

## A POLICY ROADMAP ON ADDRESSING METASTATIC BREAST CANCER

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a multi-stakeholder collaboration

















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### BUILDING A KNOWLEDGE-BASED APPROACH TO CARE



Better data on the burden of disease, including its economic burden, to inform the decision-making process.



National cancer plans to address the needs of metastatic breast cancer patients.



Adherence to evidence-based treatment guidelines.



Organisation of a single, patient-centred care pathway.

## **EVIDENCE-BASED**

UNDERSTANDING OF WHAT MATTERS
'TO MBC PATIENTS AND CARERS

## COLLECTION AND USE OF REAL WORLD DATA



Pan-European collaboration and widespread use of Real World Data to improve patient outcomes.

## **CO-OPERABILITY**

BETWEEN DATA SYSTEMS BY ALIGNING THE RESEARCH AND CLINICAL PRACTICE WHEN COLLECTING REAL WORLD DATA

## ACCESS TO CARE AND TREATMENT



Health Technology Assessment methodologies adapted to the reality of MBC care and treatment.



Patient input to the value assessment of cancer treatment and care.





## PATIENT SUPPORT, PARTICIPATION AND EMPOWERMENT



A holistic support system and shared decision-making opportunities for MBC patients and informal carers to cope with the burden of the disease.



Recognition and support for informal carers.

## HOLISTIC

SUPPORT SYSTEMS TO ADDRESS THE SPECIFIC NEEDS OF MBC PATIENTS AND CARERS



## WHY THIS INITIATIVE?

Despite significant progress made by the metastatic breast cancer (MBC) community throughout the last decade, there are still many areas in which further action is required. Limited awareness of MBC's distinctiveness from early breast cancer, for instance, remains an issue which affects access to quality treatment and support services and prevents urgently needed improvements in patient outcomes.

While many groups have worked to identify the remaining gaps in the provision of care, this policy roadmap is intended as a practical document that showcases specific policy actions that can be taken to close these gaps across Europe.

The policy roadmap was developed by a multi-disciplinary Expert Working Group (EWG) consisting of stakeholders from across the MBC pathway in Europe, including healthcare professionals, patient advocates and informal carers' advocates, policymakers, academics, industry representatives and former healthcare payers. The recommendations in this report are the result of desk research and conversations among the experts participating in the working group, with a view to making practical and actionable recommendations across the MBC care pathway.

This call for action is addressed to policymakers at EU and national levels, healthcare professionals, academia, advocates, patients and members of the MBC community and requires collective and collaborative approach across the MBC space. Therefore, the policy roadmap proposes actions to be taken at both the EU and national level, using five EU countries as practical examples: Austria, France, Germany, Italy and Spain.

## NTRODUCTION

Metastatic breast cancer (also called stage IV breast cancer) is not a specific subtype of breast cancer, but rather the most advanced stage of its progression, when the primary breast cancer has spread beyond the breast to other organs in the body (most often the bones, lungs, liver or brain). Metastasis is the leading cause of breast cancer-associated deaths<sup>2</sup>, responsible for half a million premature deaths of women around the world each year. 3

The term advanced breast cancer (ABC) encompasses two distinct clinical entities: locally advanced, inoperable breast cancer (LABC) and metastatic breast cancer (MBC). While this document focuses on MBC, it should be understood that the challenges and experiences described for MBC can very often apply equally to all forms of ABC, and are not limited to just the metastatic stages.

Breast cancer is the second most common cancer in the world and by far the most frequent cancer in women, with an estimated 1.67 million new cases diagnosed every year.<sup>4</sup> Nearly 30% of women diagnosed with early breast cancer will eventually develop metastatic disease,<sup>5</sup> even with appropriate diagnosis and treatment. In addition, one in ten women will already be at an advanced stage when first diagnosed, with a five-year survival rate of close to 25%.<sup>6</sup> The estimated incidence of breast cancer in Europe was 458,339 in 2012, with an estimated 90,000 breast cancer deaths.<sup>7</sup> Western Europe has the highest age-standardised incidence rate for breast cancer in the world.<sup>1</sup>

A gap remains between the public understanding and patient experience of MBC. General awareness of the impact it has on the patient's life and how it relates to early cancer remains low. Breast cancer is often associated with the pink movement and with a positive message of hope. Given the amount of attention early breast cancer has received, policymakers are frequently under the impression that breast cancer is a curable disease that has already been sufficiently addressed. The patient experience and journey of someone with MBC is, however, very different.

Research has shown that progress has been very slow and that there are still a number of gaps that must be addressed to improve outcomes for patients with MBC.<sup>3</sup> In the 2005-2015 period, the survival time after diagnosis with MBC has remained largely unchanged <sup>3 (p. 25)</sup> and the quality of life <sup>3 (p. 29)</sup> of MBC patients has only minimally improved.<sup>8</sup> In addition, more must be done to understand how MBC affects the family and professional life of both patients and their (often informal) carers, and the best ways to support them.

## THE POLICY ROADMAP PROVIDES RECOMMENDATIONS FOR ACTION TO POLICYMAKERS IN FOUR FOCUS AREAS:

- Building a knowledge-based approach to care: Informing improved governance and delivery of MBC care through better understanding the specific burden of disease (including economic burden), increasing adherence to science-based guidelines and adopting a more joined-up approach to the entire patient pathway.
- **Collection and use of real world data:** Addressing the need for the collection and use of high-quality real world data for research, reimbursement, and organisation of care.
- Access to care and treatment: Reducing inequalities and delays of access to care and treatment.
- Patient support, participation and empowerment: Establishing systems to support and empower patients and informal carers through shared-decision making not only at the level of their disease, but also in the development and modernisation of national cancer plans.

### PART 1 EUROPEAN POLICY ROADMAP

### FOCUS AREA 1.

### BUILDING A KNOWLEDGE-BASED APPROACH TO CARE

### A. Better data on the burden of disease, including its economic burden, to inform the decision-making process.

The exact number of people living with metastatic breast cancer is currently unknown. In-depth statistics and characteristics of people with the disease are missing<sup>9</sup> and data is limited on the number of informal carers<sup>1</sup> who provide daily support to MBC patients. The lack of data and evidence has made understanding the burden of the disease and advocating for solutions difficult.

Only a few countries, such as Denmark, Germany, Sweden and the United Kingdom have registries in place to capture and track breast cancer cases and to better understand the prevalence and burden of the disease. <sup>10</sup> However, even in the countries where we have an indication of the prevalence of breast cancer, there is often no distinction between early and metastatic breast cancer, making the data difficult to use. Moreover, prevalence registries on their own are not sufficient to fully understand the impact of MBC on society.

Ideally, a cancer registry would record the treatment and outcome of all patients throughout the disease pathway, or at least the date and site of first relapse.<sup>11</sup> In the absence of such a registry, however, other methods should be explored to estimate the prevalence of people living with MBC in a country or the whole of Europe.<sup>12</sup> Estimates can provide a new perspective on the burden of metastatic breast cancer on the general population, and have great potential for the research and advocacy community. However, their accuracy is lower than real registries.

One still somewhat untapped resource for understanding the burden of disease is the online patient community. This usually takes the form of informal, collaborative listening boards that connect patients and carers to information and resources. Online patient communities could provide real-time information relevant to understanding the patient journey and experience.<sup>13</sup>

<sup>1</sup> Informal carers are people who provide unpaid care to someone with a chronic illness, disability or other long-lasting health or care need, outside of a professional or formal framework.

At the European level and beyond, advocacy organisations have been playing a crucial role in putting the need for MBC statistics on policy agendas. For example, in the UK, Breast Cancer Care drove a project on MBC data collection at the national level and in March 2016 launched the 'Who's counting?' campaign, aimed at identifying the barriers to and facilitators of MBC data collection. The study showed that the main barriers to data collection were lack of resources, confusion over the definition of "secondary" (i.e. metastatic) breast cancer, lack of awareness of the type of data to be collected, and uncertainty on how to record it. On the other hand, identified data collection enablers were: data collection infrastructure in place, dedicated Multi-Disciplinary Teams (MDT) for metastatic breast cancer meetings, and buy-in and involvement of staff.<sup>14</sup>

#### CASE STUDY:

Cancer surveillance research on estimation of the number of women living with MBC in the  ${\rm US}.^{15}$ 

A recent study showed that the number of women in the United States living with metastatic breast cancer is growing and indicated the urgent need for more research into how to address the healthcare needs of women who live with this condition. To develop a more accurate estimate of the total number of women living with MBC, researchers used data from National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program to include women who developed MBC after diagnosis.

To estimate the number of U.S. women living with MBC, the researchers applied a back-calculation method to breast cancer mortality and survival data from the SEER Program. SEER collects clinical, demographic, and vital status information on all cancer cases diagnosed in defined geographic areas. The method they used assumes that a breast cancer death is preceded by MBC that was either found at diagnosis or after a recurrence with metastatic disease.

The researchers estimated that, as of January 2017, more than 150,000 women in the United States were living with MBC, and that 3 in 4 of them had initially been diagnosed with an earlier stage of breast cancer. Based on their calculations, the researchers estimated that the number of women living with MBC increased by 4 percent from 1990 to 2000 and by 17 percent from 2000 to 2010, and they project that the number will increase by 31 percent from 2010 to 2020.1

Another important knowledge gap exists, as the exact economic burden of MBC is not accurately captured and understood. Estimates have been drawn from an understanding that the economic costs of MBC are much higher than those related to early breast cancer. If we were to add to those a complete picture of the impact of reduced employment among patients and informal carers that results in a loss of productivity and income, the known financial impact of MBC would multiply. It is estimated that metastatic disease is a major cause of the increase in the direct cost of breast cancer. An improved, evidence-based understanding of the economic burden of MBC and qualitative research on factors that matter to patients and (informal) carers could inform and drive the most effective resource-allocation decisions.

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#### **POLICY RECOMMENDATIONS:**

Gather and process continuous, complete, consistent and relevant data around the epidemiology, incidence and burden of MBC.

The European Commission's Joint Research Centre should develop clear guidelines on how to include metastatic disease in cancer registries via the European Network of Cancer Registries (ENCR), and use MBC as a primary example.

The ENCR Steering Committee should establish an MBC Working Group to recommend improvements in MBC data collection for national cancer registries.

The work programme of Horizon 2020 should include a research collaboration between the ENCR and the European MBC community on conducting an evidence-based estimate of the number of people living with MBC in Europe.

A holistic cost-of-illness model for metastatic breast cancer, which includes indirect costs due to reduced employment among patients and increased burden on informal carers, should be used when assessing resource-allocation to MBC services.

National registries should record data on diagnostic and treatment events along the whole breast cancer pathway, including those for metastatic breast cancers, in particular, the date and site of first relapse.

National authorities should make use of existing surveys, workshops, meeting and conference reports already undertaken by patient advocacy organisations when estimating the incidence and burden of MBC.

### B. National cancer plans to address the needs of metastatic breast cancer patients

National cancer plans should be informed by data on the burden of the disease and best practices to ensure standardisation of outcomes and improvement, including minimisation of avoidable deaths, patient pain, and waste in the system.<sup>17</sup> Currently, national cancer plans do not include actions that specifically address metastatic breast cancer and, more often than not, metastatic cancer at large. The National Health Service (NHS) England cancer plan is unique among cancer plans in Europe in that it currently references metastatic disease.<sup>18</sup>

Moreover, it should be ensured that national cancer plans are developed with multi-stakeholder consultation and consensus. The role of patient representatives in appropriately capturing the patient experience cannot be overstated. Similarly, informal carers play a key role in the daily life of patients and provide an important perspective on the practical effects of plans on the patient and carer experience.

It is thus important to have expert patient and carer advocates who are sufficiently trained and empowered included in the relevant consultation processes in a consistent and sustainable manner. Patient advocacy organisations have already contributed to several national cancer plans, including the French and Irish plans, but further efforts to secure their involvement in future consultations will help to ensure patient needs and wishes are addressed.

#### **CASE STUDY:**

Achieving world-class cancer outcomes: a strategy for England 2015-2020 - Report of the Independent Cancer Taskforce

An Independent National Cancer Advisory Group, consisting of stakeholders from across the cancer pathway including various patient representatives, has been established to advise and assess on progress of implementation of Achieving World Class Cancer Outcomes (AWCCO).

In July 2015 the Taskforce published the report `Achieving world-class cancer outcomes: a strategy for England 2015-2020'.<sup>19</sup> The Strategy specifically addresses metastatic cancer underlining that many patients treated for primary cancer will also develop secondary or metastatic cancer. These patients should be given the treatment and support they need to live for as long and as well as possible, managing their cancer effectively as a chronic condition. Furthermore, the report recognises that patients with metastatic cancer have unique needs and provides for a specific recommendation to ensure this patient group is recognised as distinct by multi-disciplinary teams when planning care.

#### **POLICY RECOMMENDATIONS:**

Recognise the unique needs of patients with metastatic disease in national cancer plans.

The European Commission should pursue the implementation of the Cancer Control Joint Action (CanCon) policy papers, including via National Reform Plans that would measure member states' progress on a yearly basis.

National health authorities should ensure that appropriate consultation of various stakeholders, including patient advocates, informal carers and patients themselves, takes place in the development of national cancer plans.

National competent authorities in collaboration with Patient Advocacy Groups should implement adequate training programs to ensure that patient representatives taking part in the relevant consultation processes are informed and empowered to do so.

National cancer plans should include specific provisions for metastatic disease.

#### C. Adherence to evidence-based treatment guidelines

Better outcomes can only be achieved if evidence-based medicine is applied.<sup>21</sup> Various international professional societies have addressed the need for evidence-based cancer care by developing screening, diagnosis and treatment guidelines, including the international consensus guidelines for advanced breast cancer (ABC Guidelines) developed by the European Society for Medical Oncology (ESMO) and the European School of Oncology (ESO), the ESMO clinical practice guidelines, as well as those from the American Society of Clinical Oncology (ASCO) and the St. Gallen scientific committee. Despite these efforts, disparities in the implementation of these recommendations persist at EU level. Failure to adhere to existing expert guidelines can lead to poorer clinical and economic outcomes.

Adherence to existing guidelines is already a challenge in the management of metastatic disease, often the result of organisational, administrative or behavioural barriers. Care in specialised breast treatment units, for example, has been shown to significantly improve survival rates, <sup>22</sup> and yet, the majority of breast cancer patients in Europe are treated outside of specialised care centres. <sup>22</sup> (p.246) Furthermore, treatment does not always adhere to evidence-based guidelines, as a result of financial counter-incentives and other relationship or work flow related incentives to provide off-guideline treatment.

The most commonly cited reason for diverging from guidelines is potential financial barriers or indirect disincentives to following the guidelines' recommendations. For example, in countries such as France, Germany and Spain, local hospital management procedures and/or regional reimbursement rules favour the use of intravenous therapy over oral medicines like endocrine treatment. Reimbursement rules that favour payment per use, per session, or per day in the hospital can present a significant barrier to using oral or endocrine therapies, which may not require hospitalisation. This rigid approach risks disregarding both scientific guidance and patients' preferences.

On the other hand, under the right circumstances, reimbursement rules may encourage better classification of patients, and therefore garner better data about the prevalence and impact of disease. Unintended financial incentives to exaggerate a patient's condition may remain, for instance in systems that require verification of a diagnosis. However, if practiced properly, these standards may provide a clearer picture of the overall MBC landscape.<sup>23</sup>

#### **POLICY RECOMMENDATIONS:**

Encourage and increase adherence to evidence-based treatment guidelines throughout the treatment pathway.

The European Commission Initiative on Breast Cancer (ECIBC) should develop a scorecard on adherence to breast cancer guidelines throughout Europe, as part of its quality indicators for MBC.

The MBC clinical and advocacy community should increase the reach of existing education platforms to help facilitate the transfer of knowledge from Specialised Breast Units (SBUs) to other patient care units as a transitory measure until all patients are treated in SBUs.

National governments should modify policies and reimbursement processes to ensure counter-incentives to guidelines no longer persist.

#### D. Organisation of a single, patient-centred care pathway

The European Parliament has repeatedly called for the European Commission to develop a framework for the accreditation of Specialised Breast Units (SBUs), as well as for the implementation of multi-disciplinary teams (MDTs). This is a central focus of the ongoing European Commission Initiative on Breast Cancer (ECIBC), which is developing the European Quality Assurance scheme. The objective of this initiative is to assure that accredited SBUs offer top quality and up-to-date procedures for breast cancer screening and care, based on individual needs and evidence-based guidelines.<sup>25</sup>

Some European countries have made notable progress on expanding and improving access to SBUs and/or Breast Cancer Units. In Germany, for example, there is a solid network of certified breast centres throughout the country that are systematically audited and overseen by the German Society for Senology and the German Cancer Society. <sup>26</sup> Another example can be found in Italy, where the government established clear guidelines on breast units, with clear qualitative and quantitative criteria that take a holistic approach to patient care, and defines the multi-disciplinary services each breast unit must have, alongside the type of training required of healthcare professionals.

SBUs are often the best resource for managing a range of aspects of a breast cancer patient's care, including for management of advanced and recurrent breast cancer, but the use of SBUs is rarely mandated by law.<sup>3</sup> (p. 71) In fact, despite EUSOMA Guidelines in Breast Cancer<sup>27</sup> or the European guidelines for quality assurance in breast cancer and diagnosis<sup>28</sup> access to specialist units is still limited across European countries.<sup>22</sup>

Although there are guidelines in place for specialised centres, continuous monitoring and auditing is needed to assure improvement in quality indicators in these centres.<sup>22</sup> Moreover, the certification process for SBUs in Europe primarily focuses on quality criteria for early breast cancer care. Until recently, little to no research had been conducted on the development of quality criteria needed to evaluate the care for metastatic diseases. To address this issue, the EUSOMA and the ESO recently began working together to create quality criteria for MBC, with the aim of making them part of the quality standards for SBUs.

### CASE STUDY: NABON Breast Cancer Audit

The Dutch National Breast Cancer Platform (NABON) initiated the NABON Breast Cancer Audit (NBCA) where, since 2011, clinicians are encouraged to submit data about the breast cancer diagnosis, treatment and care plans they provide in order to measure, track and compare outcomes and ultimately help improve the quality of breast cancer care across the country. Healthcare professionals including surgeons, radiologists, pathologists, radiotherapists, oncologists and plastic surgeons contribute to the audit. In addition, input from patient associations is gathered through Patient Reported Outcome and Patient Experience Measures. To further enhance the patient voice, a pilot project started in June 2016 focusing on the registration of patient feedback.<sup>29</sup>

In addition, many patients being treated in European health systems see a different doctor for each aspect of their treatment, with insufficient coordination between specialists. The transition between oncology and palliative care, in particular, is a difficult step where patients easily feel 'lost' and abandoned. It is clear that the patient pathway was not initially built with the patient at the centre, and has expanded in different directions as treatment options and scientific knowledge organically grow.

As MBC has evolved into an increasingly longer-term condition, the role of healthcare professionals has broadened. For example, cancer clinical nurse specialists (CNSs), also known as "patient navigators", are now not only responsible for patients' clinical needs, but also their emotional, psychological, financial and social needs. ONSs have an increasing role in coordinating overall patient care and should require advanced training to take on this expanded role and comply with existing European quality criteria for breast care nurses as developed by EUSOMA. Other healthcare professionals also take on the role of "patient navigator". Moreover, psycho-oncologists are a critical element of comprehensive cancer care teams, and can provide personalised psychological support to MBC patients, through all stages of disease. However, more data is needed on the support given in outpatient care outside of a specialised breast unit.

Lastly, primary care physicians / general practitioners are a common point of contact that patients will regularly visit, and they are often the first port of call for information and advice on decision-making. However, they rarely have the necessary information on MBC that they need in order to provide the evidence-based standard of care. As health systems become more integrated and look to move care closer to home, primary care clinicians are likely to be even more involved in the ongoing care of metastatic patients, making it increasingly important to fill this gap.

#### **POLICY RECOMMENDATIONS:**

Ensure that the ECIBC develops a patient-centred pathway for MBC patients that follows the patient from diagnosis to palliative care with the involvement of a patient navigator, while ensuring continuity and high-quality care within specialised breast units.

The European Council should call on Member States to make Specialised Breast Units (SBUs) mandatory by law to increase patient outcomes and access to quality care.

National authorities should put legal requirements and accreditation systems into place, accompanied by audit processes for SBUs, using the ECIBC template.

National authorities should define and implement the MBC quality indicators for SBUs, using the ECIBC as a template.

National authorities should incentivise the development of integrated, holistic care pathways, and the involvement of Clinical Nurse Specialists.

National authorities should ensure uniform training and recognition of specialised oncologists/ breast cancer specialist nurses.

The European Oncology Nursing Society (EONS) should collaborate with the MBC advocacy community to develop and add educational courses on specific support needs for metastatic cancer patients, including psycho-oncology support, to the updated Cancer Nursing Curriculum.

## FOCUS AREA 2. COLLECTION AND USE OF REAL WORLD DATA

### A. Pan-European collaboration and widespread use of Real World Data (RWD) to improve patient outcomes

Given the growing burden of MBC, data on recurrence of disease is urgently required to support further research into the specific needs of this understudied population. Real-world data (RWD) is an umbrella term for different types of data that are not collected in conventional randomised controlled trials.<sup>34</sup> RWD in the healthcare sector comes from various sources and includes data coming from patients, from clinicians, hospitals, payers and social data.<sup>35</sup>

There are differences between patients involved in clinical trials and patients who are treated in a real-world setting. The latter are usually older, have more co-morbidities and often demonstrate different patterns of adherence to therapy. Consequently, real world outcomes can be different from clinical trial data.<sup>36</sup> Accurate RWD on the efficacy and safety of treatments that takes the distinctions between patient sub-groups into account, is essential to inform both treatment development and treatment delivery strategies. While current systems tend to rely on data collected through clinical trials, collection of RWD can expand our understanding of the disease in a less-controlled environment.<sup>11</sup>

There are several sources of pan-European RWD, however health systems maintain a degree of scepticism about the sources of this data while clinicians need a system that facilitates the capture of RWD as part of their day-to-day practice, and that returns results with apparent utility. <sup>11 (p. 6)</sup> A well-organised, high quality system for data generation, collection, interpretation and use is needed to reliably and efficiently collect RWD. Available data currently varies greatly from country to country due to asymmetry in data collection among health authorities. <sup>37</sup> Because authorities do not always monitor MBC separately from breast cancer as a whole, it can be difficult to decode data in a way that provides real insights into MBC-specific issues, indicating a need to externally validate RWD. Consequently, there is a need to align research and clinical practice when collecting RWD at the national level and to allow for cooperability between data systems to connect the data that is (already) collected by Specialised Breast Units (SBUs) to central/national databases.

#### **CASE STUDY:**

#### ASCO CancerLinQ - Enhance Cancer Diagnosis & Treatment

In June 2017 ASCO's CancerLinQ opened a partnership with the United States Food and Drug Administration (FDA) to study real world use of newly approved cancer treatments. The objective of this collaboration is to gather knowledge about patterns of care in oncology and novel insights in this space that would be hard to collect through standard research and data collection means. Also, this collaboration could possibly inform the FDA regulatory strategy and decision-making process.<sup>38</sup> CancerLinQ is a national coalition of more than 85 health organizations including community practices, academic medical centres and smaller hospitals that aim to identify evidence based treatment in order to explore new patterns for care, as well as to increase comparison between various data.

One significant remaining barrier to interoperability of data collection systems is the harmonisation of different privacy standards at the country level following the adoption of the EU General Data Protection Regulation. Furthermore, there is still resistance when it comes to sharing data sets between the various stakeholder groups collecting them (clinicians/academics, health systems, industry).

#### **POLICY RECOMMENDATIONS:**

Harmonise and maximise Real World Data collection across Europe to help improve patient outcomes.

EU and national policymakers should encourage and support collaboration between the research and clinical communities in the development of statistical and methodological tools that address the need for proper data analysis, while overcoming existing data ownership and language challenges.

EU and national policymakers should initiate specific initiatives on Real World Data (RWD) to encourage public-private partnerships (e.g. via the Innovative Medicines Initiative) between the EU oncology community to systematically collect RWD on MBC across European health systems.

National authorities should create a framework for initiatives (public-private) similar to CancerLinQ to allow for the collection and incorporation of real world evidence into the regulatory and policy decision-making process.

National authorities should incentivise the use of existing big data with the aim of improving the clinical management of MBC.

The oncology community should facilitate cross-national discussion around best practices in terms of data collection for metastatic diseases.

National authorities with the support of the MBC advocacy community should educate patients about the value of RWD for improving long-term patient outcomes.

Hospitals / Specialised Breast Units should promote and incentivise collection of RWD among clinicians.

## FOCUS AREA 3. ACCESS TO CARE AND TREATMENT

### A. Health Technology Assessment (HTA) methodologies adapted to the reality of MBC care and treatment

There can be significant differences between countries in terms of the accessibility of new, innovative oncology therapies.<sup>39</sup> This document will not explore the structural challenges that limit access to medicines, through shortages or other supply problems, which have been covered in detail through a comprehensive report on cancer medicines shortages sponsored by ESMO in 2017.<sup>40</sup>

Access to treatments is dependent on the outcome of value assessments undertaken by national or regional authorities in the form of Health Technology Assessments (HTA). Their decisions and timelines tend to vary, leading to significant delays and inequalities in access to innovative treatments.<sup>41</sup>

As science evolves, there is a growing understanding that different cancer types require different approaches to treatment, especially for metastatic stages. Regulators and payers tend to use different endpoints to assess whether a new treatment should become available to patients. At times, regulators will accept surrogate endpoints (e.g. progression-free survival) for the purposes of regulatory approval, whereas payers tend to mistrust these measures, focusing almost exclusively on overall survival to evaluate the benefit of a therapy.

From a clinical perspective, overall survival is certainly considered to be the 'gold standard'.<sup>42</sup> However, given the nature of the disease and the need to allow patients to access new treatments until mature data on overall survival becomes available, progression-free survival<sup>43</sup> should be considered an appropriate endpoint for initial approval in MBC, but only if a re-evaluation is made once overall survival data is available.<sup>43</sup> (p. <sup>33</sup>) Further reviews of reimbursement decisions should then take place once newer data, including data on overall survival, become available.

According to clinicians and patients, new non-curative interventions must demonstrate improvement in quality of life<sup>44</sup> and reimbursement systems must capture and reward that improvement appropriately. Quality of life has value for the patient when safety and tolerability is balanced against progression-free survival. However, quality of life considerations are currently not sufficiently captured in HTA methodologies due to the absence of effective measurement tools in MBC treatment settings. For patients, quality of life measures are most important and many potential treatment options can be impractical because of their effects on quality of life. In this context, it is important to note that patient reported outcomes measures are not consistent, as most of the available quality of life tools have not been developed for MBC, but for early breast cancer. This makes it difficult to allow comparisons across different countries and health systems, but this will hopefully soon change as there is work currently underway by experts to develop a specific MBC quality of life tool, by the European Organisation for Research and Treatment of Cancer (EORTC) in collaboration with ESO.

#### **POLICY RECOMMENDATIONS:**

Align value assessment methodologies for metastatic breast cancer treatment and care with the specificities of the disease.

Regulators and payers should consider using aligned data requests, including on surrogate endpoints for metastatic breast cancer, such as progression free survival.

Regulators and payers should consider the use of Real World Data for the periodic re-assessment of treatment options for MBC which have been approved on the basis of surrogate endpoints.

The MBC clinical and advocacy community should define the most appropriate endpoints for metastatic breast cancer, taking the changing treatment landscape into consideration.

The European Commission should support the MBC clinical and advocacy community to develop a specific MBC quality of life tool to be used in value assessments and standardise and more widely use Patient Reported Outcomes in MBC.

### B. Patient input to the value assessment of cancer treatment and care

Patient involvement has the highest impact on the overall understanding of the impact of technologies in a real-life context,<sup>45</sup> as patients are the ones with the real-world experience of dealing with the disease. As a result, patients and their informal carers are uniquely placed to assess the value of a new treatment or care intervention. While patients are becoming more involved in Health Technology Assessments (HTA) processes across different European health systems, involvement is not always considered meaningful or effective, as it usually only occurs at the very beginning or end of the process, leaving patients unaware of whether their contributions have been considered.<sup>45</sup>

Patient representation should consider that patients often attach different values to different factors. For example, a few weeks may make a large difference for some, whereas others will consider a difference in survival of a few weeks to be minimal when balanced against any potential side effects or risks. There is work done by the American Society of Clinical Oncology (ASCO)<sup>46</sup> and the European Society for Medical Oncology (ESMO)<sup>44</sup> to identify a more standardised way of assessing elements of value. Another example<sup>47</sup> is the pilot study conducted by the European Medicines Agency to better understand how it can collect and use patient's preferences in the regulatory review for new treatments. It uses a combination of a short questionnaire to gather ordinal statements regarding the desirability of different outcomes in the treatment of advanced cancer, followed by face-to-face meetings to gather feedback and validate the individual responses. The process appears to be an easily implementable instrument to learn about the distribution of the participants' individual preferences in a precise manner.<sup>47</sup>

Looking at the issue of inequalities of access to care and treatment, ESMO conducted an assessment on accessibility of oncology drugs in Europe, and identified major differences between countries. The assessment found that in some countries, such as Romania, access to MBC treatments that are established and accepted for their effectiveness was limited.

With the development of new therapies that target the genetic and epigenetic drivers of breast cancer, and with improved palliative care, MBC is not the immediate death sentence it once was. With optimal care, women with MBC can, and often do, live for years with reasonable quality of life, albeit undergoing continuous treatment to keep their disease under control. For this reason, MBC patient and (informal) carer preferences and quality of life considerations can be quite different from the broader set of concerns for all people affected by breast cancer. This context further complicates the tendency for MBC patients to weigh the value of treatment outcomes differently depending on their specific situation in life.

#### **POLICY RECOMMENDATIONS:**

Utilise endpoints relevant to the MBC patient experience and consistently include patient input in value assessment of MBC care and treatment.

National decision-makers should involve patients and the MBC advocacy community in the development of Health Technology Assessment (HTA) criteria and individual assessments of MBC care and treatments.

The MBC clinical and advocacy community should develop and disseminate guidance to health systems to enable informed decisions based on a method of assessing and defining value that more consistently reflects patient needs and perspectives.

## FOCUS AREA 4. PATIENT SUPPORT, PARTICIPATION AND EMPOWERMENT

## A. A holistic support system and shared decision-making opportunities for MBC patients and informal carers to cope with the burden of the disease

Metastatic breast cancer patients face several challenges including the difficulty of coordinating their care and managing their health, while also managing their lives. (p. 15) As MBC is increasingly a long-term condition, with many elements of a chronic disease, there are metastatic cancer patients who still live an active and professional life. Consequently, MBC patients face problems with coordinating flexible working schedules, coordinating care teams and maintaining their finances. Patients and their informal carers require support systems to help manage these aspects of their wellbeing. (p. 18)

It can be difficult for patients to tell their employers about their metastatic disease, as doing so may raise questions about the patient's ability to perform their duties, complicating working relationships. Far from being a secondary concern to treatment choices, these issues can greatly affect a patient's and carer's quality of life. The European Commission initiative on improving the work-life balance of carers as part of the European Pillar of Social Rights<sup>50</sup> is a step in the right direction, but more needs to be done to better understand the exact number of people that are effected and how to better support them across Europe.

Ensuring adequate involvement of patients in the treatment process remains a significant challenge.<sup>51</sup> Patient choice and shared decision making is critically important and the various people involved should have the right tools to participate in this process. A recent literature review found that, in 63% of cases, a majority of patients expressed a wish to actively participate in decisions around their treatment, and the portion of patients who state such a preference is growing over time. This was especially pronounced among cancer patients.<sup>52</sup>

In the shared decision-making process, clinicians and patients work together to select an appropriate intervention. The decision is based on clinical evidence and the patient's informed preferences, and takes the patients values and needs into account. It involves the provision of evidence-based information about options, benefits, risks, and uncertainties, combined with a system for recording and implementing patients' informed preferences. This process can be supported by electronic or paper based Patient Decision Aids. In the case of MBC, the role of (informal) carers should also be considered, as it is important for patients to have support throughout decision-making from a non-medical advocate, as well as to have support in navigating the different options they have for treatment.<sup>53</sup>

To make an informed decision, it is critical that healthcare professionals working with MBC patients are trained on the relevant communication skills. Many MBC patients currently feel that doctor-patient communication is inadequate, but practices are already beginning to change: ASCO and ESMO have made a new curriculum for oncology, which, for the first time, includes a requirement for a broadly focused training in communication, and enables better preparation for healthcare professionals to allow for shared decision making. Ideally, this kind of training would become a requirement in Continuing Medical Education curricula for all types of healthcare professionals who work with metastatic cancer patients.

#### **POLICY RECOMMENDATIONS:**

Provide wider support systems and decision-making tools for MBC patients for coping with their diagnosis, handling their disease, managing their treatment's side effects, organising their lives to allow for minimal disruption, and supporting informal carers in their caring role.

- The ECIBC should create a dedicated pathway for metastatic breast cancer, taking into account the existing work of the clinical and advocacy community in this space.
  - The European Commission should use the European Pillar of Social Rights as a policy framework to initiate adequate measures to ensure member states provide patients and informal carers with employment regulations that sufficiently protect their work-life balance.
- National authorities should ensure that clinicians are adequately trained to implement shared decision-making in their practice.
- The MBC advocacy community should build a database of resources to help informal carers and patients access support systems and connect it with social sharing tools that are already in use.
- Specialised Breast Units should ensure the proper coordination and provision of supporting services for ongoing physical health, psychological, and social needs of patients and informal carers.
- The MBC advocacy community should collaborate with key stakeholders to build MBC decision-aids for both patients and their informal carers, building on existing best practice methodologies.
- Ministries of Education and Health of all member states should disseminate the new oncology curriculum, which includes training on communication, as developed by ASCO and ESMO.

#### B. Recognition and support for informal carers

Who are informal carers?

Informal carers are people who provide unpaid care to someone with a chronic illness, disability or other long-lasting health or care need, outside of a professional or formal framework.

Finding a sustainable work-life balance is a key issue for carers. The role of informal carers differs depending on the type of care setting and the type of metastasis the person they care for is experiencing. However, many informal carers are forced to reduce their working hours, and are sometimes pushed to quit their jobs in order to manage the burden of caring for someone with a severe and long-term disease. With such a central role in the quality of life of MBC patients, carer support systems are crucial to improving outcomes. However, support systems for carers currently differ widely between European countries.

#### **BEST PRACTICE:**

In Austria, caring relatives have a variety of rights. These are largely regulated by the *Bundespflegegeldgesetz* (BPGG)<sup>55</sup> and include the right to: (1) care counselling and training courses; (2) financial aid and contributions in kind, such as long-term care allowance, allowances for remodeling existing infrastructure or annuity; (3) support for day-nursing; (4) labor law exemption and reduction of working time; and (5) the right to recovery.

Lack of recognition and prioritisation of the role of informal carers can hinder the ability of health systems to advance cancer care. Carers play an important role in the patient's decision-making process, both in selecting and adhering to treatment, and in managing their daily life. Often they are not recognised by healthcare professionals as partners in care,<sup>56</sup> which leads to situations in which the carer or the family is not fully informed about the patient's medical situation.

#### **POLICY RECOMMENDATIONS:**

Increase recognition of the role of informal carers in MBC and formalise their rights and access to available support systems.

The European Commission should encourage further Europe-wide research to better understand the socio-economic impact of informal carers who support patients with metastatic cancer, with the aim to generate and track qualitative and comparative data at EU level.

Carer organisations should be recognised and supported (including financially) at national level and involved in the discussion about the care system.

The MBC clinical community should include the notion of informal carers in the training of healthcare professionals dealing with metastatic disease.

National governments should implement concretely the principles stated in the European Pillar of Social Rights on the recognition, flexibility and support for informal carers.



## PART 2 COUNTRY SPECIFIC POLICY ROADMAPS

This section contains five country policy roadmaps on metastatic breast cancer (MBC), which have been developed for Austria, France, Germany, Italy and Spain. These five case studies represent a variety of health systems and provide numerous best practices to serve as an example for other countries.

The country policy roadmaps look at existing practices, gaps and priority areas for improvement against each of the four focus areas as set out in the European MBC Policy Roadmap.







## FOCUS AREA 1. BUILDING A KNOWLEDGE- BASED APPROACH TO CARE

### A. Better data on the burden of disease, including its economic burden, to inform the decision-making process

In Austria, more than 5,000 cases of breast cancer are diagnosed every year, of which 5% to 10% (e.g. there were 250 cases in 2016) have distant metastases at the time of initial diagnosis.<sup>57</sup> Additionally, about 30% of patients diagnosed with early disease will relapse and develop MBC. This type of MBC represents about 90% of MBC population and its numbers are unknown.<sup>58</sup> The Austrian Cancer Registry documents all new cases of cancer, and contains statistical data (age, gender, place), the length of hospital treatment, histology, method of diagnosis and therapy. There is a plan to pass a new national cancer registry law to create a national registry containing more specific medical data.

In 2015, a Study Group of Medical Tumour Therapy (AGMT) initiated an academic registry for MBC patients to enable a standardised documentation with a medical, rather than statistical aim. The registry consists of a prospective and retrospective multicentre collection of data on patients with metastatic breast cancer.<sup>57</sup> The project is expected to run until 2025, capturing data on the characteristics, medical histories and treatment sequences with the following primary endpoints: epidemiology, therapies, response, survival and predictive factors.

#### **POLICY RECOMMENDATION:**

National authorities should encourage participation in the AGMT MBC registry to increase the access and use of the data collected and shared between the breast centres.

### B. National cancer plans to address the needs of metastatic breast cancer patients

A National Cancer Plan (*Krebsrahmenprogramm Österreich*) was published in 2014, and is reviewed every 5 years by the Oncology Advisory Council, which consists of representatives of the Ministry of Health, clinical experts, Health Technology Assessment (HTA) specialists and patient organisations. <sup>59</sup> The Austrian Cancer Plan does not include specific references to metastatic disease or MBC. Patient representation in the Council is currently limited to only two organisations: the "Austrian Cancer Aid" and the "Self-help group for colorectal cancer", limiting the patient perspectives available to support development of the Cancer Plan.

#### **POLICY RECOMMENDATIONS:**

The National Oncology Advisory Council should involve more diverse patient advocates and patients to ensure metastatic stages are sufficiently reflected in the Austrian Cancer Plan.

The Oncology Advisory Council should include specific measures on metastatic cancer, including MBC, in its next revision of the National Cancer Plan.

#### C. Adherence to evidence-based treatment guidelines

While all Austrian MBC patients are treated in certified breast cancer centres, in practice the level of adherence to clinical guidelines varies between hospital and treating physicians. According to the Austrian Law On Doctors, <sup>60</sup> doctors are free in choosing therapies, with no legal obligation to follow certain guidelines.

#### **POLICY RECOMMENDATION:**

The national authorities should urge more consistent country-wide adherence to MBC treatment guidelines, while enabling sufficient flexibility to personalised treatment.

#### D. Organisation of a single, patient-centred care pathway

There are currently 28 certified breast centres in Austria. A certificate must be renewed annually after an independent commission reviews the quality standards. All breast centres cooperate closely with each other, sharing data and best practices via *Statistik Austria*, the Federal Statistical Office in the country. Although all BC patients in Austria have been treated in certified breast centres since 2016, some patients lack real time access to medical services. A discrepancy also exists between the type of insurance patients have, and the waiting time for the radiologic exams. The difference from days to months to have the results from such exams is meaningful for patients that are in the metastatic setting. In March 2017, public health insurance organisations (*Sozialversicherung*) and the chamber of radiologists agreed to reduce the Magnetic Resonance (MR) and Computed Tomography (CT) examinations waiting time to 20 and 10 days respectively, with an additional guarantee that urgent cases will be examined within a day. However, the practice does not always reflect the above agreement.

#### **POLICY RECOMMENDATIONS:**

National authorities should ensure real time access to Multi-Disciplinary Teams (MDTs) for all MBC patients, regardless of the size of the treatment units they are affiliated to.

National authorities should address the inequalities in timely access to medical services that MBC patients face due to differences in the type of health insurance held.

## FOCUS AREA 2. COLLECTION AND USE OF REAL WORLD DATA

## A. Pan-European collaboration and widespread use of Real World Data (RWD) to improve patient outcomes

Although policymakers are prioritising the improvement of data quality, there are currently no policy initiatives considered to implement the use of Real World Data in MBC. There is however, an ongoing pilot project on the use of patient generated data in the development of a myeloma registry.

#### **POLICY RECOMMENDATION:**

National authorities should create a framework for initiatives (public-private) to allow for the collection and incorporation of real world evidence into the regulatory and policy decision-making process.

## FOCUS AREA 3. ACCESS TO CARE AND TREATMENT

### A. Health Technology Assessment (HTA) methodologies adapted to the reality of MBC care and treatment

Since 2000, HTA has been used on a regular basis for investment and reimbursement decisions by several bodies, <sup>66</sup> namely the Ministry of Health, the Social Insurance and hospital cooperatives. <sup>67</sup> In 2010, a national HTA strategy was drafted by Gesundheit Österreich GmbH (GOeG), the national agency for health. This strategy has not yet been fully implemented due to the federal structure of the Austrian health system, which allows disparate processes for reimbursement depending on the location in which treatment is administered. If a medication is paid for by social insurance, or Krankenkasse, then reimbursement decisions will be made by the head organisation for social insurance, Hauptverband, through an established HTA process.

If, instead, the medication is used during a hospital stay, the treatment decision is made by the hospital, most of which are run by the federal states. While hospitals also have an HTA process organised by the Ministry of Health, there is no legal obligation for participation.<sup>68</sup> The interaction between hospital based HTA units and the national HTA agency is voluntary and ad hoc through personal networks,<sup>69</sup> leading to regional disparities in the reimbursement of new medicines.

#### **POLICY RECOMMENDATION:**

National authorities should address the regional disparities in the reimbursement systems across the country.

### B. Patient input to the value assessment of cancer treatment and care

In Austria, patients and citizens are only infrequently and unsystematically involved in HTA decisions. The only patient organisation regularly involved in political decisions is Österreichische Krebshilfe (Austrian Cancer Aid), the umbrella organisation containing most of the cancer patient initiatives. While a promotion of public participation was included in the scope of the healthcare reform in 2013, it has yet to be implemented. To

### **POLICY RECOMMENDATION:**

National and regional decision-makers should involve patients and MBC advocacy community in the development of Health Technology Assessment (HTA) criteria and individual assessments of MBC care and treatments.

# FOCUS AREA 4. PATIENT SUPPORT, PARTICIPATION AND EMPOWERMENT

## A. A holistic support system and shared decision-making opportunities for MBC patients and informal carers to cope with the burden of the disease

Breast cancer organisations in Austria, as well as numerous support groups across the country, actively provide support and information for cancer patients. These support groups, however, do not specifically focus on MBC.<sup>71</sup> To address this issue, EUROPA DONNA Austria has developed and facilitated a number of MBC specific information sources including various blog posts<sup>72</sup> and brochures.<sup>73</sup> A revised and expanded patient guide on breast cancer with a specific focus on MBC is currently being developed.<sup>74</sup> Information and support for patients is also available at the centres for female health (*Frauengesundheitszentren*) in many of the larger cities.

Recently, clinician consultation time has been diminished, limiting the time allowed for the patient-clinician interaction. The Austrian Medical Association has cautioned that ongoing restrictions on doctors' reimbursements will result in shorter appointment times and less time for consultations, despite sufficient supply of doctors in the country.<sup>75</sup>

### **POLICY RECOMMENDATIONS:**

National authorities should encourage and collaborate with patients and the patient advocacy community to develop necessary information and decision-making tools for MBC patients.

National authorities should ensure that country-wide, clinicians are provided with the necessary time for consultations, to allow for a joint clinician-patient treatment decision-making.

### B. Recognition and support for informal carers

In Austria, caring relatives have a variety of rights, regulated in the *Pflegeldgesetz* (BPGG)<sup>76</sup> but they are not specific to a disease area. These include the right to: (1) care counselling and training courses; (2) financial aid and contributions in kind, such as long-term care allowance, allowances for remodelling existing infrastructure or annuity; (3) support in nursing day; (4) labour law exemption and reduction of working time; and (5) the right to recovery. These measures do not provide paid psychological support for the carers.

### **POLICY RECOMMENDATION:**

National government should ensure the rights as set out in the BPGG are adapted to the specific disease and are sufficiently enforced and accessible for all informal carers.

## FRANCE

### FOCUS AREA 1.

### BUILDING A KNOWLEDGE-BASED APPROACH TO CARE

### A. Better data on the burden of disease, including its economic burden, to inform the decision-making process

In France, the importance of exchanging clinical data between healthcare professionals was reaffirmed in the national cancer plan of 2014-2019. Cancer records are now generated for a limited number of patients, thanks to the efforts of authorities to implement the Communication Cancer Record (DCC) system. However, these records are not the same as a national registry, and a national registry of MBC patients is still needed, as the numbers of MBC patients is unknown.

While MBC-specific data is already collected in the 20 Comprehensive Cancer Centres of the UNICANCER Group, there are currently no specific measures in place to capture MBC-specific data in all cancer centres throughout the country. In France, cancer patients can be treated in different healthcare centres (e.g. large regional public hospitals or local private clinics) that have different approaches to and use different kinds of software for data collection that do not allow for data sharing and exchange on a national scale.

### **POLICY RECOMMENDATIONS:**

The national authorities in collaboration with the National Institute for Cancer (INCa) should ensure that all cancer records collected by cancer centres and medical facilities in France contain data on diagnostic and treatment events along the whole breast cancer pathway, including for MBC.

The French authorities should provide for measures to increase the access to and use of existing data to improve the decision-making process and patient outcomes.

The competent authorities should establish a national registry of all MBC patients.

### B. National cancer plans to address the needs of metastatic breast cancer patients

Successive governments have adopted comprehensive cancer plans, including action plans for screening.<sup>77</sup> The third Cancer Plan was launched in February 2014 with the objective of addressing societal challenges posed by cancer.<sup>78</sup> While the current national cancer plan covers both early and advanced breast cancer, it does not provide any specific provisions for metastatic disease.

### **POLICY RECOMMENDATIONS:**

The National Institute for Cancer (INCa) should consult stakeholders across the MBC pathway in the development of national cancer plans and include specific provisions for metastatic disease.

The Ministry of Health should develop measures to incentivise the national cancer plan research priority to better understand metastasis including in breast cancer.

The Ministry of Health should follow up on the commitment made in the third national cancer plan with regard to breast cancer, including equal access to innovation and care pathway optimisation, with full involvement of patients and users of the health system.

### C. Adherence to evidence-based treatment guidelines

In France, the use and adherence to clinical guidelines has increased significantly through enhanced collaboration between hospitals, particularly through the UNICANCER charter.<sup>79</sup> This charter was created in 2010 to serve as a model of integrated management of oncology based on multidisciplinary, individualisation of treatments, and a research-healthcare continuum.<sup>79</sup>

Despite increased collaboration between cancer care centres, clinicians tend to follow regional guidelines. Consequently, guideline adherence still varies between cancer centres. Another barrier to guideline adherence is found in the differences between local hospitals, including their type, size and budget procedures, with some favouring the use of intravenous therapy regardless of potential clinical and patient preferences<sup>80</sup> for the use of oral medicines.<sup>8</sup>

### **POLICY RECOMMENDATIONS:**

The Ministry of Health in collaboration with the National Institute for Cancer (INCa) should encourage the development of and adherence to international and national guidelines by all French cancer centres.

The French authorities should examine regional and local policies and reimbursement processes to ensure that counter-incentives to the prescription of the most appropriate treatment no longer persist (e.g. therapeutic habits, economic incentives, guidelines) and to encourage ambulatory treatments and outpatient care.

### D. Organisation of a single, patient-centred care pathway

France has solid functioning and cooperating healthcare centres specialised in MBC as reflected in the UNICANCER charter. Furthermore, all cancer centres in France involve MDTs to decide on the individual care and treatment plans called *Réunion de Concertation Pluridisciplinaire* for early breast cancer patients.<sup>81</sup> These plans have yet to be applied to MBC patients.

In addition, the third Cancer Plan made a big step forward by recognising the role of cancer clinical nurse specialists<sup>78</sup> and the *Institut Curie* developed a nursing programme for MBC patients. Through this programme, a Nurse Specialist is specifically trained to counsel MBC patients who are on oral chemotherapy and support them in the management of side effects.<sup>82</sup> However, there are limited numbers of nurse specialists, and gaps remain in terms of access to and quality of ambulatory care for MBC patients. These gaps must be overcome to reduce geographical inequalities within the country.

### **POLICY RECOMMENDATIONS:**

The Ministry of Health in collaboration with Ministry of Education should encourage and support a wider roll-out of the specialised nursing programme model developed by *Institut Curie*, and consider the creation of a "coordinator of MBC care" or "patient navigator."

The Ministry of Health should introduce measures to improve patient pathway and support, improving the HCPs coordination, especially on the transition from/between hospital and ambulatory care (e.g. use of telemedicine, innovative follow-up tools including apps).

The French reimbursement authorities should ensure ambulatory care is fully considered in the patient pathway.

National authorities should make Specialised Breast Units mandatory for all breast cancer patients, including those with MBC.

# FOCUS AREA 2. COLLECTION AND USE OF REAL WORLD DATA

### A. Pan-European collaboration and widespread use of Real World Data (RWD) to improve patient outcomes

In 2014, the UNICANCER Group launched an Epidemiological Strategy and Medical Economic (ESME) Research Program, which provided an academic real-time data platform for MBC to host the data of approximately 28.000 patients.<sup>83</sup> Although promising results have been presented in international congresses such as ESMO and ASCO, the data has not yet been used by the relevant authorities in charge of Health Technology Assessment (HTA) decisions.

### **POLICY RECOMMENDATIONS:**

The French authorities should create a framework for initiatives (public-private) on the collection and incorporation of real world evidence into the regulatory and policy decision-making process, with the aim to improve the clinical management of MBC.

National authorities should ensure that the collection of MBC data is harmonised and covers all MBC patients, independent of the place of treatment (in cancer centres or not).

## FOCUS AREA 3. ACCESS TO CARE AND TREATMENT

### A. Health Technology Assessment (HTA) methodologies adapted to the reality of MBC care and treatment

The current HTA methodology in France does not consider the use of surrogate endpoints such as progression free survival to reflect the clinical evolution of MBC and the different impact advanced stages have on the quality of life, health economics and indirect cost of managing the disease.

### **POLICY RECOMMENDATIONS:**

Regulators and payers should consider using aligned data requests, including surrogate endpoints, such as progression free survival for metastatic breast cancer with re-evaluation once overall survival data is available.

The MBC clinical and advocacy community should define and agree on the most appropriate endpoints for metastatic breast cancer.

Competent authorities should develop policies with clear distinctions for MBC in the governance and structure of pathways, funding schemes and healthcare centres.

INCa should address the geographical inequalities regarding patient access to high quality cancer care and clinical trials.

### B. Patient input to the value assessment of cancer treatment and care

Since 2016, patient advocacy groups can provide input to the Health Technology Assessment (HTA) process of medical products and devices via an online questionnaire<sup>84</sup> on the impact of the disease on the patient and his or her environment, experience with current therapies and experience with the product considered for assessment.<sup>84</sup> The questionnaire is open to any patient advocacy group and the responses are shared with the relevant committees to inform their decision making,<sup>85</sup> but currently no measures are in place to measure the impact of these contributions. In addition, the questionnaire does not consider important patient considerations like social aspects that contribute to the quality of life of MBC patients (i.e. the possibility to work).

### **POLICY RECOMMENDATION:**

National decision-makers should further improve the way patients and MBC advocacy community are involved in the development of the Health Technology Assessment (HTA) criteria and individual assessments of MBC care and treatments. One such measure should be to reinforce the quality of data gathered from patient advocacy groups (questionnaire) and the direct consideration of their input in the HTA process.

## FOCUS AREA 4. PATIENT SUPPORT, PARTICIPATION AND EMPOWERMENT

## A. A holistic support system and shared decision-making opportunities for MBC patients and informal carers to cope with the burden of the disease

The French welfare system mandates protective workplace measures for patients living with cancer and offers extensive palliative care in hospitals for patients with late-stage cancers. Since 2013, France has an industry-funded support programme ("Ressources et vous") in place for MBC patients, which provides access to a variety of different MBC-specific information channels including leaflets, meetings with psycho-oncologists and former patients and a dedicated Web Radio. Research

### **POLICY RECOMMENDATIONS:**

The French authorities should support the patient community in expanding successful support programmes for MBC patients throughout the country.

Competent authorities should assess and reduce regional inequalities, ensuring ambulatory care is fully considered in the patient pathway through financial adjustments to encourage ambulatory treatments, and the optimisation of outpatient care.

### B. Recognition and support for informal carers

In France, informal carers are eligible to receive support from the State in the form of a monthly allowance, and their investment is recognised when calculating their pensions.<sup>88</sup> In addition, informal carers can have access to material support, but the exact nature of this support varies between the departments of residence.<sup>89</sup>

At municipal level, the Centre of Social Action organises general preventive actions and supports social development within the community, working in partnership with both public and private institutions. <sup>90</sup> It can help fill monthly allowance requests or find the other support services. However, as these systems are overloaded and demand for social support is high, social services must frequently prioritise availability of services.

### **POLICY RECOMMENDATIONS:**

The French Ministry of Health should ensure that all informal carers for MBC patients are considered in an equal way for financial support and employment protection.

The Regional Health Agencies should incentivise the development of patient support programmes for out-of-hospital treatment, providing flexibility and support measures for informal carers.

# GERMANY

### FOCUS AREA 1

### BUILDING A KNOWLEDGE-BASED APPROACH TO CARE

### A. Better data on the burden of disease, including its economic burden, to inform the decision-making process

Following the successful implementation of the Law on Early Oncologic Diagnostics and Registries (2013)<sup>91</sup> the different regional registries may now exchange information, on the federal level with the Centre for Cancer Registry Data, allowing access to this information for healthcare professionals, payers, and patients. The German Cancer Registry was among the first breast cancer registries, and grew out of the world's first ever cancer registry established in Hamburg in 1926.<sup>92</sup> While the German Cancer Registry distinguishes between MBC and early breast cancer, it does not track nuanced aspects of the experience of metastasis, and the data primarily focuses on overall mortality.<sup>93</sup>

### **POLICY RECOMMENDATIONS:**

The German Cancer Registry should record and use data on diagnostic and treatment events along the breast cancer pathway, and include data for metastatic breast cancer.

Competent authorities should leverage the data gathered already on breast cancer relapse in the decision-making process.

### B. National cancer plans to address the needs of metastatic breast cancer patients

The National Cancer Plan has been in place since 2008, and is regularly updated. The plan primarily focuses on early detection, screening, and quality assurance in care, and does not contain any reference to metastatic stages of cancer. Involvement of patient organisations is limited to patient and self-help organisations which are currently entitled to appoint patient representatives in accordance with the regulations set forth in the German Social Code. Other patient organisations are limited to a consultation at the advanced stage of the process, limiting their input in the development of the national cancer plan.

#### **POLICY RECOMMENDATIONS:**

The Health Ministry, in cooperation with the German Cancer Society and German Cancer Aid, should adopt measures to be more inclusive of MBC patient involvement in the development of national cancer plans.

The Health Ministry should include specific measures to address advanced cancers, specifically MBC, in the national cancer plan.

### C. Adherence to evidence-based treatment guidelines

The Disease Management Programmes for breast cancer are regularly updated to ensure adherence to evidence based treatment guidelines and an equivalent level of treatment nationwide. 94 One remaining barrier is that the German healthcare reimbursement system currently favours the use of intravenous therapy over oral medicines, with reimbursement foreseen for prescribing intravenous therapies but not for additional time required to counsel patients on use of oral medicines, or for the medicines themselves. These incentives can mean intravenous therapies are favoured regardless of potential clinical and patient preferences for the use of oral treatment. 80

### **POLICY RECOMMENDATIONS:**

The Health Ministry should further encourage the implementation of Disease Management Programme Guidelines, including specific guidelines for MBC disease.

The German authorities should examine policies and reimbursement processes to ensure equal incentives for prescribing all therapeutic options for MBC.

### D. Organisation of a single, patient-centred care pathway

There is a strong network of certified breast centres which are systematically audited and overseen by the German Society for Senology and the German Cancer Society. $^{95}$ 

Because nurses are not fully integrated into specialised breast cancer care teams, improvement in the care of MBC patients is inhibited. While some cancer treatment institutions, including the Breast Cancer Centre in Aachen, employ nurses as case managers, <sup>96</sup> there is no formal cancer nurse qualification. The education programme in cancer care is not mandatory for nurses who work in oncology, and the salary incentive for this training is low. <sup>97</sup>

### **POLICY RECOMMENDATION:**

The Health Ministry should incentivise the development of specialist nurses for MBC, as well as integrated, holistic care pathways.

# FOCUS AREA 2. COLLECTION AND USE OF REAL WORLD DATA

### A. Pan-European collaboration and widespread use of Real World Data (RWD) to improve patient outcomes

The interest in RWD has increased since relevant legislation in 2015 encouraged healthcare research and subsequent real life data collection. Although German stakeholders have shown interest in RWD, major hurdles in both the generation and usage of RWD remain mainly due to data quality and privacy concerns. Sharing and cooperation can also be limited by concerns about ownership of the data by the various stakeholder groups collecting them.

### **POLICY RECOMMENDATION:**

National authorities should create a framework for initiatives (public-private) to allow for the collection and incorporation of real world evidence into the regulatory and policy decision-making process.

## FOCUS AREA 3. ACCESS TO CARE AND TREATMENT

### A. Health Technology Assessment (HTA) methodologies adapted to the reality of MBC care and treatment

In Germany, randomized clinical trial data on overall survival serve as the primary driver behind initial pricing, reimbursement and market access decision making. Patients are included to an extent in the national HTA process, but their involvement is limited to patient and self-help organisations, which are currently entitled to appoint patient representatives in accordance with the regulations set forth in the German Social Code. Other patient organisations have no access to the HTA process.

This situation led to a petition "Make Patient interest a Priority" initiated by the breast cancer magazine "Mamma Mia!". The initiative is supported by the German breast cancer organisation "Brustkrebs Deutschland e.V." and demands that progression free survival be recognised as a patient relevant therapeutic outcome in Germany. Additionally, the initiative advocates that patient representatives be democratically elected by the patient groups of the indication they represent. The third request of this initiative is that a representative study (survey) of affected patients be conducted pertaining to the relevance of progression free survival (and other validated surrogate endpoints – these studies should include the patient groups' expertise from the beginning). The petition asks that once the study results become public, the HTA process is revised.

### **POLICY RECOMMENDATION:**

The Federal Joint Committee, the German Institute for Medical Documentation and Information, and the Institute for Quality and Efficiency in Health Care should define and come to an agreement with the clinical and advocacy community on the appropriate endpoints for metastatic breast cancer, including the use of surrogate endpoints like progression free survival, with re-evaluation once overall survival data is available.

### B. Patient input to the value assessment of cancer treatment and care

According to the relevant legislation, a patient attends all the meetings of the German authorities throughout the value assessment procedure of a new therapy. However, the patients attending these sessions are not allowed to vote. 101

### **POLICY RECOMMENDATION:**

Competent authorities should further elevate the inclusion of the patient voice in Health Technology Assessment (HTA) decisions by ensuring that knowledgeable and representative patient advocates or patients attend the HTA sessions, and are allowed to provide meaningful input, as well as giving other specialised patient representatives the opportunity to be heard.

## FOCUS AREA 4. PATIENT SUPPORT, PARTICIPATION AND EMPOWERMENT

## A. A holistic support system and shared decision-making opportunities for MBC patients and informal carers to cope with the burden of the disease

In Germany, there is a strong network of breast centres where patients may participate regardless of insurance status, being assessed by a tumour board. However, apart from the clinical/medical support, there is a growing need for patients and their carers to have reliable and comprehensive information on how to communicate about their disease, and how to cope with the health effects of treatment, particularly those that affect their family and professional life, and where to get support.

### **POLICY RECOMMENDATION:**

The national authorities should work with various stakeholders including clinicians and patient advocates to facilitate the development of MBC decision-aids and support solutions (including financial support) for patients, their carers and patient advocacy groups, building on existing best practice methodologies.

### B. Recognition and support for informal carers

Every person in Germany has health insurance, which automatically includes nursing care insurance. If the insured person requires an informal carer, a monetary benefit is paid by the insurance company or national care system. Informal carers are supported by cancer counselling centres (*Deutsche Krebshilfe*) and/or support groups, and are entitled to various nonfinancial benefits such as free nursing courses. The amount of monetary benefit is based on the required level and duration of care. However, the amount and quality of the available support and benefits to informal carers varies between regions, and the process can be complex.

### **POLICY RECOMMENDATIONS:**

National authorities should recognise the statute of carer organisations at the national level and involve them in the discussion about the healthcare system.

The German government should harmonise and facilitate access to available support and benefits for informal carers.



### FOCUS AREA 1.

### BUILDING A KNOWLEDGE-BASED APPROACH TO CARE

### A. Better data on the burden of disease, including its economic burden, to inform the decision-making process

In Italy, the national cancer registry (ITACAN), managed by the Association of Italian Cancer Registries (AIRTUM), collects tumour data from individual accredited registries across the country, including breast cancer data. These registries only cover 57% of the total population and have different sizes: they can be regional (e.g. Umbria), semi-regional (e.g. Veneto) or even at the city level (e.g. Turin). Not all Italian territories are covered by ITACAN, and currently there is no specific registry on MBC. However, various Specialised Breast Units (SBUs) have begun collecting useful data. Bureaucracy appears to be an influencing factor in preventing further data sharing between Regions, especially with regard to data privacy and regional planning capabilities. A new bill to establish a national network of cancer registries, overseen by the Ministry of Health, is currently being discussed in Parliament.

### **POLICY RECOMMENDATIONS:**

National authorities should expand the use of tumour registries across the national territory to gather data on the diagnosis and treatment along the breast cancer pathway, including on MBC.

Competent authorities should provide a framework to incorporate the existing MBC data into the regulatory and policy decision-making process.

### B. National cancer plans to address the needs of metastatic breast cancer patients

A technical steering document<sup>105</sup> to reduce the burden of cancer has been in place since 2011 to address the national plan on oncology<sup>106</sup> with the aim to strengthen the actions of the Ministry and the Regions in fighting cancer. While the technical steering document has been reviewed several times as of 2014, there is currently no clarity about the process and timing for implementing the plan. As it stands, there are no specific references to or provisions mentioned for MBC.

#### **POLICY RECOMMENDATION:**

The Ministry of Health should develop a progress report on the status of the national plan on oncology and include specific measures for metastatic disease, including MBC.

### C. Adherence to evidence-based treatment guidelines

Guidelines are developed by both central and regional authorities, including scientific societies. Implementation, however, is the responsibility of the Regions and autonomous provinces. There are no systematic incentives to stimulate guideline uptake, and no consistent framework to monitor their implementation at service-level.<sup>107</sup>

In 2002, the Italian Association of Medical Oncology (AIOM) established a working group to develop clinical guidelines for cancer treatment following recommendations<sup>108</sup> of the Italian National Institute of Health (Instituto Superiore di Sanità). 109 Clinical guidelines are regularly updated in Italy and surveys are regularly carried out to verify the extent of compliance. 109 Between October 2005 and November 2006, a research project took place to evaluate how guidelines have been applied in Italy for the treatment of breast cancer. 110 The study gathered input from 35 randomly selected Italian breast centres, and found that while overall adherence to the guidelines on diagnosis was high (90%), treatment guideline adherence was much lower (between 20% and 74%) due to organisational difficulties or availability of treatment facilities (e.g. radiotherapy units). 109 The research findings furthermore concluded that it was important to continue improving the standards of breast cancer care and correctly evaluate adherence to guidelines to successfully update existing guidelines and better plan for future healthcare interventions. 109 Importantly, Real World Data (RWD) show that some of the most effective guidelines for MBC are among those that are not currently followed in Italy.<sup>111</sup>

### **POLICY RECOMMENDATION:**

The Italian Association of Medical Oncology (AIOM) should further encourage the implementation and evaluation of guidelines, including specific provisions for MBC disease.

### D. Organisation of a single, patient-centred care pathway

The Italian healthcare system is organised on national, regional and local levels. There are regional disparities in the organisation and funding of MBC treatment. While MBC patients in most regions in the North (e.g. Lombardy and Emilia Romagna) generally have good access, the southern regions still need to increase patient access to Specialised Breast Units. 115

Guidelines on breast units have been developed at national level, with clear qualitative and quantitative criteria, that take a holistic approach to the patient. These guidelines set the qualitative and quantitative criteria of the multi-disciplinary services each breast unit must provide, although with a focus on early (EBC) rather than MBC criteria.

Regions enjoy significant autonomy in determining the macro structure of their health systems<sup>115</sup> and are responsible for the implementation of the guidelines. As a result, there are differences in the implementation of an adequate network of breast units across the national territory, and several regions in Italy (especially in the South of Italy) struggle to implement the guidelines due to differences in administrative processes and resources.

Since 2012 a voluntary network of breast centres (SenoNetwork Italy)<sup>115</sup> provides a platform to encourage collaboration between the different breast centres in Italy. Again, this platform mainly focuses on the management of EBC, rather than MBC.

### **POLICY RECOMMENDATIONS:**

Regions should adopt the Italian Ministry of Health guidelines on Breast Centre Organisation.

Competent authorities should examine and compare the current regional policies and reimbursement processes to identify existing administrative barriers and reduce inequalities between regional health providers.

National government should incentivise the implementation of breast unit guidelines, including on MBC, across the national territory to guarantee equal access to care for all women, regardless of where they seek treatment. To this end, a quality check on the Specialised Breast Units (SBUs) should be developed.

Southern Regions should allocate and invest more resources in improving access to SBUs.

## FOCUS AREA 2. COLLECTION AND USE OF REAL WORLD DATA

### A. Pan-European collaboration and widespread use of Real World Data (RWD) to improve patient outcomes

The importance of using real world data is recognised by the clinical <sup>116</sup> and academic community <sup>117</sup> and Italian authorities are beginning to explore the potential of RWD for conditional reimbursement. While studies using RWD to track how patients are treated are conducted and published, <sup>118</sup> they are not currently organised by health authorities, and only involve a limited number of breast centres. Broader investigation is required, but is challenging due to the differences in regional capabilities and resources as well as policy obstacles related to data protection and privacy.

### **POLICY RECOMMENDATION:**

Regional health authorities should facilitate cross-national Real World Data (RWD) collection and provide for a value based reimbursement model for MBC.

## FOCUS AREA 3. ACCESS TO CARE AND TREATMENT

### A. Health Technology Assessments (HTA) methodologies adapted to the reality of MBC care and treatment

In Italy, the National Agency for Regional Healthcare Services (AGENAS) supports the HTA process in the regions, in collaboration with the Italian Drug Agency (AIFA) and the Health Institute via a dedicated national HTA centre. In addition, several Italian Regions have issued additional regional laws or regulations to manage HTA processes to foster the introduction and diffusion of valid and relevant technologies in the regional healthcare system.

The current HTA methodology does not differentiate between various subtypes of cancer and their related impact. Overall survival is often considered as the primary endpoint to determine the value of a cancer drug. However, studies conducted on Italian data underline the need to integrate the approach by considering other endpoints, such as progression free survival, adopting a logic coherent with the principles of the HTA.<sup>116</sup>

#### **POLICY RECOMMENDATION:**

National and regional authorities should consider using in their HTA process patient-relevant endpoints such as Quality of Life (QoL) and Patient Reported Outcome Measures (PROMs) and also validated surrogate endpoints such as progression free survival providing for treatment re-evaluation once overall survival data is available.

### B. Patient input to the value assessment of cancer treatment and care

Collection and consideration of patients' perspectives is included in the current Health Technology Assessment (HTA) process as overseen by AGENAS via (online) consultation processes and surveys, 119 but stakeholders generally agree that more can and should be done to increase patient involvement in a more structured and meaningful manner. Key identified barriers to address are education for participating patients and of the organisations in charge of the process, and ensuring patients' impartiality in the process. 120

### **POLICY RECOMMENDATION:**

National and regional decision-makers should develop policy measures to educate and increase the involvement of patient and patient advocacy organisations in the development of Health Technology Assessment (HTA) criteria and individual assessments of MBC care and treatments.

## FOCUS AREA 4. PATIENT SUPPORT, PARTICIPATION AND EMPOWERMENT

A. A holistic support system and shared decision-making opportunities for MBC patients and informal carers to cope with the burden of the disease

The first national patient association focusing on MBC patients "Tumore al seno metastatico – Noi ci siamo" was founded in October 2016, with the support of EUROPA DONNA Italy. 121 The newly established association has been driving initiatives to raise awareness about MBC and supporting and empowering patients. 122 Recent examples include the collection and dissemination of patient stories, as well as targeted conferences and events aimed at bringing patients in contact with the clinical community. 123

In 2013, EUROPA DONNA conducted a survey on patients' work-related needs and identified that the most common obstacles for breast cancer patients are: the current legislative framework, its fragmentation and partial, uncertain protection, insufficient and partial information on employees' rights, and lack of awareness of the time employees will need to take off following therapy. The Italian Federation of Oncology Volunteer Associations, to which EUROPA DONNA is a member, advocates for breast cancer patient support, workplace protections and strengthening of the regional network of Specialised Breast Units (SBUs).

### **POLICY RECOMMENDATIONS:**

Competent authorities, in collaboration with patient advocacy groups, is should develop a single set of protection rules for MBC patients, including homogeneous safeguards in collective employment contracts, and a welfare program.

Competent authorities should help raise awareness about MBC among healthcare professionals and the general public.

The Italian authorities should ensure that breast cancer guidelines are being implemented nation-wide and that their implementation is regularly audited.

### B. Recognition and support for informal carers

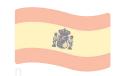
The Italian Association for Cancer Patients, their families and friends (AIMaC) provides support not only to cancer patients but also to their informal carers. It provides information as well as psychological support. Recognising the increasing importance of informal carers, the Italian Parliament is increasingly attentive to improving their situation. Currently, the Italian Senate is jointly examining three separate bills that consider 1) measures to support people taking care of family members; <sup>126</sup> 2) Norms to recognise and support informal carers; <sup>127</sup> and 3) A national framework law to recognise informal carers.

In parallel, some Regions have already taken the initiative to advance this area and have adopted regional laws to recognise and support informal carers. Emilia Romagna was the first Region in Italy to approve a regional law in 2014 to officially recognise and provide support to informal carers, including economic support, agreements with insurance companies and employers, support networks, and recognition of acquired competencies. <sup>129</sup> Several other regions have taken initial steps in the same direction. <sup>130</sup>

### **POLICY RECOMMENDATIONS:**

All regional authorities should ensure that legislation is in place to protect the rights of MBC patients and carers at the work place. Best practices from one region should be replicated among others.

All regions should recognise and provide support to informal carers of MBC patients, including economic support, agreements with insurance companies and employers, support networks, and recognition of acquired competencies.



# SPAIN

### FOCUS AREA 1.

### BUILDING A KNOWLEDGE-BASED APPROACH TO CARE

### A. Better data on the burden of disease, including its economic burden, to inform the decision-making process

In Spain, healthcare is decentralised and each Region (Autonomous Community) has its own healthcare system. Collaboration and data exchange between Communities and Regional Authorities has traditionally been limited and on an ad-hoc basis. The Spanish Network of Cancer Registries (REDECAN) was launched in 2010 with the aim to increase interregional collaboration and bring together regional and local population-based cancer registries. REDECAN does not yet cover all the regions of Spain, but regional governments can join as soon as they have implemented registries in their respective areas.<sup>131</sup>

REDECAN currently does not provide detailed data on MBC, but recently a prospective registry for MBC was initiated by the Spanish Breast Cancer Research Group, called RegistEM. The project is a collaboration between 43 hospitals and industry partners aimed at helping to understand the current distribution of the different molecular subgroups of tumours and their evolution, and includes 1400 patients diagnosed with advanced disease since June 2016. 132 Furthermore, the SOLTI academic research group 133 has been conducting various studies on MBC 134 to expand access to enabling technologies and expertise to perform molecular screening of patients and facilitate their access to clinical trials with novel targeted agents. 135

### **POLICY RECOMMENDATIONS:**

National and regional authorities should create a policy framework that makes use of the existing and upcoming data in MBC in the decision-making process.

REDECAN should consider creating a dedicated working group on metastatic cancer using MBC as a primary example.

### B. National cancer plans to address the needs of metastatic breast cancer patients

The National Healthcare System Cancer Strategy was published in 2009, <sup>136</sup> and is aimed at detecting the needs for preventing, diagnosing and treating cancer. It includes seven lines of action: health promotion and protection, early detection, provision of care, palliative care, quality of life and research. The Strategy was developed by a Technical Committee, which consists of multi-disciplinary experts, including volunteers and patient associations. <sup>136</sup> (p. 21) However, there is currently no specific reference to MBC and the strategy has not been updated since 2010.

### POLICY RECOMMENDATION:

The Spanish Ministry of Health, Social Services and Equality should update the national healthcare strategy and incorporate specific provisions for metastatic disease, including MBC.

### C. Adherence to evidence-based treatment guidelines

In 2015, the Spanish Breast Cancer Research Group developed and published national clinical guidelines for the diagnosis and multi-disciplinary treatment of MBC.<sup>137</sup> While in theory there are no deviations from the best available clinical practice guidelines, in practice there can be geographical differences in adherence to MBC treatment guidelines depending on how regional/local cancer centres are organised and financed.

#### **POLICY RECOMMENDATIONS:**

The Spanish Ministry of Health, Social Services and Equality and the Autonomous Communities should ensure nation-wide and full implementation of treatment guidelines.

The concerned medical and patient associations should consider initiating a study to compare regional and local adherence to the national clinical guidelines for the diagnosis and multi-disciplinary treatment of MBC as developed by the Spanish Breast Cancer Research Group, as well as the role of reimbursement criteria in the type of therapy prescribed (e.g. oral versus intravenous).

### D. Organisation of a single, patient-centred care pathway

In Spain, hospitals and medical institutions have a great level of autonomy, and each Autonomous Community has its own healthcare system. Therefore, patient access to treatments varies depending on their region of residence. As a result, patient advocacy groups have established campaigns against care disparity. For example, the Spanish Group of Cancer Patients (GEPAC) led two such campaigns, one of which, "Postal Code Lottery," denounced the notion that the place of residence and not the needs of patients was key in deciding which treatments patients can access.<sup>138</sup> In 2015, the group launched a campaign called «Equality of Treatment," which addressed issues such as discrimination and inequality in receiving treatment.<sup>138</sup>

There are a number of Specialised Breast Units (SBUs) operating throughout the country. However, to date, only 30 SBUs have been accredited by the Spanish Society for Mammary Senology and Pathology (SESPM).<sup>139</sup> Since healthcare is decentralised, a patient's access to clinical trials can depend on their region of residence.

### **POLICY RECOMMENDATION:**

National and Regional competent authorities should assess current regional policies and reimbursement processes to identify existing administrative barriers and propose solutions to reduce inequalities between regions.

# FOCUS AREA 2. COLLECTION AND USE OF REAL WORLD DATA

### A. Pan-European collaboration and widespread use of Real World Data (RWD) to improve patient outcomes

In 2014, an expert group conducted research to identify the value of Real World Data (RWD) for improving clinical practice and efficacy. This led to the publication of a roadmap for regional cooperation on the gathering of RWD. Since the publication of the roadmap, stakeholder discussions about the potential of RWD as a tool to help healthcare systems in the assessment of innovative treatments have further increased, the but with limited involvement and currently without a response from policymakers.

### **POLICY RECOMMENDATIONS:**

The National Health System should facilitate a nation-wide approach on Real World Data (RWD), through the Inter-Territorial Health Council.

Regional health authorities should incentivise the creation of interoperable registers integrated within day-to-day medical care, and the use of existing big data with the aim to improve the clinical management of MBC and facilitate clinical research.

## FOCUS AREA 3. ACCESS TO CARE AND TREATMENT

### A. Health Technology Assessment (HTA) methodologies adapted to the reality of MBC care and treatment

Different Regional HTA bodies in Spain coordinate and work together in the Spanish Network of Agencies for Health Technology Assessment and Services for the National Health System (RedETS). In 2013, a specific system for evaluating new medicines was implemented by the Inter-Territorial Health Council. The regional authorities who are responsible for medicines payment under National Health Service (NHS) coverage cooperate with the Spanish Medicines Agency when drafting the Therapeutic Positioning Reports for each new medicine. Each region uses its HTA or other medicines evaluating structure in this process, and prepares the complementary economic or budgetary impact assessments.

The Ministry of Health and regional authorities in the Inter-ministerial Pricing Commission make the final decisions on price and reimbursement. Despite increased collaboration, innovative treatments take longer to reach certain regions, mainly due to the different administrative layers that are in place. Redundancies remain in the process, and new evaluations are often performed by the regions or even at the hospital level.<sup>142</sup>

Currently most regional authorities consider mainly survival and do not place much emphasis on Quality of Life (QoL) considerations when assessing the value of new treatments.<sup>8</sup> Recognising the need for objective, transparent and predictable criteria, the Ministry of Health proposed a new law in 2017 concerning medicines pricing and reimbursement.<sup>143</sup> Ensuring that patients have access to the right treatments will require enhanced collaboration between regions, while identifying common criteria, facilitating common decisions, and increasing transparency and accountability.

### **POLICY RECOMMENDATIONS:**

The Spanish Inter-Territorial Council of the National Health Systems should discuss and facilitate the development of policies to address territorial disparities in MBC care.

The Spanish Ministry of Health, Social Services and Equality, and the Regional Authorities should create the framework for multi-stakeholder collaboration when identifying common criteria for the Health Technology Assessment (HTA), as well as pricing and reimbursement processes to ensure patients have access to the right treatments.

### B. Patient input to the value assessment of cancer treatment and care

The inclusion of patients in the value assessment of health technology is still limited and unsystematic. There is, however, a growing consensus<sup>144</sup> among Spanish Health Technology Assessment (HTA) bodies that the involvement of patients in the HTA process is beneficial to the quality of assessments, and that they should be included along the entire HTA pathway.<sup>145</sup> The Spanish HTA network, RedETS, recently initiated the development of a Patient Involvement Strategy consisting of short, medium and long term actions to improve patient participation in HTA assessment processes.

### **POLICY RECOMMENDATION:**

The Spanish Ministry of Health, Social Services and Equality, Regional Authorities and all participants in access to care and treatment processes should ensure successful roll-out of patient involvement strategies.

## FOCUS AREA 4. PATIENT SUPPORT, PARTICIPATION AND EMPOWERMENT

A. A holistic support system and shared decision-making opportunities for MBC patients and informal carers to cope with the burden of the disease

Awareness of MBC is still low in Spain, and, consequently, specific support for MBC patients and carers is limited and varies between regions. A recent study<sup>146</sup> published in April 2017 by the Spanish Federation of Women with Breast Cancer (FECMA) and developed in collaboration with a number of research institutes, provides an overview of patient experiences, needs and challenges. After this study was published, FECMA called on all stakeholders to increase efforts to raise awareness, recognise specific needs of MBC patients, and improve access to quality care and support systems.<sup>146</sup>

### **POLICY RECOMMENDATIONS:**

Competent authorities should increase the accreditation of breast units operating throughout the country.

The Spanish competent authorities should utilise the findings of the FECMA study to establish a system of effective HCP- patient and caregiver communication and joint decision-making process.

The national authorities should collaborate with FECMA and the wider MBC advocacy community to develop awareness raising and information sharing campaigns across the country.

### B. Recognition and support for informal carers

There are currently no support programs in place that address the specific needs for informal carers for MBC patients. While informal carers have access to some support services (e.g. psychosocial support, temporary alleviation from care tasks), this is still very limited and primarily depends on the availability of volunteer initiatives on a local level.<sup>147</sup>

### **POLICY RECOMMENDATION:**

The Spanish Ministry of Health, Social Services and Equality and Regional Authorities should develop a nation-wide support and recognition programme for informal carers, including financial support, trainings and labour agreements.

#### **ANNEX - GLOSSARY OF ACRONYMS**

**ABC** Advanced Breast Cancer **ABC Guidelines** ESO-ESMO International Consensus Guidelines for Advanced Breast Cancer **AGENAS** Italian National Agency for Regional Healthcare Services **AGMT** Austrian Study Group of Medical Tumour Therapy **AIFA** Italian Drug Agency **AIMaC** Italian Association for Cancer Patients, their Families and Friends **AIOM** Italian Association of Medical Oncology **ASCO** American Society of Clinical Oncology **AWCCO** Achieving World Class Cancer Outcomes: a strategy for England 2015-2020 **BPGG** Austrian Bundespflegegeldgesetz Cancer Control Joint Action CanCon **CNS** Clinical Nurse Specialist CT Computed Tomography DCC Communication Cancer Record system **ECIBC** European Commission Initiative on Breast Cancer **ENCR** European Network of Cancer Registries **EONS** European Oncology Nursing Society **EORTC** European Organisation for Research and Treatment of Cancer **ESMO** European Society for Medical Oncology **ESO** European School of Oncology

European Society of Breast Cancer Specialists

**EUSOMA** 

#### **ANNEX - GLOSSARY OF ACRONYMS**

**SESPM** 

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**FDA** United States Food and Drug Administration **FECMA** Spanish Federation of Women with Breast Cancer **GEPAC** Spanish Group of Cancer Patients Austrian Gesundheit Österreich GmbH **GOeG** HTA Health Technology Assessment **INCa** French National Institute for Cancer **ITACAN** Italian National Cancer Registry **LABC** Locally Advanced Inoperable Breast Cancer **MBC** Metastatic Breast Cancer **MDT** Multi-Disciplinary Team MR Magnetic Resonance **NABON Dutch National Breast Cancer Platform** National Health Service **NHS RCP** Réunion de Concertation Pluridisciplinaire or individual care and treatment plans **REDECAN** Spanish Network of Cancer Registries **RedETS** Spanish Network of Agencies for Health Technology Assessment and Services for the National Health System **RWD** Real-World Data **SBU** Specialised Breast Unit SEER United States National Cancer Institute's Surveillance, Epidemiology and End Results Program

Spanish Society for Mammary Senology and Pathology

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