

COMPETITION AND INNOVATION IN THE EU REGULATION  
OF PHARMACEUTICALS



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The Case of Parallel Trade

Claudia DESOGUS



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## LIST OF ABBREVIATIONS

ABPI	Association of the British Pharmaceutical Industry
AEP	Average European Price
AG	Advocate General
AIFA	<i>Agenzia Italiana Farmaco</i> (Italian Medicines Agency)
ATC	Anatomical Therapeutic Chemical Classification System
CAT	Competition Appeal Tribunal
CEPS	<i>Commission d'Evaluation des Médicaments</i> (Economic Committee for Health Care Products)
CFI	Court of First Instance
CPMP	Committee for Proprietary Medicinal Products
CPR	<i>Comitato Prezzi e Rimborso</i> (Italian Committee for Pricing and Reimbursement)
CTS	<i>Commissione Tecnico-Scientifica</i> (Italian Technical Scientific Committee)
DKMA	Danish Medicines Agency
DTP	Direct-to-Pharmacy distribution schemes
EAEPIC	European Association of EuroPharmaceutical Companies
EC	European Community
ECJ	European Court of Justice
EFPIA	European Federation of Pharmaceutical Industry and Associations
EFTA	European Free Trade Association
EMA	European Medicine Agency
FDA	Food and Drug Administration
FTC	Federal Trade Commission
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
IP	Intellectual Property
IPRs	Intellectual Property Rights
LFN	<i>Läkemedelsförmånsnämnden</i> (Swedish Pharmaceutical Benefits Board)
LIF	<i>Lægemedel Industrie Foreningen</i> (Danish Pharmaceutical Industry Association)
MPPA	Dutch Medicinal Product Prices Act
MRS	Dutch Medications Reimbursement System

MSD	Merck Sharp & Dohme
NAS	New Active Substance
NCE	New Chemical Entity
NHS	National Health Service
NME	New Molecular Entity
OTC	Over-The-Counter
PPI	Proton Pump Inhibitors
PPRS	Pharmaceutical Price Regulation Scheme
PRO	Pharmaceutical Price Ordinance
PRU	Pricing and Reimbursement Unit
QP	Qualified Person
R&D	Research and Development
ROC	Return on Capital
RP	Responsible Person
SPC	Supplementary Certificate Protection
SSNIP	Small but Significant and Non-Transitory Increase in Price
TEU	Treaty of the European Union
TFEU	Treaty on the Functioning of the European Union

The term ‘EU’ refers to a multiplicity of meanings within the present work: depending on the context, it is used to refer to the territorial space of the European Economic Area, to the European Union as the political and economic union of the 27 Member States, or just as a synonymous of ‘European’.

The terms ‘European Courts’ and ‘EU Courts’ refer to the General Court (formerly Court of First Instance) and the European Court of Justice jointly.

## TABLE OF EQUIVALENCE

This work has been completed after the Lisbon Treaty came into force. The enactment of this Treaty determined the suppression of the European Community. It also entailed substantial amendments to the structure of both the Treaty on the European Union and the Treaty establishing the European Community (now named ‘Treaty on the Functioning of the European Union’). Numeration also greatly changed. In the text I use the new numeration introduced by the Lisbon Treaty, except for quotations. Also, when I cite papers and books, or when I refer either to legislations and official documents enacted before the Lisbon Treaty came into force, or to the reasoning of EU Courts and of the Commission in a given case, I keep the old numeration.

In order to help the reader in getting acquainted with the structure of the new Treaties, I hereby provide a table of equivalence between the old and the new numeration, in relation to the provisions that have been cited in the text.

Old numeration	New numeration
Art. 2 EC	repealed and replaced in substance by Art. 3 TEU
Art. 3 EC	replaced in substance by Articles 3 to 6 TEU
Art. 5 EC	replaced in substance by Art. 5 TEU
Art. 14 EC	Art. 26 TFEU
Art. 28 EC	Art. 34 TFEU
Art. 30 EC	Art. 36 TFEU
Art. 81 EC	Art. 101 TFEU
Art. 82 EC	Art. 102 TFEU
Art. 86 EC	Art. 106 TFEU
Art. 95 EC	Art. 114 TFEU
Art. 113 EC	Art. 284 TFEU
Art. 234 EC	Art. 267 TFEU
Art. 251 EC	Art. 294 TFEU
Art. 295 EC	Art. 345 TFEU





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