Overview Of Authorisation Procedures For Medicinal Products

The Services Directive is one of the cornerstones for the

realization of the EU internal market and is fundamental to economic and legal experts, as well as to the general public. This book analyses in detail the different steps taken by each of the 27 EU Member States in the

implementation process of the Services Directive. It provides not only detailed information about the changes in national law adopted by the Member States, but also facilitates a comparison of the different

implementation strategies. It gives an insight in the heterogeneity or homogeneity of implementation concepts and shows how European legislation affects legislation that were originally nationally dominated,

such as the law of national administration. Valuable for academics interested in European and administrative law and the transposition of European lawmaking into domestic law, as well as for civil

servants in ministries, chambers of commerce, local governments and other comparable institutions having to implement the Directive.

In recent years public expectations for rapid

identification and prompt management of emerging drug safety issues have grown swiftly. Over a similar timeframe, the move from paper-based adverse event reporting systems to electronic capture and rapid

transmission of data has resulted in the accrual of substantial datasets capable of complex analysis and querying by industry, regulators and other public health organizations. These two drivers have created

a fertile environment for pharmacovigilance scientists, information technologists and statistical experts, working together, to deliver novel approaches to detect signals from these extensive and quickly

growing datasets, and to manage them appropriately. In following this exciting story, this report looks at the practical consequences of these developments for pharmacovigilance practitioners.

The report provides a comprehensive resource for those considering how to strengthen their pharmacovigilance systems and practices, and to give practical advice. But the report does not

specify instant solutions. These will inevitably be situation specific and require careful consideration taking into account local needs. However, the CIOMS Working Group VIII is convinced that the combination

of methods and a clear policy on the management of signals will strengthen current systems. Finally, in looking ahead, the report anticipates a number of ongoing developments, including techniques with wider

applicability to other data forms than individual case reports. The ultimate test for pharmacovigilance systems is the demonstration of public health benefit and it is this test which signal detection

methodologies need to meet if the expectations of all stakeholders are to be fulfilled.

Medical Devices and the Public's Health

Medicinal Products for Human Use: Procedures for Marketing

Authorisation

The Implementation of the EU Services Directive

Guide to EU Pharmaceutical Regulatory Law

Notice to applicants. Veterinary medicinal products. Presentation

and content of the dossier. Vol. 6B

In line with Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (hereafter: the Directive) and complementary to

the "Guiding Principles and Indicators for the practice of National Contact Points (NCPs) under the Cross-border Healthcare Directive 2011/24/EU", these Guiding Principles provide recommendations to improve

information provided to citizens on prior authorisation systems under the Directive. The purpose of these Guiding Principles is to set out key principles to help NCPs provide more transparent, accessible and understandable patient-oriented

information on prior authorisation. The Guiding Principles cover the following main areas: 1. Transparency of prior authorisation systems; 2. Clarity and consistency of prior authorisation procedures; 3. Understandable information on

prior authorisation.
Accompanied by supplements.
March 2022
Approved Prescription Drug Products with Therapeutic Equivalence Evaluations
Overview Report on a Series of

Audits Carried Out in Member States from 2012 to 2014 in Order to Evaluate Controls of Plant Protection Products

"Post-authorisation Procedures for Orphan Medicinal Products" : Notice to Applicants

Implementation and Improvement of Design and Authorisation Procedures for Proposed Tailings Facilities

The European Medicines Agency and Future Marketing Authorisation

ProceduresReport with EvidenceStudy for the Evaluation of the EMA Fee SystemSummary Report The Biocidal Products Regulation ((EU) No 528/2012 (BPR)) states that an authorisation of a biocidal

product (BP) can be granted for a maximum period of 10 years. Article 31 of the BPR sets out the procedure for the renewal of a single national authorisation granted by the Member State competent authority (MSCA).

Supplementary rules for the renewal of authorisations subject to mutual recognition (MR) procedures and having the same terms and conditions with limited exceptions (grouped renewal), in all the Member

States (MSs) where renewal is sought, are laid down in the MR Renewal Regulation (Commission Delegated Regulation (EU) No 492/2014).

Cambridge Yearbook of European Legal Studies, Vol

16 2013-2014
Pharmaceuticals, Diagnostics, Medical Devices
Guide to Marketing Authorisation Procedures in the Eu
Document Drafting Handbook
Implications of Future EU

Policy on the Provision of Medicines and on Actors in the European Pharmaceutical Sector

Guiding Principles for Information Provision on Prior Authorisation Systems Across Member States

The European Medicines Agency (EMA) is the European Union's (EU) central regulatory body to enable centralised authorisation procedures for medicinal products

for use in humans and food-producing animals across the European Economic Area (EEA). The agency is funded by general EU and EEA contributions as well as

fees paid by industry for obtaining and maintaining marketing authorisations and providing other authorisation-related services. The EMA works

in close collaboration with national competent authorities (NCAs) in EEA Member States, which undertake activities related to assessments aimed at granting,

maintaining and monitoring EU marketing authorisations, and other services related to medicinal products for human and veterinary use including

pharmacovigilance activities for medicines for human use at EU level. NCAs are remunerated by the EMA for undertaking these activities. The fee and

remuneration system is defined in Council Regulation (EC) No 297/95, which establishes the services provided by the EMA and related fees payable to

the agency for undertaking authorisation procedures, as well as through a set of implementing rules and Regulation (EU) No

658/2014 for pharmacovigilance activities. The fee system also provides fee incentives and reductions for specific types of products

including orphan designated medicines, veterinary medicines, products for paediatric use, and advanced therapy medicinal products and for

specific user groups such as micro, small and medium-sized enterprises (SMEs).
This book contributes towards EU studies and the growing discourse on

law and public health. It uses the EU's governance of public health as a lens through which to explore questions of legal competence and its

development through policy and concrete techniques, processes and practices, risk and security, human rights and bioethics, accountability and

legitimacy, democracy and citizenship, and the nature, essence and 'future trajectory' of the European integration project. These issues are explored first by

situating the EU's public health strategy within the overarching architecture of governance and subsequently by examining its

operationalisation in relation to the key public health problems of cancer, HIV/AIDS and pandemic planning. The book argues that the centrality and

valorisation of scientific and technical knowledge and expertise in the EU's risk-based governance means that citizen participation in decision-making is

largely marginalised and underdeveloped – and that this must change if public health and the quality, accountability and legitimacy of EU governance and its

regulation are to be improved. Subsequently the book goes on to argue that the legitimating discourses of ethics and human rights, and the

developing notion of EU (supra-)stewardship responsibility, can help to highlight the normative dimensions of governance and its interventions in public

health. These discourses and dimensions provide openings and possibilities for citizens to power 'technologies of participation' and

contribute important supplementary knowledge to decision-making.

Evaluation Carried Out on Behalf of the European Commission

EU Law, Regulation and

Biopolitics

Session 1991-92, 3rd Report [pharmaceutical Industry].

veterinary medicinal products

Medicinal Products for

Human Use. Vol. 2,
Notice to applicants.
Procedures for marketing authorisation
Practical Aspects of Signal Detection in Pharmacovigilance

Medical devices that are deemed to have a moderate risk to patients generally cannot go on the market until they are cleared through the FDA 510(k) process. In recent years,

individuals and organizations have expressed concern that the 510(k) process is neither making safe and effective devices available to patients nor promoting innovation in

the medical-device industry. Several high-profile mass-media reports and consumer-protection groups have profiled recognized or potential problems with medical devices cleared

through the 510(k) clearance process. The medical-device industry and some patients have asserted that the process has become too burdensome and is delaying or stalling the

entry of important new medical devices to the market. At the request of the FDA, the Institute of Medicine (IOM) examined the 510(k) process. Medical Devices and the Public's

Health examines the current 510(k) clearance process and whether it optimally protects patients and promotes innovation in support of public health. It also identifies legislative,

regulatory, or administrative changes that will achieve the goals of the 510(k) clearance process. Medical Devices and the Public's Health recommends that the U.S. Food and Drug

Administration gather the information needed to develop a new regulatory framework to replace the 35-year-old 510(k) clearance process for medical devices. According to the report, the

FDA's finite resources are best invested in developing an integrated premarket and postmarket regulatory framework.

Everybody who has performed multi-center

clinical trials knows that it is a real challenge to prepare a clinical trial application in different European countries. Frequently asked questions are: Which documents should be

included into the submission package? Which timelines apply for the Competent Authority and Ethics Committee evaluation procedure? Are the Competent Authority and

Ethics Committee procedures linked together or independent? Regarding the ten European Countries Austria, Belgium, Czech Republic, Germany, Italy, Slovenia, Spain, The

Netherlands, Poland and UK your questions will be answered in this book. Beyond the answers to these questions short-, middle- and long-term measures are proposed in

order to improve the harmonisation of the clinical trial authorisation procedures in the EU and finally to increase Europe's attractiveness for clinical research and to ensure

global market competitiveness. Procedures for the examination and authorisation of proposals involving capital expenditure

Medical Product Regulatory Affairs

The European Medicines Agency and Future Marketing Authorisation Procedures, with Evidence

Code of Practice

Covert Human Intelligence Sources

The European Medicines Agency and Future Marketing Authorisation Procedures

This is the first book to offer a

profound, practical analysis of the framework for the judicial and pre-judicial protection of rights under the supranational banking supervision and resolution powers in the European Banking Union (EBU). It is also unique in its in-depth commentary on the

developing case law from the European Court of Justice in this new field of EU litigation.

Drawing on her many years as a consultant to numerous companies big and small, author Rose Hightower infuses Internal Controls Policies and

Procedures with her wealth of experience and knowledge. Instead of reinventing the wheel, your company can use this useful how-to manual to quickly and effectively put a successful program of internal controls in place. Complete with flowcharts and

checklists, this essential desktop reference is a best practices model for establishing and enhancing your organization's control framework.

Identification of the Main Constraints in the European Union

Major Regulatory Objectives for a

Real Harmonisation in Europe
A Manual for National Medicines Regulatory Authorities (NMRAs).
Production and Commercialization of Insects as Food and Feed
Notice to applicants
The FDA 510(k) Clearance Process at

35 Years

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.

Written in a clear and

concise style by an experienced author, this attractively-priced book covers regulatory affairs in all major global markets for pharmaceuticals and

medical devices, making it the most comprehensive in its field. Following a look at drug development, complete sections are devoted to national and

EU regulatory issues, manufacturing license application and retention, and regulation in the USA. Other topics dealt with include CDER, CBER and

marketing and manufacturing licenses, the ICH process and Good Laboratory/Clinical/Manufacturing Practices. Everything pharmacologists,

bioengineers, pharma engineers, students in pharmacy and those working in the pharmaceutical industry need to know about medical regulatory

affairs.

2001/20/EC – A European Directive?

Procedures for Marketing Authorisation

Emergency Use Authorization and the

Postal Model: Workshop Summary

The Rules Governing Medicinal Products in the European Union: v. 2A. Notice to applicants : medicinal products for

human use : procedures for marketing authorisation

Report of CIOMS Working Group VIII.

Internal Controls Policies and Procedures

During public health emergencies such as terrorist attacks or influenza outbreaks, the public health system's ability to save lives could depend on dispensing medical countermeasures such as antibiotics, antiviral medications, and vaccines to a large

number of people in a short amount of time. The IOM's Forum on Medical and Public Health Preparedness for Catastrophic Events held a workshop on November 18, 2009, to provide an overview of current threats, recent

progress made in the public health system for distributing and dispensing countermeasures, and remaining vulnerabilities.

“The challenge in all settings is to make the difficultdecisions in a way that is defensible, justifiable, ethical,

andequitable" So write Nick Freemantle and Suzanne Hill in their introductionto this important discussion on decision making in thereimbursement of pharmaceuticals. Based around a programmesupported by the World

Health Organization, chapters by leadingacademics involved in the research tackle such major issues asinternational pharmaceutical policy, tensions in licensingpolicies, priority setting, and relationships between thestakeholders. Chapters

include Development of marketing authorisation procedures forpharmaceuticals Interpreting clinical evidence International pharmaceutical policy: health creation or wealthcreation? Development of fourth hurdle

policies around the world Economic modelling in drug reimbursement Priority setting in health care: matching decision criteriawith policy objectives Tensions in licensing and reimbursement decisions: case ofriluzole for amytrophic lateral

sclerosis Relationship between stakeholders: managing the war ofwords Medicine and the media: good information or misleadinghype? How to promote quality use of cost-effective medicines Using economic

evaluation to inform health policy andreimbursement: making it happen and making it sustainable Pricing of pharmaceuticals Evaluating pharmaceuticals for health policy in low and middleincome country settings.

Besides the controversial issues there is a wealth of practicalinformation including economic modelling and the experiences fromthe WHO programme, providing readers with workable examples. Thisis essential reading for clinical researchers in

pharmaceuticalsand policy makers everywhere.

Veterinary Medicinal Products: Procedures for Marketing Authorisation

Medical Countermeasures

Dispensing

Study for the Evaluation of the EMA Fee System

Judicial Review in the European Banking Union

Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource

(generic) Products

Summary Report

?Forecasts point out an exponential growth in the global population, which raises concerns over the ability of the

current agri-food production systems to meet food demand in the long term. Such a prospect has led international organizations and the

scientific community to raise awareness about, and call for, the need to identify additional sources of food to feed the world. From this perspective, insects

qualify as a suitable and more environmentally friendly alternative to meat and other foods that are sourced from animal proteins. However, uptake of the

production and commercialization of insects as food has been facing regulatory hurdles, consumer skepticism and rejection in many markets. This is

particularly true in the context of western societies in which insects do not always constitute part of the local traditional diets. Production and

Commercialization of Insects as Food and Feed: identification of the Main Constraints in the European Union analyses and discusses the regulatory state-of-

the-art for the production and commercialization of insects as food and feed in the European Union. The EU has been taking concrete legislative

steps with a view to opening up its market for insect foods, although some key regulatory constraints still exist today which ultimately prevent the

industry sector from growing, consolidating and thriving. The main regulatory constraints in the EU for insects as food include the fragmentation of the EU

market as a result of the adoption of different policy solutions by EU Member States for novel foods and the lengthy and complex authorization

procedures. Also, ad hoc safety and quality requirements tailored to the needs and specificities of the insect food sector are currently missing. This

work constitutes the first comprehensive overview of the evolution and current state-of-the-art of the regulatory framework for insect foods in the EU,

based on a multidisciplinary approach that combines science, policy and law. It proposes a legislative roadmap which the EU should

follow in order to make its regulatory framework fit for insect foods in the long term by providing a detailed comparison between the current EU legal

framework and other regulatory systems of western countries with a view to singling out the markets which are better equipped to address the production and the

commercialization of insect foods. The text provides an updated overview of the overall market and of European consumers’ perspectives on the use of insect

foods. With the proper legislative steps and consolidation, the EU can be a global leader for insects as food and feed both as a market and as a standard-

setting body.
This report provides an overview of the outcome of a series of audits carried out by the Food and Veterinary Office (FVO) in 19 Member

States (MSs) of the European Union (EU) between January 2012 and June 2014. This was the fourth series of FVO audits in this area. The objective of the audits

was to evaluate the control systems in place for pesticides, in particular, the implementation of requirements for the authorisation of plant

protection products (PPPs) and official controls on the marketing and use of PPPs under Regulation (EC) No 1107/2009 and Directive 2009/128/EC,

and the implementation of the requirements for official controls of PPPs at growers, as specified in Regulation (EC) No 882/2004.^While there were systems and

procedures for the authorisation of PPPs in place in all Member States, related shortcomings were identified in two areas: (a) Delays with re-

authorisations of PPPs under Directive 91/414/EEC, and with mutual recognitions under Regulation (EC) No 1107/2009: Many authorised PPP had not

been evaluated to EU standards, more than 15 years after the principles for evaluation had been established. Similarly, delays and problems with

cooperation between Member States were identified for the zonal authorisation system under Regulation (EC) No 1107/2009. This highlights the

difficulty of MSs to implement authorisation systems based on EU legislation; (b) Emergency authorisations of PPPs under Regulation (EC) No 1107/2009: The

report identifies problems with misuse of emergency authorisations for minor uses of PPPs, but also for other use extensions of approved PPPs.^In addition,

emergency authorisations for the same products have been granted for consecutive years, thus undermining the effectiveness of the strict criteria for

regular authorisations established by EU legislation. Systems were in place for official controls on the marketing and use of PPPs. One common

weakness in controls at both market and user level, was the coverage of operators. With regard to official controls on the marketing of PPPs, there

were further weaknesses related to unsatisfactory labelling checks and unsatisfactory quality controls of pesticides. As a consequence, there

was insufficient assurance that counterfeit and illegal pesticides would be detected. In general, official controls on the use of PPPs were more

effective than controls on the marketing of PPPs.^In most of the MSs visited, all relevant aspects were covered during inspections and comprehensive checks of

records kept by professional users were taking place, which provided guarantees that PPPs are applied in accordance with the conditions specified on

the labels. Weaknesses were identified with regard to prioritisation of official controls. Co-ordination and co-operation between and, in some cases, within

CAs was considered to be weak. Initial measures were adequately put into place for the implementation of Directive 2009/128/EC, in particular, training

and certification of professional users, safe handling and storage of PPPs, their containers and remnants, Integrated Pest Management (IPM) and application

equipment. This is a step forward to ensure the sustainable use of pesticides. Good practices were found with regard to systems for official controls as

a whole, or certain aspects. These are described in the relevant chapters of the report.

Notice to Applicants. Medicinal Products for

Human Use. Procedures for Marketing Authorisation Report with Evidence Transposition, Problems and Strategies Evaluation of the

Operation of Community Procedures for the Authorisation of Medicinal Products European Medicines Agency and Future Marketing Authorisation

Procedures
Third Report from the Select Committee on the European Communities with Evidence Taken Before Sub-committee C (Social and Consumer

Affairs)..

The Cambridge Yearbook of European Legal Studies provides a forum for the scrutiny of significant issues in EU Law, the law of the European Convention on Human Rights, and Comparative Law with a

'European' dimension, and particularly those issues which have come to the fore during the year preceding publication. The contributions appearing in the collection are commissioned by the Centre for European Legal Studies

(CELS) Cambridge, a research centre in the Law Faculty of the University of Cambridge specialising in European legal issues. The papers presented are at the cutting edge of the fields which they address, and reflect the views

of recognised experts drawn from the University world, legal practice, and the institutions of both the EU and its Member States. Inclusion of the comparative dimension brings a fresh perspective to the study of European law, and highlights the

effects of globalisation of the law more generally, and the resulting cross fertilisation of norms and ideas that has occurred among previously sovereign and separate legal orders. The Cambridge Yearbook of European Legal

Studies is an invaluable resource for those wishing to keep pace with legal developments in the fast moving world of European integration.

This code of practice provides guidance and rules on

authorisations for the use or the conduct of covert human intelligence sources under Part 2 of the Regulation of Investigatory Powers Act 2000. It sets out the authorisation procedures to be followed for the grant, review,

renewal and cancellation of authorisations, and for the management of sources, as well as special rules for authorisations in respect of confidential and legally privileged information or juvenile sources

Evaluating Pharmaceuticals for Health Policy and Reimbursement
Governing Public Health
The Rules Governing Medicinal Products in the European Union: Notice to applicants : medicinal products for human use. Pt.A

Procedures for marketing authorisation Pt.B. Presentation and content of the dossier
The Rules Governing Medicinal Products in the European Union
Practical Guide on Renewal of National Authorisation and

Authorisations Subject to Mutual Recognition