Rules And Guidance For Pharmaceutical Manufacturers And Distributors Orange Guide 2015 The Orange Guide 2015

Examine the rules governing medicinal products for use in Europe, in this five volume collection. Volume I contains rules governing medicinal products for human use; Volume II provides notice to applicants for marketing authorizations and includes 2 disks; Volume III presents guidelines on quality, safety, and efficacy of medicinal products for human use; Volume IV is a guide to good manufacturing practices for medicinal products for human and veterinary use; Volume V contains rules governing medicinal products for veterinary use.

MCQs in Pharmaceutical Calculations aims to help pre-registration trainees and pharmacy students with their study enabling them to perform calculations accurately and with confidence. Pharmacists frequently perform simple calculations as part of their professional practice. It is therefore vital that they are able to employ basic numeracy skills accurately so as not to compromise patient safety. The pharmaceutical societies of Great Britain and Northern Ireland (RPSGB and PSNI) have introduced compulsory calculations elements into the registration examinations. These sections must be passed independently of the rest of the examination. Many Schools of Pharmacy worldwide have also recently increased their emphasis on numeracy skills. It includes:

* 360 calculations questions in three commonly used multiple choice formats * questions based on important areas in pharmaceutical science and practice: * manipulation of formulae and dilutions * dosing * pharmacokinetics * formulation and dispensing * pharmaceutical chemistry * descriptive answers giving the reasoning behind the answers Note: This book is accompanied by an additional 100 calculation-based multiple choice questions, arranged into five 1-hour tests, which will be available from the Pharmaceutical Press FASTtrack website. Importantly, these questions are available in the format of both The Royal Pharmaceutical Society and the Pharmaceutical Society of Northern Ireland registration examinations. The fourth title in the Tomorrow's Pharmacist series, MCQs in Pharmaceutical Calculations, will be indispensable to pre-registration trainees and pharmacy students to help them prepare for their future career. Also available in this series: Hospital Pre-registration Pharmacist Training Pre-registration Interview, The Registration Exam Questions

The World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations advises the Director-General of WHO in the area of medicines quality assurance. It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality, safety and efficacy in all WHO Member States. Its advice is developed through a broad consensus-building process and covers all areas of quality assurance of medicines, from their development to their distribution to patients. In the area of quality control, the Expert Committee

reviewed new and revised specifications and general texts for inclusion in The International Pharmacopoeia, and received the annual report of the European Directorate for the Quality of Medicines & HealthCare (EDQM), the custodian centre for International Chemical Reference Substances (ICRS). The Committee adopted a number of monographs, general texts and ICRS. It noted the report on Phase 6 of the External Quality Assurance Assessment Scheme (EQAAS) and on new approaches to ensure sustainability of this scheme through user fees. The Committee further acknowledged the progress of good pharmacopoeial practices (GPhP), and adopted the document on GPhP which was prepared by the consecutive international meetings of world pharmacopoeias. In the various quality assurance-related areas the Expert Committee was presented with a number of new and revised guidelines related to good manufacturing practices (GMP), distribution and trade of pharmaceuticals and regulatory practice. It adopted 10 guidelines as listed below as well as 22 new specifications and general texts for inclusion in The International Pharmacopoeia. The Committee took note of ongoing work to promote collaboration and information exchange through the good regulatory practice project and welcomed the development of a comprehensive set of guidelines for all national regulatory authorities through this project.

FASTtrack Pharmaceutics – Dosage Form and Design focuses on what you really need to know in order to pass your pharmacy exams. It provides concise, bulleted information, key points, tips and an all-important self-

assessment section, including MCQs.

The term 'medical devices' covers a wide range of equipment essential for patient care at every level of the health service, whether at the bedside, at a health clinic or in a large specialised hospital. Yet many countries lack access to high-quality devices, particularly in developing countries where health technology assessments are rare and there is a lack of regulatory controls to prevent the use of substandard devices. This publication provides a guidance framework for countries wishing to create or modify their own regulatory systems for medical devices, based on best practice experience in other countries. Issues highlighted include: the need for harmonised regulations; and the adoption, where appropriate, of device approvals of advanced regulatory systems to avoid an unnecessary drain on scarce resources. These approaches allow emphasis to be placed on locally-assessed needs, including vendor and device registration, training and surveillance and information exchange systems.

With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience

in all phases of pharmaceutical manufacturing.
A collection of recommended procedures for analysis and specifications for the determination of pharmaceutical substances, excipients and dosage forms intended to serve as source material for reference by any WHO member state.
Martindale: The Complete Drug Reference provides unbiased and evaluated information on drugs and medicines in use around the world. It is prepared by an experienced team of pharmacists and life scientists who use their professional expertise to select the most clinically relevant and appropriate information from reliable published sources.
Standards for unlicensed aseptic preparation in the UK, as well as practical information for implementing the standards.
Commonly known as the Red Book, Guidelines for the Blood Transfusion Services in the United Kingdom 8th Edition contains best practice guidelines for all materials produced by the United Kingdom Blood Transfusion Services (UKBTS) for both therapeutic and diagnostic use. Key features: Sets standards to be met, describes technical details of processes and states legally binding requirements under Blood Safety and Quality Regulations 2005; Reflects the work of Joint UKBTS/HPA Professional Advisory Committee (JPAC) experts with the overall aim of ensuring as far as possible the safety of Blood transfusion for both donor and patient in the UK;Focuses on products rather than their use
Introduction to Pharmaceutical Calculations is an essential study aid for pharmacy students. The book contains worked examples and sample questions and answers.
Commonly known as the Orange Guide, this book remains an essential reference for all manufacturers and distributors of

medicines in Europe. It provides a single authoritative source of European and UK guidance, information and legislation relating to the manufacture and distribution of human medicines.

Part I: Process design -- Introduction to design -- Process flowsheet development -- Utilities and energy efficient design -- Process simulation -- Instrumentation and process control -- Materials of construction -- Capital cost estimating -- Estimating revenues and production costs -- Economic evaluation of projects -- Safety and loss prevention -- General site considerations -- Optimization in design -- Part II: Plant design -- Equipment selection, specification and design -- Design of pressure vessels -- Design of reactors and mixers -- Separation of fluids -- Separation columns (distillation, absorption and extraction) -- Specification and design of solids-handling equipment -- Heat transfer equipment -- Transport and storage of fluids.

Drug overdose, driven largely by overdose related to the use of opioids, is now the leading cause of unintentional injury death in the United States. The ongoing opioid crisis lies at the intersection of two public health challenges: reducing the burden of suffering from pain and containing the rising toll of the harms that can arise from the use of opioid medications. Chronic pain and opioid use disorder both represent complex human conditions affecting millions of Americans and causing untold disability and loss of function. In the context of the growing opioid problem, the U.S. Food and Drug Administration (FDA) launched an Opioids Action Plan in early 2016. As part of this plan, the FDA asked the National Academies of Sciences, Engineering, and Medicine to convene a committee to update the state of the science on pain research, care, and education and to identify actions the FDA and others can take to respond to the opioid epidemic, with a particular focus on informing FDA's development of a

formal method for incorporating individual and societal considerations into its risk-benefit framework for opioid approval and monitoring.

This is an inclusive reference exploring the scientific basis and practice of drug therapy. The key concept is to look at the balance between the benefits and risks of drugs but in this context also the social impact which drugs have in modern societies is highlighted. Taking an evidence-based approach to the problem, the practice of clinical pharmacology and pharmacotherapy in the developing as well as the developed world is examined. For this purpose the book * Covers general clinical pharmacology, pharmacology of various drug groups and the treatments specific to various diseases * Gives guidance on how doctors should act so that drugs can be used effectively and safely * Encourages the rational use of drugs in society This book brings together a large amount of excellent content that will be invaluable for anyone working within, or associated with, the field of clinical pharmacology and pharmacotherapy - undergraduates, postgraduates, regulatory authorities and the pharmaceutical industry.

This new edition of The Green Guide provides a single source of guidance to, and legislation for, the distribution of medicines in Europe and UK. The Green Guide takes all the elements of the new Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2014 (the Orange Guide) that are relevant to distributors, and reproduces them. Since the last edition in 2007, there have been significant changes and additions to the detailed European Community guidelines on Good Distribution Practice (GDP). The Community code relating to medicinal products for human use has also been substantially amended and the new edition brings together information about these important changes

Drug discovery involves multiple disciplines,

technologies, and approaches. This book selects important topics related to drug discovery, including emerging tool (Chapter 1), cutting-edge approaches (Chapters 2, 3, and 4), examples of specific therapeutic area (Chapter 5), quality control in drug development (Chapter 6), and job and career opportunities in the pharmaceutical sector, a topic rarely covered by other books (Chapter 7). This book draws knowledge from experts actively involved in different areas of drug discovery from both industrial and academic settings. We hope that this book will facilitate your efforts in drug discovery.

The adulteration and fraudulent manufacture of medicines is an old problem, vastly aggravated by modern manufacturing and trade. In the last decade, impotent antimicrobial drugs have compromised the treatment of many deadly diseases in poor countries. More recently, negligent production at a Massachusetts compounding pharmacy sickened hundreds of Americans. While the national drugs regulatory authority (hereafter, the regulatory authority) is responsible for the safety of a country's drug supply, no single country can entirely guarantee this today. The once common use of the term counterfeit to describe any drug that is not what it claims to be is at the heart of the argument. In a narrow, legal sense a counterfeit drug is one that infringes on a registered trademark. The lay meaning is much broader, including any drug made with intentional deceit. Some generic drug companies and civil society groups object to calling bad medicines counterfeit, seeing it as the deliberate conflation of public health and

intellectual property concerns. Countering the Problem of Falsified and Substandard Drugs accepts the narrow meaning of counterfeit, and, because the nuances of trademark infringement must be dealt with by courts, case by case, the report does not discuss the problem of counterfeit medicines.

This is the ninth edition of Rules and Guidance for Pharmaceutical Manufacturers and Distributors, compiled by MHRA. Commonly known as the Orange Guide, it remains an essential reference for all manufacturers and distributors of medicines in Europe. It provides a single authoritative source of European and UK guidance, information and legislation relating to the manufacture and distribution of human medicines. The new 2015 edition incorporates all the significant updates and additions to the detailed European Community guidelines on GMP since the last edition, including the revised EU Guidelines on Good Distribution Practice. In addition, it contains new sections on: The Gold Standard for Responsible Persons MHRA Innovation Office The Application and Inspection process for new licences - "what to expect" MHRA Compliance Management and Inspection Action Group MHRA Risk-based inspection programme Naming Contract Quality Control (QC) laboratories GDP Quality Systems A new flow chart on registration requirements for UK companies involved in the sourcing and supply of active substances (ASs), to be used in the manufacture of licensed human medicines Building on the restructured contents and fresh redesign of the last edition, you'll find all the answers you need to stay informed.

This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Collaborations of physicians and researchers with industry can provide valuable benefits to society, particularly in the translation of basic scientific discoveries to new therapies and products. Recent reports and news stories have, however, documented disturbing examples of relationships and practices that put at risk the integrity of medical research, the objectivity of professional education, the quality of patient care, the soundness of clinical practice guidelines, and the public's trust in medicine. Conflict of Interest in Medical Research, Education, and Practice provides a comprehensive look at conflict of interest in medicine. It offers principles to inform the design of policies to identify, limit, and manage conflicts of interest without damaging constructive collaboration with industry. It calls for both short-term actions and long-term commitments by institutions and individuals, including leaders of academic medical centers, professional societies, patient advocacy groups, government agencies, and drug, device, and pharmaceutical companies. Failure of the

medical community to take convincing action on conflicts of interest invites additional legislative or regulatory measures that may be overly broad or unduly burdensome. Conflict of Interest in Medical Research, Education, and Practice makes several recommendations for strengthening conflict of interest policies and curbing relationships that create risks with little benefit. The book will serve as an invaluable resource for individuals and organizations committed to high ethical standards in all realms of medicine.

A comprehensive guide to all the laws that affect Texas pharmacies on a daily basis, Texas Pharmacy Laws and Regulations is a trusted and indispensable resource for Texas pharmacy professionals. You'll find coverage of a range of Texas pharmacy laws, including the Texas Pharmacy Act, the Texas Pharmacy Rules, the Texas Controlled Substances Act and Rules, the DEA Pharmacist's Manual, the Texas Dangerous Drug Act, the Texas Food, Drug, and Cosmetic Act, and all the procedures, forms, and addresses you need. Purchasing this regularly updated publication means you can keep abreast of the latest changes in the law, including over-the-counter sales of ephedrine, pseudoephedrine, and norpseudoephedrine. Students studying for a pharmacy license, pharmacy technicians, and managers purchasing for a chain of pharmacies will find the Texas Pharmacy Laws and Regulations is the resource you need at a price you can afford.

Rare diseases collectively affect millions of Americans of all ages, but developing drugs and medical devices to prevent, diagnose, and treat these conditions is

challenging. The Institute of Medicine (IOM) recommends implementing an integrated national strategy to promote rare diseases research and product development.

Accompanied by supplements.

WHO's international guidelines, written and physical standards developed under the aegis of this Expert Committee for more than 60 years are designed to serve all Member States, international organizations, United Nations agencies, regional and interregional harmonization efforts, and underpin important initiatives, including the prequalification of medicines, the Roll Back Malaria Programme, Stop TB, essential medicines and medicines for children. The Forty-seventh WHO Expert Committee on Specifications for Pharmaceutical Preparations adopted 26 new monographs and general texts for inclusion in The International Pharmacopoeia,/I>. The specifications under development are internationally applicable test methodologies for anti-infective, antimalarial, antituberculosis, contraceptives and antiretroviral medicines, as well as medicines for children. In addition, the following four written standards were adopted in the area of quality assurance and are now available for implementation : * Release procedure for International Chemical Reference Substances (update); * WHO guideline on quality risk management (new) * WHO guideline on variations to a prequalified product (update) * Collaborative procedure between the WHO Prequalification of Medicines Programme and national medicines regulatory authorities in the assessment and

accelerated national registration of WHO-prequalified pharmaceutical products (new).

This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends.

In the European Union (EU) and its Member States, as elsewhere, the marketing of pharmaceuticals has become subject to an increasingly complex web of legislation and regulation, resulting from the intense scrutiny necessary to ensure such essential products are not only efficacious but safe. This useful volume lays out this system with extraordinary clarity and logic. Adopting a Europe-wide perspective on the law governing pharmaceuticals, expert authors from the law firm Bird & Bird LLP map the life cycle of a medicinal product or medical device from development to clinical trials to product launch and ongoing pharmacovigilance, offering comprehensive and unambiguous guidance at every stage. A brief overview of how the proposed exit from the EU by the UK will affect the regulatory regime is also included. Following an introductory overview focusing on the regulatory framework for pharmaceuticals in Europe – from its underlying rationales to the relevant

committees and agencies – each of fifteen incisive chapters examines a particular process or subject. Among the many topics and issues covered are the following: - obtaining a marketing authorisation; - stages and standards for creating a product dossier; - clinical trials; - how and when an abridged procedure can be used; - criteria for conditional marketing authorisations; - generic products and 'essential similarity'; - paediatric use and the requisite additional trials; - biologicals and 'biosimilars'; - homeopathic and herbal medicines; - reporting procedures; - pharmacovigilance; - parallel trade; - relevant competition law and intellectual property rights; and - advertising. In addition, national variation charts in many of the chapters illustrate eight major jurisdictions (Belgium, France, Germany, Italy, The Netherlands, Spain, Sweden, and the UK). Sample forms and URLs for the most important Directives are included. Pharmaceutical lawyers and regulatory advisers, both in-house and in private practice, will welcome this unique book. It offers immeasurable value for all who need to understand the process of bringing a medicinal product or medical device to market and the continuing rights and obligations.

The fifth edition of Pharmacy Law and Practice provides a straightforward and useable guide for students, practitioners, academics and others interested in pharmacy law and practice in the United Kingdom. This multi-dimensional book includes discussions of socio-political influences on legal developments to provide greater insight to the reader. It clearly sets out the background to regulatory issues together with simple and

practical statements of what a pharmacist has to do to obey the law. As in previous editions, this book discusses topics thematically rather than by statute. It is a unique and reader-friendly guide that boils down the complex or difficult language of the law, describes the reasons behind it, and illustrates the application to pharmacy practice. Thoroughly updated to reflect regulatory and legal developments in areas including employment law, online transactions and internet pharmacies, non-medical prescribing and more Takes an intuitive, problem-solving approach and discusses topics thematically rather than by statute to show how all of the larger pieces fit together The electronic version of this book contains valuable links to provide readers with the most current information in a rapidly changing subject area

Basic Optics: Principles and Concepts addresses in great detail the basic principles of the science of optics, and their related concepts. The book provides a lucid and coherent presentation of an extensive range of concepts from the field of optics, which is of central relevance to several broad areas of science, including physics, chemistry, and biology. With its extensive range of discourse, the book's content arms scientists and students with knowledge of the essential concepts of classical and modern optics. It can be used as a reference book and also as a supplementary text by students at college and university levels and will, at the same time, be of considerable use to researchers and teachers. The book is composed of nine chapters and includes a great deal of material not covered in many of

the more well-known textbooks on the subject. The science of optics has undergone major changes in the last fifty years because of developments in the areas of the optics of metamaterials, Fourier optics, statistical optics, quantum optics, and nonlinear optics, all of which find their place in this book, with a clear presentation of their basic principles. Even the more traditional areas of ray optics and wave optics are elaborated within the framework of electromagnetic theory, at a level more fundamental than what one finds in many of the currently available textbooks. Thus, the eikonal approximation leading to ray optics, the Lagrangian and Hamiltonian formulations of ray optics, the quantum theoretic interpretation of interference, the vector and dyadic diffraction theories, the geometrical theory of diffraction, and similar other topics of basic relevance are presented in clear terms. The presentation is lucid and elegant, capturing the essential magic and charm of physics. All this taken together makes the book a unique text, of major contemporary relevance, in the field of optics. Avijit Lahiri is a well-known researcher, teacher, and author, with publications in several areas of physics, and with a broad range of current interests, including physics and the philosophy of science. Provides extensive and thoroughly exhaustive coverage of classical and modern optics Offers a lucid presentation in understandable language, rendering the abstract and difficult concepts of physics in an easy, accessible way Develops all concepts from elementary levels to advanced stages Includes a sequential description of all needed mathematical tools Relates fundamental concepts to

areas of current research interest

Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide) 2017

This title is a general introduction aimed at all those involved in the engineering stages required for the manufacturr of the active ingredient and its dosage forms.

Quality assurance of pharmaceutical products is a continuing concern of WHO. Despite efforts made around the world to ensure a supply of quality and effective medicines, substandard, spurious and counterfeit products still compromise health care delivery in many countries. To respond to the global need for adequate quality assurance of pharmaceuticals, WHO's Expert Committee on Specifications for Pharmaceutical Preparations has over the years made numerous recommendations to establish standards and guidelines and to promote the effective functioning of national regulatory and control systems and the implementation of internationally agreed standards by trained personnel. Many of the relevant documents endorsed by the Committee are reproduced in this volume providing guidance covering all aspects of good manufacturing practices (GMP). Important texts on inspection are also included. Most of the material has been published separately in the Expert Committee's reports. This compendium brings it together to make it more accessible and of greater practical value to those working in faculties of pharmacy, in medicines regulation and control and in the pharmaceutical industry. This is the second updated edition of the compendium and

includes texts published in 2005 and 2006 in the WHO Technical Report Series.

This publication, known as the "Orange Guide", has been an essential reference for those involved in the manufacture or distribution of medicines in Europe. The Orange Guide collates in one convenient and authoritative source European and UK guidance documents and information on legislation relating to the manufacture and distribution of medicines for human use. In the production and distribution of medicines for human use, compliance with Good Manufacturing Practice and Good Distribution Practice is a necessity. Changes to this particular edition include: detailed changes to the EU guide to good manufacturing practice; detailed revisions to the EU Directive on medicinal products for human use; the new Directive on the Principles and Guidelines on Good Manufacturing Practice of Medicinal Products for Human Use. The document is compiled by the Inspection and Standards Division of the Medicines and Healthcare products Regulatory Agency.

This book provides a comprehensive introduction to modern auction theory and its important new applications. It is written by a leading economic theorist whose suggestions guided the creation of the new spectrum auction designs. Aimed at graduate students and professionals in economics, the book gives the most up-to-date treatments of both traditional theories of 'optimal auctions' and newer theories of multi-unit auctions and package auctions, and shows by example how these theories are used. The analysis explores the limitations of prominent older designs, such as the Vickrey auction design, and evaluates the practical responses to those limitations. It explores the tension between the traditional theory of auctions with a fixed set of bidders, in which the seller seeks to squeeze as much revenue as possible from

the fixed set, and the theory of auctions with endogenous entry, in which bidder profits must be respected to encourage participation.

While the last few decades have witnessed incredible leaps forward in the technology of energy production, technological innovation can only be as transformative as its implementation and management allows. The burgeoning fields of renewable, efficient and sustainable energy have moved past experimentation toward realization, necessitating the transition to more sustainable energy management practices. Energy Management is a collective term for all the systematic practices to minimize and control both the quantity and cost of energy used in providing a service. This new book reports from the forefront of the energy struggle in the developing world, offering a guide to implementation of sustainable energy management in practice. The authors provide new paradigms for measuring energy sustainability, pragmatic methods for applying renewable resources and efficiency improvements, and unique insights on managing risk in power production facilities. The book highlights the possible financial and practical impacts of these activities, as well as the methods of their calculation. The authors' guidelines for planning, analyzing, developing, and optimizing sustainable energy production projects provide vital information for the nations, corporations, and engineering firms that must apply exciting new energy technology in the real world. Shows engineering managers and project developers how to transition smoothly to sustainable practices that can save up to 25% in energy costs! Features case studies from around the world, explaining the whys and hows of successes and failures in China, India, Brazil, the US and Europe Covers a broad spectrum of energy development issues from planning through realization, emphasizing efficiency, scale-up of renewables and risk mitigation Includes

software on a companion website to make calculating efficiency gains quick and simple

This title combines all of the human and veterinary Regulations, Directives and guidance for medicinal products used by the pharmaceutical industry as their main source when manufacturing and distributing medicinal products in the European Union.

Commonly known as the "Orange Guide," this publication brings together the main pharmaceutical regulations and directives which manufacturers and wholesalers are expected to follow when making and distributing medicinal products in the European Union and European Economic Area.

A single source of guidance to, and legislation for, the distribution of medicines in Europe and UK.

This User's Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who

have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User's Guide was created by researchers affiliated with AHRQ's Effective Health Care Program, particularly those who participated in AHRQ's DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.