# Table Of Content

**Statistical data and Guidance Document for medicinal product pricing and for the use of ERP** ........................................ 2

**Summary** .................................................................................. 3

**Work Package** ........................................................................... 9
- Project management ................................................................. 9
- Dissemination ............................................................................ 9
- Evaluation .................................................................................. 9
- Determining an optimized dataset and data lay-out for the presentation of information related to medicinal products pricing to better coordinate national policies in the area of external reference pricing ................................................. 9
- Organization and maintenance of the provision of information related to medicinal products pricing in a standardized web-based format ................................................................. 9
- Development of a Guidance Document on a coordinated approach of national authorities regarding the use of external reference pricing to avoid/mitigate negative impact for patient access to medicines ............................................................................. 9

**Coordinator, Leader contact and partners** .................................. 12
- GESUNDHEIT ÖSTERREICH GMBH ........................................... 12
- PHARMEC A S ............................................................................. 12
- TANDVARDS-OCH LAKEMEDELSFORMANSVERKET ........... 12
- STATNI USTAV PRO KONTROLU LECIV ................................ 12

**Outputs** ....................................................................................... 14
- Layman version of the final report ............................................. 14
- Final report ................................................................................. 14
- Short media text ....................................................................... 14
- Final evaluation report .............................................................. 14
- Evaluation report of the optimization ....................................... 14
- Guidance Document ................................................................ 14
- New website features .............................................................. 14
- Periodic report(s) ..................................................................... 14
- Half-time evaluation report ...................................................... 14
- Needs analysis report .............................................................. 14
- Dataset and lay-out optimization plan ...................................... 14
- Updated fact sheet template .................................................... 14
- Best practice models for ERP .................................................. 14
- Leaflet ....................................................................................... 14
Statistical data and Guidance Document for medicinal product pricing and for the use of ERP

JA2015 - GPSD [705038]

| START DATE:       | 01/08/2015          |
| END DATE:         | 31/07/2018           |
| DURATION:         | 36 month(s)          |
| CURRENT STATUS:   | Finalised            |
| PROGRAMME TITLE:  | 3rd Health Programme (2014-2020) |
| PROGRAMME PRIORITY: | -                  |
| CALL:             | Call for Proposals for Projects 2014 |
| TOPIC:            | Statistical data for medicinal product pricing |
| EC CONTRIBUTION:  | 299999.7 EUR         |
| KEYWORDS:         | Dataset Optimisation, Guidance, Patients' Access To Medicines, Statistical Data On Medicinal Products Pricing |
| PORTFOLIO:        | Medicinal products for human use |
Project abstract

The proposal is an answer of the Executive Committee of the EURIPID Collaboration to the call “Statistical data for medicinal product pricing” of the EC, DG Sanco, operated by the CHAFEA. EURIPID is a joint undertaking of currently 24 EU Member States, EEA and candidate countries to operate an online database for medicinal products prices and related information. The proposal’s main objective is to achieve a better coordination at the EU level in order to facilitate the control by the Member States of public budgets for medicinal products (e.g. external reference pricing, ERP) and to avoid/mitigate possible negative impacts on patient access to medicines.

To attain this objective the proposal identifies the following specific objectives: 1) optimisation of the dataset and layout of the existing EURIPID database and website, 2) providing the necessary information related to medicinal product pricing in a standardised web-based format and 3) developing a Guidance Document (an operational policy paper) on a coordinated approach of national competent authorities regarding the use of ERP to avoid/mitigate negative impact for patient access to medicines.

The expected outcomes of the proposed activity are: 1) an optimised dataset and layout in EURIPID database, 2) continuous information provision for the national authorities in a sustainable way to improve their understanding and use of ERP and 3) a Guidance Document that could serve as a technical reference document for countries using ERP.

The national competent authorities in Europe and stakeholders as e.g. represented in the Platform on Access to Medicines in Europe will be invited to jointly reach the objectives.

The proposal was approved by the Board of Participants of EURIPID Collaboration. The broad support of the national authorities, the experienced project team and the proven technical platform of EURIPID which is operational since 2010 is a solid and reliable basis to successfully achieve these objectives.

Summary of context, overall objectives, strategic, relevance and contribution of the action

Pricing of pharmaceuticals is a national competence in the European Union therefore a better coordination of pricing in Europe could only take place on a voluntary basis.

EURIPID is a Europe-wide voluntary collaboration of national competent authorities for pricing and reimbursement established in 2010. The focus of the collaboration is to make prices of reimbursable pharmaceuticals transparent with the help of an online-accessible, comprehensive, reliable, continuously maintained and up-to-date database. The EURIPID database
contains publicly available information about medicinal products (including but not limited to prices) in a standardised format based on the data delivery of the national competent authorities. The project’s main objective was to achieve a better coordination at the EU level in order to support Member States in their endeavour to manage public budgets for medicinal products (e.g. external reference pricing) and to mitigate the possible negative impacts on patient access to medicinal products. To attain this purpose the critical revision of the current data set and the identification of the optimised data set was necessary.

The adequate interpretation of information related to pricing procedures of medicinal products is an important precondition for doing external reference pricing (ERP) in an appropriate way. The EURIPID Collaboration provides background information to support users when interpreting prices of medicinal products. Therefore it is considered as essential to further develop and improve information provision/sharing within the EURIPID Collaboration. Technical recommendations for the national competent authorities were intended to be elaborated during the course of the project in cooperation with all stakeholders to help the coordination of external reference pricing activity in Europe thus mitigating any potential negative aspect of ERP on patients’ access to medicines.

A main activity is to further maintain the already existing EURIPID database in order to provide regularly updated and reliable information on pricing of medicinal products.

Methods and means

1. Determining an optimised dataset and data lay-out for the presentation of information related to medicinal products pricing to better coordinate national policies in the area of external reference pricing

The national competent authorities of the EU Member States, EEA/EFTA countries and the members of the EURIPID Collaboration as well the stakeholders of the Platform on Access to Medicines, supranational organisations were invited to contribute to achieve the objective of the proposal. The invitation was sent to the national competent authorities of 31 countries of the EU and EEA/EFTA and to 19 stakeholders.

Following the needs assessment survey as the shared planning document of the first phase IT developments the User’s Requirement Specification document was prepared and shared with the participants and the users of the EURIPID website. The User’s Requirement Specification was endorsed by the stakeholders and formally approved by the Board of Participants of the EURIPID Collaboration.

The intended update of the country “fact sheet” (i.e. the country background information that contains the country specific information which is important for the right interpretation of the prices but cannot be linked to the products)
was changed to an integration into the website. The development of the EURIPID website was based on the User's Requirement Specification and carried out following the software development standards of NEAK.

2. Provision of necessary (additional) information related to medicinal products pricing in a standardized web-based format

The data provision happened in the same way as in previous years (data provision by the national competent authorities, data standardisation and upload by the project team) but the data upload procedure was improved: new quality assurance measures were introduced. The data content of the EURIPID database was extended: information on sales volumes and on the existence of managed entry agreements became available. The data provision and upload of this data follows the same business model as of the price information.

Recruitment activity was focusing on including the missing EU Member States and EEA/EFTA countries, no new member could be recruited and Croatia quit the Collaboration in 2018 however the Croatian data are regularly updated even after.

Data validation reports were presented to the BoP members in the meeting in Stockholm in April 2017 and in Vienna in June 2018.

3. Developing a Guidance Document on a coordinated approach of national authorities regarding the use of external reference pricing to avoid/mitigate negative impact for patient access to medicines

Following a literature analysis, the EURIPID needs assessment and the EURIPID best practice report, the “Technical Guidance Document on External Reference Pricing” was compiled. Two internal team workshops and two workshops with the stakeholders were organised. The document consists of: a (1) concise overview of the principles in form of an Executive Summary and (2) a more detailed technical background report also explaining the method how the principles were developed. The Board of Participants of the EURIPID Collaboration endorsed the twelve principles and the whole document in accordance with the decision making procedure of the EURIPID Collaboration.

Work performed during the reporting period

Nearly all functionalities of the EURIPID website were renewed in the reporting period including the user management, search interface, country background information management, predefined queries, graphic interface, data management (data input, data quality control and data editing). The developments took place in two phases: the general developments were done in the first phase while the extension of the data-content of the website (information on sales volumes of reimbursed medicinal products and information on the existence of managed entry agreements) took place in the
second round.

In addition to the described project activities, the regular operation of the EURIPID Collaboration went on with the price information update of the EURIPID database, the data standardisation revision and the price information validation.

Based on the findings of the literature analysis and an assessment of best practices on ERP in Europe, the study authors developed a technical guidance document of ERP. The guidance document neither debates the appropriateness of ERP nor discusses alternative policy options or approaches, but tries to give guidance on how to apply it by avoiding or mitigating potential negative effects on access to medicines by patients. The guidance document consists of: a (1) concise overview of the principles in form of an Executive Summary and (2) a more detailed technical background report which explained how the principles were derived.

The main output achieved so far and their potential impact and use by target group (including benefits)

The project envisaged three main outcome: optimised dataset and lay-out in the EURIPID website, continuous information provision for the national competent authorities in a sustainable way and a technical guidance document on ERP. All stakeholders were invited to participate in achieving the first and third outcome while the impact of the second outcome will be restricted to those who can get access to the EURIPID website: the experts of the national competent authorities of the participating countries and the services of the European Commission.

The EURIPID website was completely renewed during the reporting period and the new website supports better interpretation of price information for the users of the website. Furthermore, the most important information about the EURIPID Collaboration became available for the general public. The new website also contributes to the improvement of the maintenance of high quality information.

The price information from 25 countries was continuously available throughout the whole project period while the information on the existence of managed entry agreements and sales volumes was available from 5 countries by the end of the project.

The technical guidance document on ERP was finalised and approved by the members of the EURIPID Collaboration. Members of the EURIPID Collaboration are committed to further collaborate on matter of pharmaceutical pricing and bring the guidance document in national dialogues -where relevant and within their remit- and to consider its principles in national decision-making.
Pharmaceutical pricing and reimbursement experts of the national competent authorities are the primary target group of the project. The national competent authorities will benefit from the improved functionalities of the website and especially from the extended data content. Stakeholders in the field of pharmaceutical pricing policies constitute the secondary target group of the project. A significant novelty of the grant activities is – compared to the previous activities of the EURIPD Collaboration – that a formal cooperation was started with the stakeholders who were invited to take part in the revision of the functionalities of the EURIPID website and in the development of the technical guidance document on ERP. The dialogue with the stakeholders of the pharmaceutical sector is intended to continue and to be institutionalised.

Achieved outcomes compared to the expected outcomes

The development of the project outcomes are in line with the expectations of the project plan, no major discrepancy has been identified so far.

Dissemination and evaluation activities carried out so far and their major results

The website of the EURIPID Collaboration (www.euripid.eu) is exclusively available for the experts of the national competent authorities of its participating countries and for the services of the European Commission. The EURIPID Collaboration has never promoted its activities outside of the circle of the European national competent authorities but under the grant a formal cooperation in form of a multi-stakeholder dialogue was started with stakeholders in the field of the pharmaceutical pricing and reimbursement policies. The stakeholders were invited to contribute to the project by sharing their perspectives.

An information leaflet was prepared which includes the most important facts and figures about the EURIPID project for the public.

The activities required in the area of evaluation, in the second half of the project, were concentrated primarily on the preparation of the final evaluation report and the continuous monitoring of the project accomplishments. The evaluator had to keep the track of the project and collected evidence on reaching the milestones and finalising the deliverables from the participant web portal. In general, the performed evaluation confirmed positive results of
the project, since all deliverables and milestones scheduled for the second half of the Project period have been achieved.
Work package

Work Package 1: Project management
Start month: 1
End month: 36
Work Package Leader: OEP

- Overall contract management (compliance with rules of the European Commission reporting, accounting, controlling, time sheets and internal regulation of the applicants)
- Organization and documentation of meetings and telephone conferences (EC, Executive Committee, Board of Participants, team meeting)
- Preparation of annual work plan and seeking approval of Executive Committee and EC services
- Monitoring the evolution of the project via the Executive Committee
- Strategic decisions (Board of Participants)

Work Package 2: Dissemination
Start month: 1
End month: 36
Work Package Leader: OEP

- Continuous update of the website with materials (focus is online)
- Preparation of a project newsletter on a quarterly basis
- Preparation of reports (incl. editing, graphics, proof reading, etc.)
- Drafting a laymen summary for publication
- Drafting a text for a press release or text for DG Health and Consumers Newsletter
- Use of the logo of the European Union on all materials and on the website

Work Package 3: Evaluation
Start month: 6
End month: 36
Work Package Leader: Pharmeca a.s.

- Checking on the project progress through reaching indicator targets, deliverables and milestones of the individual WPs.
- Reporting any discrepancies found in comparison with the plan to the Executive committee
- Checking on the achieving the indicator targets, deliverables, reaching the
milestones and reporting as outlined above will be conducted twice during the project period

Work Package 4: Determining an optimized dataset and data lay-out for the presentation of information related to medicinal products pricing to better coordinate national policies in the area of external reference pricing
Start month: 2
End month: 36
Work Package Leader: G

- invitation of members of the EURIPID Collaboration and further national authorities and stakeholders to actively participate in the undertaking
- surveying the participants and stakeholders experiences and assess their needs in relation to external reference pricing in the light of its aspects on patients’ access to medicines on the EU level
- assessing the need for further online reports and develop them (e.g. Visualization price changes triggered by changes in exchange rate rather the actual local price changes.)
- planning the implementation of the dataset and lay-out optimization
- testing the implementation of the optimization on the website
- final adaption of the optimization
- updating the country fact sheet template and have participants complete it with necessary information
- development of IT platform for the country background information provision

Work Package 5: Organization and maintenance of the provision of information related to medicinal products pricing in a standardized web-based format
Start month: 1
End month: 36
Work Package Leader: OEP

- Recruitment of participants
- Management of their participation, e.g. keeping contact with the target group, supporting them in the use of the database, offering training sessions etc.
- Standardization of pharmaceutical information of the newly uploaded products according to the Standardization Manual in case of list updates or in case of a new
country.
• EURIPID database and website server updates
• EURIPID database and website development in accordance with the accepted annual IT development plan
• revision of the already standardized information (data standardization revision)
• revision of the calculation formulas of the calculated prices
• control of price validity
• annual revision of country background information

Work Package 6: Development of a Guidance Document on a coordinated approach of national authorities regarding the use of external reference pricing to avoid/mitigate negative impact for patient access to medicines
Start month: 6
End month: 36
Work Package Leader: G�G

• literature review
• ERP best practice survey in two phases
• elaboration of the Guidance Document in collaboration with the participants
• adaption of the Guidance Document in a workshop
COORDINATOR, LEADER CONTACT AND PARTNERS

COORDINATOR

NEMZETI EGESZSEGBIZTOSITASI ALAPKEZELO (OEP)
Váci Street 73/A
1139 Budapest
Hungary
WEBSITE: http://neak.gov.hu

PARTNERS

GESUNDHEIT ÖSTERREICH GMBH
Street: Stubenring 6
City: 1010 Wien
Country: Austria
Website: http://neak.gov.hu

PHARMECA AS
Street: V haji 217
City: 25206 Mechenice
Country: Czech Republic
Website: http://neak.gov.hu

TANDVARDS-ÖCH LAKEMEDELSFORMANSVERKET
Street: FLEMINGGATAN 7
City: 12862 SKONDAL
Country: Sweden
Website: http://neak.gov.hu
Country: Sweden
Website: http://neak.gov.hu

STATNI USTAV PRO KONTROLU LECIV
Street: Za Trati 386
City: 747 81 Otice
Country: Czech Republic
Website: http://neak.gov.hu
Layman version of the final report

Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
Published on: 09/08/2018
This is a short (e.g. 10 pages) version of the final report, written for the interested public as a target group.

Final report

Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
Published on: 21/11/2018
This report describes the project implementation and the results achieved. The deliverables are annexed.

Short media text

Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
Published on: 21/11/2018
Short text for EC website or newsletters as well as for countries websites or press releases outlining the conclusions and recommendations from the Guidance Document.

Final evaluation report

Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
Published on: 21/11/2018
Describing the final status of the project.

Evaluation report of the optimization

Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
the use of ERP (EURIPID)
Published on: 09/08/2018
Evaluation report of the testing phase of the implementation of the dataset and lay-out optimization.

Guidance Document
G‡G
Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
Published on: 09/08/2018
Finalized and endorsed Guidance Document.

New website features
OEP
Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
Published on: 29/06/2018
IT implementation of the dataset and lay-out optimization.

Periodic report(s)
OEP
Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
Published on: 19/06/2017
This report describes the activities carried out, milestones and results achieved in the first half of the project.

Half-time evaluation report
Pharmeca a.s.
Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
Published on: 19/06/2017
Describing the half-time status of the project.

Needs analysis report
G‡G
Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
Published on: 19/06/2017
Report on the outcome of the needs assessment.

Dataset and lay-out optimization plan
OEP
Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
Published on: 19/06/2017
Database and website development plan in the light of the survey outcome report.

Updated fact sheet template
GG
Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
Published on: 19/06/2017
Updated country fact sheet template that helps the background information provision in order to allow users to rightly interpret the presented information.

Best practice models for ERP
GG
Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
Published on: 19/06/2017

Leaflet
OEP
Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)
Published on: 02/05/2017
Leaflet to introduce the project will be available on the website.