was to identify existing definitions of innovation, values inherent in innovation initia-
tives, and important considerations for the development of policies to promote innova-
tion of health technologies. METHODS: A literature search of bibliographic databases 
including PubMed, EMBASE, Web of Science, Centre for Reviews and Dissemination 
databases, the Library of Medicine Grey Literature collection was conducted for the period January 2005 to April 2010. The search terms were intended to capture concepts of "innova-
tion" and "policy" in the health technology (drugs, devices, etc.) sector. Two research-
ers reviewed titles and abstracts of over 4500 references identified; 200 papers were 
retrieved for full review. Key components of innovation were extracted and summa-
rized in tabular form to identify trends and emerging themes. RESULTS: System 
disrupting, development of relationships and improvement on current practice are 
examples of components of, or criteria for defining, health technology innovation. 
Thematic concepts that emerged during the review include innovative health technol-
ogy as a novelty and as a mechanism for achieving some benefit or good (broadly-
deﬁned) at various levels of the health system. CONCLUSIONS: Based on the variety 
of deﬁnitions in the literature and a lack of a common understanding of innovation may 
result in policy incoherence. The use of a consistent and unambiguous deﬁnition provides a solid framework from which to develop policy that is measurable, mean-
ingful and, therefore, has a greater chance of being effective.

PHYSICIANS VIEWS ON BIOMEDICAL TECHNOLOGY IN GREECE


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OBJECTIVES: Given the signiﬁcant impact of biomedical technology on health, the present study aims at identifying the accessibility to certain biomedical technologies and the factors that affect their use and diffusion, in Greece. METHODS: A strictly structured questionnaire was designed and sent to a sample of 388 internists and GPs over 50 years old, stratiﬁed by geographical area and employment sector. Participants were asked a) to evaluate on a 1 to 10 point scale patient access to selected biomedical 
technologies and b) to rank certain factors effect on the diffusion of biomedical 
technologies. RESULTS: The response rate was 76%. The statistical analysis revealed that the most accessible biomedical technologies were ultrasonography (9.4), PSA (9.3), cardiac enzymes (8.99), MRI and CT (8.86), and mammography (8.84). The most important factors affecting participants’ decision to use a technology were the treatment outcome (9.23), the disease severity (9.11) and the appropriateness of the technology for each condition (8.27) while factors such as health system and patient 
choice were more inﬂuential. 61.8% of participants claimed delayed in the diffusion of 
illegal biomedical technologies in Greece. The most important barriers of diffusion of 
customized human resources deﬁciencies. CONCLUSIONS: Based on our results, higher 
access was observed to technologies related to neoplasms and cardiovascular diseases, 
which represent the main causes of morbidity and mortality in Greece. Furthermore, our 
ﬁndings support the view that when it comes to use a technology physicians are mostly 
concerned with the clinical effectiveness of an intervention and less with its 
impact on health care expenditures. Finally, the major diffusion barriers identiﬁed in 
this study show a suboptimal resource allocation practice, stressing the need for 
measures to be taken in this direction in order to enhance diffusion of biomedical 
technologies in Greece.

IMPLEMENTATION OF THE TRANSPARENCY DIRECTIVE IN HUNGARY

By Kalo Z†, Nagyjossi L†

†Eötvös Loránd University, Budapest, Hungary; †Tygen Research Institute, Budapest, Hungary

OBJECTIVES: Transparency Directive (TD) of the European Union aims to ensure 
the transparency of procedures for the pricing and reimbursement of medicinal prod-
ucts by Member States. TD proposes strict timelines for the pricing and reimbursement 
process and indicates the necessity of objective and veriﬁable criteria for decisions and 
the availability of remedies for negative decisions. Our objective was to compare the 
routine process of pharmaceutical pricing and reimbursement with the TD in Hungary. 
METHODS: We analysed ofﬁcial resolutions of 29 pricing and reimbursement sub-
missions by the National Health Insurance Fund (NHIF) between January and June 
2008. In 14 cases the NHIF granted reimbursement, in 15 cases the reimbursement 
claim was rejected. We calculated the time period between the submission of the 
reimbursement dossier and the ofﬁcial decision. We assessed the consistency of apply-
ing objective and veriﬁable criteria in positive or negative decisions. RESULTS: The average time period for pricing and reimbursement procedure was 172 days (min: 43 
days; max: 534 days). We could not justify the consistency of employing objective and 
veriﬁable criteria in positive or negative decisions. The drug innovation criteria (insufﬁcient experience with the drug) to 4 (relevant therapeutic improvement). 
The drug evaluation results were gathered from JCNDE reports and from the Regional 
Drug evaluation centre reports. The time period analyzed was from 2004 to 2009. 
RESULTS: Ninety drug evaluations were held; considering 86 different drugs and 11 
evaluations for a new drug indication for the same drug. Seventy-eight (87%) of the 
evaluations were negative (scores 0–1), not ﬁnding any 0 in the last 2 years of the 
study. Ten and 2 evaluations were scored as 2 and 3 respectively. None of the drugs 
asessed were considered a relevant therapeutic improvement compared to the existing 
options. Five drugs not reimbursed were evaluated. Median time since commercializa-
tion to evaluation was 6 months (IQR: 2–11 months) and 32 drug evaluations were 
held before up to a maximum of 3 months after commercialization. CONCLUSIONS: 
The JCNDE has been an efﬁcient instrument to develop new drugs for rare diseases. 
A strictly structured and, therefore, has a greater chance of being effective.

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THE JOINT COMMITTEE FOR NEW DRUGS EVALUATION IN SPAIN: 6 YEARS OF EXPERIENCE

By Collar J, Yepp Z, Collar J

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OBJECTIVES: The Spanish Joint Committee for New Drugs Evaluation (JCNDE) was created in 2003 and is formed by 5 Regional Drug Evaluation Centres. JCNDE has 
implemented Standard Operating Procedures (SOPs) to unify drug assessments and where 
the comparators availability is a key issue. Each individual Drug Evaluation Centre has its own new drug therapeutic bulletin to spread information between their health 
professionals. The objective of this study was to quantify the uniformity degree 
which represent the main causes of morbidity and mortality in Greece. Furthermore, our 
ﬁndings support the view that when it comes to use a technology physicians are mostly 
concerned with the clinical effectiveness of an intervention and less with its 
impact on health care expenditures. Finally, the major diffusion barriers identiﬁed in 
this study show a suboptimal resource allocation practice, stressing the need for 
measures to be taken in this direction in order to enhance diffusion of biomedical 
technologies in Greece.

Implementation of the Transparency Directive in Hungary

By Kalo Z, Nagyjossi L

†Eötvös Loránd University, Budapest, Hungary; †Tygen Research Institute, Budapest, Hungary

OBJECTIVES: Transparency Directive (TD) of the European Union aims to ensure 
the transparency of procedures for the pricing and reimbursement of medicinal prod-
ucts by Member States. TD proposes strict timelines for the pricing and reimbursement 
process and indicates the necessity of objective and verifiable criteria for decisions and 
the availability of remedies for negative decisions. Our objective was to compare the 
routine process of pharmaceutical pricing and reimbursement with the TD in Hungary. 
METHODS: We analysed ofﬁcial resolutions of 29 pricing and reimbursement sub-
missions by the National Health Insurance Fund (NHIF) between January and June 
2008. In 14 cases the NHIF granted reimbursement, in 15 cases the reimbursement 
claim was rejected. We calculated the time period between the submission of the 
reimbursement dossier and the ofﬁcial decision. We assessed the consistency of apply-
ing objective and verifiable criteria in positive or negative decisions. RESULTS: The average time period for pricing and reimbursement procedure was 172 days (min: 43 
days; max: 534 days). We could not justify the consistency of employing objective and 
veriﬁable criteria in the pricing and reimbursement resolutions of innovative Pharma-
ceuticals. CONCLUSIONS: The pharmacetical pricing and reimbursement process in Hungary is neither transparent nor predictable. There are several open pricing and 
reimbursement submissions without resolution for long period. Although we could 
analyze only cases with resolution, the time period for pricing and reimbursement 
decision was still longer in several cases than 90 + 90 days recommended by TD. The 
appropriate use of scarce public health care resources could not be justiﬁed in case of 
possibility, there is no remedy for negative reimbursement decisions. TD has been implemented only partially in Hungary.

ACCESSIBILITY TO ORPHAN DRUGS IN JAPAN—HAS THE ORPHAN 
DESIGNATION SYSTEM CONTRIBUTED?

By Tominaga N†, Kodama T‡, Inagaki A‡

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OBJECTIVES: To promote the development of new drugs for rare diseases, like other 
countries, orphan designations have been granted to pharmaceuticals in Japan since 1993. 
We investigated the accessibility of orphan drugs in Japan by comparing the accessibility of orphan designated and marketing authorised drugs in the 
EU and the US. METHODS: The present study used the data available until the November 30, 2009 from the European Medicines Agency, US Food and Drug 
Administration and National Institute of Biomedical Innovation. The International 
Nonproprietary Names (INNs) were used for comparing authorised orphan design-
atived drugs in Japan, the EU and the US. RESULTS: A total of 528 authorized orphan-designated pharmaceuticals in INNs in these 3 regions, 165 were inaccessible in Japan through the orphan designation system. Among such drugs, 25 (15%) were authorised orphan designated in both the EU and the US, 15 (9%) were authorised orphan designated in the EU alone and 125 (76%) were authorised orphan designated in the US alone. CONCLUSIONS: We

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DRUG COMPARATOR DIFFERENCES IN THE THERAPEUTIC BULLETINS 
OF THE JOCNDE EXPERIENCE

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OBJECTIVES: The Spanish Joint Committee for New Drugs Evaluation (JCNDE) was created in 2003 and is formed by 5 Regional Drug Evaluation Centres. JCNDE has 
implemented Standard Operating Procedures (SOPs) to unify drug assessments and where 
the comparators availability is a key issue. Each individual Drug Evaluation Centre has its own new drug therapeutic bulletin to spread information between their health 
professionals. The objective of this study was to quantify the uniformity degree