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Compliance GMP e regolatoria: novità e aggiornamenti

Milano, 2 maggio 2018

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What is EudraLex?

European Drug Regulatory Legislation

Publication issued by the European Commission

In the European Union (EU), EudraLex is the collection of rules and regulations governing medicinal products (for human use as well as for veterinary use)

https://ec.europa.eu/health/documents/eudralex_en

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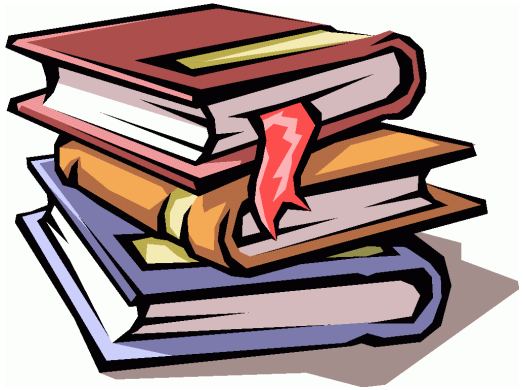
EudraLex general structure



Eudralex consists of 10 volumes, of which only Volume 1 (concerning medicinal products for human use) and Volume 5 (concerning medicinal products for veterinary use) present official legislation.
The basic legislation is supported by a series of guidelines that are published within the other eight volumes.

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EudraLex overview

Concerning Medicinal Products for Human use

Volume 1 - Pharmaceutical Legislation

Volume 2 - Notice to Applicants

Volume 2A deals with procedures for marketing authorisation.
Volume 2B deals with the presentation and content of the application dossier.
Volume 2C deals with Guidelines.

Volume 3 - Guidelines.

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Concerning Medicinal Products for human use in clinical trials (investigational medicinal products).

Volume 10 - Clinical trials.

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Concerning Veterinary Medicinal Products:

Volume 5 - Pharmaceutical Legislation

Volume 6 - Notice to Applicants

Volume 7 - Guidelines

Volume 8 - Maximum residue limits

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Concerning Medicinal Products for Human and Veterinary use:

Volume 4 - Good Manufacturing Practices

Volume 9 - Pharmacovigilance

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Miscellaneous

Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03)

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Basic Legislations

EudraLex - Volume 1 - Pharmaceutical legislation for medicinal products for human use

Represents the EU legal framework for medicinal products for human and guarantees high standards of quality and safety of medicinal products, while promoting the good functioning of the internal market with measures that encourage innovation and competiveness.

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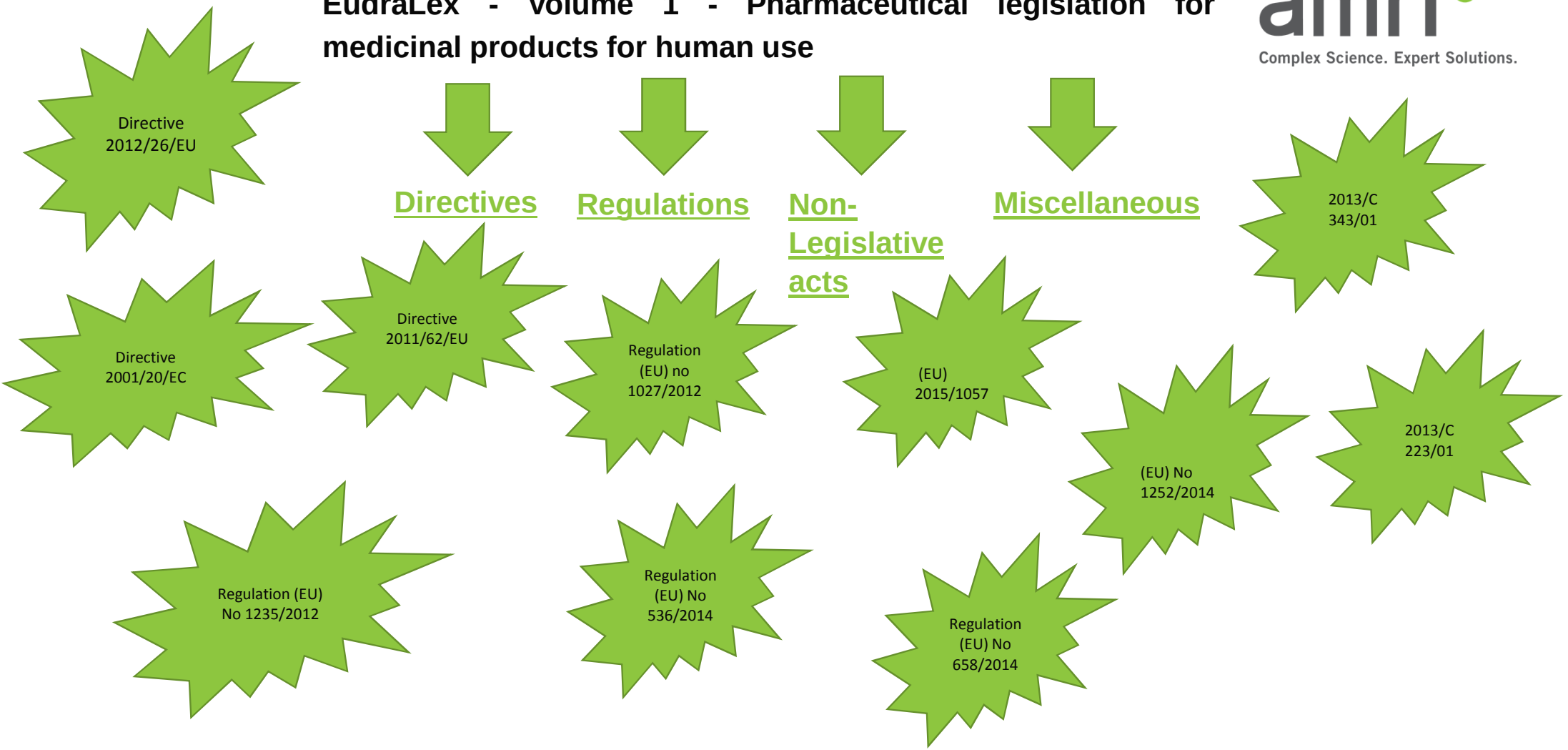
EudraLex - Volume 1 - Pharmaceutical legislation for medicinal products for human use



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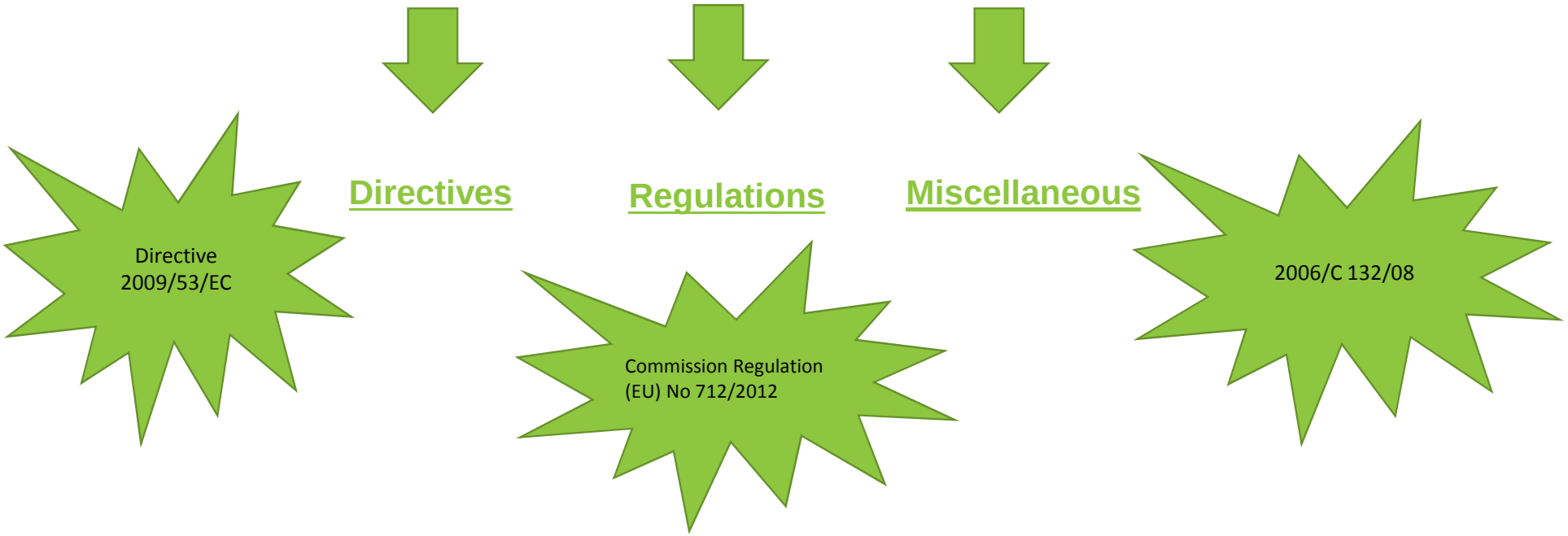
EudraLex - Volume 5 - Pharmaceutical legislation for medicinal products for veterinary use

Volume 5 of the publications "The rules governing medicinal products in the European Union" compiles the body of European Union legislation in the pharmaceutical sector for medicinal products for veterinary use.



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Guidelines

EudraLex - Volume 2 - Pharmaceutical legislation on notice to applicants and regulatory guidelines for medicinal products for human use

Volume 2 of the publications "The rules governing medicinal products in the European Union" contains a list of **regulatory guidelines related to procedural and regulatory requirements such as renewal procedures, dossier requirements for Type IA/IB variation notifications, summary of product characteristics (SmPC), package information and classification for the supply, readability of the label and package leaflet requirements.**

Volume 2A - Procedures for marketing authorisation

Chapter 1 - Marketing Authorisation

updated version - December 2017

updated version – March 2018

Volume 2C - Regulatory Guideline

Guideline on excipients in the label and package leaflet of medicinal products for human use

- Annex (October 2017) - List of the excipients for which specific information should appear in the package leaflet, published on European Medicines Agency website.

October 2017

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EudraLex - Volume 3 - Scientific guidelines for medicinal products for human use

Volume 3 of the publications "The rules governing medicinal products in the European Union" contains **scientific guidelines prepared by the Committee for Medicinal Products for Human Use (CHMP) in consultation with the competent authorities of the EU Member States, to help applicants prepare marketing-authorisation applications for medicinal products for human use.**

Guidelines are intended to provide a basis for practical harmonisation of the manner in which the EU Member States and the EMA interpret and apply the detailed requirements for the demonstration of quality, safety and efficacy contained in the Community Directives. They also help to ensure that applications for marketing authorisation are prepared in a manner that will be recognised as valid by the EMA.

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EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines

Volume 4 of "The rules governing medicinal products in the European Union" contains guidance for the **interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use** laid down in Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively.

Part I - Basic Requirements for Medicinal Products- Chapters 1 to 9

Part II - Basic Requirements for Active Substances used as Starting Materials

Part III - GMP related documents

Annexes 1 to 19

Part IV - GMP requirements for Advanced Therapy Medicinal Products

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EudraLex - Volume 6 - Notice to applicants and regulatory guidelines for medicinal products for veterinary use

Volume 6 of the publications "The rules governing medicinal products in the European Union" contains a **list of regulatory guidelines related to procedural and regulatory requirements such as renewal procedures, dossier requirements for Type IA/IB variation notifications, summary of product characteristics (SPC), package information and classification for the supply, readability of the label and package leaflet requirements.**

This "Notice to Applicants" has been prepared by the European Commission, in consultation with the competent authorities of the Member States and the European Medicines Agency. This Notice has no legal force and does not necessarily represent the final views of the Commission. The "Notice to Applicants" was first published in 1986 and is regularly updated.

Volume 6A - Procedures for marketing authorisation

Chapter 1 - Marketing authorisations

November 2017

Chapter 3 - Union Referral Procedures

April 2017

Volume 6C - Regulatory Guidelines

Guidance on environmental risk assessment for veterinary medicinal products consisting of or containing genetically modified organisms (GMOs) as or in products

March 2017

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EudraLex - Volume 7 - Scientific guidelines for medicinal products for veterinary use

Volume 7 of the publications "The rules governing medicinal products in the European Union" contains scientific guidelines prepared by the Committee for Medicinal Products for Veterinary Use (CVMP) in consultation with the competent authorities of the EU Member States, to help applicants prepare **marketing-authorisation applications for medicinal products for veterinary use.**

Guidelines are intended to provide a basis for practical harmonisation of the manner in which the EU Member States and the EMA interpret and apply the detailed requirements for the demonstration of quality, safety and efficacy contained in the Community Directives. They also help to ensure that applications for marketing authorisation are prepared in a manner that will be recognised as valid by the EMA.

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EudraLex - Volume 8 - Maximum residue limits guidelines (MRLs)

Volume 8 of the publications "The rules governing medicinal products in the European Union" contains guidance on the application of Council Regulation (EEC) No 2377/90, as amended, which provides the **legal framework for the establishment of maximum residue limits (MRLs) for medicinal products for veterinary use**.

Notice to applicants and Guideline - Veterinary medicinal products - Establishment of maximum residue limits (MRLs) for residues of veterinary medicinal products in foodstuffs of animal origin

For the Council Regulation (EEC) N° 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits for veterinary medicinal products in foodstuffs of animal origin und updates, see EudraLex - Volume 5.

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EudraLex - Volume 9 - Pharmacovigilance guidelines

Volume 9 of "The rules governing medicinal products in the European Union" contains Pharmacovigilance guidelines for medicinal products for both human and veterinary use. Such guidelines are drawn up by the European Commission in consultation with the European Medicines Agency, Member States and interested parties in accordance with Article 77 of Directive 2001/82/EC as amended and Article 51 of Regulation (EC) 726/2004

Volume 9B - Pharmacovigilance for Medicinal Products for Veterinary Use

Guidelines on Pharmacovigilance for Medicinal Products for Veterinary Use (Volume 9B - Version October 2011).

Good pharmacovigilance practice (GVP) guidelines

In the past the European Commission also published pharmacovigilance guidance for human medicinal products **(Volume 9A).** The most recent of this guidance documents dates from September 2008: Pharmacovigilance for medicinal products for human use

With the application of the new pharmacovigilance legislation as from July 2012 Volume 9A is replaced by the good pharmacovigilance practice (GVP) guidelines released by the European Medicines Agency. However, until the availability of the respective GVP modules Volume 9A remains the reference.

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EudraLex - Volume 10 - Clinical trials guidelines

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Volume 10 of the publication "The rules governing medicinal products in the European Union" contains guidance documents applying to clinical trials.

A number of documents in Volume 10 are being revised and updated to bring them in line with the changes required by the Clinical Trials Regulation (EU) No 536/2014. Additionally, new documents were prepared to cover new aspects introduced by the same Regulation.

Until the Clinical Trials Regulation becomes applicable sponsors should follow the documents relevant to the Clinical Trials Directive.

During the transitional period, which will last for a period of 3 years starting from when the Regulation becomes applicable, both sets of documents will apply accordingly and should be referred to respectively according to the legislation under which the Clinical trial is conducted.

At the end of the transitional period all clinical trials shall be conducted under the Regulation and should follow only the set of documents applicable to the Regulation.

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EudraLex– recent updates

09/10/2017

Publication in EudraLex - Volume 10: new documents, in view of preparing for entry into application of the Regulation (EU) No 536/2017

New Clinical Trials Expert Group recommendations on *Auxiliary medicinal products in clinical trials*, *Risk proportionate approaches in the clinical trials, Summaries of Clinical Trials Results for Laypersons* have been published in Eudralex - Volume 10.

Those documents, which are in principle developed in order to prepare for the entry into application of new Clinical Trials Regulation, may be taken into account to the extent possible for in the context of the clinical trials conducted on the basis of Directive 2001/20/EC

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EudraLex– recents updates

20/12/2017

Targeted stakeholders consultation on the revision of annex 1, on manufacturing of sterile medicinal products, of the Eudralex volume 4

Period of consultation

From 20 December 2017 to 20 March 2018.

From 20 December 2017 to 20 March 2018.

Objective of the consultation

Annex 1 was first published in 1971, since then it has undergone a number of targeted updates but, until now it has not undergone a full review. This revision is intended to add clarity, introduce the principles of Quality Risk Management to allow for the inclusion of new technologies and innovative processes and to change the structure to a more logical flow.

Key changes

Introduction of new sections: scope, utilities, Environmental and process monitoring sections and glossary

Introduction of QRM Principles

Restructured to give more logical flow

Added detail to a number of the previous sections to provide further clarity.

Acknowledgment

In order to maintain the global alignment of standards, achieving at the same time assurance for the highest quality, the proposed revised version was prepared in cooperation with WHO and PIC/S. The document will be subject to parallel public consultation by WHO and PIC/S.

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