PH39
DRUG PRICING REFORM IN CHINA - AN ANALYSIS OF PILOTED PRICING APPROACHES IN THE CONTEXT OF INTERNATIONAL COMPARISONS
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OBJECTIVES: Since 2009, the Chinese government has launched a global price rationalization program aiming to control healthcare expenditure and increase the quality of care. In 2015, a new drug pricing reform was initiated sparking a debate. The objective of this study is to describe the changing landscape of drug pricing policy in China.

METHODS: We conducted a thorough research on drug pricing reform using three Chinese databases (CNIK, Wanfang, Weipu), Chinese health authorities’ websites, relevant press releases, pharmaceutical blogs and discussion forums. This research was complemented with targeted interviews with Chinese key opinion leaders representing authorities’ and prescribers’ perspectives.

RESULTS: The reform may include introduction of internal reference pricing (IRP) for drugs with the same active ingredient and dose, instead of the current international interchangeability, which is an important barrier to cost containment. Introduction of IRP may provide a way to reduce prices as reimbursement caps. First results of Sanming and Shaoxing pilots have already been reported, proving their potential for drug budget saving.

Conclusions: The reform requires a comprehensive approach.

PH40
CURRENT PATH AND FUTURE PATH FOR HEALTH ECONOMIC ASSESSMENT OF PHARMACEUTICALS IN FRANCE
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OBJECTIVES: The Economic and Public Health Assessment Committee (CEESP) was introduced in 2012 as a specialised committee affiliated with the “Haute Autorité de Santé” (HAS) in charge of providing health economic opinions. This research provides an overview of how drug economic assessment in France is evolving and its impact on market access of drugs. It also provides likely directions of the future French HTA organisation and processes.

METHODS: We conducted a literature search on the HAS websites and decided to focus on publically available NLT recommendation documents up to 1st May 2015. The objective of this study is to describe the changing landscape of drug pricing policy in China. The secondary research was complemented with targeted interviews with Chinese key opinion leaders representing authorities’ and prescribers’ perspectives. The current reform, the government attempts to replace its direct control over prices with reimbursement caps. First results of Sanming and Shaoxing pilots have already been reported, proving their potential for drug budget saving. Current approaches are being a key criterion by contrast. The national HTA of pharmaceuticals in France will imply the expansion of health economic assessment scope, the implementation of an impactful ICER threshold, the generalisability of evidence with evidence, and eventually the possible merge of the CEESP and the CT.

CONCLUSIONS: The HTA has been, and it is expected, and it may become the unique or leading committee addressing the HTA of pharmaceuticals in France. However, it is likely that the robust and well-established methodology developed by the CT (SMR, ASMR) to assess comparative efficacy or effectiveness will remain in force.

PH41
ARE THE IRISH SLOMER SLOWER THAN THEY THINK? A SYSTEMATIC ANALYSIS OF ALL RECENT NCPE APPRAISALS
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OBJECTIVES: The National Centre for Pharmacoeconomics (NCPE) reviews the cost effectiveness of new medicines following an application for reimbursement in Ireland. All medicines are subjected to a preliminary rapid review (RR, stated to take 2 weeks) with only high cost products and those with significant budget impact subjected to formal pharmacoeconomic assessments (PEA, stated to be completed in <3 months). This research aims to review all recent NCPE appraisals to determine what proportion of drugs require a full appraisal, the review times and rates of approvals.

METHODS: Publically available decision summaries from the NCPE were identified (from 1st January 2013 to 31st May 2015) and the outcome, date, indication, and whether a full PEA was needed were extracted.

RESULTS: 110 appraisals were identified: 47 (42.7%) were approved, only 21% (10/47) were reviewed within <2 weeks; the rest taking on average >2x longer than stated (29 days). Of the 57% (63/111) appraisals deemed to require a full PEA, 52% (32/63) were reviewed >5 months past RR. Only 31% (11/35) of full PEA were eventually recommended, adding another 5 months (average 152 days) to the process. 27% (30/110) appraisals were for oncology medicines; 90% (27/30) of which were for a full PEA. Only 11% (11/110) of NCPE appraisals were not recommended (87%, 13/15).

CONCLUSIONS: The total average length of time between start of the RR to final PEA recommendation is up to a year (12 months), which is substantially longer than what is claimed. If companies can convince the NCPE that the drug has low cost, not high cost, not high budget impact, the RR process can enable rapid reimbursement within 1-2 months. However, if a full PEA is required, this significantly delays reimbursement decisions, with positive recommendations being difficult to achieve, especially for oncology medicines.

PH42
COULD GIVING COST-UTILITY HTA BODIES NEGOTIATING POWER HELP BRIDGING THE GAP BETWEEN COST-CONTAINMENT AND BROADENING COVERAGE? A SYSTEMATIC REVIEW OF ALL SWEDISH NLT APPRAISALS OF HOSPITAL PHARMACOTHERAPIES
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RENA, Stockholm, Sweden
OBJECTIVES: The Swedish Dental and Pharmaceutical Benefits Agency (TIV) make recommendations on whether outpatient prescription drugs should be publicly reimbursed. A key cost-effectiveness criterion in the Swedish reimbursement system is traditionally implemented for hospital pharmaceuticals, which were typically individually appraised by each county council. However, since January 2011, a national co-ordinating group of Swedish county councils (NLT) can request that selected in-patient therapies undergo a health economic assessment by the NLT, on which the NLT can conduct price negotiations and issue a national recommendation. This research aims to review all recent NCPE appraisals to determine what proportion of drugs require a full appraisal, the review times and rates of approvals. A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes. METHODS: A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes. METHODS: A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes. METHODS: A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes. METHODS: A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes. METHODS: A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes. METHODS: A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes. METHODS: A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes. METHODS: A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes. METHODS: A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes. METHODS: A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes. METHODS: A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes. METHODS: A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes. METHODS: A systematic search for all publically available NLT recommendation documents up to 1st May 2015 was undertaken and the lecture. The outcomes were then compared with the final outcomes.

CONCLUSIONS: 62% (39/63) were initiated, on average, 21% (10/47) were reviewed within <2 weeks; the rest taking on average >2x longer than stated (29 days). Of the 57% (63/111) appraisals deemed to require a full PEA, 52% (32/63) were reviewed >5 months past RR. Only 31% (11/35) of full PEA were eventually recommended, adding another 5 months (average 152 days) to the process. 27% (30/110) appraisals were for oncology medicines; 90% (27/30) of which were for a full PEA. Only 11% (11/110) of NCPE appraisals were not recommended (87%, 13/15).

CONCLUSIONS: The total average length of time between start of the RR to final PEA recommendation is up to a year (12 months), which is substantially longer than what is claimed. If companies can convince the NCPE that the drug has low cost, not high cost, not high budget impact, the RR process can enable rapid reimbursement within 1-2 months. However, if a full PEA is required, this significantly delays reimbursement decisions, with positive recommendations being difficult to achieve, especially for oncology medicines.

PH43
CLOSING THE GAP BETWEEN HTA AND INNOVATION UPTAKE IN FINNISH HOSPITALS
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OBJECTIVES: Health technology assessment (HTA) is not deeply rooted in Finnish health care. HTA is conducted by a small group of HTA experts in market access and health economics, HTA and public health to discuss the current functioning and the likely future path of health economic assessment in France. This research provides an overview of how drug economic assessment in France is evolving and its impact on market access of drugs. It also provides likely directions of the future French HTA organisation and processes. METHODS: We conducted a systematic search on the HAS websites and decided to focus on publically available NLT recommendation documents up to 1st May 2015. The objective of this study is to describe the changing landscape of drug pricing policy in China. The secondary research was complemented with targeted interviews with Chinese key opinion leaders representing authorities’ and prescribers’ perspectives. The current reform, the government attempts to replace its direct control over prices with reimbursement caps. First results of Sanming and Shaoxing pilots have already been reported, proving their potential for drug budget saving. Current approaches are being a key criterion by contrast. The national HTA of pharmaceuticals in France will imply the expansion of health economic assessment scope, the implementation of an impactful ICER threshold, the generalisability of evidence with evidence, and eventually the possible merge of the CEESP and the CT.

CONCLUSIONS: The HTA has been, and it is expected, and it may become the unique or leading committee addressing the HTA of pharmaceuticals in France. However, it is likely that the robust and well-established methodology developed by the CT (SMR, ASMR) to assess comparative efficacy or effectiveness will remain in force.
evaluating, deciding and procuring new technologies. A mini-HTA sheet was tested during the interviews and questions asked about the relevance and clarity of the questions. **RESULTS:** The current processes of the uptake of technologies is relatively similar in all studied hospitals. There are no standard, transparent evidence requirements, nor systems to assess and document the rationales for uptake. The clinical impact and economic impact in free format. For high priority treatments, Tundvårsbro Läkenedelsföremålsverket (Tlv), will perform a health economic evaluation, upon which the NT-råd will base their recommendation, which will be accompanied by a monitoring group. A protocol that introduces a recommendation will be sent to the county councils. For low priority treatments, only a health economic evaluation and recommendation will be issued. Any other treatments will go through decentralised reimbursement processes. **CONCLUSIONS:** The NT-råd plan to publish recommendations on approximately 55 products per year. With these recommendations, including one joint recommendation for the use of six Hepatitis C therapies. This particular recommendation followed a first of its kind risk-sharing agreement between 21 counties, councils and industry, which was a key product of this new process. **CONCLUSIONS:** The new assessment process has centralised the evaluation of some in-patient drugs, but not all. Most new treatments will still undergo the decentralised process. Due to its infancy, the impact of the NT-råd process on the uptake of new expensive drugs remains to be confirmed.

**PHP44 REIMBURSEMENT OF TELEMEDICINE IN GERMANY: QUO VADIS - ANYTHING BEYOND SELECTIVE CONTRACTS?**

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**OBJECTIVES:** Telemedicine has been an innovation driven within e-health initiatives in healthcare in recent years. However, the uptake of such initiatives in Germany is low. Key question on that is on non-adverse reimbursement/funding might be the key reason for the slow introduction of e-health. **METHODS:** We have reviewed Germany’s Health Technology Assessment (HTA) bodies and assessed the total reimbursement pathways specifically for telemedicine initiatives in Germany and grouped them according to the application setting. **RESULTS:** Overall there are currently 289 e-health initiatives presented in Germany, with the majority conducted in Lower Saxony, Oeheunen, Munich, Hamburg, Hamburg. Telemedicine is being handled as medical devices in Germany within the market access pathway. The exact process depends if the device is a diagnostics or a therapeutic one. As the Ministry of Health and consumer rights (Zusatzentgelt) device is an inpatient or outpatient product. In the inpatient setting relevant DRG and OPS codes are applicable; theoretically NUB and additional fee (Zusatzentgelt) could also be applied for. In the outpatient setting, the reimbursement of e-health devices is driven through the respective catalogue of aids and appliances whereas the actual physical therapy service would need to be billed under the EBM (Einheitlicher Bewertungsmaassstab). Currently there is no specific EBM code available, and health politicians have missed a deadline in 2014 to create one. Besides the self-promotion as an individual physicians services (IGeL) there is the opportunity through selective contracts, particularly Disease Management Programs (DMPs) or integrated care contracts. Most telemedicine projects are currently being covered and tested in the latter ones (e.g. telemonitoring CHF, video Parkinson therapy). An alternative new route could also be the experimental coverage by the joint federal committee.

**CONCLUSIONS:** Currently the most relevant market access pathway for telemedicine initiatives in Germany is through selective contracts. Once health politicians cut e-health as a priority the introduction of specific DRG and EBM codes could initiate fast adaption and more telemedicine introductions in Germany.

**PHP45 THE BRITISH ISLES HTA LEAGUE TABLE 2014**


**OBJECTIVES:** The British Isles comprise 4 countries, each with their own distinct Health Technology Assessment (HTA) body: National Institute of Health and Care Excellence (NICE) in England, National Centre for Pharmacoeconomics (NCPE) in Sweden, Health Technology Assessment (HTA) body: National Institute of Health and Care Excellence (NICE) in England, National Centre for Pharmacoeconomics (NCPE) in Sweden, and the Scottish Medicines Consortium (SMC) in Scotland. The Scottish Medicines Strategy Group (AWMSG) in Wales. Although all four bodies are obligate cost-utility assessment bodies, they do utilise distinct assessment processes. This research aims to compare the number and type of appraisals and recommendation rates between these bodies during 2014. Moreover, if any local market structure and market access regulations.

**METHODS:** Since 2013, Food and Drugs Administration (FDA) Breakthrough Therapy status has enabled expedited development and review of therapies where preliminary evidence suggests substantial clinical improvements for serious/life-threatening conditions. However, there was a pre-existing FDA expedited pathway: Accelerated Approval enabling market entry of drugs for serious conditions based on surrogate success criteria. Since 2011, when the first therapy was approved under Breakthrough status, 13 drugs have been FDA-approved under Accelerated Approval and 21 under Breakthrough Status including 8 supported by both expedited programs. For the 14 approvals under Breakthrough Status alone, 1 (7%) were supported by Phase 3 data with the remaining 3 (21%) supported by Phase 2. Of the 6 drugs under Accelerated Approval alone, 2 (33%) were approved on Phase 3 data with the remaining 4 (66%) supported by Phase 2. Of the 7 approved under both programs, only 1 (14%) was supported by Phase 3 data, 4 (57%) by Phase 2 data and 2 (29%) by only Phase 1 data. 86% (12/14) Breakthrough Status alone approvals were for non-oncology drugs versus just 46% (6/13) for Accelerated Approval alone and 0% (0/7) for both programs approvals.

**CONCLUSIONS:** Whereas Accelerated Approval is typically used for oncology drugs, Breakthrough Status has been frequently applied to non-oncology medicines. Accelerated Approval also frequently enables expedited access without available supporting Phase 3 data, unlike Breakthrough Status. Products with approved by both programs have gained access supported by only Phase 1 data.

**PHP47 A COMPARISON OF TIME TO LAUNCH AND REIMBURSEMENT FOR NEW MEDICINES ACROSS DEVELOPED COUNTRIES**

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**OBJECTIVES:** To understand the differences in time to launch between countries and the differences in time to reimbursement from launch. **METHODS:** We compared the time to reimbursement for new molecular entities granted marketing authorization between 2009 and 2013 across 18 developed countries. In addition, we conducted a sub-analysis comparing these measures for oncolytics and non-oncology. A cross-country analysis of regulatory and market access landscapes was also assessed in order to understand the reasons behind any differences. **RESULTS:** A large variation in time to launch of all new molecular entities (90 to 430 days) and time to reimbursement from launch was observed across these countries. For oncolytics, it could be classified into three distinct groups: Countries with faster time to launch as well as faster time to reimbursement from launch - tended to have regulations mandating quick access, especially immediate coverage through public reimbursement after regulatory approval (e.g. Germany, Japan). Countries with faster time to launch, slower time to reimbursement - had large private insurance markets but delayed public reimbursement negotiations (e.g. Canada). Countries with slower time to launch, slower time to reimbursement - had large public insurance markets and delayed public reimbursement negotiations (e.g. France and Italy).

**CONCLUSIONS:** Time to launch and reimbursement from launch in a country is highly dependent on local market structure and market access regulations.

**PHP48 FDA BREAKTHROUGH STATUS VERSUS ACCELERATED APPROVAL – WHAT’S THE DIFFERENCE?**

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**METHODS:** Since 2013, Food and Drugs Administration (FDA) Breakthrough Therapy status has enabled expedited development and review of therapies where preliminary evidence suggests substantial clinical improvements for serious/life-threatening conditions. However, there was a pre-existing FDA expedited pathway: Accelerated Approval enabling market entry of drugs for serious conditions based on a surrogate endpoint likely to predict clinical benefit with confirmatory trials completed post-approval. This abstract aims to compare access of therapies under both pathways to determine in which distinct circumstances they are being used. **METHODS:** All FDA approvals from January 2013-March 2015 were screened for any approvals under Breakthrough Status and/or Accelerated Approval and the disease areas and supportive data packages were extracted. **RESULTS:** Since November 2011, when the first therapy was approved under Breakthrough status, 13 drugs have been FDA-approved under Accelerated Approval and 21 under Breakthrough Status including 8 supported by both expedited programs. For the 14 approvals under Breakthrough Status alone, 11 (79%) were supported by Phase 3 data with the remaining 3 (21%) supported by Phase 2. Of the 6 drugs under Accelerated Approval alone, 2 (33%) were approved on Phase 3 data with the remaining 4 (66%) supported by Phase 2. Of the 7 approved under both programs, only 1 (14%) was supported by Phase 3 data, 4 (57%) by Phase 2 data and 2 (29%) by only Phase 1 data.

**CONCLUSIONS:** Accelerated Approval enabling market entry of drugs for serious conditions based on a surrogate endpoint likely to predict clinical benefit with confirmatory trials completed post approval. This abstract aims to compare access of therapies under both pathways to determine in which distinct circumstances they are being used. **METHODS:** All FDA approvals from January 2013-March 2015 were screened for any approvals under Breakthrough Status and/or Accelerated Approval and the disease areas and supportive data packages were extracted. **RESULTS:** Since November 2011, when the first therapy was approved under Breakthrough status, 13 drugs have been FDA-approved under Accelerated Approval and 21 under Breakthrough Status including 8 supported by both expedited programs. For the 14 approvals under Breakthrough Status alone, 11 (79%) were supported by Phase 3 data with the remaining 3 (21%) supported by Phase 2. Of the 6 drugs under Accelerated Approval alone, 2 (33%) were approved on Phase 3 data with the remaining 4 (66%) supported by Phase 2. Of the 7 approved under both programs, only 1 (14%) was supported by Phase 3 data, 4 (57%) by Phase 2 data and 2 (29%) by only Phase 1 data. 86% (12/14) Breakthrough Status alone approvals were for non-oncology drugs versus just 46% (6/13) for Accelerated Approval alone and 0% (0/7) for both programs approvals. Accelerated Approval also frequently enables expedited access without available supporting Phase 3 data, unlike Breakthrough Status. Products with approved by both programs have gained access supported by only Phase 1 data.