



GLOBAL REPORT ON ACCESS TO HEPATITIS C TREATMENT

FOCUS ON OVERCOMING BARRIERS

OCTOBER 2016

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TABLE OF CONTENTS

Acknowledgements	IV
Abbreviations	V
Executive summary	VI
1. Introduction	1
1.1. HCV epidemiology	1
1.2. New medicines: moving towards elimination	3
1.3. WHO Global Health Sector Strategy on Viral Hepatitis	4
1.4. Examples of country action towards elimination of hepatitis	7
2. Status of the response	8
2.1 Estimated number of people who received direct-acting antivirals (DAAs)	8
2.2 The HCV treatment cascade: diagnosis and linkage to care	9
2.2.1 HCV testing	10
2.2.2 Pre-treatment assessment: HCV genotyping and liver disease staging	11
2.2.3 Treatment guidelines	12
2.2.4 HCV treatment delivery	13
2.2.5 DAA treatment in the present and the future	14
3. Accessing affordable DAA medicines in different settings	15
3.1 Price developments	15
3.2 Price transparency, price negotiation and price control	17
3.3 International quality assurance standards	20
3.4 Registration of DAAs in countries	20
3.5 Overcoming patent-related barriers to access	21
3.5.1 Patent oppositions	22
3.5.2 Voluntary license agreements	22
3.5.3 Compulsory licensing	26
3.6 Procurement	27
4. Overcoming access barriers: examples from selected countries	28
4.1 Approaches in different countries	28
4.2 Generic competition and local production	30
4.3 Civil society advocacy fuels negotiations	31
4.4 Political will	31
4.5 Efficient regulatory processes for rapid scale up	31
4.6 Starting out	32
4.7 Building on a national plan and adopting treatment guidelines	32
4.8 Donor support and NGO partnerships	34
5. Drug profiles	38
5.1 Daclatasvir	39
5.2 Ombitasvir/paritaprevir/ritonavir ± dasabuvir	41
5.3 Simeprevir	43
5.4 Sofosbuvir	44
5.5 Sofosbuvir/ledipasvir	45
References	50

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ACRONYMS AND ABBREVIATIONS

ALCS	The Association against AIDS (Morocco)
API	active pharmaceutical ingredient
APRI	aspartate aminotransferase-to-platelet ratio index
ARIPO	African Regional Intellectual Property Organization
ART	antiretroviral therapy
CDC	United States Centers for Disease Control and Prevention
DAA	direct-acting antiviral (medicine)
DBS	dried blood spot
EMA	European Medicines Agency
EML	WHO Model List of Essential Medicines
EMP	WHO Department of Essential Medicines and Health Products
EOI	expression of interest
FDC	fixed-dose combination
FPP	finished pharmaceutical product
GCC	Gulf Cooperation Council
GDP	gross domestic product
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HCV	hepatitis C virus
HCC	hepatocellular carcinoma
I-MAK	Initiative for Medicines, Access & Knowledge
ITPC-MENA	International Treatment Preparedness Coalition-Middle East and North Africa
LMICs	low- and middle-income countries
MdM	Médecins du Monde
MoH	Ministry of Health
MSM	men who have sex with men
NAT	nucleic acid test/testing
NGO	nongovernmental organization
NHSO	National Health Security Office (Thailand)
OAPI	Organisation Africaine de la Propriété Intellectuelle
OECD	Organisation for Economic Co-operation and Development
OECS	Organisation of Eastern Caribbean States
PWID	people who inject drugs
RNA	ribonucleic acid
SSFFC	substandard, spurious, falsely labelled, falsified and counterfeit (medical products)
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
USA	United States of America
US FDA	United States Food and Drug Administration
WTO	World Trade Organization

EXECUTIVE SUMMARY

Towards the vision of “...a world where viral hepatitis transmission is halted and everyone living with viral hepatitis has access to safe, affordable and effective prevention, care and treatment services”.

– WHO Global Health Sector Strategy on Viral Hepatitis, 2016

Worldwide, approximately 80 million people are living with chronic hepatitis C virus (HCV) and millions more are newly infected each year. Annually, 700 000 people die from HCV-related complications, including cirrhosis and hepatocellular carcinoma (HCC). Despite the scope and severity of the epidemic caused by HCV, until recently, the global response to reduce the burden of this disease has been very limited and the available treatment was expensive, poorly tolerated and had low cure rates. Once infected with hepatitis C there was little chance of being cured, particularly for people living in low- or middle-income countries.

The field of HCV therapeutics has evolved rapidly: in 2013, the treatment of HCV was transformed by the introduction of a new class of medicines called direct-acting antivirals (DAAs). An 8–12-week course of these medicines can cure more than 90% of persons with chronic HCV infection. These new oral treatments offer tremendous opportunities and hope to all those who are infected. As with the upcoming new HIV treatment 20 years ago, we now have to ensure that these lifesaving treatments become accessible to all those who need them. This requires all stakeholders to work together to overcome barriers to access.

This is the first-ever global report on treatment access to hepatitis C medicines. The report provides the information that countries and health authorities need to identify the appropriate HCV treatment, and procure it at affordable prices. The report uses the experience of several pioneering countries to demonstrate how barriers to treatment access can be overcome. It also provides information on the production of new hepatitis C drugs and generic versions worldwide, including where the drugs are registered, where the drugs are patented and where not, and what opportunities countries have under the license agreements that were signed by some companies as well as current pricing of all recommended DAAs, including by generic companies all over the world.

Comparable to the early days of HIV treatment, high prices are a barrier to the scale up of HCV treatment. The new medicines were introduced at very high prices, in particular, in high-income countries. However, the pricing situation is not

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