treatments will ensure more systematic and equitable access

- It is clear that access to PM depends on:
  1. The existence of early access mechanisms that take into account unmet need and provide funding for early reimbursement.
  2. The approach to HTA, with countries that have a more pragmatic approach to use of clinical and economic evidence (or requirements for additional data collection) to assess the relative benefit of a new personalised medicine exhibit faster access.
  3. A fast process for updating treatment guidelines and care pathways. Although this varies depending on the role of clinical guidelines, this clearly has an important impact on enabling access in countries such as Denmark and Poland.

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**Average access timeline for personalised oncology medicines**

<table>
<thead>
<tr>
<th>Location</th>
<th>Months to reimbursement</th>
<th>Inclusion in guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denmark</td>
<td>4.2</td>
<td>10.8</td>
</tr>
<tr>
<td>England</td>
<td>9.8</td>
<td>34</td>
</tr>
<tr>
<td>France</td>
<td>7.8</td>
<td>23.2</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>8.2</td>
<td>19</td>
</tr>
<tr>
<td>Poland</td>
<td>30.3</td>
<td>10.5</td>
</tr>
</tbody>
</table>

Notes: Average access timeline from first-in-class PM in NSCLC, Melanoma and Ovarian Cancer (gefitinib; crizotinib; vemurafenib; pembrolizumab; olaparib)

Source: CRA analysis
We have developed policy recommendations to improve equitable access to PM

- **National policy to ensure prioritisation of PM should work hand in hand with existing health strategic plans** (e.g. National Cancer Plans).
  - The level of resources and funding needs to be aligned to aspirations and the strategy should articulate the genomic profiling strategy.

- **Continued emphasis is needed on better management of care, consolidating expertise and resources to ensure the adequate ‘personalisation of care’**.
  - This can be achieved through a centralised approach (i.e. developing ‘centres of excellence’) or via cross-functional collaboration through healthcare networks.

- **National governments should continue investing and cooperating in next-generation testing infrastructure (such as molecular genetics labs) as well as developing dedicated funding pathways to ensure access to diagnostics.**
We have developed policy recommendations to improve equitable access to PM

- Collecting data to track access to diagnostics (and making this public) as well as putting a greater emphasis on External Quality Assessments (EQA) of labs will help to ensure consistent testing quality throughout Europe and allow comparison between approaches.
  - This means promoting international platforms for EQA of labs and research into quality (e.g. IQN Path) to improve diagnostics testing and make EQA participation mandatory for labs across the EU.
  - This should also promote consequences for poor performance of labs, e.g. report to a supervisory authority.

- Tackling delays to reimbursement of new treatments will ensure more systematic and equitable access. This can be improved by:
  - Supporting better alignment of data requirements between regulators and health technology assessment (HTA) bodies – this would improve evidence development and facilitate the value assessment process
  - Sharing best practices on HTA methodology for PM
  - Developing a more flexible approach that incorporates new technologies (e.g. NGS)
  - Being pragmatic in using the available evidence.
  - Introducing Interim/early access programmes