**Table 1: Evidence requirements received and analysed\***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Country** | **Agency** | **Submission template used for data extraction** | **English version** | **Page Numbers** |
| Austria | Hauptverband derösterreichischenSozialversicherungsträger | Verfahrensordnung zur Herausgabe des Erstattungskodex nach § 351g ASVG - VO-EKO*Procedural rules for publication of the reimbursement code* | Provided | 174 |
| Arbeitbehelf Erstattungskodex*Reimbursement code* |
| Belgium  | Rijksinstituut voor ziekte- en invaliditeitsverzekeringInstitut National Assurance Maladie-Invalidité | Demande d’admission au remboursement d’une specialite en classe 1 (2009)*Request for a reimbursement admission of a specialty in category 1 (2009)* | Provided | 7 |
| Belgian guidelines for economic evaluations and budget impact analyses: second edition | Provided | 94 |
| Bulgaria | National Council for Pricing and Reimbursement of the Medicinal Products | ДО НАЦИОНАЛНИЯ СЪВЕТ ПО ЦЕНИ И РЕИМБУРСИРАНЕ НА ЛЕКАРСТВЕНИТЕ ПРОДУКТИ З А Я В Л Е Н И Е*TO NATIONAL COUNCIL ON PRICES And reimbursement of MEDICINES: Application* | Summary provided | 13 |
| Croatia | Agency for Quality and Accrediation in Health Care and Social Welfare AAZ provided documents on behalf of Croatian Institute for Health Insurance | Pravilnik: O mjerilima za stavljanje lijekova na osnovnu i dopunsku listu lijekova hravatskog zavoda za zdravstveno osiguranje (2010) *Ordinance: Establishing the criteria for inclusion of medicinal products in the basic and the supplementary reimbursement list of the Croatian institute for health insurance (2010)*  | Provided | 19 |
| The Croatian Guideline for Health Technology Assessment | Provided | 41 |
| Cyprus | Ministry of Health, Department of Pharmaceutical Services | Did not respond to requests for evidence requirements |  |  |
| Czech Republic | Ministry of Health | Žádost o stanovení maximální ceny výrobce a výše a podmínek úhrady léčivého přípravku / potraviny pro zvláštní lékařské účely (2013) | Summary provided | 3 |
| Denmark  | Sundhedsstyrelsen*Danish Health and Medicines Authority* | Ansøgning om generelt tilskud eller generelt klausuleret tilskud til et lægemiddel *Application for general reimbursement or conditional reimbursement of a pharmaceutical product* | Provided | 1 |
| Vejledning til ansøgning om generelt tilskud.*Guidelines for application for general reimbursement of medicinal products*. | Provided | 8 |
| Vejledning om procedure for revurderinger*Guidelines on procedure for reassessment of reimbursement status* | Provided | 7 |
| Standardised reporting structure for health economic analyses in applications for general reimbursement | Provided | 5 |
| England | National Institute of Health and Care Excellence | Specification for manufacturer/sponsor submission of evidence (June 2012) | Provided | 76 |
| Estonia  | Tartu University Department for Public Health provided documents on behalf of the Estonia Health Insurance Fund | Eesti haigekassa tervishoiuteenuste loetelu muutmise taotlus*Application form to add new health care service or to modify the health insurance service list* | Provided | 5 |
| Finland | Finnish Medicines AgencyAssessment of Pharmacotherapies ProcessFIMEA provided documents on behalf of The Pharmaceutical Pricing Board | Application for reimbursement status and wholesale price for a medicinal product subject to marketing authorization. | Provided | 4 |
| Application instructions: Reimbursement status and whole-sale price for a medicinal product subject to marketing authorization. | Provided | 11 |
| France | Haute Autorite de Sante (HAS) | Dossier Type: Premiere inscription ou extension des indications d’un medicament*Standard Dossier: First assessment of extension of indication(s) of a medicine* | Provided | 18 |
| Notice de depot: Modalites de depot d’un dossier de demande aupres de la Commission de la Transparence*Submission instructions: Procedure for submitting an application dossier to the Transparency Committee* | Provided | 7 |
| Germany | Institute for Quality and Efficiency in Health Care (IQWIG) | Dossier zur Nutzenbewertung gemäß § 35a SGB V | Generated | 115 |
| Greece | National School of Public Health | Did not respond to requests for evidence requirements |  |  |
| Hungary | National Institute for Quality and Organisational Development in Healthcare and Medicines (GYEMSZI) provided documents on behalf of the National health insurance fund (OEP) | OEP evidence requirements (National Health Insurance Fund) | Summary provided | 1 |
| Attempt to increase the transparency of fourth hurdle implementation in Central-Eastern European middle income countries: publication of the critical appraisal methodology BMC Health Services Research 2012, 12:332 http://www.biomedcentral.com/1472-6963/12/332 | Provided | 10 |
| Supplementary file from: Attempt to increase the transparency of fourth hurdle implementation in Central-Eastern European middle income countries: publication of the critical appraisal methodology BMC Health Services Research 2012, 12:332 | Provided | 7 |
| Ireland | Health Information and Quality Authority (HIQA)National Centre for Pharmacoeconomics | Guidance on the Reporting Format and Layout of Pharmacoeconomic Submission to the National Centre for Pharmacoeconomics (Feburary 2013) | Provided | 25 |
| Guidelines for Evaluating the Clinical Effectiveness of Health Technologies in Ireland (23rd November 2011) | Provided | 75 |
| Italy | Agenzia Italiana Del Farmaco (AIFA) | Schema del dossier a supporto della domanda di rimborsabilita e prezzo*Template for the file supporting the coverage and price application* | Provided | 8 |
| Latvia | National Health Service, Centre of Health Economics (VECS) | Evidence requirement in accordance with Davinet Regulation No. 899, adopted 31 October 2006 “Procedures for the Reimbursement of Expenditure for the Acquisition of Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment” | Provided | 3 |
| Lithuania | Ministry of Health | PARAIŠKA: ĮRAŠYTI VAISTINĮ PREPARATĄ Į LIGŲ IR KOMPENSUOJAMŲJŲ VAISTINIŲ PREPARATŲ JOMS GYDYTI SĄRAŠĄ (A SĄRAŠĄ) Application for including of medicinal product into the reimbursement system | Provided | 11 |
| Luxembourg | Union de Caisses de Maladie | Demande d'inscription d'un medicament sur la liste positive des medicaments pris en charge par l'assurance maladie au Grance Duche de Luxembourg | Generated | 11 |
| Malta | Directorate for Pharmaceutical Affairs (DPA) | Application to the Superintendent of Public Health for the consideration of a medicinal product to be covered by the Government Formulary List as per the Government Health Services (Medicinal Products) Regulations, 2007. | Provided | 7 |
| The Netherlands | College voor zorgverzekeringen (CVZ) | Template pharmacotherapeutic dossier for outpatient medicines (GVS) | Provided | 16 |
| Norway | Norwegian Knowledge Centre for the Health Services, NOKC provided documents on behalf of the Norwegian Medicines Agency  | Application standard for acceptance to the drug reimbursement scheme | Provided | 3 |
| Guidelines on how to conduct pharmacoeconomic analyses (1st March 2012) | Provided | 27 |
| Poland | Agency for HTA in Poland (AHTAPol) provided documents on behalf of the Polish Ministry of Health | Regulation of the minister of health of 2nd April 2012 on the minimum requirements to be satisfied by the analyses accounted for in the applications for reimbursement and setting the official sales price and for increasing the official sales price of a drug, a special purpose dietary supplement, a medical device, which do not have a reimbursed counterpart in a given indication. | Provided | 5 |
| Guidelines for conducting Health Technology Assessment (HTA) | Provided | 44 |
| Portugal | National Authority of Medicines and Health Products (INFARMED) | Requests for prior assessment of medicinal products for human use in hospital setting | Provided | 6 |
| Romania | National School of Public Health, Management and Professional Development NSPH MPD | Replied to say there were no templates available |  |  |
| Russia | National Center for Health Technology Assessment provided documents on behalf of the Ministry of Health | Submission template | Provided | 1 |
| Form for reporting the results of scientific evaluation of the proposal on including a pharmaceutical in the Essential Drug List | Provided | 2 |
| Regulation of the ministry of health on the procedure of compiling draft essential drug list | Provided | 6 |
| Scotland  | Scottish Medicines Consortium (SMC) | New Product Assessment Form (March 2012) | Provided | 14 |
| Guidance to Manufacturers for Completion of New product Assessment Form (March 2012) | Provided | 51 |
| Slovakia  | Ministry of Health of Slovak Republic, Section of Pharmacy and Medicines Policy, | Farmako-ekonomický rozbor lieku (na účely kategorizácie liekov)*Pharmacoeconomic analysis of a drug (for the reimbursement process concerning to a drug)* | Provided | 2 |
| Slovenia  | National Institute of Public Health (NIPH) provided documents on behalf of the Health Insurance Institute of Slovenia  | Priloga pravilnik zdravila HTA | Provided | 10 |
| Spain | Directorate General for Pharmacy and Health Care Products (Spanish Ministry of Health) | Replied to say there was no national level reimbursement process |  |  |
| Sweden | Dental and Pharmaceutical Benefits Agency (TLV) | ANSÖKAN - om att ingå i läkemedelsförmånerna samt om pris på läkemedel | Generated | 5 |
| Guide for companies when applying for subsidies and pricing for pharmaceutical products | Provided | 54 |
| Switzerland | Swiss Federal Office for Public Health (SNHTA) | Données-clés pour une nouvelle demande d'admission (ND) d’une préparation originale de médecine classique | Generated | 11 |
| Handbuch betreffend die Spezialitaten-liste | Generated | 77 |
| Turkey | Turkish Evidence-based Medicine Association (KDTD) provided documents on behalf of the Social Security Institution | Summary of submission template for manufacturers in Turkey | Summary provided | 13 |