Ed Schoonveld

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The Price of Global Health

Drug Pricing Strategies to Balance Patient Access and the Funding of Innovation

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List of Abbreviations

€	Euro Currency
AD	Alzheimers' Disease
AEMPS	Agencia Española de Medicamentos y Productos Sanitarios
AFSSAPS	Agence Française de Securité Sanitaire des Produits de Santé
AHFS – DI	American Hospital Formulary Service – Drug Information
AIDS	Acquired Immunodeficiency Syndrome
AIFA	Agencia Italiana del Farmaco
AIOCD	All India Organization of Chemists and Druggists
AMCP	Academy of Managed Care Pharmacy
AMP	Average Manufacturer Price
ANVISA	Agência Nacional de Vigilância Sanitária
AOK	Allgemeine Ortskrankenkasse
ASMR	Amélioration du Service Medical Rendu
ASP	Average Selling Price
ATC	Anatomical Therapeutic Classification
AWP	Average Wholesale Price
AZT	Azidothymidine
BEST PRICE	Framework: Benefits, Evidence, STory, PRICE
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
BGTD	Biologics and Genetic Therapies Directorate
BHIS	Basic Health Insurance Scheme
BKK	Bundesverband Betriebskrankenkassen
BMG	Bundesministerium für Gesundheit
BMS	Bristol-Myers Squibb
BRIC	Brazil, Russia, India, China
CAP	Competitive Acquisition Program
CCDSM	Collaborating Centre for Drug Statistics Methodology
CCOHTA	Canadian Coordinating Office for Health Technology Assessment
CEPS	Comité Economique des Produits de Santé

CDR	Common Drug Review
CED	Coverage with Evidence Development
CGHS	Central Government Health Scheme
CHIP	Children's Health Insurance Program
CIPE	Comitato Interministeriale per la Programmazione Economica
CIPM	Comisión Interministerial de Precios de los Medicamentos
CMED	Câmara de Regulação do Mercado de Medicamentos
CML	Chronic Myelogenous (or Myeloid) Leukemia
CMS	Center for Medicare and Medicaid Services
CODEM	Comité de Evaluacion de los Medicamentos de Uso Humano
COPD	Chronic Obstructive Pulmonary Disease
CPI	Consumer Price Index
CT	Commission de Transparence
CTS	Commissione Tecnico Scientifica
CUF	Commissione Unica del Farmaco
DDD	Daily Defined Dose
DMARD	Disease Modifying Anti-Rheumatic Drug
DoD	Department of Defense
DP	Direct Price
DPCO	Drugs Price Control Order
DRG	Diagnosis Related Group
DTC	Direct To Consumer (Advertising)
ECJ	European Court of Justice
ECT	Electroconvulsive Therapy
EMA	European Medicines Agency
EMEA	see EMA
EORTC	European Organization for Research and Treatment of Cancer
ESIS	Employee State Insurance Scheme
EU	European Union
EU-5	France, Germany, Italy, Spain, UK
FDA	Food and Drug Administration
FPA	Foreign Price Adjustment
FSS	Federal Supply Schedule
FUL	Federal Upper Limit
G-BA	Gemeinsamer Bundesausschuss
GDP	Gross Domestic Product
GI	Gastro-Intestinal
GSK	GlaxoSmithKline
GVS	Geneesmiddelen Vergoedings Systeem (Netherlands)

HAM-D	Hamilton Depression Rating Scale
HAS	Haute Authorité de Santé
HbA1C	Haemoglobin A1C
HE	Health Economics
HEOR	Health Economics and Outcomes Research
HER-2	Human Epidermal growth factor Receptor 2
HIPC	Highest International Price Comparison
HIV	Human Immunodeficiency Virus
HMO	Health Maintenance Organization
HO	Health Outcomes
HPFB	Health Products and Food Branch
HQ	Headquarters
HTA	Health Technology Assessment
IKK	Bundesverband der Innungskrankenkassen
IPP	Indifference Price Point
IRDA	Insurance Regulatory Development Authority Bill
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
IV	Intravenous
GKV	Gesetzliche Krankenversicherung (Spitzenverband Bund der Krankenkassen)
KOL	Key Opinion Leader
LDL	Low Density Lipoprotein
LEEM	Les Enterprises du Médicament
MA&P	Market Access and Pricing
MAC	Maximum Allowable Cost
MAP	Minimally Acceptable Profile
MBS	Medicare Benefits Schedule
MCO	Managed Care Organization
MHRA	Medicines and Healthcare product Regulatory Agency
MIPC	Median International Price Comparison
MLSS	Ministry of Labor and Social Security
MMA	Medicare Modernization Act
MS	Multiple Sclerosis
NCCN	National Comprehensive Cancer Network
NCE	New Chemical Entity
NDRC	National Development and Reform Commission
NEDL	National Essential Drug List
NGO	Non-Governmental Organization
NHI	National Health Insurance

NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIH	National Institute of Health
NPPA	National Pharmaceutical Pricing Authority
NRCMS	New Rural Cooperative Medical System
OPP	Optimal Price Point
OPPI	Organization of Pharmaceutical Producers of India
OTC	Over-The-Counter
P&L	Profit and Loss
P&MA	Pricing and Market Access
P&R	Pricing and Reimbursement
PA	Prior Authorization
PBAC	Pharmaceutical Benefits Advisory Committee
PBM	Pharmaceutical Benefit Manager
PBMI	Pharmacy Benefit Management Institute
PBS	Pharmaceutical Benefits Scheme
PCP	Primary Care Physician
PCT	Primary Care Trust
PDL	Preferred Drug List
PEI	Paul Ehrlich Institute
PFN	Prontuario Farmaceutico Nazionale
PLA	Provincial Listing Agreement
PMC	Point of Marginal Cheapness
PME	Point of Marginal Expensiveness
PMPRB	Patented Medicine Prices Review Board
PODiUM	Framework: Treatment **P**ractice, Promise **O**ptions, **Di**rect Competition, **U**nmet Needs, **M**oney Flow
PP	Public Policy
PPO	Preferred Provider Organization
PPRS	Pharmaceutical Price Regulation Scheme
PR	Public Relations
PRM	Prezzi, Rimborso e Mercato
PTOA	Prontuario Terapeutico Ospedaliero Aziendale
QALY	Quality Adjusted Life Years
QOL	Quality Of Life
R&D	Research and Development
RBP	Reference-Based Pricing
RBP-I	RBP Phase I
RBP-II	RBP Phase II
RENAME	Relação Nacional de Medicamentos Essencias

Rx	Prescription
SCHIP	State Children's Health Insurance Program
SF-36	Short Form 36 (QOL questionnaire)
SMR	Service Médical Rendu
SNRI	Serotonin-Norepinephrine Reuptake Inhibitor
SNS	Sistema Nacional de Salud
SSN	Servizio Sanitario Nazionale
SSRI	Selective Serotonin Reuptake Inhibitor
SU	Sulfonylurea
TCC	Therapeutic Class Comparison
TOP	Target Opportunity Profile
tPA	Tissue Plasminogen Activator
TPD	Therapeutics Products Directorate
TR	Therapeutic Referencing
TRIPS	Trade-Related Aspects of Intellectual Property Rights
Tx	Treatment
TZD	Thiazolidinedione
UK	United Kingdom
UNCAM	Union National des Organismes d'Assurance Maladie Complémentaires
US	United States
VA	Veterans Administration
WAC	Wholesale Acquisition Cost
WHO	World Health Organization
WTO	World Trade Organization

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I owe gratitude to many colleagues and friends from the pharmaceutical industry and consulting firms that I have worked with over the last twenty two years, as well as clients that I have had the pleasure of assisting in their strategic and supporting research needs. Contents of this book have shaped over the last ten years, since I first considered writing this book, as colleagues and clients have endorsed or challenged the individual ideas that have gone in to this work.

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Preface

Many people have asked me to recommend a book about global drug pricing. I never had an answer. Others have suggested that I write that book. Well, here it is ...

It is puzzling that there are hardly, if any, books written about global drug pricing. The topic is certainly garnering interest and emotion from politicians, healthcare professionals, drug industry professionals and the public. Also inside pharmaceutical companies there is a great need for a better understanding of the topic. As a client recently noted, many drug marketing people are not really proficient in pharmaceutical market access and pricing.

Global drug pricing is a very complex topic, partly because patents give companies a period of market exclusivity. It is also different from most other industries due to the fact that government payers have a lot of buying power. In economic terms it could be typified as "monopoly vs. monopsony" that causes a very unique and interesting dynamic, particularly when considering the situation on a larger global scale. Payers and politicians sometimes complain about lack of competition for a new drug category. Drug manufacturers complain about government controls in drug pricing. In any case, in the pharmaceutical market dynamic, general pricing principles do not directly apply without significant customization. This is why general pricing textbooks are essentially useless for application in pharmaceutical pricing cases.

In contrast to drug pricing, many books have been written about health economics, a discipline that provides a systematic methodology to make health resource decisions under budget constraints. Health economics is used, for example in the United Kingdom, to decide whether a new anti-cancer drug should be included in their drug formulary or whether liver transplants should be reimbursed for every eligible patient. In most countries, however, payers and politicians are struggling to strictly base drug coverage decisions on a

calculation that is only understood in detail by academics. In reality, only few payers strictly use health economics principles in pricing and market access decision making. Global drug pricing includes health economics and health outcomes considerations, but is in reality even broader and more complicated.

As a leader in global pricing and health outcomes and economics disciplines in three large global drug companies and serving as a consultant to many others, I have had the privilege of observing the evolving roles of pricing and health economics over the years. It is particularly interesting that the two disciplines that focus on payer decision making are usually reporting into different corporate branches, that is commercial and research and development. It makes successful collaboration of the two areas heavily dependent on having similar viewpoints among the leaders of both fields, in a setting where even a joint textbook on best practices did not exist until this present work.

Healthcare is a matter that is and should be near and dear to all of us. In times of a health scare, for example caused by H1N1 or Anthrax, we call for miracle solutions to protect ourselves from harm. Whether during recent debates on US Health Care Reform or previous ones on pricing of HIV/AIDS drugs or patient co-payments in a European country, the public seems to be very engaged, yet very poorly informed about the topic. Politicians who go to bat for drug pricing issues are often equally poorly informed and are driven by short-term political motives rather than a long-term societal perspective. Welcome to the age of the sound byte.

The drug industry is often mentioned for its lobbying muscle. However, with all its capabilities, it has certainly not managed to gain the heart of the public. For an industry that is saving lives and improving patient wellbeing, to be outperformed in gaining public sympathy by the gun and tobacco industries is remarkable. Yes, there are a number of factors that make the pharmaceutical company story complicated. These are outlined in this book. However the full story is worth telling, as the interested public deserves more than sound bytes.

High prices for new biotechnology drugs can create a lot of issues for individual patients, as they may not be able to afford the cost of co-payment for the treatment. There are patient assistance programs in place to offset some of that pain, but these cannot eliminate the issue entirely, particularly not in emerging countries, such as China. However, the ability to charge these prices within reason, is essential to ensure that we are able to address future

healthcare challenges, such as the next H1N1 epidemic, emerging resistant MRSA infected patients, multi-drug resistant HIV/AIDS patients, to continue to improve treatment and compliance of common conditions such as diabetes, and to find new treatment approaches for rare diseases that currently don't have drug solutions.

Unfortunately, our dietary and sedentary lifestyle and our litigious nature are likely to further increase the cost of healthcare. Any healthcare reform in any country is unlikely to address that effectively without fundamentally changing the underlying factors or significantly reduce healthcare coverage. Many governments are choosing price control mechanisms to address their funding issues. History has shown that failing controls lead to more controls, resulting in a patchwork of government bureaucracy, which is creating more problems rather than restoring a market mechanism. I have frequently challenged, and will continue to challenge government payers to explore ways of restoring market mechanism rather than putting another layer on all existing controls. It is in the interest of all of us, to find acceptable solutions to healthcare funding, while securing sufficient innovative research efforts to be ready to battle the next healthcare challenge in addition to all the existing ones.

Hopefully this book will make a contribution in the ability to educate professionals, students, policy makers, politicians and the broader public about global drug pricing, its challenges and potential solutions. If anything, it would be great to at least achieve a common understanding on the issues. For the pharmaceutical industry, this book will hopefully form a basis for a more structured approach to addressing market access and pricing challenges and to build a solid working relationship between the pricing and market access function and other commercial and scientific functions. A good understanding of this field is critical for the survival of any pharmaceutical company.

About the Author

Ed Schoonveld is a renowned global expert on global pricing and market access for pharmaceuticals with experience in global, regional and local pricing and market access strategy formulation and implementation through various positions in industry and consulting over more than 20 years.

Ed is currently a Principal with ZS Associates in New York, NY and Leader of their Global Market Access and Pricing Practice. He has gained extensive experience in the pharmaceutical industry through various sales, marketing and general management positions for Lederle, Wyeth, Eli Lilly and BMS in the United States and Europe. He has gained deep expertise in Global Pricing and Reimbursement both on an affiliate level as a general manager of a European affiliate and at corporate headquarters as the responsible leader for global pricing and health economics groups in Wyeth, Eli Lilly and BMS.

Prior to his recent leadership position at BMS, Ed has been leading pricing and reimbursement consulting practices in Cambridge Pharma Consulting/ IMS, the Analytica Group and his own consultancy firm. During this time he has advised many large drug companies on product pricing and market access strategy, global pricing policy and internal organizational and process challenges. Most of these projects involved global payer and pricing research through a host of qualitative and quantitative methodologies.

Ed has also served as an expert pricing consultant in a WHO/WTO sponsored dialog on differential pricing of drugs between governments, industry, consumer organizations and NGOs.

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