1 – Identification:

- Title of the case: “e-appointment system”
- Name of the organisation:
  HELLENIC REPUBLIC
  MINISTRY OF HEALTH AND SOCIAL SOLIDARITY
  NATIONAL ORGANIZATION FOR MEDICINES (EOF)
  Validation of Applications & Marketing Authorization Division (DDYEP)
- Name of the person in charge: Dr. A. Koutsouki
- Email koutsoukil@eof.gr & sgiannakou@eof.gr / phone: +30 210 65 07 208
- Level: National
- Sector healthcare/ public services
- Conference sub-theme: 1: Improving citizen’s lives

2 – Summary

In its continues effort to stream-line administrative procedures and reduce administrative burden, DDYEP has implemented an on-line e-appointment system, through which interested parties (applicants) arrange schedule visits. The explicit objective of this initiative has been to balance the Division’s strategic priorities with its stakeholders’ needs, while increasing process transparency, and to simplify departmental processes through the use of available technologies.
3 - Quality Improvement issues

The Validation of Applications & Marketing Authorization Division (DDYEP) of The National Organization for Medicines (EOF) of Greece, is the Organization’s first-stop in assessing the quality, efficacy and safety of pharmaceutical products (for human and veterinary use) and authorizing their sale in Greece. Prior to their submission for consideration, all applications are physically accepted and reviewed (validated) for completeness and quality by the Division’s assessors. The validation process often requires multiple visits by the interested parties (applicants), both for the purpose of documentation review as well as provision of guidelines through which to address National and European regulatory requirements.

Through the implementation of the e-appointment system the Division has been able to cope with the increasing pressure on resource utilisation, and to meet the challenges of orienting its approaches to be more customer-focused; to consolidate individual effort and embrace a team based approach within its policy boundaries; and to continuously improve on existing systems by making use of available technologies, while preparing for future challenges.

The initiative’s strategic objectives were the following:

- to increase process transparency by directly involving the applicants in the formulation of the visit schedule,
- to ensure fair treatment of all applicants, independent of their Organization’s size, influence, and market share considerations,
- to provide services which meet applicant needs rather than to arrange services based on Division capabilities,
- to create an environment of common purpose and cooperation between the Division and the applicants, and finally,
- to develop a standardized process, which can be monitored, measured, analysed and continuously improved.

The system’s operational objectives were the following:

- to increase the Division’s operational effectiveness by controlling the amount and quality of time spend with each applicant,
- to control the variance between the time spend with each applicant, ensuring that all receive the services they require,
- to eliminate idle time between applicant visits,
- to ensure effective long term scheduling of Division staffing.

During the system’s design process, applicant input was solicited and captured through planned meetings with a number of Associations, representing applicant interests.

Prior to the system’s implementation, standard operating procedures were documented and incorporated into the Division’s Quality Management System. Further, a user-friendly work instruction was developed and disseminated through the Organization’s official web page. Formal training was instrumental in ensuring that Division personnel were aware of the relevance and importance of their performance relative to achieving the Division’s objectives.

4 – Project Background

The National Organization for Medicines of Greece (EOF) was established in 1983, and is a public entity of the Ministry of Health. EOF’s mission is to ensure public health and safety with regard to the following products, marketed in Greece: medicinal products for human and veterinary use, medicated animal foods and food additives, foodstuffs intended for particular nutritional use and food supplements, biocides, medical devices, and cosmetics.

EOF is administered by a Management Board. The Organization’s present structure was established in Presidential Decree 142/89. It has 9 Divisions.

Currently, EOF is staffed by 239 employees, including pharmacists, chemists, physicians, biologists, and veterinarians as well as economists, mathematicians, lawyers, information scientists and administrative assistants. The Organization also cooperates with approximately 400 external health related scientists of various specialties.

The Validation of Applications & Marketing Authorization Division (DDYEP), is the Organization’s official “portal”. Prior to their submission for consideration, all applications
are physically accepted and reviewed (validated) for completeness and quality by the Division’s personnel. The Division also issues all of EOF’s decisions pertaining to approval, renewal, variation and recall, of Marketing Authorizations. Finally, the Division is responsible for the storage and maintenance of all the Organization’s archives.

The Division is currently staffed by 27 employees, structured in 4 Departments (Sections). These are:

- Secretariat and Administrative Control Section
- Validation and Registration of Applications Section
- Electronic Data Management
- Archives Section

There has been increased recognition that public agencies have to improve and modernize their services through the implementation of quality management tools and techniques, in order to satisfy the needs of their stakeholders. The Validation of Application & Marketing Authorization Division of EOF has embraced the concept of quality, and has assumed a proactive strategy towards meeting its stockholder’s needs. The first step towards this was to develop a documented Quality Management System consistent with the requirements of ISO 9001:2000. The ultimate goal of the ISO 9000 certification, which was achieved in May of 2006, was to improve the consistency and control of the Division’s core processes which operate with complete integrity and transparency. The next step is to challenge practices, pursue stretch goals, benchmark the Division’s performance against other Organizations, and provide a source of inspiration.

In view of continuous improvement within the Division’s quality policy and scope, an Internet application for the scheduling of meetings with DDYEP’s personnel for the purpose of administrative assessment/ validation and guidance, referenced as “E-appointment system” has been developed. The necessity of this application rose through customer’s satisfaction questionnaires, evaluation of complaints, outcomes of internal inspections, employee suggestions and improvement of procedures.

The driving force behind the development and implementation of “e-appointment system” within DDYEP is to cope with the increasing pressure on resource utilisation, to meet the
challenges of orienting its approaches to be more customer-focused, to seek out and make use of available technologies, to ultimately utilize the time of personnel and stakeholders, to secure transparency and equity and to continuously improve on existing systems, while preparing for future challenges.

5 – The Actors

The need for the development of the **e-appointment system** was the result of a structured review conducted by the Division’s Quality Team (lead by the Division’s Director) in an effort to assess the Division’s adequacy and effectiveness. The system’s development was supervised by the Division’s Director and managed by a working group comprised of Division personnel, representing the various functions.

An initial feasibility study was conducted which lead to a project proposal that was presented for approval to the Organization’s Management Board. The feasibility study included the strategic and operational objectives of the initiative, cost considerations and a relative implementation time-line.

Following Board Approval, a number of meetings were held between the Division’s Director and Associations representing applicant interests, in which specific requirements were discussed, identified and prioritized. Division personnel provided functional information relevant to the system’s development, and contributed positive ideas, which led to a user-friendly application.

The **e-appointment system** was developed in cooperation with an external vendor, which the Organization contracted for that purpose. System requirements *(deliverables)* were defined and agreed within the technical capacity of the Industrial technology Division of the Organization. An action plan was formulated identifying development stages, responsibilities, time-lines, quality considerations and reviews. Planned training ensured the competence of all Division personnel.

Prior to the system’s deployment, a multi-day conference was organized and attended by stakeholders and Division personnel. The objective of the conference was to introduce the system, to provide training on the use of the system, and to collect feed-back relevant to system adequacy.
Following the system’s deployment, stockholder’s perception relating to the system’s effectiveness was captured through the use of structured questionnaires and analyzed by the Quality Management Team as part of its formal system review. A number of system improvements were identified and incorporated in subsequent upgrades.

6 – The Work process / the Approach

Following the Organization’s Management Board approval for the implementation of e-appointment system, a five-member team was formulated, and an external vendor was contracted to assist in the development of the required software application. All requirements were considered early in the system’s development process, through planned meetings with Division personnel and a number of Associations, representing applicant interests. The Division went to great lengths to ensure that all pertinent process, customer, regulatory, and other requirements were discovered early in the process. Missing or conflicting requirements were identified and resolved before they negatively affected the system’s development. The system was developed in a total of six months.

At the end of each development phase the team conducted a lessons learned analysis to identify opportunities to improve the development process.

The results of each step in the development process were documented in a design process workbook. Key activities were assessed systematically to ensure that they conformed to the objectives of the initiative.

Development errors, mistakes, and problems were logged so that additional analysis can be performed and so that critical failure information was not lost.

Corrections based on development errors were specifically analyzed to determine where the development process failed.

Development methods, practices, schedules, reviews, and other elements were studied to ensure that they were working effectively and efficiently, and that the resulting application met all of the requirements imposed by the initiative’s strategic objectives.
The table below highlights the actions and timeline of the **e-appointment system** initiative’s development.

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The development cost of the **e-appointment system** relative to the design of the software application was less than 20,000 euros. The system was designed so that it could be deployed using the existing hardware which the Organization had available.

### 7 – *The Measure of Success*

The implementation of the **e-appointment system** has had a positive impact on the Division’s ability to effectively cope with the increasing requirements of application documentation. The direct involvement of the applicant in the scheduling process has resulted in a well-structured relationship between the applicants and the Division, the assurance of transparency in the validation scheduling process, and a means through which to collect valuable data on applicant visits. Analysis of operational performance data, including audits, provides an indication of how well the Division’s capabilities are being improved.

Process indicators, both qualitative as well as quantitative, are used to monitor performance. These include, number of appointments scheduled, held, missed, repeated, per category, per assessor, for a give time period, etc.
Through the use of a customer satisfaction survey the Division has been able to accurately capture applicant satisfaction with the performance of the e-appointment system and to introduce corrective actions where deemed necessary. The Division’s customer satisfaction survey processes are evaluated annually to improve the survey questions and survey response rate.

A number of access mechanisms are in place to allow customers to seek assistance, voice complaints, get information, and communicate with the Division relative to the e-appointment system. The approaches have been designed to reflect the preferences of applicants for the specific “means of access” that they want. Resolving complaints effectively and efficiently has helped the Division improve satisfaction and build positive relationships with applicants.

There is an Annual Management review where the relevant process owners present performance issues to the Division’s Management. A strategy and/or action plan is developed and incorporated into the Division’s Objectives to ensure that performance issues are addressed.

Through ongoing internal/external assessments and audits, observations are identified and corrective action plans put in place to address them. On a quarterly basis, the Division publishes a report that summarizes this information and the progress made in closing any outstanding items. Annually, this information is consolidated and reported to the Organization’s Management Board.

8 – The Main Obstacles of the Case

The development of the on-line scheduling system required an alignment of the Division’s processes with the remaining functions necessary in application review. The application review process involves a number of successive stages, which must be successfully completed in order for medicinal products to be licensed so that they can be marketed in Greece. An ineffective application documentation review process may cause delays on the part of the Organization, and/or need for subsequent documentation submission and revision, on the part of the applicant (licensee).
The Division’s on-line scheduling system needed to replace the existing (manual) system in a relatively short period of time so as to proactively control the anticipated “resistance to change”. It was believed that the use of the e-appointment system in conjunction with (rather than instead of) the manual system would have an adverse affects on the system’s effectiveness and thus on the initiative’s strategic objectives. The technical competence of both Division personnel as well as that of the applicants was essential to the systems successful deployment. Formal education and training ensured that the required competence was achieved and that any shortcomings addressed. Feedback collected during the training sessions were communicated to the system’s development team. Corrective actions on the system’s modules were implemented and their impact on the system’s effectiveness verified.

A number of circulars (formal communications on part of the Organization) were drafted and made available through the Organization’s web page. In addition to ensuring that applicants were made aware of the Division’s policies pertaining to the e-appointment system, the circulars were intended to provide the necessary information on required actions on the part of the applicants prior to system use.

The Division compiled appropriate process-related documentation for the processes and sub-processes involved in the on-line scheduling system. This documentation allowed these processes to be understood in detail. The Division’s on-line scheduling process documentation also includes “connections” or “linkages” to other processes, so that these interactions can be studied and improved.

9 – Lessons learned

The utilization of technological innovations to improve traditional processes has been successful in achieving the desired results.

The direct involvement of the Applicants in the Division’s scheduling process has had a positive impact on the effectiveness and efficiency of the Division’s validation activities.

The systematic capture of stakeholder requirements leads to initiatives aligned with expressed and implied needs and encourages results achieved through a common approach and co-operation.
The increased transparency of the validation scheduling process has proactively addressed applicant grievances, and has resulted in cultivating a spirit of common purpose.

Analysis of visitation scheduling statistics allows for better staffing decisions, hence providing better services which meet applicant needs. Process control obtained through systematic analysis expedites the required workload and makes better use of limited resources.

10 – Project Innovation Content and Adaptability

Through the use of the e-appointment system non-value adding activities pertaining to applicant visits has been minimised. Processes requiring bureaucratic procedures can be redefined with the use of innovative approaches. The use of technology to augment traditional procedures will result in an increase in the effectiveness of existing systems and resources, including human resources.

This application would be of value in an environment where highly skilled professionals are burdened with bureaucracy, which adds little value to the outcome of the process.

Any size organization could benefit from the use of an e-appointment system given that the implementation of the system is effectively communicated and deployed.

The initiative’s explicit objectives have been to streamline the communication process between DDYEP and its customers in a manner, which embraces integrity, efficiency, and transparency. The project’s implicit objectives have been to better utilize the existing personnel so as to achieve higher productivity levels, thus allowing more time for administrative reviews and the delivery of consultation services. DDYEP’s performance in relation with these objectives as monitored through indicators as well as customer satisfaction measurements obtained with questionnaires designed for this purpose demonstrates an increase in productivity with a parallel increase in customer satisfaction.