

# **RPM HUNGARY COUNTRY PROGRAM FINAL REPORT**

Tomoko Fujisaki  
Anthony V. Savelli

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Management Sciences for Health  
1515 Wilson Boulevard, Suite 710  
Arlington, VA 22209 USA  
Phone: 703-524-6575  
Fax: 703-524-7898  
E-mail: [rpm@msh.org](mailto:rpm@msh.org)

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Appendix A: Summary of Sample Analysis of OEP Drug Database

### List of Acronyms

DUR	Drug Utilization Review
HSMTC	Health Service Management Training Centre of the Semmelweis University of Medicine
GP	General Practitioner
HUF	Hungarian Forint (currency)
MSH	Management Sciences for Health
OEP	National Health Insurance Fund Administration (in Hungarian acronym)
RPM	Rational Pharmaceutical Management Project
USAID	US Agency for International Development

# **I. PROJECT OVERVIEW**

## **A. Background**

In the fall of 1997, the US Agency for International Development (USAID) Mission in Hungary requested that the Rational Pharmaceutical Management (RPM) develop and carry out a limited country program on pharmaceutical management in Hungary before the close of the Mission's activities in Hungary in July 1999. In October 1997, RPM Director Anthony Savelli visited Hungary to gain local perspectives on problems in the pharmaceutical sector, and identify appropriate areas for interventions.

Through discussions with the Mission and Hungarian health officials and experts, RPM identified major problems and concerns in the pharmaceutical sector as follows:

- The number of drug products registered in Hungary increased dramatically following the market liberalization and was still increasing. Drug costs were becoming increasingly burdensome to the public health care system.
- Anecdotal information suggested irrational prescribing and use of drugs. Physicians did not consider drug costs in the course of prescribing. Also, they did not have adequate training in clinical pharmacology needed for rational selection and prescribing.
- The list of drugs that was fully subsidized by the government through the National Health Insurance Fund (NHIF) might contain drugs that were not safe or effective.

Based on these findings, RPM and the USAID Mission in Hungary explored the probable focus of RPM activities in Hungary as follows:

- RPM would conduct an analysis, with recommendations, on the list of fully subsidized drugs by the government looking at drug costs, safety, effectiveness, duplication, clinical necessity.
- RPM would work to improve prescribing practices by general practitioners (GP). This group is responsible for the bulk of drug prescription in Hungary. RPM would give serious consideration to working through one of the associations in its work in this technical area.
- RPM would work to improve pharmaceutical services provided at the Vac Hospital. This would support the USAID-funded Hospital Partnership Project and the Disease-Related Group (DRG) Project. (The exact technical activities were to be identified depending on the assessment and discussion with the hospital officials.

## **B. Technical Areas and Activities**

RPM and the Mission agreed on the following three technical areas for RPM activities in Hungary.

### **Technical Area 1**

#### **Assessment of the Subsidized Drug List of the National Health Insurance Fund**

**Objective: Help local counterparts improve appropriateness and sustainability of the drug subsidy system**

**Activities:**

- Conducted desk-top analysis of fully subsidized drug database and recommended a number of deletions of duplicative drug products from the subsidized drug list and promotion of generic and therapeutic drug substitution
- Provided OEP officials with hands-on training in the analysis of drug utilization database
- Recommended steps to improve the use of drug database for monitoring and improving the prescribing decisions by physicians and options for improving drug procurement practices.

### **Technical Area 2**

#### **Survey on General Practitioners' Prescribing Patterns of Antihypertensive Drugs**

**Objective: Provide objective information about prescribing patterns by general practitioners (GPs) in management of hypertension**

- Conducted a survey of prescribing records of GPs
- Presented recommendations on how to promote rational use of antihypertensives by GPs

### **Technical Area 3**

#### **Assessment of Utilization of Hospital Drug Formulary Systems in Hungary**

**Objective: Improve pharmaceutical management at hospitals through promotion of drug formulary systems**

- Conducted a mail survey targeting all 150 hospitals in Hungary to determine the current status of drug formulary systems
- Presented key findings and recommendations to policy makers through individual meetings and the USAID conference

(Note: After an RPM visit to the Vac hospital site and several sessions of discussion with hospital officials, a gap existed between what RPM recommended for feasible and necessary technical assistance and what the hospital officials recognized their needs. The Mission and RPM agreed to drop this line of activity from the work plan.)

## **II. RPM HUNGARY PRORAM IMPLEMENTATION**

### **A. Assessment of the Subsidized Drug List of the National Health Insurance Fund**

#### **Background**

With the liberalization of the Hungarian pharmaceutical market in the 1990s, the number of drugs in the country dramatically increased: It was reported that about 300-400 new drug products were introduced each year in Hungary. As a result, the number of registered drug products increased fourfold between 1990 and 1997, including many “me-too” products and expensive imported drugs whose cheaper equivalents already existed.

Against this background, there were growing concerns among health officials about appropriateness of the selection criteria for drugs subsidized by the National Health Insurance Fund (NHIF). The Hungarian list of subsidized drugs covers a large number of products (3,428 drug products in the 1996 list), and there were concerns that the list might include too many, too expensive, or unsafe drugs with financial and public health implications for the national health care system.

The USAID Mission in Hungary and RPM agreed that the latter would conduct an initial assessment of the subsidized drug list by focusing on 1,095 fully subsidized drug products (Phase 1). During the first phase in the spring of 1998, however, RPM experienced difficulties in obtaining full cooperation of the NHIF Administration (OEP in Hungarian acronym) and gaining access to necessary information to conduct the assessment.

In the summer of 1998, there were major changes in the Cabinet and the Government of Hungary as a result of the parliament election. This dramatic change in the political scenery in the country created a favorable environment for RPM’s collaboration with the OEP. New leadership at the OEP not only supported the further assessment of the subsidized drug list by RPM but also requested RPM for additional technical assistance in exploring ways to rationalize the pharmaceutical benefit scheme (Phase 2).

#### **Objectives of the RPM Activity**

- Evaluate products for potential lack of therapeutic efficacy and possible toxicity risk
- Identify duplication of products within generic drug grouping and within therapeutic classes
- Suggest ways to reduce the duplication on the list

#### **Mode of Implementation**

##### ***Phase 1 – Desk-Top Analysis of subsidized Drug Database for Rational Selection***

Between February and March 1998, RPM consultant Edward P. Armstrong and RPM Senior Program Associate Tomoko Fujisaki conducted a desk top analysis of the 1996 subsidized drug list database obtained from the OEP. Results and recommendations were presented to the USAID Mission in Hungary and key officials at the OEP during the second RPM visit during April and May 1998. At these meetings, Armstrong and Fujisaki proposed joint activities by the OEP and RPM in further therapeutic and financial analysis of the subsidized drug policy. However, the Administration officials did not respond to the proposal.

## ***Phase 2 – Direct Technical Assistance to OEP***

RPM Director Tony Savelli and Fujisaki visited Hungary in February 1999 to determine the area of collaboration with the OEP during the remaining project period. RPM presented to the USAID Mission in Hungary and the executive officials at the OEP key observations from RPM activities in all three technical areas (i.e., subsidized drug list, prescribing survey, and hospital formulary system), and made recommendations that the rationalizing the drug selection and pricing system should be the priority for the Fund Administration. RPM also suggested that the Fund might wish to consider conducting a pilot implementation of hospital drug formulary system at selected hospitals using the RPM manual on hospital drug formulary system development as the first step to the introduction of such a system at larger scale.

In responding the subsequent proposal from Director-General of OEP, RPM consultant Edward P. Armstrong visited Hungary again in May 1999 to provide direct technical assistance to officials at the Administration in analyzing the drug benefit scheme. Armstrong found that although a rich database of drug use at national level existed which could be sorted by patient and by physician, there were no routine report created to assess and monitor medication use within the OEP. Building upon the findings from the first phase of the assessment by RPM, Armstrong conducted detailed analysis of drug utilization patterns together with the OEP officials. The recommendations for possible strategies to address most critical issues were presented to the Director-General and his advisors, some of which were used by the Fund Administration in their reports the Committee of the Pharmaceutical Benefit Scheme – a technical committee reporting to the prime minister on the health reform.

The activity also provided the Fund Administration officials with hands-on training opportunity in analyzing the drug use patterns and designing the reporting system. RPM also provided a number of standard reference materials to the OEP. In addition, RPM prepared and submitted a technical paper on the Reference Drug Pricing Systems for consideration as an option for rationalizing the procurement and pricing of drug products through the Fund.

## **Key Findings and Recommendations**

### ***Phase 1 – Desk-Top Analysis of Subsidized Drug Database for Rational Selection***

The first phase of the assessment of 1,095 fully subsidized drug products revealed that:

- The number of drug products on the list could be reduced by up to 40%. The vast majority of the recommended deletions were for different brand names for the same generic entity. Under the current system of reimbursement, this type of reduction results in inventory savings. (Under a system of reference pricing, the market would determine which brand of a particular drug a pharmacy stocks.)
- A number of recommended deletions were made for drugs known to be ineffective (i.e., papaverine, pentoxifylin), or unsafe (e.g., metamizol, aminophenazon).
- There were very few products with dubious efficacy among items listed for full subsidy.
- The greatest number of fully-subsidized products, as well as the greatest number of recommendations for possible deletion from the list were found in four therapeutic categories according to the ATC Main Groups—
  1. alimentary tract and metabolism,
  2. cardiovascular system,
  3. nervous system

## 4. respiratory system.

These suggested deletions represent 33 % of all fully subsidized drug products. Table 1 presents the summary of fully-subsidized drug products by therapeutic classes.

**Table 1. Summary of Fully-Subsidized Drug products by Therapeutic Classes**

ATC Main Group	Group	Number of Unique Chemical Entities Total N=347	Number of Products in the Class N=1,095	% of Total Number of Products	Number of Suggested Deletions N=442	% of Suggested Deletions Mean =40.4%
<b>A</b>	<b>Alimentary Tract and Metabolism</b>	<b>53</b>	<b>177</b>	<b>16.2%</b>	<b>107</b>	<b>60.5%</b>
B	Blood and Blood Forming Organs	13	24	2.2%	3	12.5%
<b>C</b>	<b>Cardiovascular System</b>	<b>45</b>	<b>160</b>	<b>14.6%</b>	<b>81</b>	<b>50.6%</b>
D	Dermatologicals	27	45	4.1%	4	8.9%
G	Genito Urinary System and Sex Hormones	18	33	3.0%	1	3.0%
H	Systematic Hormonal Preparations, excl. Sec Hormones	14	53	4.8%	23	43.4%
J	General Antiinfectives for Systematic Use	15	44	4.0%	11	25.0%
L	Antineoplastic and Immunomodulating Agents	28	76	6.9%	11	14.5%
M	Musculo-skeltal Syetm	18	51	4.7%	21	41.2%
<b>N</b>	<b>Nervous System</b>	<b>62</b>	<b>220</b>	<b>20.1%</b>	<b>116</b>	<b>52.7%</b>
P	Antiparasitic Products, Insecticides and Repellents	5	5	0.5%	1	20.0%
<b>R</b>	<b>Respiratory System</b>	<b>26</b>	<b>82</b>	<b>7.5%</b>	<b>58</b>	<b>70.7%</b>
S	Sensory Organs	23	32	2.9%	5	15.6%
V	Various	N/A	93	8.5%	N/A	N/A

RPM recommended that:

- Further analysis should be conducted to determine the current patterns of product choice and proportion of drug costs spent by the NHIF for each group of drugs and individual products. For this, data on frequency of use is necessary.
- Introduction of generic and therapeutic substitution be considered in selection, procurement, and use of drug products in Hungary.
- Establishment of a Reference Pricing System be considered as an option for drug reimbursement by the NHIF.

## ***Phase 2 – Technical Assistance for Improving the Drug Selection, Procurement, and Prescribing***

At the second phase of the drug subsidy system analysis, detail information became available to RPM including national level drug utilization data by individual drug products and by prescribers. Summary of key findings and recommendations by RPM is presented below.

### *Drug Utilization Patterns*

Drug utilization patterns and potential financial savings by promoting rational drug prescribing and consumption were examined by reviewing the data of the largest expenditure items. Major observations are listed below. (See Appendix A for detail results.):

- The largest single item in terms of reimbursement costs for the NHIF was vinpocetine (*Cavinton*). This is a product in the “psychostimulant” category. This product has not been shown to be effective in the treatment of dementia or stroke. Potentially huge cost savings (over \$9 million dollars annually) could be achieved by eliminating the product from the subsidy list.
- Similarly, piracetam (*Nootropil 2000*) was another psychostimulant with unproven efficacy that should no longer be covered by the NHIF drug benefit scheme.
- It was estimated that substantial savings could be made when a generic or therapeutic class substitutions are promoted. For example, generic substitutions for major items such as captopril, fluoxetine, and ranitidine could result in 10 billion HUF per year (over \$41,000,000).

As an illustrative example of using the existing OEP drug database for monitoring prescribing patterns of physicians, Armstrong demonstrated to OEP officials an analysis of antibiotic use by physicians. The data indicated that:

- Most of the 39 antibiotics with over 100,000,000 HUF (approximately \$435,000) of annual reimbursement levels were costly penicillin combinations, macrolides, cephalosporins, and quinolones.
- A relatively small number of physicians, especially general practitioners, had costly antibiotic prescriptions that were much higher than those of their peers. For example, 290 out of 3,457 (8.4%) general practitioners accounted for more than \$664,889 (22.4%) out of a total of \$2,968,429 per month costs for antibiotics in Hungary.

Modifying prescribing practices is critical to ensure rational and cost-effective pharmaceutical care. Armstrong recommended the Fund Administration officials to:

- Collect additional data from research in disease management, outcome research, and pharmacoconomics which should provide scientific basis for OEP stopping OEP payment for products without documented efficacy;
- Expansion of standard treatment guidelines development and dissemination of treatment algorithms should be encouraged;
- Develop drug monitoring reports from OEP database (discussed more below);

- Create a physician “report card” for feedback regarding medication use to provide individual physicians. OEP should provide education outreach consultation with providers when opportunities to improve patient care are identified;
- Consider implementation of a “prior authorization” procedure for selected medications or procedures when problems in use have been identified;
- Development of patient information leaflets by OEP should be encouraged to improve patient knowledge about their medications.
- Development of a research and education foundation should be encouraged by strengthening affiliations with universities, non-governmental organizations, Ministry of Health, Ministry of Finance, and industry organizations to encourage research in disease management, health care outcomes, pharmacoeconomics, and database research.

### *Drug Information System*

RPM encouraged OPE to use the existing database for more active assessment and monitoring of health care delivery, especially focusing on the following:

- OEP should consolidate pieces of the database that existed in different parts of the organization and create routine (e.g., quarterly) reports to more accurately monitor changes in disease management, health care trends, and medication use.
- Monitoring of medication use at the individual physicians level should be initiated as it would identify practice variations and help OEP .
- The current data elements should be used in disease modeling and pharmacoeconomic assessments of treatment options.

Following types of routine reports were recommended to the Fund Administration. All reports should be produced by therapeutic class (e.g., ATC group), brand name, and generic name of drug products:

<b>Type of Report</b>	<b>Objective</b>	<b>Necessary Information</b>
1. Rank of Drugs by HUF Spent	Determine spending patterns NHIF	<ul style="list-style-type: none"> <li>- Rank of drug product</li> <li>- ATC group</li> <li>- Brand name</li> <li>- Generic name</li> <li>- Total HUF spent</li> <li>- HUF paid by NHIF</li> <li>- Patient co-payment</li> </ul>
2. Rank of Drugs by the Number of Prescriptions	Determine prescribing patterns of physicians	<ul style="list-style-type: none"> <li>- Rank of drug product</li> <li>- ATC group</li> <li>- Brand name</li> <li>- Generic name</li> <li>- Total HUF spent</li> <li>- HUF paid by NHIF</li> <li>- Patient co-payment</li> </ul>
3. Changes (%) in Monetary Value Spent (HUF) Compared with the Previous Quarter and Year	Determine recent changes in spending patterns for NHIF	<ul style="list-style-type: none"> <li>- Rank of drug product</li> <li>- ATC group</li> <li>- Brand name</li> <li>- Generic name</li> <li>- Total HUF spent</li> <li>- HUF paid by NHIF</li> <li>- Patient co-payment</li> <li>- % HUF spent in last quarter</li> <li>- % HUF spent in last year</li> </ul>
4. Changes (%) in the Number of Prescriptions from the Previous Quarter and Year	Determine recent changes in prescribing patterns by physicians	<ul style="list-style-type: none"> <li>- Rank of drug product</li> <li>- ATC group</li> <li>- Brand name</li> <li>- Generic name</li> <li>- Total HUF spent</li> <li>- HUF paid by NHIF</li> <li>- Patient co-payment</li> <li>- % HUF spent in last quarter</li> <li>- % HUF spent in last year</li> </ul>

Type of Report	Objective	Necessary Information
5. Amount of Patient Co-payment	Determine the financial costs to patients	<ul style="list-style-type: none"> <li>- Rank of drug product</li> <li>- ATC group</li> <li>- Brand name</li> <li>- Generic name</li> <li>- Total HUF spent</li> <li>- HUF paid by NHIF</li> <li>- Patient co-payment</li> </ul>
6. Drugs by Volume of HUF by Physician	Determine high and low cost prescribing physicians	<ul style="list-style-type: none"> <li>- Rank of drug product</li> <li>- ATC group</li> <li>- Brand name</li> <li>- Generic name</li> <li>- Total HUF spent</li> <li>- HUF paid by NHIF</li> <li>- Patient co-payment</li> <li>- Physician's name</li> <li>- Physician's specialty</li> </ul>
7. Number of Prescriptions by Physician	Determine prescribing patterns of physicians	<ul style="list-style-type: none"> <li>- Rank of drug product</li> <li>- ATC group</li> <li>- Brand name</li> <li>- Generic name</li> <li>- Total HUF spent</li> <li>- HUF paid by NHIF</li> <li>- Patient co-payment</li> <li>- Physician's name</li> <li>- Physician's specialty</li> </ul>

After experience is gained from these basic reports, it is suggested that they will be modified into exception reports based on key parameters.

### *Improve Drug Procurement Practices*

Under the current health insurance system, drug prices were negotiated between OEP and individual manufactures for each individual drug product (product-by-product pricing). Products include innovator (brand name) products as well as generic products. Under this model, factors considered in pricing decisions typically include:

- Cost of manufacturing, plus a “reasonable” margin for profit
- Cost-effectiveness compared with existing drugs of choice
- Additional therapeutic benefits over existing products
- Price of comparable products.

This system of pricing is time consuming and labor intensive, and objective data may be difficult to obtain. In addition, in absence of active generic and therapeutic substitution practices and incentives among physicians and patients to select lower priced but therapeutically equivalent product, product-by-product pricing tends to push the drug costs, as observed in Hungary. The same situation was observed from drug procurement practices by the OEP (which reimburse drug costs for out-patient care) as well as hospitals that were paid by the OEP based on the DRG system including drug costs.

To improve drug procurement practices, RPM recommended OEP to:

- Evaluate feasibility of introducing alternative procurement mechanisms, such as bidding/tendering and reference pricing system through which OEP can strengthen its negotiating power as a purchaser of pharmaceutical products;
- Revise the subsidized drug list with reduced numbers of products and make it a restrictive drug formulary for the OEP’s coverage for drug treatment;
- Encourage hospitals to improve their procurement practices, including development of hospital drug formulary system and pooled procurement of drugs with other hospitals and introduction of transparent tendering system.

RPM developed a technical paper on the reference pricing system and provided it to the OEP officials for their reference.

## **Outcomes**

### *Training*

OEP officials who worked with RPM and were familiarized with the pharmaceutical management are now teaching modules in pharmaceutical reimbursement, regulation, purchasing, etc., as part of a new curriculum at health service management schools in Hungary.

### *Selection*

Findings and recommendations from the RPM assessment of subsidized drug list were used in a report prepared by OEP officials and submitted to the Committee of the Pharmaceutical Benefit Scheme of the Government of Hungary.

## **Procurement**

OEP developed a plan to centralize drug procurement for hospitals using tenders with explicit selection criteria developed.

OEP is planning to make it compulsory for hospitals to develop a drug formulary. A proposal was submitted to the Ministry of Health and Ministry of Finance to develop a national guideline on how to develop hospital-based drug formulary. An RPM formulary development manual was included in the proposal as the basis of such a guideline.

## **Outputs**

The following documents were developed during the project.

- Assessment of Fully Subsidized Hungarian Medication List
- RPM Hungary Drug Reference Pricing: Models and Issues
- RPM Hungary Trip Report, November 5, 1997
- RPM Hungary Trip Report, April 18 – May 9, 1998
- RPM Hungary Trip Report, May 15-22, 1999

## **References provided to the National Health Insurance Fund Administration**

- American Hospital Formulary System Drug Information, American Society of Health-System Pharmacists, 1999
- Drug Information Handbook, Lexi-Comp Inc. and the American Pharmaceutical Association, 4th edition, 1996
- Medication Formulary, Cigna Health Care of Arizona, Spring 1988
- RPM Manual for the Development and Maintenance of Hospital Drug Formularies (Hungarian translation)
- RPM Guidelines for Implementing Drug Utilization Review Programs in Hospitals (Hungarian translation)
- RPM Assessment of Fully Subsidized Hungarian Medication List (completed April 20, 1998)
- ASHP Guidelines for Pharmacists on the Activities of Vendors' Representatives in Organized Health Care Systems, *Practice Standards of ASHP 1997-1998*, American Society of Health-System Pharmacists, Inc., Deffenbaugh JH, ed, Bethesda, MD, 1998.
- Professional Relations, Chapter 66, *Handbook of Institutional Pharmacy Practice*, 2nd edition, Brown TR, Smith MC, eds, Williams and Wilkins, Baltimore, MD, 1986.
- Managing Procurement, Chapter 13, *Managing Drug Supply, The Selection, Procurement, Distribution, and Use of Pharmaceuticals*, 2nd edition, Kumarian Press

## **B. Survey on General Practitioners' Prescribing Patterns of Antihypertensive Drugs**

### **Background**

While a number of key personnel interviewed by RPM expressed concerns regarding the problematic prescribing patterns among health care providers, documentation of evidence to support the concern was generally limited. The survey would help determine the extent and the common types of prescribing problems among general practitioners who are at the front line of the Hungarian health care system.

Treatment of hypertension was selected as the focus of this survey because:

- it is a major cause of morbidity and mortality among the Hungarian population;
- most of drugs for hypertension control are covered by the drug subsidy policy; and
- proposed treatment guidelines for hypertension had been created by the (then) Ministry of Welfare.

### **Objectives of the RPM Activity**

The survey was conducted to:

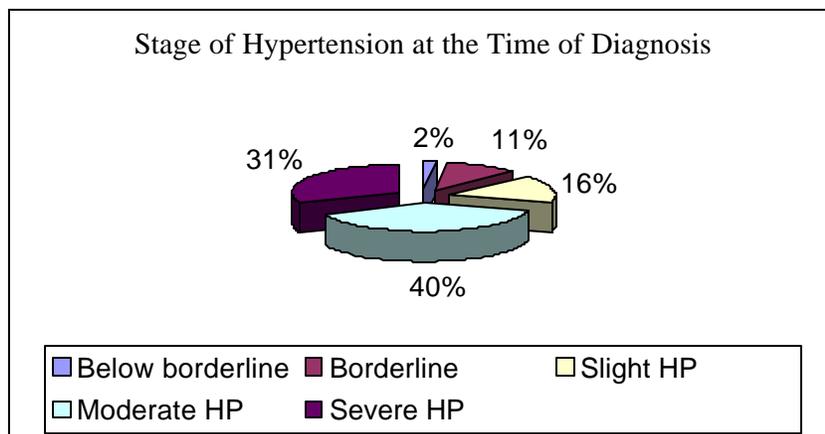
- Identify common forms and the magnitude of prescribing problems among general practitioners in Hungary in treating patients with hypertension.
- Recommend possible forms of interventions to improve prescribing practices.

### **Mode of Implementation**

RPM entered into a subcontract agreement with the Green Cross, a Hungarian association for private physicians. Green Cross collected data on patient background, blood pressure and other laboratory tests, and drugs prescribed from 800 case records with diagnosis of hypertension, using a standardized questionnaire developed by the RPM. Data was collected from 40 general practitioners offices in Budapest and 4 other randomly selected counties. RPM compared prescribing patterns with the treatment guidelines for hypertension proposed by the Ministry of Welfare (1996) and the 6<sup>th</sup> Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure by the US National Institute of Health (1997).

## Key Findings

1. The majority of cases were not detected at an early stage: 40% of cases were first diagnosed with moderate hypertension, and another 31% was severe hypertension.

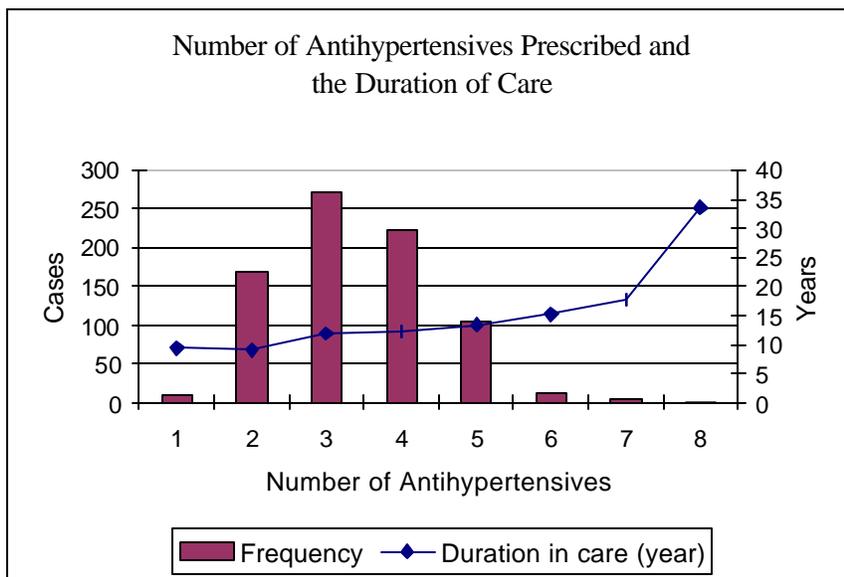


2. There are a great number of therapeutic choices for drug treatment of hypertension, as shown in the right two columns in the table below. The most frequently prescribed classes of drugs were ACE inhibitors, Calcium channel blockers, and Beta blockers. Six products<sup>1</sup> accounted for nearly half (47%) of all drugs prescribed among the surveyed 800 cases.

Class of Antihypertensives	Frequency prescribed (% of total 1921 drugs prescribed)		Number of items mentioned in the survey	
			(in chemical entity)	(in product)
ACE inhibitor	576	30%	7	13
Calcium channel blocker	382	20%	10	17
Beta blocker				
Cardio-selective	316	17%	5	7
Non cardio-selective	35	2%	4	6
Diuretic				
Thiazides	100	5%	3	3
Loop diuretics	92	5%	2	2
Potassium-sparing agent	3	0.2%	2	2
Thiazide+potassium-sparing agent	116	6%	1	1
Other				
Pyscostimulant ( <i>vinpocetin</i> )	101	5%	1	1
Alpha-2 stimulant	100	5%	3	3
Alpha-1 inhibitor	75	4%	2	2
Beta blocker (non selective) + Diuretic	12	0.6%	1	1
Vasodilator	9	0.5%	3	3
ACE inhibitor+Diuretic	4	0.2%	1	1

<sup>1</sup> They are BETALOC (metoprolol), EDNYT (enalapril), RETINEC (enalapril), AMILORID (hydrochlorothiazid+amilorid), CORINFAR (nifedipin), and TENSIOMIN (captopril).

3. The majority of cases (78%) were prescribed multiple antihypertensive drugs at a time.



4. Treatment guidelines proposed by the Ministry of Welfare (1996) for the initial treatment of hypertension leave practitioners with a wide range of choices that include the use of diuretics, Beta blockers, calcium channel blockers, ACE inhibitors, Alpha-1 inhibitors, Alpha-2 stimulants, and Vasodilators.
5. Cost analysis suggests potential drug cost savings through the use of reference pricing system for the subsidized drugs, or the use of generic and therapeutic drug substitutions. The table below presents comparative costs of most frequently prescribed drug products against the least expensive drug product of the same chemical entity using the Defined Daily Dose (DDD). Potential size of drug cost savings could not be assessed in the absence of patient volume data.

*Most frequently prescribed ACE Inhibitors*

Generic Name	Product Name	Frequency Prescribed	Daily Therapeutic Cost (HUF)	Monthly Therapeutic Cost (HUF)	Relative drug cost compared with the least expensive equivalent product
Enalapril (DDD 10 mg)	EDNYT, 10 mg tab	57	23.7	711	108%
	EDNYT, 5 mg tab	58	32.0	960	146%
	RENITEC, 10 mg tab	58	24.8	744	113%
	RENITEC, 5 mg tab	32	33.8	1014	154%
Captopril (DDD 50 mg)	TENSIOMIN, 25 mg tab	48	16.8	504	100%
	TENSIOMIN, 12.5 mg tab	33	20.2	606	120%
	TENSIOMIN, 25 mg tab	30	22.3	669	133%
Perindopril (DDD 4 mg)	COVEREX, 4 mg tab	54	39.0	1170	-

*Most frequently prescribed Beta Blockers*

Generic Name	Product Name	Frequency Prescribed	Daily Therapeutic Cost (HUF)	Monthly Therapeutic Cost (HUF)	Relative drug cost compared with the least expensive equivalent product
Metprolol (DDD 200 mg)	BETALOC, 50 mg tab	110	14.0	420	132%
	BETALOC ZOK, 100 mg tab	96	29.6	888	279%
Atenolol (DDD 75 mg)	ATENOLOL Pharmavit, 50 mg filmtab	15	10.6	318	141%

**Recommendations**

1. There is a need to strengthen the regular blood pressure monitoring at the ambulatory settings, so that more cases will be detected at an early stage of hypertension.
2. A study should be conducted to identify potential cost savings of using the more cost-effective drug within therapeutic categories based on the patient volume data.
3. Recommendations from the study for the most cost-effective treatment of hypertension should be disseminated to health care providers through various means including the treatment guidelines and the continuing education of physicians.
4. When there are too many duplications of therapeutic choices elimination of less cost-effective drugs from the subsidized drug list should be considered.

**Outcomes****Outputs**

RPM report on the Survey on General Practitioners' Prescribing Patterns of Antihypertensive Drugs

## C. Assessment of Utilization of the Hospital Drug Formulary Systems

### Background

Hospital expenditures for drugs typically make up a significant portion of any health system's overall budget. Without a system for controlling the number of drugs purchased by the hospital, stocks inevitably swell to contain an unmanageable number of duplicate or unnecessary products. Additionally, some products on the market in many countries are unsafe or ineffective. Finally, it is well known that irrational prescribing and use routinely occur in health-care settings in which drug use is not regularly monitored and evaluated. These important financial and clinical issues are typically addressed through the use of drug formulary systems<sup>2</sup>, implemented and maintained by drug and therapeutics committees.

It was known that formulary systems were used at some Hungarian Hospitals, although the extent of its application was not known. Furthermore, little was known regarding the effectiveness of the systems, or what implementation or ongoing problems are being encountered by hospital managers and clinicians. It was reported anecdotally that hospitals routinely stock and use large numbers of products.

### Objectives of the RPM Activity

RPM and the Semmelweis University of Medicine Health Service Management Training Centre (HSMTC) conducted a mail survey to obtain the information on:

- The degree to which elements of a formulary system were in use in Hungary
- How widely the concept of hospital formulary systems was known to hospital managers and pharmacists.
- Patterns that might exist among various types of hospitals in Hungary about the way in which the drug formulary system is implemented.
- Challenges that were experienced and areas that need additional supports in developing and maintaining formulary systems.

### Mode of Implementation

During the second visit by RPM to Hungary in April 1998, RPM identified HSMTC as the local partner in this technical area based on its unique position as one of few academic and research institutions in Hungary focusing on health care management and its past history in working with projects supported by the USAID and other European donor agencies. RPM Hungary Country Program Manager Fujisaki presented the staff assigned to this project basic concepts of hospital-based drug formulary system and its significance in an overall management at hospitals.

RPM and the HSMTC developed a survey instrument to collect information on hospital-based drug formulary activities in Hungary. The survey questionnaire was mailed to 150 hospitals, of which 102 hospitals (68%) responded to the survey. The data was collated and analyzed by the HSMTC in consultation with RPM.

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<sup>2</sup> Drug Formulary System activities include: (1) maintaining and enforcing the list of drugs approved for procurement and use, (2) provision of unbiased, summary drug information, usually in the form of a manual, (3) monitoring and evaluating drugs use, (4) adverse drug reaction monitoring, (5) development and dissemination of newsletters, and (6) educational programs.

The findings were reported to key policy makers and professionals in the Hungarian health sector at the USAID-DHHS All Health Transition Conference on June 3, 1999. Key findings and RPM's recommendations were also presented to the Director-General of the OEP and his advisors.

## Key Findings

All hospitals in Hungary (150) received the questionnaire, and the response rate was 68% (102). The survey data indicated that:

1. Basic concepts of drug formulary list development were well known in Hungary, even in those hospitals that had not been involved. It was less clear whether the idea of a comprehensive formulary system – including drug utilization review (DUR) and provision of information and education – were known. The substantial citing of financial need, and improvement of quality of care indicated understanding of the rationale for formulary systems. The fact that 17 respondents did not feel that formulary systems were useful suggested the need for additional advocacy activities.
2. Sixty five responding facilities (43% of all hospitals) had developed formulary lists, distributed as follows:

Table 2 Distribution by Hospital Size

BED SIZE	FACILITIES WITH FORMULARY LISTS
200-400	19
400-600	9
600-800	10
800-1000	4
>1000	14
TOTAL	65

Table 3 Distribution by Hospital Type

TYPE	FACILITIES WITH FORMULARY LISTS
COUNTY	13
MUNICIPAL	27
BUDAPEST	5
NATIONAL INSTITUTE	7
UNIVERSITY	5
OTHERS	8
TOTAL	65

3. Seventy-three facilities reported having programs to monitor and evaluate drug use.
4. Challenges to the implementation of formulary systems included:

- Formulary products are most commonly listed by brand name only (60%) This practice can bias thinking toward particular manufacturers, and discourages generic substitution.
- There is a lack of unbiased drug information, critical for making formulary decisions, developing treatment guidelines, and developing Drug Use Evaluation Criteria. Discussion of evidence-based medicine approaches may be useful.
- While it is impossible to arrive at a “correct” number of drugs for a particular type or size of hospital should use, the it appears that additional deletions can be made in some hospitals (71% of respondents with formularies have greater than 400 drug products)
- An over reliance on education/information dissemination interventions (58%) to correct problems identified through Drug Utilization Review, as compared to managerial and policy change interventions (42%).

### **Recommendations:**

Based on survey findings and RPM knowledge of the current situation in the hospital-based pharmaceutical management, RPM recommended the following to the USAID Mission in Hungary, senior officials at the OEP and the Ministry of Health.

1. A national strategy for formulary system implementation should be developed. (What levels of the healthcare system should have formularies? Where should selection decisions be made?) A Policy Options Workshop might be a useful venue for this purpose.
2. Additional advocacy for formulary development may be necessary to arrive at a “critical mass,” as evidenced by the number of respondents that did not feel that formularies were useful.
3. A model site for formulary systems could be developed at one of the many hospitals that have already gone through the process. Trained staff from the model site(s) could be used for further training and rollout efforts, as well as staff of the Semmelweis University of Medicine HSMTC.
4. Regardless of the strategy and approach chosen, training in formulary systems implementation and maintenance should be conducted. RPM had already developed a standard manual for this purpose in Hungarian language. In addition to the operational aspects of the formulary system, clinical pharmacology education, and pharmacoeconomic evaluation should be included in training efforts.
5. Readily available and unbiased sources of drug information are needed in Hungary, including textbooks, international medical and pharmacy refereed journals, and the Internet. Evidence-based medicine concepts should be further promoted.
6. Selection and prescribing of drugs by generic name only should be promoted by law.
7. Formulary activities should be closely coordinated with changes in DRG policies and reimbursement rates.

## **Outcomes**

As described in the section for Technical Area 1 (Assessment of Subsidized Drug List of the National Health Insurance Fund), OEP is planning to make it compulsory for hospitals to develop a drug formulary. A proposal was submitted to the Ministry of Health and Ministry of Finance to develop a national guideline on how to develop hospital-based drug formulary. The RPM formulary development manual was included in the proposal as the basis of such a guideline.

## **Outputs**

The following documents were developed during the project.

- RPM Manual for Developing and Maintaining Hospital Drug Formulary System (into Hungarian)
- RPM Manual for Drug Utilization Review at Hospitals (into Hungarian)
- Report on the Hungarian Hospital Survey for Use of Formulary System

### **III. LIKELY NEEDS AFTER THE END OF THE PROJECT**

#### **A. Drug Subsidy System under the National Health Insurance**

Additional technical assistance to the OEP and the MOH in the following areas will be beneficial in supporting initiatives for the drug subsidy system reforms.

- Model development to compare costs of drug subsidies under various reform options, such as reference pricing, spending caps, and simply revising the current subsidized drug list. Such an analysis will guide the policy dialogue and decisions regarding the reform.
- Help OEP and MOH organize a policy options meeting on reforming the subsidized drug system to promote policy dialogue between key stakeholders based on objective information.
- Upon the decisions at the above policy options meeting, technical assistance can be provided to develop and implement a reformed drug subsidy system. This could include revising the list of drugs for subsidy, establishing reference prices, or deciding on the maximum drug spending or the utilization level.

Technical expertise in health economics and financing, pharmaceutical management, and clinical pharmacology would be necessary to support these activities.

#### **B. Rational Prescribing for Treatment of Hypertension by General Practitioners (GPs)**

Next steps in this technical area include the following:

- Identifying the most cost-effective treatment of various stages and types of hypertension
- Development of continuing education modules for treatment of hypertension by GPs
- Training on treatment of hypertension management to GPs
- Evaluation of impacts of educational interventions to improve prescribing of antihypertensives by GPs

These activities should involve all key stakeholders among policy makers (e.g., MOH and OEP), medical schools, and professional organizations (e.g., Hungarian Chamber of Physicians, Association of General Practitioners, Green Cross).

#### **C. Hospital Drug Formulary System**

Given the potential leadership by OEP in this area, the future technical assistance should be focused on the following:

- Technical assistance to one or more health facilities in formulary system implementation.
- Facilitate a policy options meeting on expanding and strengthening hospital drug formulary systems.

- Help organize a workshop on developing and maintaining the hospital drug formulary systems.

The above activities will take place at policy level as well as at facility level. It may be useful to plan the activities in the order as listed above so that understanding and support for introduction of drug formulary system can be built based on the experience at model facilities.

#### **IV. LESSONS LEARNED**

- The concept of drug management as a cycle of components consisting of selection, procurement, distribution, and use, and supported by legal and policy framework proved to be very useful in understanding and communicating major issues in the pharmaceutical sector in Hungary. Underneath various problems identified at the health system level, hospital level, and practitioners' level, there were a few common factors in the current system; prevalent use of brand names instead of generic names in identifying drugs, lack of cost consciousness in selecting drugs, need for systematic approach in disease management and monitoring current practices. By using the drug management cycle in addressing the three technical areas of activities in Hungary, RPM was able to identify the linkage between seemingly isolated observations from different parts of the pharmaceutical sector and point out areas for effective interventions for addressing the problems.
- Political changes in early 1998 resulted in a breakthrough for RPM in establishing a cooperative working relationship with OEP. Although the shift came in relatively late stage of the project life in Hungary, the reform-minded leadership at the OEP took the full advantage of technical supports provided by RPM and was able to use information and skills gained in advancing its reform agenda.
- Subcontracting activities to the Semmelweis University of Medicine Health Service Management Training Centre and the Green Cross helped RPM conduct multiple activities components within a short period of time without extensive local presence. Initially, however, RPM encountered difficulties in identifying capable subcontractors outside the government system due to the fact that Hungary was still in transition from centrally managed socialist system to the privatized system. The Role played by the local coordinator (supported by the DHHS) was also significant in the environment where rapid changes were taking place politically.

## Appendix A Summary of Sample Analysis of OEP Drug Database

ATC group	Generic name	Brand name	price of one box	unit price (Ft/mg)	DDD (mg)	cost of DoT	Reimbursement rate (%)	Co-payment (Ft)	Paid by Fund	Possible Actions	Projected Savings
N06BX18	Vinpocetine	Cavinton	387	1.5	15	23.2	90	10	2,126,777,495 Ft	delete	2,126,777,495 Ft
N06BX18	Vinpocetine	Cavinton	669	1.5	15	22.3	90	10		delete	
C01DA02	nitroglycerine	Nitromint R	568	3.6	5.2	18.9	90	10	2,013,856,715 Ft	switch to Isosorbide	426,213,061 Ft
C09AA04	perindopril	Coverex 4	1720	14.3	4	57.3	90	10	1,752,722,752 Ft	switch to captopril	1,156,858,193 Ft
N06AB04	citalopram	Seropram	5400	9.6	20	192.9	100	0	1,666,427,135 Ft	switch to fluoxetine	549,303,759 Ft
N06AB05	paroxetine	Seroxat	5810	9.7	20	193.7	100	0	1,444,819,345 Ft	switch to fluoxetine	544,604,882 Ft
L02AE03	goserelin	Zoladex depot	38000	10555.6	0.128	1351.1	100	0	1,394,360,784 Ft	guideline	
C09AA02	enalapril	Ednyt 10 mg x28	970	3.5	10	34.6 fix		10	1,244,484,623 Ft	switch to captopril	529,445,481 Ft
C09AA02	enalapril	Ednyt 10 mg x100	2970	3.0	10	29.7	90	10			
C08CA01	amlodipin	Norvasc 5 mg	2870	19.1	5	95.7	70	30	1,218,007,680 Ft	switch to nifedepine R	727,409,464 Ft
N06AB06	sertraline	Zoloft	4970	3.6	50	177.5	100	0	1,159,077,214 Ft	switch to fluoxetine	314,839,887 Ft
A02BA02	ranitidine	Ulceran 150	1850	0.2	300	61.7 fix			1,140,830,820 Ft	switch to generic ranitidine	295,999,347 Ft
L03AA04	interferon alpha 2b	Intron A 10 milliú	16900	16900.0	287300.0	287300.0	100	0	1,117,766,000 Ft		
C09AA02	enalapril	Renitec 10 mg	970	3.5	10	34.6 fix			1,108,429,994 Ft	switch to captopril	476,624,897 Ft
A02BA03	famotidine	Quamatel 20 mg 28	939	1.7	40	67.1	100	0	1,033,791,486 Ft	switch to generic	330,196,086 Ft
J01CR02	amoxicillin +	Augmentin 625 mg	2640	0.2	1000	201.1	70	30	1,014,369,257 Ft		
A10BB01	glibenclamide	Gilemal	305	2.0	10	20.3	90	10	1,002,237,128 Ft	maintain	
C09AA02	enalapril	Ednyt 20,0 mg	1450	2.6	10	25.9 fix			974,219,378 Ft		
B01AC05	ticlopidine	Ticlid 250 mg	2850	0.6	500	285.0	70	30	934,634,925 Ft	guideline	
J01CR02	amoxicillin +	Augmentin-Biogal 375 mg	1860	0.2	1000	236.2	70	30	893,717,515 Ft		
A11CC03	alfacalcidol	Alpha D3 0,25 mcg	1940	129333.3	1000	12933333 3.3	100	0	867,603,432 Ft	guideline	
M01AB05	diclofenac	Diclofenac Duo Pharmavit	946	0.4	40	16.8	90	10	847,377,413 Ft	switch to generic	

ATC group	Generic name	Brand name	price of one box	unit price (Ft/mg)	DDD (mg)	cost of DoT	Reimbursement rate (%)	Co-payment (Ft)	Paid by Fund	Possible Actions	Projected Savings	
		75 mg										
A02BA03	famotidin	Quamatel 40 mg	939	1.7	40	67.1	100	0	834,093,278 Ft			
C09AA02	enalapril	Renitec 20 mg	1450	2.6	40	103.6	fix		829,613,983 Ft			
R06AX13	loratidin	Claritine	1350	6.8	10	67.5		90	10	791,404,380 Ft		
R06AE07	cetirizin	Zyrtec	1270	6.4	10	63.5		90	10	789,103,962 Ft		
C09AA02	enalapril	Ednyt 5,0	686	4.9	10	49.0	fix			749,343,808 Ft		
C01DA02	nitroglycerine	Nitroderm TTS-5 tapasz	2320	3.1	5	15.5		70	30	737,280,270 Ft		
C05BX01	calcium dobesilat	Doxium	466	0.1		0.0		70	30	697,445,398 Ft		
L02BB01	flutamid	Fugerel	21700	0.9	750	651.0		100		687,644,550 Ft		
N06BX03	piracetam	Nootropil 1200	1940	0.0	2400	64.7	90/ fix		10	670,156,396 Ft	delete	670,156,396 Ft
N06AB03	fluoxetin	Prozac 20 mg	4870	8.7	20	173.9		100	0	629,619,764 Ft	switch to generic	161,606,715 Ft
C04AD03	pentoxifyllin	Trental 400 drg	1220	0.0	1000	30.5	fix			623,221,550 Ft	delete	623,221,550 Ft
A10AB01	human insulin	Humulin M3	1290	0.9	40	34.4		100	0	609,745,288 Ft		
C07AB02	metoprolol	Betaloc 100 mg	367	0.2	150	27.5		90	10	598,666,591 Ft		
M05BA04	alendronic acid	Fosamax 10 mg	7660	27.4	10	273.6		90	10	591,236,334 Ft		
H05BA01 (nincs 200)	calcitonin	Miacalcic 200	8070	1.4	200	288.2		90	10	579,363,861 Ft		
C04AD03	pentoxifyllin	Chinotal drg.	1140	0.0	1000	28.5	fix			579,198,445 Ft	delete	579,198,445 Ft
A06AB06	senna glycosidok	Tisasen A + B drg.	225	0.8		0.0		90	10	566,727,623 Ft	delete	
A12BA01	kalium chlorid	Kalium-R	299	10.0	3000	29900.0		90	10	565,247,604 Ft		
C08CA05	nifedipin	Corinfar drg.	378	0.4	30	11.3	fix			554,508,479 Ft		
C07AB02	metoprolol	Betaloc 50 mg	252	0.2	150	25.2	fix			552,837,240 Ft		
J01FA10	azithromycin	Sumamed 250	3610	2.4	300	722.0		70	30	527,706,719 Ft	guideline	
M05BA02	natrium clodronat	Lodronat	44000	0.9	1500	1375.0		100	0	522,775,667 Ft		
C09AA02	enalapril	Renitec 5,0 mg	686	4.9	10	49.0	fix			504,221,343 Ft		
A02BA02	ranitidin	Zantac 150 mg	1850	0.2	300	61.7	fix			497,181,268 Ft		
L02AE04	triptorelin	Decapeptyl	35700	9520.0	0.134	1275.7		100	0	486,422,200 Ft	guideline	

ATC group	Generic name	Brand name	price of one box	unit price (Ft/mg)	DDD (mg)	cost of DoT	Reimbursement rate (%)	Co-payment (Ft)	Paid by Fund	Possible Actions	Projected Savings
C07CA03	pindolol +	Viskaldix	637	3.2		0.0	90	10	486,132,461 Ft		
M01AB05	diclofenac K	Cataflam 50 mg	685	1.4	100	137.0	50	50	486,063,618 Ft		
A10BA03	buformin	Adebit	230	0.1	200	23.0	90	10	485,017,773 Ft		
C03EA01	hydrochlorothiazid +	Amilorid comp.	411	0.3		0.0	90	10	482,332,842 Ft		
C10AA01	simvastatin	Pharmavit Zocor 10 mg	3660	13.1	15	196.1	70	30	481,050,170 Ft	switch to cheapest	
										Total	9,512,455,658 Ft