orphan drugs assessments between January 2011 and May 2015 and compari-
son with assessments conducted by HTA agencies in France, Netherlands, the
UK and Canada, to examine similarities and differences in benefit evaluations,
reimbursement and drug access. RESULTS: Germany has 23 completed assess-
ments for 21 orphan drugs during the time frame. 9 received non quantifiable additional benefit assessment and 3 significant. Out of 5 drugs where different patient subgroups were identified, only 1 (vaccine) received different ratings across two patient subgroups (marginal and significant). This 21 orphan drug sub-
set was then searched across the other countries. Methods: In France, in the
Decision Resources Group’s ‘Global Market Access Solution’ database were
reviewed. METHODS: The healthcare systems in Brazil, Argentina and Mexico
are decentralised, while that of Colombia is centrally managed. All countries have
a national health service for all residents, but the proportion of the population
that relies solely on this varies greatly between countries. In Brazil, 25% of the
population relies on private health insurance, while only a small proportion of the popula-
tion relies on private insurance in the other countries. In Mexico and Argentina,
residents in formal employment are obliged to enrol in one of the social security
sponsored schemes. In Brazil, Argentina and Colombia, national formularies include
the mandatory minimum healthcare provision. In Mexico, the national formulary
is not binding and the different social security schemes decide which treatments
to cover. The role of health technology assessment (HTA) in the reimbursement
processes in Brazil, Argentina, Mexico and Colombia, HTA is criti-
cal in the reimbursement decision process, while in Argentina it has been mostly
used to assess treatments for catastrophic illnesses; although there is a drive to
include more HTA opportunities into the reimbursement process for Pharmaceuticals,
and challenges include decentralised healthcare systems and high use
of generics. CONCLUSIONS: Most countries have a decentralised system where
reimbursement decision making occurs at the regional level or at the social security
level. However, there are differences in the extent to which HTA is used. In Mex

PHP212
AN ANALYSIS OF GERMAN AMONG RE-VIEW ASSESSMENTS AND LEARNINGSFOR MANUFACTURERS
Stooff T, Falk K, Brown A
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OBJECTIVES: The primary focus of manufacturers’ reimbursement submissions in
Germany is on demonstrating the added benefit of a product versus the appropri-
ate comparator. Within the submissions, the decision was made based on either a
result in a time-limited approval, after which there should be a review. This study
analyses any completed reviews conducted by the G-BA. METHODS: G-BA deci-
sions were searched to identify restricted decisions and subsequent reviews. Data
were collected and analysed for the restrictions and the ways these were addressed;
in the reviews, were analysed. RESULTS: 20% (27/135) of all decisions identified
were time restricted. Restrictions were mainly applied to products with small or
no added benefit. The most common reason for a restriction was incomplete evi-
dence profiles, and the most common restriction period was three years. Of the 27
restricted decisions, two reviews have taken place, two restriction periods have
been extended and five more decisions are expected by the end of 2015. An analysis
of the remaining restricted decision showed that the manufacturer was granted suf-
ficient time to collect additional evidence and that the G-BA adjusted its recom-
endations in a favourable manner once further evidence was provided. However,
during the wenevonfchen review the level of added benefit did not change from the
original evaluation. This indicates the manufacturer did not present sufficient data
to address the original criticism and was therefore unable to raise the level of added
benefit. Furthermore, it is evident that the G-BA takes regulatory guidance into con-
sideration in decision making. CONCLUSIONS: The results indicate that restricted
decisions provide manufacturers with the opportunity to collect additional data
and improve the final added benefit recommendation. If manufacturers address
the challenges and opportunities of additional benefits, more favourable added benefit levels
are achieved during the review. Furthermore, it shows that EMA decisions influ-
ence G-BA decision making.

PHP213
ASSESSING PHARMACEUTICALS WITH LIMITED EVIDENCE IN GERMANY – CURRENT EXPERIENCE
Ecker T, Staal F, Ecker C, Linstaedt J
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OBJECTIVES: Benefit assessment usually requires RCT data. Orphan drugs are
granted additional benefit by law, but not drugs with conditional or exceptional
approval or PUMA. The objective of this study was to assess how their status is
handled in benefit assessment. METHODS: All resolutions until June 2016 were
analysed whether they have been approved by EMA under these circumstances.
Those which do were assessed regarding underlying evidence, extent of additional
benefit and other aspects of the result. RESULTS: 7 out of 104 resolutions (7%) met
these criteria – 5 with conditional approval, 1 with exceptional circumstances
and 1 PUMA. 2 out of 7 products had only non-RCT evidence. For 6 products the
IQWiG found no additional benefit and for 1 product a major additional benefit. The
G-BA increased three products to minor (or considerable) additional benefit, even
though one approval was based only on a case series. However, for three products
the result was still “additional benefit not proven”. 4 out of 7 resolutions had been
limited. CONCLUSIONS: Special regulatory status gives no formal advantage in
benefit assessment. However G-BA seems to take their status into account and
using limitations to account for future evidence.

PHP214
CURRENT CHALLENGES AND OPPORTUNITIES TO MARKET ACCESS IN BRAZIL, ARGENTINA, MEXICO AND COLOMBIA
Faria- Billinton E1, Dymond A2, Ribeiro A3, Antunes NT4, Moore B5, Brown A2
1Abacus International, Manchester, UK; 2Decision Resources Group, Exton, PA, USA, 3Decision
Resources Group, Brazil, 4Decision Resources Group, Nashville, TN, USA
OBJECTIVES: To define the current processes and key decision makers involved in
gaining market access in Brazil, Argentina, Mexico and Colombia, and identify
opportunities and challenges to have access to these countries. METHODS:
The websites of the appropriate authorities and agencies in each country and
the Decision Resources Group’s ‘Global Market Access Solution’ database were
examined. CONCLUSIONS: The healthcare systems in Brazil, Argentina and Mexico
are decentralised, while that of Colombia is centrally managed. All countries have
a national health service for all residents, but the proportion of the population
that relies solely on this varies greatly between countries. In Brazil, 25% of the
population relies on private health insurance, while only a small proportion of the popula-
tion relies on private insurance in the other countries. In Mexico and Argentina,
residents in formal employment are obliged to enrol in one of the social security
sponsored schemes. In Brazil, Argentina and Colombia, national formularies include
the mandatory minimum healthcare provision. In Mexico, the national formulary
is not binding and the different social security schemes decide which treatments
to cover. The role of health technology assessment (HTA) in the reimbursement
processes in Brazil, Argentina, Mexico and Colombia, HTA is criti-
cal in the reimbursement decision process, while in Argentina it has been mostly
used to assess treatments for catastrophic illnesses; although there is a drive to
include more HTA opportunities into the reimbursement process for Pharmaceuticals,
and challenges include decentralised healthcare systems and high use
of generics. CONCLUSIONS: Most countries have a decentralised system where
reimbursement decision making occurs at the regional level or at the social security
level. However, there are differences in the extent to which HTA is used. In Mex

PHP215
FROM CENTRALIZED MARKETING AUTHORIZATION TO NATIONAL REIMBURSEMENT – A CHALLENGING JOURNEY FOR NEW MEDICAL PRODUCTS WITH PLACEBO CONTROLLED TRIALS
Eheberg D1, Paulus G2, Dannemann S3, Batscheider A2
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BACKGROUND: The governing principle ruling all aspects of a new medical product. Marketing authorization organizations and health tech-
nology agencies focused on the reimbursement aspects of a new product are both
influenced by the decisions incorporated in the prospective on clinical data of the highest pos-
ible evidence. While marketing authorization is an increasingly international process
with standardized rules, the reimbursement process is conducted on a national
level with country-specific requirements. In some indications, e.g. in chronic dis-
ease, where a clearly diagnosed product is difficult to use, the pharmaco-
therapy review of the G-BA explicitly referred to limited quality of evidence. Expectations for better data
are not binding and the different social security schemes decide which treatments
to cover. The role of health technology assessment (HTA) in the reimbursement
processes in Brazil, Argentina, Mexico and Colombia, HTA is criti-
cal in the reimbursement decision process, while in Argentina it has been mostly
used to assess treatments for catastrophic illnesses; although there is a drive to
include more HTA opportunities into the reimbursement process for Pharmaceuticals,
and challenges include decentralised healthcare systems and high use
of generics. CONCLUSIONS: Most countries have a decentralised system where
reimbursement decision making occurs at the regional level or at the social security
level. However, there are differences in the extent to which HTA is used. In Mex

PHP216
LIMITATION OF BENEFIT ASSESSMENTS IN GERMANY – CURRENT EXPERIENCE
Ecker T, Ecker C, Linstaedt J
Ecker + Ecker GmbH, Hamburg, Germany
OBJECTIVES: The primary focus of manufacturers’ reimbursement submissions in
Germany is on demonstrating the added benefit of a product versus the appropri-
ate comparator. Within the submissions, the decision was made based on either a
result in a time-limited approval, after which there should be a review. This study
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decisions provide manufacturers with the opportunity to collect additional data
and improve the final added benefit recommendation. If manufacturers address
the challenges and opportunities of additional benefits, more favourable added benefit levels
are achieved during the review. Furthermore, it shows that EMA decisions influ-
ence G-BA decision making.

PHP217
REIMBURSEMENT AND PRICING OF INNOVATIVE MEDICINES: EU POLICIES AND IMPLICATIONS FOR MARKET ACCESS
Abacus International, Manchester, UK
OBJECTIVES: The use of innovative medicines has been associated with increased
healthcare-related expenditure in the EUS (Italy, France, Spain, UK and Germany).
In some countries, this has raised concerns in the clinical and economic assess-
ment of such medicines and has led to the introduction of additional criteria to

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