



ACCESS TO MEDICINES, VACCINES AND PHARMACEUTICALS

TECHNICAL REPORT

## Pricing of cancer medicines and its impacts

A comprehensive technical report for the World Health Assembly Resolution 70.12 Operative paragraph 2.9 on pricing approaches and their impacts on availability and affordability of medicines for the prevention and treatment of cancer



TECHNICAL REPORT

# Pricing of cancer medicines and its impacts

Pricing of cancer medicines and its impacts

ISBN 978-92-4-151511-5

© World Health Organization 2018

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

**Suggested citation.** Pricing of cancer medicines and its impacts. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.

**Cataloguing-in-Publication (CIP) data.** CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

**Third-party materials.** If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

**General disclaimers.** The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use

# Contents

Abbreviations .....	vi
Executive summary.....	vii
1 Introduction.....	1
1.1 Prevention and treatment of cancer .....	1
1.2 Purpose of this report.....	5
1.3 Scope and methods .....	6
1.4 Report structure.....	9
2 Benefits and risks of cancer medicines .....	10
2.1 Evidence of benefits and risks of newer cancer medicines .....	10
2.2 Opinion of the EML Cancer Medicines Working Group.....	13
2.3 Summary.....	15
3 Pricing approaches for cancer medicines.....	16
3.1 Objectives of national pricing policy and pricing approaches .....	16
3.2 Industry's pricing approaches.....	17
3.3 Payers' pricing approaches .....	32
3.4 Summary.....	52
4 Impacts of pricing approaches or lack thereof .....	53
4.1 Impacts on price .....	53
4.2 Impacts on availability.....	68
4.3 Impacts on affordability.....	75
4.4 Impacts on research and development.....	80
4.5 Impacts on price and pricing transparency.....	90
4.6 Unintended negative consequences .....	95
4.7 Summary.....	102
5 Options that might enhance the affordability and accessibility of cancer medicines .....	103
5.1 Strengthening pricing policies at the national and regional levels .....	103
5.2 Improving the efficiency of expenditure on cancer medicines .....	105
5.3 Improving the transparency of pricing approaches and prices of cancer medicines .....	106
5.4 Promoting cross-sector & cross-border collaboration for information-sharing, regulation & procurement .....	108
5.5 Managing factors that would influence demand for medicines .....	109
5.6 Realignment of incentives for research and development.....	110
5.7 Conclusion.....	111

References.....	I
Appendices.....	XXVI
Appendix A: Resolution WHA70.12.....	XXVIII
Appendix B: Five-year age standardized survival rates for cancers.....	XXXIII
Appendix C: Members of informal advisory groups .....	XXXVIII
Appendix D: List of key publications relating to reviews of medicine pricing.....	XL
Appendix E: Health expenditure on pharmaceuticals and disease burden.....	XLI

## Figures

Fig. 1.1: Year-on-year growth rates of expenditures on cancer medicines and health care .....	3
Fig. 1.2: Comparison of expenditures on cancer medicines and health based on per-capita expenditures, by (a) incident cases and (b) prevalent cases.....	4
Fig. 1.3: Points along the value chain and product life-cycles for price setting and management.....	6
Fig. 3.1: Cost structure of pharmaceutical and life science industry, by company type and year .....	20
Fig. 3.2: Timeline of price planning activities for palbociclib .....	22
Fig. 3.3: Timeline of price planning activities for sofosbuvir .....	23
Fig. 3.4: Threshold analysis of revenue return, by R&D expenses and years since product launch .....	25
Fig. 3.5: Cumulative sales incomes of cancer medicines in 2017 US dollars, by molecule .....	26
Fig. 3.6: Distribution of market share by 2017 sales value and Herfindahl-Hirschman Index .....	28
Fig. 3.7: Comparison of factors of profit.....	31
Fig. 3.8: Dimensions that may be considered for determining the value of medicines .....	34
Fig. 3.9: External reference pricing, by country and country GDP-per-capita ranking.....	37
Fig. 3.10: Types of MEA applied for cancer medicines in European countries.....	42
Fig. 4.1: Comparative expenditure on cancer medicine in (a) Australia and (b) Norway .....	54
Fig. 4.2: Comparative expenditure on high-cost specialty medicine in the USA.....	55
Fig. 4.3: Median prices of EML cancer medicines, by country income and cancer incidence.....	57
Fig. 4.4: Cumulative percentage change from baseline mean monthly cost in the USA, by year .....	58
Fig. 4.5: Costs of cancer medicines (a) without and (b) with adjustment for purchasing power.....	60
Fig. 4.6: Cumulative real pharmaceutical price inflation in (a) Australia and US with year 1981 as the baseline year (b) Australia, US and Euro area with year 2000 as the baseline year .....	61
Fig. 4.7: Australian Government's reimbursement for cancer medicines dispensed (2011–2016).....	63
Fig. 4.8: Availability of cancer medicines in national formularies of non-European countries in 2016, by country ranked by GDP per capita in 2016.....	69
Fig. 4.9: Availability of cancer medicines in national formularies of European countries in 2014, by country ranked by GDP per capita in 2016 .....	70
Fig. 4.10: Decision outcomes on the coverage of cancer medicines (2002–2014) in 10 European countries or areas ..	72

Fig. 4.11: Distribution of pharmaceutical preclinical and clinical trials in 2016, by disease .....	81
Fig. 4.12: Distribution of medicines approved by the US FDA from 1998 to 2007, by sector .....	84
Fig. 4.13: Cumulative changes in the average list price and average net price from 2012 to 2017 for a US\$ 100 medicine in 2011, in the United States .....	91
Fig. 4.14: Proportion of US FDA-approved orphan drugs 1983–2016, by decade and category .....	96
Fig. 4.15: Number of cases of shortages reported to US FDA (2011–2016), by category .....	98
Fig. 4.16: Causes of shortages reported to national reporting systems in Europe (2010–2013) and US FDA (2011–2016) .....	99
Fig. 5.1: Summary of options that might enhance the affordability and accessibility of cancer medicines .....	103

## Tables

Table 2.1: Examples of medicines with marginal benefits and potential harms .....	12
Table 3.1: Examples of cost-based pricing, by jurisdiction .....	32
Table 3.2: Examples of tendering and negotiation for cancer medicines .....	38
Table 3.3: Mark-ups and dispensing fees in 2018, by jurisdiction .....	39
Table 3.4: Weighted average import tariffs and value-added tax for pharmaceuticals .....	43
Table 3.5: Revision of medicine prices, by jurisdiction .....	44
Table 3.6: Generic and biosimilar substitution policies .....	46
Table 3.7: Summary of pricing approaches for medicines .....	49
Table 4.1: Studies that examined price variability of cancer medicines .....	56
Table 4.2: Estimated annual expenditure on cancer medicines per patient by country income level .....	77
Table 4.3: Estimated costs of cancer pharmacotherapies, by cancer type and country .....	78
Table 4.4: R&D pathways and public and private sources of funding for cancer medicines .....	85
Table 4.5: R&D incentives for pharmaceutical companies and clinical research organizations .....	86

## Abbreviations

AIFA	Italian Medicines Agency
ASCO	American Society of Clinical Oncology
DALY	disability-adjusted life-year
EMA	European Medicines Agency
EML	WHO Model List of Essential Medicines
EML Working Group	Essential Medicine List Cancer Medicines Working Group
ERP	external reference pricing
ESMO	European Society for Medical Oncology
GDP	gross domestic product
HHI	Herfindahl-Hirschman Index
HPV	human papillomavirus
IARC	The International Agency for Research on Cancer
ICR	Institute of Cancer Research
Informal Advisory Group	Informal Advisory Group on Availability and Affordability of Cancer Medicines
IRP	internal reference pricing
MCBS	Magnitude of Clinical Benefit Scale
MEA	Managed Entry Agreement
NGO	nongovernmental organization
NICE	National Institute for Health and Care Excellence
NIH	National Institutes of Health
OECD	Organisation for Economic Co-operation and Development

预览已结束，完整报告链接和二维码如下：

[https://www.yunbaogao.cn/report/index/report?reportId=5\\_25662](https://www.yunbaogao.cn/report/index/report?reportId=5_25662)

