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Therapeutic risk management of medicines is an authoritative and practical guide on developing, implementing and evaluating risk management plans for medicines globally. It explains how to assess risks and benefit-risk balance, design and roll out risk minimisation and pharmacovigilance activities, and interact effectively with key stakeholders. A more systematic approach for managing the risks of medicines arose following a number of high-profile drug safety incidents and a need for better access to effective but potentially risky treatments. Regulatory requirements have evolved rapidly over the past decade. Risk management plans (RMPs) are mandatory for new medicinal products in the EU and a Risk Evaluation and Mitigation Strategy (REMS) is needed for certain drugs in the US. This book is an easy-to-read resource that complements current regulatory guidance, by exploring key areas and practical implications in greater detail. It is structured into chapters encompassing a background to therapeutic risk management, strategies for developing RMPs, implementation of RMPs, and the continuing evolution of the risk management field.The topic is of critical importance not only to the pharmaceutical and biotechnology industries, but also regulators and healthcare policymakers.Some chapters feature contributions from selected industry experts. An up-to-date practical guide on conceiving, designing, and implementing global therapeutic risk management plans for medicines A number of useful frameworks are presented which add impact to RMPs (Risk Management Plans), together with regional specific information (European Union, United States, and Japan) A comprehensive guide for performing risk management more effectively throughout a product's life-cycle

What is money, where does it come from, and who controls it? Money makes the world go round; but what is it really? And how is it produced? Above all, who controls its production, and in whose interests? Money is never a neutral medium of exchange. Nor are bankers simply go-betweeners for savers and borrowers. In this accessible, brilliantly argued book, leading political economist Ann Pettifor explains in straightforward terms history's most misunderstood invention: the money system. Pettifor argues that democracies can reclaim control over money production and subordinate the out-of-control finance sector to the interests of society, and also the ecosystem. She also examines and assesses popular alternative debates on, and innovations in, money: positive money, helicopter money and the rise of goldbugs. She sets out the possibility of linking the money in our pockets (or on our smartphones) to the change we want to see in the world around us.

This publication highlights new evidence on policies to support job creation, bringing together the latest research on labour market, entrepreneurship and local economic development policy to help governments support job creation in the recovery.

This book is based on the author's experience of working for more than two decades in over thirty conflict and post-conflict zones. It is written for those involved in UN peacekeeping and the protection of civilians. It is intended to be accessible to non- lawyers working in the field who may need to know the applicable legal standards relating to issues such as the use of force and arrest and detention powers on the one hand and the delivery of life-saving assistance according to humanitarian principles on the other. It will also be of interest to scholars and students of peacekeeping, international law and international relations on the practical dilemmas facing those trying to operationalise the various conceptions of 'protection' during humanitarian crises in recent years.

Revised edition of Transportation planning handbook, 2009.

This book assesses the UN Peace Operations in Haiti and establishes what lessons should be taken into account for future operations elsewhere. Specifically, the book examines the UN's approaches to security and stability, demobilisation, disarmament and reintegration (DDR), police, justice and prison reform, democratisation, and transitional justice and their interdependencies through the seven UN missions in Haiti. Drawing on extensive fieldwork and interviews conducted in Haiti, it identifies strengths and weaknesses of these approaches and focuses on the connections between these different sectors. It places these efforts in the broader Haitian political context, emphasises economic development as a central factor to sustainability, provides a civil society perspective, and discusses the many constraints the UN faced in implementing its mandates. The book also serves as a historical account of UN involvement in Haiti, which comes at a time when the drawdown of the mission has begun. In an environment where the UN is increasingly seeking to conduct security sector reform (SSR) within the context of integrated missions, this book will be a valuable contribution to the debate on intervention, UN peace operations and SSR. This book will be of interest to students of peace operations and peacekeeping, conflict studies, security studies and IR in general.

The European economic crisis has been ongoing since 2008 and while austerity has spread over the continent, it has failed to revive economies. The media have played an important ideological role in presenting the policies of economic and political elites in a favourable light, even if the latter's aim has been to shift the burden of adjustment onto citizens. This book explains how and why, using a critical political economic perspective and focusing on the case of Ireland. Throughout, Ireland is compared with contemporary and historical examples to contextualise the arguments made. The book covers the housing bubble that led to the crash, the rescue of financial institutions by the state, the role of the European institutions and the International Monetary Fund, austerity, and the possibility of leaving the eurozone for Europe's peripheral countries. Through a systematic analysis of Ireland's main newspapers, it is argued that the media reflect elite views and interests and downplay alternative policies that could lead to more progressive responses to the crisis.

From award-winning journalist Jack Shenker, The Egyptians is the essential book about Egypt and radical politics In early 2011, Cairo's Tahrir Square briefly commanded the attention of the world. Half a decade later, the international media has largely moved on from Egypt's explosive cycles of revolution and counter-revolution - but the Arab World's most populous nation remains as volatile as ever, its turmoil intimately bound up with forms of authoritarian power and grassroots resistance that stretch right across the globe. In The Egyptians: A Radical Story, Jack Shenker uncovers the roots of the uprising that succeeded in toppling Hosni Mubarak, one of the Middle East's most entrenched dictators, and explores a country now divided between two irreconcilable political orders. Challenging conventional analyses that depict contemporary Egypt as a battle between Islamists and secular forces, The Egyptians illuminates other, far more important fault lines: the far-flung communities waging war against transnational corporations, the men and women fighting to subvert long-established gender norms, the workers dramatically seizing control of their own factories, and the cultural producers (novelists, graffiti artists and illicit bedroom DJs) appropriating public space in defiance of their repressive and increasingly violent western-backed regime. Situating the Egyptian revolution in its proper context - not as an isolated event, but as an ongoing popular struggle against a certain model of state authority and economic exclusion that is replicated in different forms around the world - The Egyptians explains why the events of the past five years have proved so threatening to elites both inside Egypt and abroad. As Egypt's rulers seek to eliminate all forms of dissent, seeded within the rebellious politics of Egypt's young generation are big ideas about democracy, sovereignty, social justice and resistance that could yet change the world.

For decades, governments have tried to foster industrial competitiveness and economic growth. Many instruments are known to work, and many lessons have been learned. However, humanity is increasingly feeling the effects of natural resource depletion. The rate of this depletion is deeply unsustainable, and it is - as of yet - inextricably linked to economic growth and development. To preserve acceptable living conditions for future generations, while at the same time creating these conditions for millions of poor in the first place, we must achieve a de-linking of economic activity and resource depletion. This book identifies the drivers and success factors of green industrial policy, which seeks to reconcile the synergies and trade-offs which exist between economic and environmental goals. Greening the economy is a goal which will require enormous investment. As markets are currently failing to provide the required incentives for environmental sustainability, governments must intervene and provide 'policy rents' for investments in sustainability while withdrawing rents from polluting investments. In this they will face the risk of political capture by interest groups and difficult choices among technologies. Rent management is therefore the heart of green industrial policy and the focus of this book. On top of this, the country examples provided in this volume focus on the emerging powers, which will have an important influence the future of our planet. However, the lessons learned are valuable not only for countries introducing green industrial policies for the first time, but also for those under pressure to reform existing policies. This book will be of interest to students, researchers and policymakers in the areas of energy policy, sustainable development, industrial economics and ecological economics.

This is the first book to focus explicitly on how China's rise as a major economic and political actor has affected societies in Southeast Asia. It examines how Chinese investors, workers, tourists, bureaucrats, longtime residents, and adventurers interact throughout Southeast Asia. The contributors use case studies to show the scale of Chinese influence in the region and the ways in which various countries mitigate their unequal relationship with China by negotiating asymmetry, circumventing hegemony, and embracing, resisting, or manipulating the terms dictated by Chinese capital.

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