ESMO 2017 Press Release: Licensing and Reimbursement Discrepancies Impact Patient Access to Cancer Treatment

Date: 10 Sep 2017

LUGANO-MADRID – Discrepancies between licensing and reimbursement decisions have an impact on patient access to cancer treatment, according to research presented at the ESMO 2017 Congress in Madrid. (1)

Conducted on behalf of Bristol-Myers Squibb, the study evaluated decisions by authorities in 11 European countries and Canada on anti-cancer medicines approved by the European Medicines Agency and Health Canada between 2006 and 2016 for six tumour types. It found that 34% of assessments led to complete or partial restrictions in access to medicines, potentially impacting more than 200,000 patients. (2) Differences between countries on the number of drugs with restricted access were independent of gross domestic product (GDP).

The researchers said that licensing and reimbursement decisions appear to be fragmented, resulting in varying restrictions that impede the use of effective medicines among clinically eligible patients and result in substantial loss of life years.

“There are potentially 200,000 patients in 12 countries who by licence should have access to drugs but are not getting them because of the reimbursement decision,” said lead author Mrs Jan McKendrick, senior director, PRMA Consulting Ltd, Fleet, UK.

“The findings were independent of GDP so this was not purely down to a country’s financial situation,” she added. “In some countries the reasons were clear – for example Canada only reimburses the trial population and the UK conducts a cost-effectiveness assessment – but many countries don’t publish the rationale.”

“Facilitating equal access to optimal cancer care to all patients is a key part of ESMO’s mission,” said ESMO President-Elect Professor Josep Tabernero, Head, Medical Oncology Department, Vall d’Hebron University Hospital, Director of the Vall d’Hebron Institute of Oncology (VHIO), Barcelona, Spain. (3) “The ESMO Cancer Medicines Working Group brings together representatives of patient groups, pharmaceutical companies, national and regional health systems, and reimbursement bodies to work towards value based reimbursement based on local parameters.”

“The ESMO European and International Consortium Studies on the Availability and Accessibility of Anti-Neoplastic Medicines give data to health authorities to assess whether anti-cancer medicines are available and affordable to patients who are prescribed them,” he added.

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Notes to Editors
Please make sure to use the official name of the meeting in your reports: ESMO 2017 Congress

References

1. Abstract 1124P_PR ‘Impact of licensing and reimbursement discrepancies on patient access to cancer treatments across Europe and Canada’ will be presented by Mrs Jan McKendrick during Poster Display session on Sunday, 10 September 2017, 13:15 to 14:15 (CEST) in Hall 8 (https://cslide.ctimeetingtech.com/library/esmo/browse/itinerary/5404/2017-09-10#2Bb5p).

2. The abstract reports that 26% of published assessments led to complete or partial restrictions. This rose to 34%, potentially impacting more than 200,000 patients, when unpublished assessments were included.

3. ESMO 2020 vision (/About-Us/ESMO-2020-Vision)

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About the European Society for Medical Oncology (ESMO)

ESMO is the leading professional organisation for medical oncology. With 16,000 members representing oncology professionals from over 130 countries worldwide, ESMO is the society of reference for oncology education and information. We are committed to supporting our members to develop and advance in a fast-evolving professional environment.

Abstract 1124P_PR

Impact of licensing and reimbursement discrepancies on patient access to cancer treatments across Europe and Canada

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Background: The European Medicines Agency (EMA) grants licenses to safe, effective cancer treatments where access to the drug can improve and prolong life. Subsequent country-specific health technology assessment (HTA) and reimbursement decisions may restrict access to sub-populations of clinically eligible patients. This study is the first to quantify the impact of licensing discrepancies in terms of Years of Life Lost (YLL) across a range of countries.

Methods: Oncology drugs approved by the EMA for six cancers (breast, kidney, lung, multiple myeloma, melanoma, prostate) between 2006 and 2016 were identified. Associated HTA reimbursement decisions from 13 agencies (Belgium, Canada, Denmark, France, Germany, Italy, the Netherlands, Poland, Portugal, Spain, Sweden, UK) were classified by degree of restriction between the populations clinically eligible and eligible for reimbursement: "no restriction", "partial restriction" (by percent of clinically eligible population restricted)" or "complete restriction". Epidemiology data (GLOBOCAN 2012) and population sizes from HTA submissions informed the estimated number of patients impacted. Potential survival gains from pivotal studies were applied to quantify the YLL impact of licensing discrepancies.

Results: Overall, 26% of published decisions resulted in complete or partial restriction; the extent of restrictions differed across countries (from 0% in Germany to 4% in Portugal and 63% in Scotland), cancer types and drugs. The restrictions impacted approximately 100,000 clinically eligible patients annually and, result in over 30,000 YLL
across the scope countries. Restriction rationale was often not publically available. Results show differences between countries regardless of GDP or timing of HTA assessment.

**Conclusions:** Despite one regulatory system for the approval of new medicines, results suggest that access to cancer therapies remains inequitable across Europe and Canada. Reimbursement decisions appear fragmented, resulting in varying restrictions that impede use of effective medicines among clinically eligible patients and result in substantial YLL burden.

**Keywords:** reimbursement, burden, YLL, restricted access

**Funding:** Bristol-Myers Squibb Pharmaceuticals Ltd

**Disclosure:** J. McKendrick, X. Song: PRMA Consulting (my employer) were paid to conduct the study and contribute to abstract preparation by BMS
B. Malcolm: Employee of Bristol-Myers Squibb Pharmaceuticals Ltd
K. Sheahan: Ms. Sheahan reports receiving payment outside the submitted work from Bristol Myers Squibb Pharmaceuticals as a Worldwide Heath Economics and Outcomes Research Fellow.
I. Katsoulis: Dr Katsoulis is employed by PRMA Consulting who were paid to conduct the study and contribute to abstract preparation by BMS
J. van Loon: Mrs van Loon is employed by PRMA Consulting who were paid to conduct the study and contribute to abstract preparation by BMS