VALUE IN HEALTH REGIONAL ISSUES 2 (2013) 284–289

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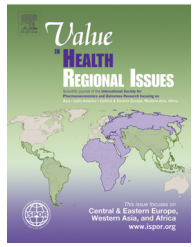

Dossier System as a Practical Tool for Compiling Reimbursement Lists

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ABSTRACT

The article describes the procedure for preparing reimbursement lists with the "Dossier" automated system at the regional level. Basic advantages and characteristics of the system, procedures for filling out the application form (dossier) for the inclusion of the drug into reimbursement lists, and the algorithm of expert evaluation are presented.

Keywords: "Dossier" automated system, health technology assessment (HTA), reimbursement lists.

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Introduction

The project of preparing formulary lists of pharmaceutical drugs at various levels, from formularies for particular medical organizations to federal lists, has been going on in Russia for nearly 20 years. These lists are made by different expert bodies and serve a number of functions: provide the basis for state regulation of prices, determination and adjustment of wholesale and retail surcharges, drug reimbursement, and state supply orders in health care.

At present, the system of drug selection at the federal level is the most transparent and well regulated [1–3], while that at the level of medical organizations is the least developed. As for the rules and procedures for making reimbursement lists at the regional level, in practice there are no standardized requirements or criteria for drug evaluation: the principles and rules of drug evaluation, decision-making criteria, and requirements concerning the information to be submitted vary to a considerable extent (if such mechanisms exist at all) [4]. The need to standardize the requirements for expert evaluation and submission of information about the drug, the decision-making criteria, the implementation of the principles of evidence-based medicine, and clinical and economic analysis (pharmacoeconomics), as well as the need to make the process of decision making for the inclusion of particular drugs in the regional reimbursement lists more transparent, has led to the creation of an automated system called "Dossier" for the preparation of formulary lists.

This system was originally created as a potential health technology assessment (HTA) tool for compiling reimbursement drug lists on the regional level. If and when necessary, however, such a system can be easily adapted for the purpose of compiling formulary lists on the federal and hospital/medical organization's levels.

Currently, there is no accredited official HTA body in Russia. Formulary commissions working on the different levels of the health care system can serve as prototypes of such HTA bodies. Unified algorithms, criteria, and decision-making rules as well as evidence-based medicine and clinical and economic analysis principles that were developed within the framework of the Dossier automated system represent an important platform for incorporating the HTA methodology in the activities of the aforementioned expert organizations.

Dossier: An Automated System for the Preparation of Reimbursement Lists

Dossier, an automated system for preparing reimbursement lists (hereafter referred to as "the system"), was developed in the Research Center for Clinical and Economic Evaluation and Pharmacoeconomics of the N.I. Pirogov Russian National Research Medical University in 2010. It is designed to help formulary commissions of the ministries/departments of health in federal subjects of Russia in their task of preparing reimbursement lists of pharmaceuticals (formulary lists) on the regional level. The online system Dossier allows the user to enter, update, store, and evaluate information about the medicines when they are submitted for inclusion into reimbursement lists. The entire cycle of evaluation is thus supported by the system, from the initial application to the final decision of the formulary commission to grant or refuse inclusion of the drug in the reimbursement list.

Three basic principles were taken into account during the development of the Dossier system: the principle of objective evaluation, the principle of intellectual support, and the principle of informatization, or the information technology principle.

The principle of *objective evaluation* presumes a multilevel assessment of pharmaceutical drugs that includes three main stages: technical evaluation, scientific evaluation (by nonstaff chief specialist of the regional Department/Ministry of Health in different fields of medicine), and the final decision to include (or not to include) the drug into the reimbursement list.

Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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2212-1099/$36.00 – see front matter Copyright © 2013, International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Published by Elsevier Inc.
http://dx.doi.org/10.1016/j.vhri.2013.06.012

Technical evaluation is a preliminary stage of processing the application (drug dossier), which includes verifying whether the data submitted by the applicant meet all relevant requirements. Scientific evaluation is the stage of assessment by a chief specialist. This task calls for expertise in a particular medical field and a good working knowledge of modern therapies and management of the disease in question in real-life clinical practice and its current financial burden. The evaluation includes an analysis of data on clinical efficacy and cost-effectiveness of the drug, real-life management of patients covered by the regional reimbursement scheme, the cost of the new medication, and so on.

The first two stages of the evaluation take place on the Web page of the automated system. At the third stage, members of the formulary commission meet and discuss the issue with chief specialists, and after their meeting, the decision of the commission is posted on the Internet page.

The principle of *intellectual support* refers both to the applicant (usually members of the pharmaceutical industry) and to health care authorities (regional ministries or departments of health, formulary commissions). To implement this principle, the application form contains sections that encourage the applicant to take a more rational approach to the task of determining prioritized indications, target patient groups, and the requested reimbursement. For example, the system asks to specify the patient group, the number of patients covered by the regional reimbursement scheme, the cost of medical treatment of the disease in question, and the estimated cost to the budget of purchasing the drug if it is included in the list for the prioritized group. Thus, the applicant (when requesting that the drug be included in the list), the chief specialist of the Department of Health (when providing recommendations regarding the expediency of adding the new medication to the reimbursement list), and the representative of the Ministry/Department of Health (when deciding whether to include the drug in the list) focus on the actual costs and the actual patients who are already reimbursed for the treatment of this particular medical condition. Thanks to this approach, it becomes possible to provide a clear justification of the need to include the new drug and the additional financial costs that it entails, or, alternatively, of the need to reject the application. The essential considerations that determine whether the drug will be included in the list within the framework of the Dossier system are the following: a reasonable (scientifically proven) reduction in costs for the budget, an adequate (effective and economically expedient) deployment of the available resources, and a clear recognition of the existing situation with regards to the provision of medications to patients covered by the regional reimbursement scheme.

The principle of *informatization* presumes that the submission, evaluation, and scientific analysis of the dossier (application for inclusion in the list) take place online, while the wizard presents prompts (requirements) that guide the user in the process of filling in the blanks. Besides, informatization of the entire process of adding a new drug to the reimbursement list makes the final decision more transparent because the system allows users to track and time each stage of evaluation and decision making and to view comments by experts. Working online makes it possible to ensure interregional cooperation of formulary commissions, and the involvement of experts from various fields (more than 25) enables an interdisciplinary approach to selecting the drugs to be included in the reimbursement lists.

At the moment of publication, the automated system consisted of four independent modules, one for each of the following regions: Moscow region, Sverdlovsk region, Khanty-Mansi autonomous area, and Samara region. More regional modules can be added to the system as required.

Registration and User Levels in the Dossier Automated System

To start using the system, it is first necessary to choose the right region and section and to register. Depending on the accessibility of particular databases and the procedures used for evaluating the submitted applications and for their revision/modification (changing application status), there are five possible user levels: applicant, technical expert, scientific expert, member of the formulary commission, and regional Ministry/Department of Health. The lowest level of access to databases of the system is the applicant level, and the level of regional Ministry/Department of Health is the highest.

Access to various databases of the automated system, authorization to edit/moderate applications (dossiers), menu types, and other options that depend on the user level can be changed (adjusted) depending on the needs of particular regions and medical organizations.

Status of the Applications Stored in the Dossier Automated System

Depending on the stage of evaluation, the application (dossier) stored in the automated system is assigned a particular status (moderation). The system specifies by whom (the name of applicant and expert), when (time), and how (comments on the evaluation and its result) the application was submitted and evaluated and at which time it was assigned a particular status. The status of an application can be modified in the "Moderation" section. The system supports eight different statuses, for example, "under evaluation," "passed" or failed" technical or scientific evaluation, "approved" or "rejected" by the formulary commission, and others. The entire cycle of expert evaluation is thus fully transparent, from the submission of the initial application until the final decision of the formulary commission.

Application Form for Inclusion in the Regional List and Its Completion

The application (dossier) for inclusion of the drug in the regional reimbursement list contains more than 30 sections that may be divided into three main blocks: general information about the medication, or the passport block (name and pharmaceutical group of the drug, etc.); study results, or the evidence block (results of clinical and pharmacoeconomic studies); and the regional specification block (the number of patients entitled to reimbursement in the region, local cost of pharmacotherapy for this disease, as determined by the system based on the submitted *International Statistical Classification of Diseases, 10th Revision* [ICD-10] code, high-priority groups of patients who will be receiving this medication, including the number of patients, the cost of therapy, etc.) (Table 1). The application thus contains as much information as possible not only about the drug but also about the current situation with supply of reimbursed medications in the region. Submitting an application for inclusion in the list and evaluating submitted applications, applicants, chief specialists, and members of the formulary commission together determine the strategy of drug promotion and its potential/optimal place ("niche") in the system of drug reimbursement.

Now we describe in greater detail how to fill out the application and some sections that are particularly problematic in terms of the frequency of mistakes made by the applicants. The sections that seldom give rise to questions and mistakes are mentioned only briefly.

Sections 1 to 8, 10 to 13, and 30 may be called the "passport" part of the application that provides a description of the drug: its name, pharmaceutical form, pharmacotherapeutic group, group of Anatomical Therapeutic Chemical classification, grounds for

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