Pharmaceuticals in the European Union

Pharmaceuticals in the European Union:

Law and Economics

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Part 1: Law

Part 2: Economics

> *(...) a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.*

Research Handbook on EU Health Law and Policy, *ad hoc*

Health Systems Governance in Europe: The Role of European Union Law and Policy

Health systems Governance in Europe: The Role of European Union Law and Policy,

European Union Public Health Policy – Regional and Global Trends

Journal of Common Market Studies

biggest power shift since the single market was set up”

Journal of European Public Policy

European Voice

Health Systems Governance

Health Systems Governance in Europe: The Role of European Union Law and Policy

Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality,

PART 1:

LAW

1.1 The EU Legal Basis for Health

Health law and the European Union

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Journal of European Social Policy

ad hoc

> *The action of Community in the field of public health shall respect precisely the responsibility of Member States in organizing and supplying health and medical assistance services*[29]*.*

Health Systems Governance in Europe: The Role of European Union Law and Policy

Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities

The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation

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(...) will take as a base a high level of protection, taking account in particular of any new development based on scientific facts[43]

European Union Law,

Federal Republic

The Impediment of Health Laws. Values in the Constitutional Setting of the EU *Research Handbook on EU Health Law and Policy,*

Federal Republic

1.2 The Developments of EU Legislation on Pharmaceuticals

Helix Magazine

Toxicological Sciences

> *(...) trade in proprietary medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products (...) [and since] such disparities directly affect the establishment and functioning of the common market (...) such hindrances must accordingly be removed [giving priority to the removal of] the disparities liable to have the greatest effect on the functioning of the common market*

Biologics, a history of agents made from living organisms in the twentieth century

any ready-prepared medicinal product placed on the market under a special name and in a special pack

Biologics

(...) such forwarding shall be deemed to be equivalent to submitting an application for marketing authorisation, within the meaning of Article 4 of Directive 65/65/EEC, to the said authorities[69]
