Metabolic Syndrome Pharmaceutical Care Programme

Hungarian National Committee of Pharmaceutical Care

Supported by EuroPharm Forum

2009

Table of Contents

1. Introduction

1.1 Epidemiology of cardiovascular diseases

The 2002 WHO report has brought attention to the fact that relatively small number of preventable risk factors are highly responsible for the growing healthcare load and the high number of premature deaths. Smoking, alcohol consumption, hypertension, hypercholesterolemia, obesity and physical inactivity together are responsible for nearly the 50 % of the total healthcare load in developed countries. Table 1 shows the disability adjusted life years in attributable risk factors.

Risk factors	**DALY (% of total)**
Hypertension	12.8
Smoking	12.3
Alcohol consumption	10.1
Hypercholesterolemia	8.7
Obesity	7.8
Low vegetable/fruit consumption	4.4
Physical inactivity	3.5
Total	**59.6**

Table 1: The 7 most frequent risk factors' contribution to DALY, WHO Europe, 2000
(DALY: Disability adjusted life years)

Last years' epidemiological researches (OLEF2000, OLEF2003, Public Health Report – Hungary 2004 (Népegészségügyi Jelentés 2004)) and professional councils' declarations have found the following: The Hungarian population's opinion about their own health shows a disappointing picture compared to other European Union citizens. In Hungary three times more people consider their health status worse or far worse than EU average. According to the Hungarian Central Statistical Office, the cardiovascular ratio is increasing precipitously as a leading cause of mortality among people over 45.

39 % of women and 32 % of men are suffering from cardiovascular diseases. The life expectancy in Hungary is the third worse among the EU countries, after Lithuania and Latvia. An early detection of the risk factors of these diseases and an early start of the therapy are essential to reduce the high mortality, the life quality loss and the reduced working ability caused by these diseases. Only symptomatic treatment is available so far to treat most of the cardio- and cerebrovascular diseases. In 2003 29 % of women and 42 % of men were smokers, and the vast majority (25 % of women and 38 % of men) smoked on a daily basis.

There is no international consensus for the measurement of physical activity, so comparison is very difficult. According to the National Health Report made in 2000 (Országos Egészségfelmérés, 2000), two-fifth of women and one third of men made physical exercise (sport or work) less than once a week during the previous year of the report. Half of the women and two-third of the men made psychical exercise regularly (twice a week or more). The relation analysis found that people who had a higher education and lived in good financial conditions did more exercise. The situation is even worse if we only take physical exercises

made for sport purposes into account: one third of men and one fifth of women have sport activities. Time spent on sport is even worse: men's average is 14 minutes per day, women's is 8.

Hypertension is the leading risk factor for cardiovascular diseases. The prevalence of hypertension in Hungary is 29 %, which is 70 % higher than the EU average (17 %). Cardiovascular mortality can be reduced by 21 % by a proper treatment of hypertension. The control of hypertension earlier in the disease process reduces the risk of stroke by 45 %, and the risk of myocardial infarction by 24 %, and it reduces the risk of hospitalisation for heart failure by 34 %.

The estimated number of diabetes patient in Hungary is about 700 - 800,000, which is about 7-8 % of the whole population, and about 90 % of them belong to the type-2 diabetes group. According to Zimmet, one unrecognized sufferer of type-2 diabetes should be counted for every recognized patient.

The main risk factors for cardiovascular mortality and morbidity are obesity, hypertension, and alteration of the lipid and carbohydrate metabolism. The combination of these medical disorders are called metabolic syndrome.

1.2 Pharmaceutical care

Pharmaceutical care services are parts of the daily routine in several European countries and are regulated by national and international protocols. The EuroPharm Forum developed two protocols in the field of cardiovascular diseases: Pharmadiab protocol, Pharmacy-based hypertension management model: protocol and guidelines. Many studies confirmed the efficacy of pharmaceutical care interventions.

1.3 Hungarian results

The Hungarian pharmaceutical associations have already finished the reference trials for diabetes and hypertension care, and among the cardiovascular diseases there is a new field (dyslipidaemia) where postgraduate courses have started. This has founded the basis for the Metabolic Syndrome Pharmaceutical Care Programme. The results have confirmed the necessity of pharmaceutical care. More than 500 pharmacists took the postgraduate course for the accreditation for diabetes care, and in the year of the trial they carried out more than 80,000 blood glucose measurements. The pharmacists sent nearly 20 % of the patients to physicians, thus facilitating an early recognition of diabetes in several patients. The efficiency of the pharmaceutical care was proven by comparative studies in the hypertension model research.

1.4 The aims of the Metabolic Syndrome Pharmaceutical Care Programme

The main fields of the programme are the following:

- To inform the patient about a healthy lifestyle and the possibilities for preventing from the metabolic syndrome
- To call attention on the necessity of an early diagnosis
- To determine the metabolic syndrome risk factors in patients visiting the pharmacy
- To recognize the patients who present an increased risk for developing the metabolic syndrome, and to refer them to a physician
- To increase the patients' adherence to therapy (medication, life style)
- To assure a wide availability to a self-check of hypertension, blood cholesterol, triglycerol and blood-glucose level
- To educate patients to increase the adherence and tolerance to their disease
- To monitor therapy and results
- To detect and solve medication errors
- To document and evaluate the pharmaceutical care work and patients' health status
- To facilitate pharmacist-physician contribution

The protocol was initiated by the following protocols and programmes:

- EuroPharm Forum protocols
  - Ask about your medicine
  - Pharmadiab protocol
  - Pharmacy-based hypertension management model
- Dader method, Granada consensus
- The outcome of the Hungarian pilot pharmaceutical care programmes (diabetes, hypertension)

- The actual medical/clinical guidelines

2. Metabolic syndrome pharmaceutical care programme

2.1 Programme construction, staffing, equipment and other requirements

2.1.1 Programme structure

2.1.1.1 Hungarian National Committee of Pharmaceutical Care (HNCPC)

The HNCPC is the operative controller, professional coordinator, preparative, operative, evaluative and assessive body of this programme. Its duties are to coordinate the programme, choose the participating pharmacies, solve any programme-related problems, give professional education to the participants, offer patient education, information leaflets and other tools required for the programme. The Committee will evaluate the results of the programme according to the incoming documentation.

2.1.1.2 Participating Pharmacies

Pharmacies can take part in the programme voluntarily after fulfilling the staffing and equipment requirements. This programme-trained pharmacist is responsible for the proper administration of this protocol in the pharmacy. The Committee will send the list of the pharmacists who had completed this training to the Chief Pharmaceutical Officer of the National Public Health. If the pharmacy fulfils the staffing and equipment requirements, the National Public Health and Medical Officer Service (NPHMOS) will give permission for the operation and monitor it during the programme period.

2.1.1.3 Professional and civil organisations

This programme will be started with the help of the Hungarian medicinal and pharmaceutical organisations (Hungarian Chamber of Pharmacists, Hungarian Society for Pharmaceutical Sciences, Hungarian Private Pharmacists' Association, Hungarian Society of Hypertension, Association of Hungarian Medical Societies).

2.1.2 Tools of the programme

The tool of the programme is the protocol (chapter 2.2) which was made on the basis of Hungarian and international guidelines, and it was modified by the results of previous Hungarian metabolic syndrome related programmes. The parts of the protocol (diabetes, hypertension, dyslipidaemia, obesity) can be used separately, but the aim is that the metabolic syndrome pharmaceutical care is made by the pharmacist.

2.1.3 Staffing requirements of the programme

2.1.3.1 Requirements of the pharmacist

The pharmacist should work in a pharmacy which has all the required conditions, should take all the required trainings and have a professional attitude and good communication skills, and, furthermore, accept all the terms and conditions of the programme. The required qualifications and trainings are the following:

- Pharmacist degree and metabolic syndrome continuing education course, or any other equivalent (diabetes, hypertension, dyslipidaemia) course - equivalence should be confirmed by the HNCPC. To participate in the programme, the pharmacist should participate in all the courses of metabolic syndrome continuing education.

2.1.3.2 General practitioner

The programme's general practitioner (GP) is the doctor who works in the area of the involved pharmacy, and co-operates with the pharmacist. The GP takes notice of the pharmacist's work and should co-operate with him. The pharmacist should send the patient needing further treatment to the GP, and he/she should treat the patient by professional protocols and inform the pharmacist of the results. The pharmacist should inform all the GPs in the area of the pharmacy prior the programme initiation. The HNCPC will offer the necessary referral letter to the pharmacies.

2.1.3.3 The patient

According to the Act of CLIV of 1997 on Health Care, any person who resorts to health care – independently from his/her health status –should be considered as a patient.

- First level (primary prevention): The patient who visits the pharmacy (which takes part in the programme)
- Second level (secondary prevention): The patient who visits the pharmacy asks for self-check of his/her metabolic parameters, or the patient who carries certain risk factors.
- Third level (tertiary prevention): The patient who has already been diagnosed to have any of the metabolic diseases (hypertension, diabetes, dyslipidaemia – hypercholesterinaemia, hypertriglyceridaemia) and/or obesity.

2.1.4 Equipment requirement of the programme

The requirements of the pharmacy are the following:

- *First level:*
  - Structured questionnaire, form
  - Professionally accepted patient education forms. Hungarian National Committee of Pharmaceutical Care (HNCPC) accepted patient information form.
  - Patient consultation area required by the Ministry of Health statute 41 of 2007.

- *Second level:*
  - Everything required at first level, and
  - Professional quality equipments (as fixed in the guideline):
    - ☐ Glucometer, cholesterol and triglycerol testing device
    - ☐ Blood pressure meter
    - ☐ Body fat monitoring equipment
    - ☐ Step counter
  - A separate area in the dispensary, or any other part of the pharmacy where the measuring can be take place as written in the guidelines.
  - The security arrangement of the self-check should be adequate as written in the guideline
  - Scales, height-meter, nomogram board

- *Third level*
  - Everything required in the previous levels, and documentation forms for the evaluation of the drug-related problems.
  - Official computer programme available for the participating pharmacies.

The requirements for equipments are different from the requirements for the self-check equipments used at home by the patient. This protocol does not cover the corresponding criteria of the self-check equipments used at home by the patient. The pharmacist should give information about these on the patient's request.

2.1.5 The programme period

The planned period of the whole programme is one year including the preparation period. The pharmaceutical care programme will have no time limits after the first year's evaluation.

2.1.6 Continuing education

2.1.6.1 Basic and compulsory training

The project of the training is the following:

- Metabolic syndrome
- Hypertension
- Diabetes mellitus
- Obesity
- Treatment of dyslipidaemia
- Basics of the drug therapy management
- Drug therapy of the metabolic syndrome
- Non-medicinal treatment of metabolic syndrome
- Improving communication skills

References to help preparation:

- Diabetes mellitus, a gyógyszerészi gondozás alapelvei. Budapest, Galenus kiadó 2005 (only available in Hungarian)
- Soós Gyöngyvér. Gyógyszerészi gondozás. Budapest, Magyar Gyógyszerésztudományi Társaság 2004 (only available in Hungarian)
- Dobson Szabolcs. A magas vérnyomás gyógyszerészi gondozása. Budapest, Magyar Gyógyszerészi Kamara, 2005 (only available in Hungarian)

2.1.6.2. Seminars of the prevention of metabolic syndrome, and drug treatment follow-up

To have up-to-date knowledge of cardiovascular diseases and skills in drug therapy monitoring, the pharmacist must participate in seminars and other trainings (twice a year). These seminars offer pharmacists a great opportunity to share their experiences and knowledge with their colleagues.

2.1.7 Ethical standards

Participating pharmacists and other health care providers should follow the ethical standards of their profession. Participants should engage with the higher ethical standards of the programme. Pharmacists and other healthcare providers should work in cooperation with mutual confidence to all drug-related problems and the patient's needs.

The pharmacist should inform the patient about all the programme-related relevant information. The language used should be adapted to individual understanding and skills. Education and information should respect the patient's autonomy and should empower patients to take informed decisions about their treatment. Improving the pharmacist's communication skills can improve the patient's understanding. Patient medication record should be drawn up, with written patient consent and respecting the patient's privacy and confidentiality.

Education and information should be given under calm circumstances by respecting the patient's privacy and confidentiality.

2.1.8 Data security, ethical standards of confidentiality and data collection

Programme participants must respect the Hungarian law of confidentiality and health care, patient personal law, ethical standards, and all the rules in the ethical codex of the Hungarian Chamber of Pharmacists. Patients should give informed consent to participate in the programme. This should be done in writing (Appendix 1). Data can leave the local site only in an anonymous form. Both the GP and the patient must be informed about the data collection for performance monitoring. The design and administration of databases shall separate identifiable data for the direct care of a single patient and anonymous data to support population-based care.

2.2 Programme protocol

2.2.1 Promotion of the healthy life style for the prevention of metabolic syndrome (Primary prevention)

2.2.1.1 Objectives

The main objectives of the Protocol are to provide information and advice to the patients in the metabolic risk group (hypertensive, diabetic, dyslipidaemic, obesity) about:

1. Risk factors, and
2. Life style changes to prevent metabolic syndrome-related diseases.

2.2.1.2 Target population

The pharmacists on pharmacy level should evaluate the patients by target-oriented questions and by their medicines and should start the prevention process in case of the following:

- Cardiovascular risk group
  - Patients over age 45 and/or
  - Obesity (BMI > 25 kg/m^2) and/or
  - Patient with diabetes and/or
  - She or he is on oral anti-diabetic drugs
  - His or her plasma glucose exceeds the normal range
  - Patient with dyslipidaemia and/or
  - She or he is on antilipemic drugs
  - His or her plasma cholesterol exceeds the normal range
  - Patient with hypertension
  - He or she is on antihypertensive medication
  - His or her blood pressure exceeds the normal range
  - The patient is a smoker

In case of informed patient consent (Appendix 1) the pharmacist should take all the general details of the patients and their general practitioners and take all the general risk factors according to the pharmacist's prevention form regarding metabolic syndrome (Appendix 2):

- Smoking habits
- Age (over 45 for men, over 55 for women)
- Physical activity: Does the patient do regular exercises? – at least 30 minutes' mild exercises five times a week, or 20 minutes' high-intensity exercises three times a week.
- Cardiovascular risk factors. Are there any hereditary risk factors for cardiovascular diseases? Close relatives with type-2 diabetes, stroke, myocardial infarction, angina developed before 55 years (male), 65 years (female).

2.2.1.3 Patient education, health promotion

The pharmacist should inform the patient having at least 1 risk factor of the following:

- Risk factors
- Metabolic syndrome and its complications
- Benefits from a healthy life style to reduce metabolic risk factors
- Body weight reduction programmes, benefits from physical activities, slimming diet
- Reducing the aggravating factors for hypertension, and metabolic diseases (smoking, excessive salt and alcohol consumption)

Patient information leaflets

The pharmacist should give the patient the HNCPC's and other relevant patient information leaflets. The leaflets should contain the following information:

- Information about the possibilities for enhancing physical activities
- Healthy diet recommendation
- Information on the opportunities of BMI reduction
- Information on the metabolic syndrome and its complications

Other information
The pharmacist should offer the patient an opportunity to get further information.

2.2.2 Cooperation for the early diagnosis of metabolic syndrome (second level)

2.2.2.1 Objectives

The objectives of the second level are the following:

- To draw attention to the dangers of high cardiovascular risk metabolic syndrome, and the symptoms of the early stage of the disease. To call attention to the importance of regular self-check of the metabolic parameters (blood sugar, serum cholesterol and triglycerol), blood pressure, body mass index and waist circumference
- Provide opportunities for self-check to patients who need to have these parameters checked
- Sending patients who have any abnormalities detected to a GP
- Patient follow-up

2.2.2.2 Target population

The target population corresponds to the population as described in 2.2.1.2, completed with patients who ask for any of their metabolic parameters to be checked at the pharmacy.

2.2.2.3 Measuring and checking at the pharmacy

If the patient has at least one risk factor from 2.2.1.2., or the patient asks for a measurement, the pharmacist shall help the patient with the measurement.

2.2.2.3.1 Blood pressure

In the programme, blood pressure measurement should be made as described in the Guideline of blood pressure monitoring at the pharmacy.

2.2.2.3.2 Blood glucose

In the programme, blood glucose measurement should be made as described in the Guideline of biological parameter measurement from blood at the pharmacy.

2.2.2.3.3 Blood lipid level

In the programme, blood lipid measurement should be made as described in the Guideline of biological parameter measurement from blood at the Pharmacy.

2.2.2.3.4 The grade of the obesity

In the programme, assessing obesity should be made as described in the Guideline of obesity monitoring at the pharmacy.
The pharmacist should calculate the BMI and measure the waist circumference.

2.2.2.4 Publishing and evaluating the results, referring the patient to a GP, metabolic syndrome pharmacist prevention form, referral letter, and guiding protocol

The pharmacist should record the results of self-monitoring on the metabolic syndrome patient form (Appendix 3). The pharmacist should record the patient's name, the pharmacy's and his/her own name, all the results measured in the pharmacy, should record the hours passed since last food intake and give professional advice.

If the guiding protocol allows so, the patient can be suggested to repeat the pharmacy visit where the pharmacist can evaluate the results of the life style changes and in case of ineffectiveness, the pharmacist should refer the patient to a GP.

The pharmacist should record the general data of the patient and his/her GP according to the 2.2.1.3, and should record all the general risk factors. After that the pharmacist should record all the measured data on the prevention form, and should follow the steps shown in the following charts. All the steps should be documented on the triplicate prevention form (Appendix 2). If the patient is diagnosed as hypertensive patient, or diabetic, or dislipidaemic, the following categories should not be applied in relation with the

diagnosed field. In these cases the pharmacist should act according to the third level of prevention, and the fact of the patient is diagnosed should be recorded on the prevention form.

2.2.2.4.1 Blood pressure monitoring

The pharmacist should evaluate and refer the patient according to the following chart.

	Blood pressure at the beginning (Hgmm)		**Regular check, patient information, follow-up**
	Systolic	Diastolic	
Normal range	<130 mmHg	<85 mmHg	Yearly
Elevated-Normal Blood Pressure	130-139 mmHg	85-89 mmHg	Yearly
1st level (mild hypertension)	140-159 mmHg	90-99 mmHg	Check within a month
2nd level (moderate hypertension)	160-179 mmHg	100-109 mmHg	Refer to the GP
3rd level (severe hypertension)	>180 mmHg	>110 mmHg	Refer to the GP

Table 2: Guiding protocol of the measured values
(Source: Hungarian Ministry of Health: Protocol of hypertension and treatment)

For a patient with normal blood pressure, the pharmacist should:
- inform the patient of
  - the importance of a healthy life style
  - the importance of smoking cessation (if necessary)
  - the metabolic syndrome and its complications
  - the symptoms and complications of hypertension
  - the importance of yearly blood-pressure control
- offer the patient an information leaflet (2.2.1.3)

For a patient with elevated-normal blood pressure, the pharmacist should:
- inform the patient of
  - the fact that his/her blood pressure level is elevated
  - the importance of a healthy life style
  - the importance of smoking cessation (if necessary)
  - the metabolic syndrome and its complications
  - the symptoms and complications of hypertension
  - the importance of yearly blood pressure control
- offer the patient an information leaflet (2.2.1.3)

For a patient with mild hypertension, the pharmacist should:
- inform the patient of
  - the fact that his/her blood pressure level is elevated, and she/he has mild hypertension
  - the metabolic syndrome and its complications
  - hypertension, symptoms and complications
  - changeable risk factors which can delay the onset of the disease
  - the importance of smoking cessation (if necessary)
- offer the patient an information leaflet (2.2.1.3)
- inform the patient of the necessity of life style changes, and the possibilities. The pharmacist and the patient should make an agreement on life style changes aiming at a blood pressure reduction. This should be recorded on the prevention form, and the metabolic syndrome patient form.
- make an appointment with the patient for the next blood pressure monitoring, and this appointment should be recorded on the prevention form, and the metabolic syndrome patient form.

For a patient with moderate or severe hypertension, the pharmacist should:
- inform the patient of

    - the fact that his/her blood pressure level is elevated, exceeds the normal range, and it requires immediate medical check-up – this should be recorded on the metabolic syndrome patient form
    - the metabolic syndrome and its complications
    - the importance of smoking cessation (if necessary)
    - hypertension, symptoms and complications
    - changeable risk factors which can reduce the risks of the disease
- offer the patient an information leaflet (2.2.1.3)
- encourage the patient to visit the GP, inform the patient of the necessity of a medical check-up, and of the benefits of an early started medical treatment.
- refer the patient to the GP, and
    - send referral letter to the GP (Appendix 4), and send a copy of the metabolic syndrome patient form enclosed.
    - call up the GP, if necessary.
- Record all these data on the prevention form.

2.2.2.4.2 Blood glucose level

The pharmacist should evaluate the measured and counted blood glucose level and guide the patient according to the following:

Time of food	Blood glucose level	Category	Regular check, patient information, follow up
Fasting blood glucose (no food for 8 hours or more)	<5.6 mmol/l	Normal	Yearly regular blood glucose monitoring, health promotion
	5.6 - 6.1 mmol/l	Elevated fasting blood glucose level, possible malignancy	Health promotion, refer to the GP
	>6.1 mmol/l	Possibility of diabetes mellitus, elevated blood glucose level, possible malignancy	Health promotion, refer to the GP
postprandial blood sugar	<7.8 mmol/l	Normal	Yearly regular blood glucose monitoring, health promotion
	7.8-11.0 mmol/l	Possibility of impaired glucose tolerance, elevated blood glucose level	Health promotion, refer to the GP
	> 11.1 mmol/l	Possibility of diabetes mellitus, elevated blood glucose level, possible malignancy	Health promotion, refer to the GP

Table 3: Guiding protocol related to the measured blood glucose level

For a patient with a normal blood glucose level, the pharmacist should:

- inform the patient of
    - the importance of a healthy life style
    - the metabolic syndrome and its complications
    - the importance of smoking cessation (if necessary)
    - the symptoms and complications of the diabetes
    - the necessity of yearly blood glucose monitoring
- offer the patient an information leaflet (2.2.1.3)

For a patient with an elevated blood glucose level and possible malignancy the pharmacist should:

- inform the patient of:
    - the fact that his/her blood glucose level is elevated, exceeds the normal range, and it requires immediate medical check-up – this should be recorded on the metabolic syndrome patient form
    - the metabolic syndrome and its complications
    - the importance of smoking cessation (if necessary)

- diabetes, its symptoms and complications
- changeable risk factors which can reduce the risks of the disease

- offer the patient written information-leaflet (2.2.1.3)
- encourage the patient to visit the GP, inform the patient of the necessity of a medical check-up, and of the benefits of an early started medical treatment.
- refer the patient to the GP, and
  - send areferral letter to the GP (Appendix 4) and a copy of the metabolic syndrome patient form enclosed
  - phone the GP, if necessary.

All these data should be recorded on the prevention form.

2.2.2.4.3 Blood lipid level

Pharmacist should calculate the LDL cholesterol (LDL-C) from total cholesterol (Tot-C) and triglycerides (TG) by a formula called the Friedewald equation. This formula can only be used if the triglyceride level does not exceed a level of 4,5 mmol/l.
LDL–C = Tot-C - (HDL–S + TG/2.2)
The pharmacist should evaluate the measured and counted blood lipid level and guide the patient according to the following:

Total cholesterol		
<5.2 mmol/l	Required	Check-up in a year
5.2-6.2 mmol/l	Threshold limit value elevated	Check-up in a month
>6.2 mmol/l	Elevated	Refer to the GP
LDL-C		
<2.6 mmol/l	Optimal	Check-up in a year
2.6-3.3 mmol/l	Exceeds the optimal range	Check-up in a month
3.4-4.1 mmol/l	Threshold limit value elevated	Refer to the GP
4.2-4.9 mmol/l	Elevated	Refer to the GP
>4.9 mmol/l	Highly elevated	Refer to the GP
HDL-C		
<1.0 mmol/l	Low	Refer to the GP
≥1.6 mmol/l	Elevated	Check-up in a year
Triglycerol		
<1.7 mmol/l	Required	Check-up in a year
1.7-2.3 mmol/l	Border-line	Check-up in a month
>2.3 mmol/l	Elevated	Refer to the GP

Table 4: Guiding protocol in relation to the counted and measured blood lipid level

For a patient with a normal (required, optimal) lipid level the pharmacist should:

- inform the patient of the importance of a healthy life style, metabolic syndrome and its complications
- offer the patient an information leaflet (2.2.1.3)

For a patient with an elevated-normal lipid level (the threshold limit value is elevated, exceeds the optimal level, threshold limit), the pharmacist should:

- inform the patient of
  - the fact that his/her blood lipid level is elevated, exceeds the normal range.
  - hyperlipidaemia, its symptoms and complications
  - changeable risk factors which can reduce the risks of the disease
  - the metabolic syndrome and its complications
  - the importance of smoking cessation (if necessary)
- offer the patient an information leaflet (2.2.1.3)
- encourage the patient to make a life style change aiming at a blood lipid level reduction within the following month - this should be recorded on the prevention form
- make an appointment with the patient for the next blood lipid control - this should be recorded on the prevention form.

For a patient with an elevated-highly elevated blood lipid level the pharmacist should:

- inform the patient of
  - the fact that his/her blood lipid level is elevated, exceeds the normal range, and it requires immediate medical check-up – this should be recorded on the metabolic syndrome patient form.
  - the metabolic syndrome and its complications
  - the importance of smoking cessation (if necessary)
  - hyperlipidaemia, its symptoms and complications
  - changeable risk factors which can reduce the risks of the disease
- offer the patient an information leaflet (2.2.1.3)
- encourage the patient to visit the GP, inform the patient of the necessity of a medical check-up, and of the benefits of an early started medical treatment
- refer the patient to the GP, and
  - send referral letter to the GP (Appendix 4), and send a copy of the metabolic syndrome patient form enclosed.
  - call the GP, if necessary

All these data should be recorded on the prevention form.

2.2.2.4.4 Classification of obesity

The pharmacist should evaluate the measured and counted level of obesity and guide the patient according to the following:

BMI (kg/m^2)	**Class**	**Regular check, follow up**
<18.5 kg/m^2	Anorectic	Check-up in a year
18.5-24.9 kg/m^2	Normal range	Check-up in a year
25-29.9 kg/m^2	Overweight	Check-up in 3 months
30-34.9 kg/m^2	Class I obesity	Check-up in 3 months
35-39.9 kg/m^2	Class II obesity	Refer to the GP
>40 kg/m^2	Class III obesity (morbidly obese)	Refer to the GP
Waist circumference (cm)	**Class**	
Male		
< 94	Normal	Check-up in a year
94-102	Higher risk	Check-up in 3 months
> 102	Significantly higher risk	Refer to the GP
Female		
< 80	Normal	Check-up in a year
80-88	Higher risk	Check-up in 3 months
> 88	Significantly higher risk	Refer to the GP

Table 5: Evaluation of the level of obesity

For a patient with a normal BMI or waist circumference, the pharmacist should:

- inform the patient of
  - the importance of a healthy life style
  - the symptoms and complications of obesity
  - the metabolic syndrome and its complications
  - the importance of smoking cessation (if necessary)
  - the necessity of regular weight monitoring
- offer the patient an information leaflet (2.2.1.3)
- inform the patient that a quarterly check-up is required in case of genetic predisposition, or co-morbid diseases. The pharmacist should liaise with the patient, and encourage him/her to make life style changes - this should be recorded on the prevention form
- make an appointment with the patient for the next check-up - this should be recorded on the prevention form.

For a patient of Class I obesity and elevated waist circumference, the pharmacist should:

- inform the patient of
  - the measured value being higher than normal, and this is associated with higher risk of cardiovascular diseases in people with genetic predisposition and other co-morbid diseases

    - the symptoms and complications of obesity
    - changeable risk factors which can reduce the grade of obesity
    - the importance of smoking cessation (if necessary)
    - the metabolic syndrome and its complications
- offer the patient an information leaflet (2.2.1.3)
- encourage the patient to make a life style change aiming at a weight reduction (by 5-10 %) within the following months (3 months - this should be recorded on the prevention form
- offer the patient a step-counter
- make an appointment with the patient for the next check-up - this should be recorded on the prevention form.

For a patient of Class II or III obesity and with a highly elevated waist circumference, the pharmacist should:

- inform the patient of
    - the measured value being higher than normal and inform that this is associated with higher risk of cardiovascular diseases in people with genetic predisposition and other co-morbid diseases
    - the metabolic syndrome and its complications
    - the symptoms and complications of the obesity
    - changeable risk factors which can reduce the grade of obesity
    - the importance of smoking cessation (if necessary)
- offer the patient an information leaflet (2.2.1.3)
- encourage the patient to visit the GP, inform the patient of the necessity of a medical check-up, and of the benefits of an early started medical treatment.
- offer the patient a step-counter
- refer the patient to a GP, and
    - send a referral letter to the GP (Appendix 4) and send a copy of the metabolic syndrome patient form enclosed.
    - phone the GP, if necessary.

All these data should be recorded on the prevention form.

2.2.2.5 Recognizing the signs of Metabolic Syndrome

The pharmacist should evaluate whether there is a chance for the patient to develop a metabolic syndrome. The main signs of a metabolic syndrome are the following:

- The patient's measured blood pressure exceeds the level of 130/85 Hgmm, or the patient is already a registered hypertensive patient.
- The patient's measured fasting glucose equals or exceeds the value of 5.6 mmol/l, or the patient is already a registered diabetic patient.
- The patient's measured HDL level does not exceed the level of 1.0 mmol/l in men, and 1.3 mmol/l in women.
- The patient's measured triglycerol level exceeds 1.7 mmol/l, or the patient is already a registered hyperlipidaemia patient.
- The patient's waist circumference exceeds 102 cm for men, and 88 cm for women.

If the patient suffers from 3 or more signs, there is a high risk of metabolic syndrome, and the patient should be referred to the GP.
The pharmacist should:

- inform the patient of
    - the importance of a healthy life style
    - the importance of the adherence with the drug therapy
    - the importance of smoking cessation (if necessary)
    - the metabolic syndrome and its complications
    - changeable risk factors which can reduce the grade and progression of the disease
- offer the patient an information leaflet (2.2.1.3)
- refer the patient to the GP, and
    - send referral letter to the GP (Appendix 4), and send a copy of the metabolic syndrome patient form enclosed.
    - phone the GP, if necessary.

If the patient suffers from two signs and has two or more metabolic syndrome risk factors, the patient should be referred to the GP.
The pharmacist should:

- inform the patient of
  - the importance of a healthy life style
  - the importance of smoking cessation (if necessary)
  - the metabolic syndrome and its complications
  - changeable risk factors which can delay the development and progression of the disease
- offer the patient an information leaflet (2.2.1.3)
- refer the patient to the GP, and
  - send a referral letter to the GP (Appendix 4), and a copy of the metabolic syndrome patient form enclosed.
  - phone the GP, if necessary.

All these data should be recorded on the prevention form.

2.2.2.6 Feedback

The pharmacist should always offer the patient further information. The pharmacist must follow the patient's health status and get information about the results of the patient's previous GP visit. The results should be recorded on the prevention form. The pharmacist should contact the GP if necessary in order to help better patient care. This should be recorded on the prevention form. Appendix 8 helps this process.
The pharmacist should offer further information to the already diagnosed patients; this is the 3rd level of the programme.
For patients whom have been recalled for a 1 or 3-month visit according to the protocol, the pharmacist should evaluate if they have already achieved the set goals.

- If the patient has achieved the set goals, further terminal visits are recommended. This should be recorded on the prevention form.
- If the patient has not achieved the set goals, but his/her measured values show progress, and no further risk factor has appeared, the pharmacist should motivate the patient, and they should in common redefine life style changes, if necessary. They should set a date for the next visit, and the interval between this and the next visit should not exceed the interval between this and the previous visit.
- If the patient has not achieved the set goals, and a further risk factor has appeared, the pharmacist should refer the patient to the GP and fill up a referral letter. This should be recorded on the prevention form.

2.2.2.7 Professional information should be given to the Hungarian National Committee of Pharmaceutical Care

The pharmacist must finally send the third copy of the prevention form (the personal data of the patient and GP are not recorded on them, but the patient's identifying number is) (Appendix 2) to the Committee (HNCPC).

2.2.2.8 Documentation

At the pharmacy the informed consents (Appendix 1) should be recorded chronologically.

The metabolic syndrome prevention form is triplicate. The first copy should be collected by the pharmacy. The second copy should be sent to the GP as an appendix to the referral letter, and the third copy should finally be sent to the HNCPC.

The pharmacist should always give the patient the metabolic syndrome patient form (Appendix 3) after recording the relevant data.

The pharmacist should send the referral letter to the GP, if necessary. The pharmacy does not have to keep a copy of it, but the sending should be recorded on the prevention form.

All the documentation (informed consent, first copy of the pharmacist's prevention form re. metabolic syndrome, the data form with the identifying numbers) should be kept recorded as written in the Act on Health Care related sections.

2.2.3 Medical management of the diagnosed patient (Metabolic syndrome pharmaceutical care programme: Third level)

2.2.3.1 Objectives

The aims of the third level of the metabolic syndrome pharmaceutical care programme are the following:

- Pharmaceutical support to hypertensive, obese, diabetic, dislipidaemic patients.
- Life style and drug therapy education to improve quality of life and reduce the progression of diseases
- Monitoring of therapeutic results
- Detection, solving or prevention of drug-related problems
- Improvement of adherence and compliance.

2.2.3.2 Identifying target population

The pharmacist should ask the patient target-oriented questions or identify the target population by patients' drug profile. According to the results they can be involved in the programme.

In order to give informed consent, the individual concerned must have adequate information about the programme. The third level of the programme involves all the patients whom have been screened, identified and referred to the GP on the second level of the programme. The pharmacist should record the general data of the GP and the patient on the metabolic syndrome drug therapy patient form (Appendix 5).

2.2.3.3 Identifying cardiovascular risk factors

The pharmacist should ask the patient target-oriented questions or identify them by their drug profile. According to the results, the pharmacist should identify the cardiovascular risk group of the patient.

- Extreme high risk group
  - Cardiovascular disease and
    - Diabetes
    - Heavy smoker
    - Metabolic syndrome
- High risk group
  - Coronary artery disease
  - Peripheral vascular disease
  - Cerebrovascular disease
  - Diabetes mellitus
  - Chronic kidney failure
- High risk group without cardiovascular symptoms
  - At least one high risk factor is present
    - Total lipid level > 8 mmol/l
    - Blood pressure > 180/110 Hgmm
    - Body Mass Index > 40 kg/m^2
  - At least one of main, independent risk factors
    - Positive family history
    - Ankle-arm index ≤ 0.9
  - Metabolic syndrome
- Moderate or low risk group
  - None of the previous symptoms is present

The pharmacist should record the assessment of the metabolic syndrome on the metabolic syndrome drug therapy patient form (Appendix 5).

2.2.3.4 Metabolic parameters for the assessment of a cardiovascular risk group

The target values for the patient according to relevant protocols are as shown in Table 11. The pharmacist should regularly check the patient's blood pressure, blood glucose level, blood lipid level, and assess the level of obesity. The measures should be performed by 2.2.2.3 Measuring and checking at the pharmacy. The pharmacist should constantly record all the results on the metabolic syndrome drug therapy patient form (Appendix 5).

- If the patient reaches the target level, the pharmacist should:

- inform the patient that the measured value is in the normal range
- encourage the patient to keep these metabolic parameters

- If the patient's measured value does not reach the target level, the pharmacist should:
  - inform the patient of
    - the measured value exceeding the normal range
    - the patient's carrying a higher risk of cardiovascular diseases
    - the necessity of life style changes
  - assess the patient's adherence to the drug therapy
  - inform the patient's GP of all the inadequate parameters of the patient in the referral letter (Appendix 4).

Risk group	Blood pressure (Hgmm)	Blood glucose level (mmol/l) Self-check	TC (mmol/l)	LDL-C (mmol/l)	HDL-C (mmol/l)	TG (mmol/l)	BMI (kg/m^2)/ waist circum-ference (cm)
Extreme high risk group	< 130/80	Fasting: < 5.6 Pp: < 7.5	< 3.5	< 1.8	> 1.0 (M) > 1.3 (F)	<1.7	< 25 M < 94 F < 80
High risk group	< 130/80	Fasting: < 5.5 Pp: < 7.5	< 4.5	< 2.5	> 1.0 (M) > 1.3 (F)	<1.7	< 25 M < 94 F < 80
Cardiovascular symptom free group	< 140/90	Fasting: < 5.5 Pp: 7.5	< 5.0	< 3.0	> 1.0 (M) > 1.3 (F)	<1.7	< 27 M < 102 F < 88
Metabolic syndrome	< 130/85	Fasting: < 5.5 Pp: < 7.5	< 5.0	< 3.0	> 1.0 (M) > 1.3 (F)	<1.7	< 27 M < 102 F < 88
Moderate-low risk group	< 140/90	Fasting: < 5.5 Pp: < 7.5	< 5.0	< 3.4	> 1.0 (M) > 1.3 (F)	<2.3	< 30 M < 102 F < 88

Table 6: Target values in different cardiovascular risk groups

2.2.3.5 Drug therapy monitoring

For patients who participate in the third level of the programme, a systematic review of the drug therapy is necessary. This involves proper drug documentation at the first pharmacist-patient meeting. At the following meetings the aim is to evaluate the changes and encourage the patient to reach the therapeutic goals. The process should be evaluated and recorded by the protocol.

2.2.3.5.1 Medical history record

The aim is to identify the current health problem of the patient and the medications that the patient is taking. The pharmacist should fill in the relevant parts of the metabolic syndrome drug therapy patient form (Appendix 5).
Questioning of the patient is divided into three main parts:

- Detecting diagnosed and non-diagnosed health problems
  - In this phase the patient should be asked about his/her current therapy, and the attitude towards his/her treatment and drug therapy (Is he/she satisfied? Does he/she feel necessity of any change in the therapy? Does he/she have any untreated complaint?)
- Medicines
  - The pharmacist should always ask 9 general questions and 1 about the patient's compliance. These questions help to assess the patient's adherence to and knowledge about his/her drugs.
    1 What disease are you taking your drugs for?
    2 Who prescribed the drug?
    3 What is the drug's mechanism of action?
    4 How long have you been taking that particular drug?
    5 What is the dosage of the taken drug?

6 When should the drug be taken?
7 How long do you have to take this drug?
8 Do you have any problem with consuming the drug?
9 Did you experience anything unusual when you were taking the drug?
10 Questions about adherence
- Since the last medicine purchase has the patient
  - Skipped medicine?
  - Forgotten to take the medication?
  - Stopped taking his/her medicine when felt better?
  - Stopped taking his/her medicine when experienced side effects?

- General review
  - The pharmacist should assess the patient's health state and try to find undiagnosed health problems by asking about the following:
    1 Head, hair
    2 Ear, eyes, nose, throat, mouth, neck,
    3 Hands (fingers, nails, etc…)
    4 Arms, upper limb muscles
    5 Heart
    6 Lungs
    7 Gastrointestinal tract
    8 Kidneys, urinal system
    9 Genital system
    10 Legs, feet
    11 Skeletal muscles
    12 Skin
    13 Psychiatric diseases, central nerve system problems
    14 Other
    - Smoking
    - Alcohol consumption
    - Coffee consumption
    - Vitamins and health supplements
    - Special vaccination
    - Allergies

The relevant questions should be asked at further patient-pharmacist meetings.

2.2.3.5.2 Patient education enhancing adherence

The pharmacist should educate the patient and offer the relevant patient information leaflets according to the answers given to questions 1 to 10 in section 2.2.3.5.1. If the patient answers at least 2 out the 10 questions negatively, the patient's adherence should be considered to be inappropriate. Adherence enhancement is necessary. The pharmacist should:

- Find out the reasons which led to the lack of adherence
  - Intentional non-adherence can be due to:
    - Side effects of medicine
    - Feeling of ineffectiveness of the drug
    - Multiple daily administration
    - High price of the drug
    - Other

    In such cases the pharmacist should identify the problem and should proceed according to section 2.2.3.5.4
  - Unintentional non-adherence
    - The patient forgets to take his/her medicine

    In this case the pharmacist should motivate the patient to keep a drug administration schedule and give the patient an information leaflet enhancing adherence.

2.2.3.5.3 Assessing the drug-related problems

First the health problems mentioned by the patient should be recorded.
The following should be noted down:

- The diagnosis date

- Whether the disease is controlled according to the measured metabolic parameters and reaches the target value. Target values should be evaluated according to section 2.2.3.4
- Does the health problem make the patient worry, or does it disturb the patient's daily routine?

All the drugs taken should be reported in the indication column. The following should be noted:
- The beginning date of the drug consumption
- The taken drug and its active agent
- The prescribed and taken dosages
- The pharmacist should evaluate the patient knowledge of the drug and of adherence
    - The compliance can be categorised in 3 main groups according to the relevant questions of section 2.2.3.5.1:
        - Incomplete knowledge/non-compliant patient
        - Partial knowledge/partly compliant patient
        - Well informed patient/good compliance
    - In case of patient from the 1st or 2nd category the pharmacist should proceed according to section 2.2.3.5.3

2.2.3.5.4 Evaluating drug-related problems (DRP)

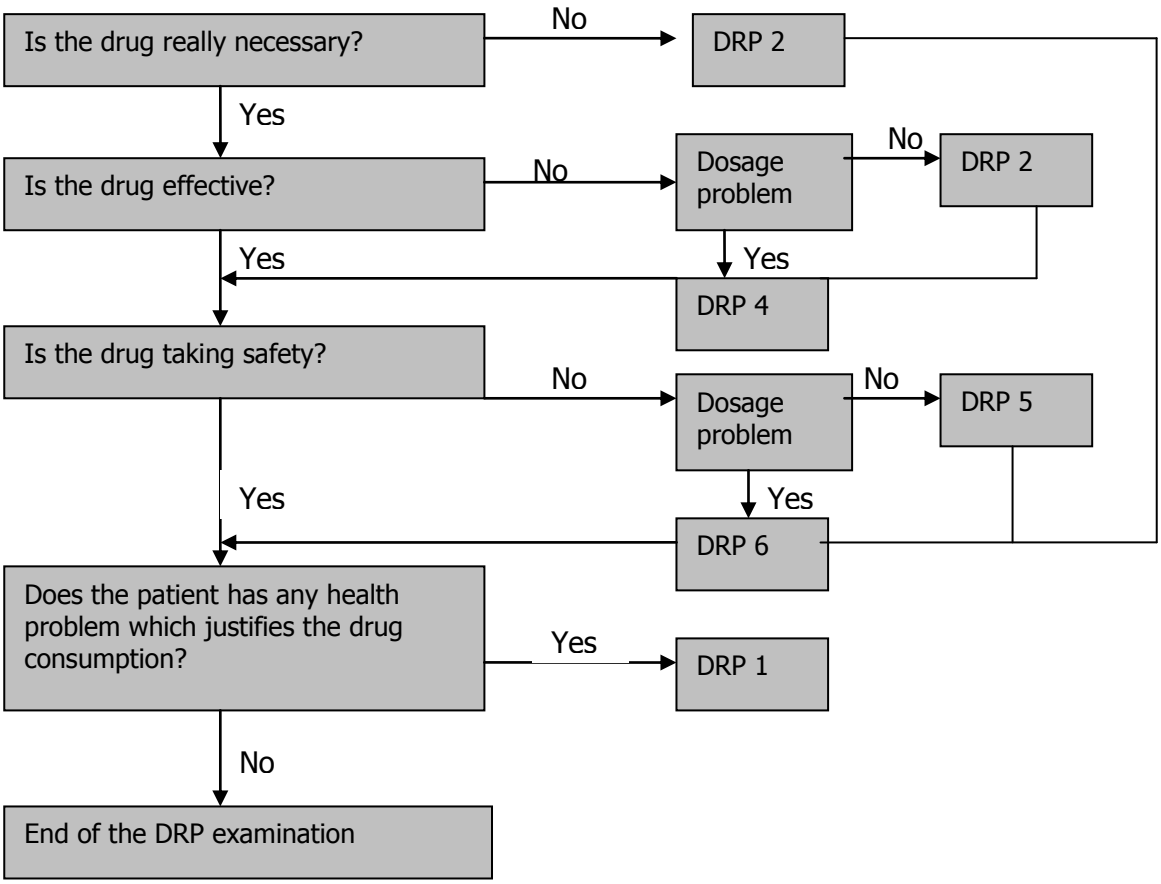
For the evaluation of drug-related problems the pharmacist should know the taken drugs and health problems of the patientin order to help evaluate whether the patient has proper treatment aims. If not, the evaluation of the drug-related problems will help avoid this problem. According to the Granadian classification, drug-related problems can be the following:

Necessity	
DRP1	**Untreated health problem.** The patient suffers from a health problem as a consequence of not receiving the medicine that he/she needs.
DRP2	**Effect of unnecessary medicine.** The patient suffers from a health problem as a consequence of receiving the medicine that he/she does not need.
Effectiveness	
DRP3	**Non-quantitative ineffectiveness.** The patient suffers from a health problem associated with a non-quantitative ineffectiveness of the medication.
DRP4	**Quantitative ineffectiveness.** The patient suffers from a health problem associated with a quantitative ineffectiveness of the medication.
Safety	
DRP5	**Non-quantitative safety problem.** The patient suffers from a health problem associated with a non-quantitative safety problem of the medication.
DRP6	**Quantitative safety problem.** The patient suffers from a health problem associated with a quantitative safety problem of the medication.

Table 7: Drug-related problems

To categorise the drug-related problems the pharmacist should ask 3 basic and 1 additional questions:
- Is the drug really necessary? The drug is necessary to take when the patients' health status requires it. Otherwise the medication is unnecessary (DRP2). If the medication is necessary, the pharmacist should ask the following question:
- Is the medical treatment effective? The medicinal treatment can be considered to be effective if the patient reaches the target value related to his/her health problem (Target values of section 2.2.3.5.1).
- Is the drug taking safe? The drug must being considered unsafe when there are any current or potential health problem which was noted on the documentation and can be a consequence of the consumption of the drug, or there is a current health problem which excludes the consumption of the particular drug.
- Has the patient any complaint which requires medicinal treatment, and the patient currently takes no medicine for it? This is a categorised drug-related problem (DRP1)

All the examinations should be documented on the metabolic syndrome drug therapy patient form (Appendix 5) by the pharmacist.
The algorithm of the examination of drug-related problems is shown on the following graph:



In case of drug-related problems the pharmacist should fill in the pharmacist's intervention form concerning the drug-related problem (Appendix 6).

2.2.3.5.5 Step following the assessment of drug-related problems

After identifying a drug-related problem, the next step is planning and implementing the pharmacy care programme. In case of parallel drug-related problems, the plan should be started by solving the higher risk problem. In case of drug-related problems the underlying causes should be identified. These can be the following, according to the drug-related problem:

Drug-related problem	**Underlying cause**
DRP1	Medication is necessary (lack of necessary medication)
	Unnecessary taken drug
	Multiply drug use from the same pharmacological category
	Non-adherence
	Improper medication choice
DRP4	Improper dosage
	Interaction
	Side effects
DRP6	Improper dosage
	Other:

Table 8: Underlying causes of drug-related problems

The pharmacist can recommend the following in the drug therapy plan:

- Change in dosage
    - Change in strength

    - Change in drug form, or frequency
- Change in medication
    - Change to new medication
    - Stop medication
    - Medication replacement (not by generic drug)
- Patient education
    - Reducing voluntary non-adherence
    - Reducing involuntary non-adherence
    - Life style counselling

To attain the drug therapy plan the pharmacist can use the following channels of communication:
- Oral communication with the patient
- Oral communication with the patient and information leaflet
- Oral communication with the physician
- Written referral to the physician

In case of drug-related problems the pharmacist should fill in the 2 copies of pharmacist's intervention form concerning drug-related problems (Appendix 6), and if the patient was referred to the GP, one copy should be also sent to the GP.

The pharmacist should always indicate the date of the pharmacy visit, and this is the latest time when the medication plan should be evaluated. Next time, if the patient's status has already changed, it should be indicated on the patient prevention form (Appendix 5).

2.2.3.6 Feedback

The pharmacist should follow the referred patient. The pharmacist should ask the patient information about the results of the visit to the GP, and should recorded it on the pharmacist's intervention form concerning drug-related problems (Appendix 6). If there is no information about the patient either from the patient or from the GP, the pharmacist should contact GP to get information about the patient's health status. This contact can be helped by the so-called referral letter to the GP (Appendix 8). The result should be indicated on the pharmacist's intervention form concerning drug-related problems (Appendix 6).

2.2.3.7 Professional information should be given to the Hungarian National Committee of Pharmaceutical Care

The pharmacist must finally send the report form of the third level of the metabolic syndrome (Appendix 7) to the Committee (HNCPC) and should also send the anonymous form of the metabolic syndrome patient form (Appendix 5).

2.2.3.8 Documentation

At the pharmacy all the informed consents (Appendix 1) should be recorded chronologically. The metabolic syndrome drug therapy patient forms (Appendix 5) should be recorded in patient order. The pharmacist's intervention form concerning drug-related problems (Appendix 6) should be double-copied. The second copy should be sent together with the referral letter. The first copy should be enclosed with Appendix 5 at the pharmacy.

If necessary the pharmacist should fill in the referral letter and send it to the GP (Appendix 4). The pharmacy should not keep any record of it, but the sending should be documented on the pharmacist's intervention form concerning drug-related problems.

The pharmacist must finally send the report form of the third level of the metabolic syndrome (Appendix 7) to the Pharmaceutical Care Professional Committee (HNCPC). The pharmacy should keep a record of it.

The following documentation (informed consent, metabolic syndrome drug therapy patient form, first copy of the pharmacist's intervention form concerning drug-related problems and the second copy of the report form of the third level of the metabolic syndrome) should be kept at the pharmacy according to the Act of data security in Health Care.

3. Appendices

Appendix 1: Informed consent

Informed consent:

I agree that (the pharmacy representative) of (pharmacy) may share the relevant information about my health status with my general practitioner, and send anonymous data to the programme coordinator (Hungarian National Committee of Pharmaceutical Care (HNCPC).

I agree that the results of my treatment may be published for scientific purposes in an anonymous way.

……, …. (day) …… (month) 200…. (year)

Name of the patient:……

Patient's ID number:……

Signature: ……

Appendix 2: Pharmacist's Prevention Form concerning Metabolic Syndrome

Pharmacist's prevention form concerning Metabolic Syndrome

triplicate prevention form pharmacist-GP-HNCPC

Name of the patient:…… Phone number:……..
Adress of the patient:……..
Name of the GP:…… Phone number:……..

Pharmacy:…… Pharmacist:……
Patient randomisation code:□□□□ Gender: □male □female
Year of birth:□□□□//prev. date:……(day)……(month)……(year)

I. General risk factors
□ Smoking □ Physical inactivity:Minimum 30 minutes long, mild excercises less than twice a week, or at least 20 minutes long, high intensity excercises less than three times a week.
□ Age males > 45, females >55 □ Family history: type-2 diabetes, stoke, MI, angina under the age of 55 for men, and under the age of 65 for women among close realtives.

II. Hypertension equipment:……
……arm □ check in a year (< 139/89 Hgmm)
…../….. □ check in a month and life style Hgmm change (140-159/90-99 Hgmm)
□ Refer to the GP (≥ 160/≥ 100 Hgmm)

III. Diabetes mellitus equipment:……
……. Mmol/l fasting (more than 8 hours after the last meal)
□ check in a year (fasting: < 5.6, pp: 7.8 mmol/l)
……. Mmol/l random (…. Hours after the last meal)
□ refer to the GP (fasting ≥ 5.6, pp ≥ 7.8 mmol/l)

IV. Dyslipidaemia (the worst value must be considered) equipment:……
….. hours since last meal □ Check in a year
…… mmol/l TC (TC < 5.2 mmol/l; LDL-C < 2.6 mmol/l; HDL-C ≥ 1.6 mmol/l; TG < 1.7 mmol/l)
…… mmol/l LDL-C □ Check in a month and life style change
…… mmol/l HDL-C (TC = 5.2-6.2 mmol/l; LDL-C = 2.6-3.3 mmol/l; TG = 1.7-2.3 mmol/l)
…….mmol/l TG □ Refer to the GP
(TC > 6.2 mmol/l; LDL-C > 3.3 mmol/l; HDL-C < 1.0 mmol/l; TG > 2.3 mmol/l)

V.Obesity (the worst value must be considered) equipment:……
……. Cm waist circumference (WCF) □ Check in a year BMI < 25 kg/m^2, WCF(M/F) < 94 cm; < 80 cm
……. kg body weight □ Check in 3 month, life style change
…… cm height BMI =25-35 kg/m^2; WCF (M/F) = 94-102 cm; 80-88 cm
…….kg/m^2 BMI □ Refer to the GP BM I≥ 35 kg/m^2; WCF (M/F) > 102 cm; > 88cm

VI Metabolic syndrome

Hypertension	Diabetes Mellitus	Dyslipidaemia	Dyslipidaeimia	Obesity
□ Diagnosed	□ Diagnosed	□ Diagnosed	□ Diagnosed	□ WCF (M) > 102 cm
□ Measuring in the pharmacy	□ Measuring in the pharmacy	□ Measuring in the pharmacy	□ Measuring in the pharmacy	□ WCF (F) > 88cm
≥ 130/≥ 85 Hgmm	Fasting: ≥ 5.6 mmol/l	HDL-C(M) < 1.0 mmol/l HDL-C(F) < 1.3 mmol/	TG ≥ 1.7 mmol/l	

Suggested life style changes (oral, written motivation)
□ Enhancing physical activity □ Diet □ Weight reduction □ Smoking cessation

Refer to the GP
- □ for measured metabolic parameter
- □ The patient has 3 or more metabolic syndrome criteria
- □ The patient has 2 metabolic syndrome criteria and 2 or more general risk factors

Control
Date1:…… □ appeared □ diagnosis, life style change □ absolute □ partly □ no change
Date1:…… □ appeared □ diagnosis, life style change □ absolute □ partly □ no change
□ Unsuccesfull life style change - refer to the GP

The guiding values are valid for non-diagnosed patients

Appendix 3: Metabolic syndrome patient form

Ask your pharmacist!
What is the metabolic syndrome?

Hypertension frequently occurs among obese people; high blood cholesterol level, high blood glucose level and diabetes are common as well. These symptoms altogether are called metabolic syndrome. Metabolic syndrome is also called the deadly four because these risk factors increase the risk of myocardial infarction 4-8 folds and increase the risk for developing arteriosclerosis, coronary heart disease, thrombosis and stoke. The development of metabolic syndrome is mainly due to bad eating habits, and lack of exercise.

Hypertension

Hypertension does not in itself give dramatic symptoms, but it is dangerous because it causes a highly increased risk for heart infarction and stroke, and heart and circulatory system diseases, atherosclerosis, thrombosis and renal failure are caused by it. 120/80 or lower is a normal blood pressure, 120 and 139 for the top number, or between 80 and 89 for the bottom number is prehypertension, 140/90 or higher is high blood pressure, and it requires treatment.

High blood glucose level

Sugar (glucose) provides energy to the body. In healthy people the glucose absorption is fast from the blood to the cells. In pathologic cases the absorption slows down, and the blood glucose level gets elevated. If the fasting glucose (no food intake for more than 8 hours) is regularly higher than 6.1 mmol/l, gets higher than 7.8 mmol/l after meals and does not reach the take-off level within 2 hours, it will refer to diabetes or pre-diabetic stage. In case of self-check, the borderline for fasting glucose level is 5.6 mmol/l. Type-2 diabetes is part of the metabolic syndrome.

High cholesterol level

The cholesterol level is high if the total cholesterol level exceeds 5.2 mmol/l. A high cholesterol level can lead to atherosclerosis. The Low Density Lipoprotein (LDL) cholesterol is sometimes called bad cholesterol, and its elevated level carries a higher risk for atherosclerosis. The High Density Lipoprotein (HDL) cholesterol is sometimes called good cholesterol and has a cardioprotective effect. In case of a metabolic syndrome another fat (trigriceride) level is elevated. Its normal level is under 2.3 mmol/l. Obesity elevate the level of LDL and reduce the level of HDL.

Obesity

Apple-type obesity is not just an aesthetical problem, but the metabolism of the abdominal fat cells are different from the metabolism of subcutaneous fat cells and this, combined with other risk factors, can lead to developing new risk factors. The Body Mass Index helps assess the grade of obesity. To calculate the body mass index: Divide weight (kg) by height (metres) squared (kg/m^2). The normal range is 20 to 25.

If the total is in the range of 25 to 30, then it means that you have an overweight. A BMI of 30 or greater indicates obesity. Waist circumference above 88 cm for women and 94 cm for men indicates abdominal obesity.

Measurement sheet at the pharmacy*

Name:

Name of the pharmacy

Name of the pharmacist

Measuring circumstances: ..... hours after meal

Blood pressure: ...../..... Hgmm

Blood glucose level: ..... mmol/l

Total cholesterol level: ..... mmol/l

Triglycerol level: ..... mmol/l

BMI: ..... kg/m^2

Waist circumference: ..... cm

Recommendations by the pharmacist:

□ **Patient should visit their GP**
□ **Control at the pharmacy: 1 .....**
2 .....
□ **Life style changes**

*The measured values are only for informative purposes, they are not valuable for the establishment of a diagnosis or a modification of the treatment. Please inform your general practitioner of the results.

Life style changes

Weight reduction

In case of obesity, weight reduction is suggested, and the grade of weight reduction should be in the range of 7-10 % of the total body weight over half a year. This target should be reached by increased physical activity and diet changes.

Physical activity

Doing mild-moderate exercise 30-60 minutes per day 5-7 times per week (e.g.: walking) reduces the risk of developing metabolic risk factors. More intensive exercise (e.g.: running) increase the effect, but for men over 40, and women over 50, or in case of any chronic disease, consultation with the physician is necessary. Dynamic type, aerob exercises are recommended (e.g.: walking, cycling, horse riding, swimming, ball games). The intensity of the exercise can be described by the pulse beats which should be in a range from 120 to 150 beats/min. In case of chronic cardio-vascular or metabolic diseases, low intensity exercises are suggested, and the burden should be raised gradually. Mild intensity exercises for 60-90 minutes are suggested in case of obesity.

Diet

The energy intake should keep balance with the physical activity. Diet should be rich in vegetables, fruit (> 400 g/day); whole grain, fibre rich cereals and fish. Consumption of low-fat meat, vegetable protein, fat-free milk is also beneficial. Reducing the intake of high-sugar soft drinks and food is recommended. Meals should be made with low salt content. Alcohol intake should be moderate. These recommen-dations are valid when eating out as well.

Smoking cessation

Smoking is an independent risk factor for cardiovascular morbidity. Passive smoking and "light" cigarettes increase the risk for developing cardiovascular diseases as well. Quitting smoking reduces the risk of cardiovascular diseases in a year. To stop smoking, ask your health care provider for advice.

Self-check

You should check your weight, blood pressure, after-meal blood glucose level and cholesterol level regularly.

Appendix 4: Referral letter to the general practitioner about the metabolic syndrome assessment at the pharmacy

Referral letter to the general practitioner about the metabolic syndrome assessment at the pharmacy.

Dear Dr. ……,

Mr/Ms ……. (Patient name)

Has the following cardiovascular profile, and we measured the following values at the pharmacy:

- A ……/……. Hgmm blood pressure
- B……. mmol/l blood glucose level
- C……. mmol/l total cholesterol,…… mmol/l LDL-C ..... mmol/l HDL-C
- D……. mmol/l triglicerol
- E…….. kg/m^2 BMI, ……. cm waist circumference
- F At least three of the criteria for metabolic syndrome coexist
- G General risk factors and at least two criteria for metabolic syndrome coexist.

  In these cases, further examinations are necessary. If you agree with these suggestions, please initiate the necessary examinations.

The patient has the following results for the already treated diseases at the pharmacy:

- A ……/……. Hgmm blood pressure
- B……. mmol/l blood glucose level
- C……. mmol/l total cholesterol,…… mmol/l LDL-C ..... mmol/l HDL-C
- D……. mmol/l triglicerol
- E…….. kg/m^2 BMI, ……. cm waist circumference, which exceeds the required target value, and changing in the therapy may be necessary.
- F There is a chance for medicinal error in the medicinal therapy.

Please inform me of the results!

Date:

Thank you for your cooperation:

Pharmacist Pharmacy

Appendix 5: Metabolic syndrome drug therapy patient form

Metabolic syndrome drug therapy patient form (duplicated pharmacist-HNCPC)

Name of the patient:……..

Address of the patient:…… Phone: ……..

Name of the general practitioner:…… Accessibility: ……..

Name/address of the pharmacy:……..

Randomisation code: □□□□ Gender: □ Male □Female Year of birth: □□□□

Assessment of cardiovascular risk factors

□ Very high risk group
- □ Cardiovascular disease and
- □ Diabetes, or
- □ Heavy smoking, or
- □ Metabolic syndrome

□ High risk group
- □ Coronary heart disease
- □ Peripheral vascular disease
- □ Diabetes mellitus
- □ Chronic renal failure

□ High risk group, lack of cardiovascular symptoms
- □ TC > 8 mmol/l
- □ BP > 180/110 Hgmm
- □ BMI > 40 kg/m^2
- □ Primary familial heritage
- □ Ankle-arm index ≤ 0.9
- □ Metabolic syndrome

□ Low-risk group

None of the symptoms are present

Mesured values	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	**Target value**
BP (Hgmm)											
Fasting blood glocuse (mmol/l)											
Blood glucose pp. (mmol/l)											
TC (mmol/l)											
LDL-C (mmol/l)											
HDL-C (mmol/l)											
TG (mmol/l)											
BMI (kg/m^2)											
Waist circumf. (cm)											

Metabolic syndrome drug therapy patient form (duplicated)
Name of the patient……
Randomization code: □□□□ Name/address of the pharmacy:……
Drug allergy:……

Health problem				**Medication**					**DRP category**		**Interv.**
Beginning (…year,…month)	Health problem (disease)	Control (Y/N)	Worry? (Y/N)	Beginning (since)	Drug/active agent	Dosage	Adher. 1-3	Knowl. 1-3	DRP cat.	Result	Date

Note	DRP1: Medicinally not treated health problem DRP2: Health problem caused by unnecessary drug consumption	DRP3: Health problem caused by qualitative inefficiency DRP4:Health problem caused by quantitative inefficiency	DRP5: Qualitative safety problem. Health problem caused by drugs DRP6: Quantitative safety problem. Healthy problem caused by dosing problems

Appendix 6: Pharmacist's intervention form concerning drug-related problems

Pharmacist's intervention concerning drug-related problems
(Duplicated: pharmacist-doctor)

Name of the patient: ..... Availability:.....
Health problem: .....

Name of the drugs concerned by the drug-related problems	
Name of the drugs, dosage forms	**Dosage**

Identifying drug-related problems		
	DRP1	Medicinally not treated health problem
	DRP2	Health problem caused by unnecessary drug consumption
	DRP3	Health problem caused by qualitative inefficiency
	DRP4	Health problem caused by quantitative inefficiency
	DRP5	Qualitative safety problem. Health problem caused by drugs
	DRP6	Quantitative safety problem. Healthy problem caused by dosing problems

Drug-related problem	
	Present
	Risk

Presumed cause of drug-related problem	
	Interaction
	Non-adherence
	Duplication
	Drug excretion
	Side effect
	Dosage
	Other:

Intervention to solve drug-related problem		
Change in the dosage	Change in the strength	
	Change in the dosage forms	
Change in the medication	New medication	
	Leaving current medication	
	Change in the current medication	
Patient education	Reducing voluntary non-adherence rate	
	Reducing involuntary non-adherence rate	
	Life style education	
Other		

Communication channel	
Oral communication with the patient	Date of the next visit
Written communication with the patient	
Oral communication with the GP (referral letter)	
Written communication with the GP (referral letter)	

Result	Health problem solved	Health problem unsolved
Accepted intervention		
Not accepted intervention		

Appendix 7: Report form of the third level of the metabolic syndrome protocol

Report form of the metabolic syndrome pharmaceutical care third level
Name/address of the pharmacy: ……..
Name(s) of the pharmacist(s): ……
Time period: …….. year …….. quarter
Involved patients: ……
Newly involved patients (in the last quarter): ……..
Assessment of cardiovascular risk factors: ……..
Very high risk group: ……..
High risk group: ……..
High risk group lack of cardiovascular symptoms: ……..
Low-risk group: ……

Number of blood pressure checks: ……
Number of patients who reach the target value: ……
Number of patients who do not reach the target value: ……
Number of referrals to the GP: …….
Number of answers: …; therapy has been changed: …, no therapy change: ….

Number of blood glucose checks: ……
Number of patients who reach the target value: ……
Number of patients who do not reach the target value: ……
Number of referrals to the GP: …….
Number of answers: …; therapy has been changed: …, no therapy change: ….

Number of blood lipid checks: ……..
Incl. blood cholesterol checks: ……
Number of patients who reach the target value: ……
Number of patients who do not reach the target value: ……
Number of referrals to the GP: …….
Number of answers: …; therapy has been changed: …, no therapy change: ….

Incl. blood triglycerol checks: ……
Number of patients who reach the target value: ……
Number of patients who do not reach the target value: ……
Number of referrals to the GP: …….
Number of answers: …; therapy has been changed: …, no therapy change: ….

Assessment of the grade of obesity: ……..
Number of determined BMI: ……
Number of patients who reach the target value: ……
Number of patients who do not reach the target value: ……
Number of referrals to the GP: …….
Number of answers: …; therapy has been changed: …, no therapy change: ….

Number of determined waist circumference: ……
Number of patients who reach the target value: ……
Number of patients who do not reach the target value: ……
Number of referrals to the GP: …….
Number of answers: …; therapy has been changed: …, no therapy change: ….
Assessment of drug-related problems

Identifying drug-related problems		
	DRP1	Medicinally not treated health problem
	DRP2	Health problem caused by unnecessary drug consumption
	DRP3	Health problem caused by qualitative inefficiency
	DRP4	Health problem caused by quantitative inefficiency
	DRP5	Qualitative safety problem. Health problem caused by drugs
	DRP6	Quantitative safety problem. Health problem caused by dosing problems

Presumed cause of drug related problem	
	Interaction
	Non-adherence
	Duplication
	Drug excretion
	Side effect
	Dosage
	Other:

Intervention to solve drug-related problem		
Change in the dosage	Change in the strength	
	Change in the dosage forms	
Change in the medication	New medication	
	Leaving current medication	
	Change in the current medication	
Patient education	Reducing voluntary non-adherence rate	
	Reducing involuntary non-adherence rate	
	Life style education	
Other		

Communication channel	
Oral communication with the patient	
Written communication with the patient	
Oral communication with the GP (referral letter)	
Written communication with the GP (referral letter)	

Result	Health problem solved	Health problem not solved
Accepted intervention		
Not accepted intervention		

Date:

Pharmacy, pharmacist:

Appendix 8: Model reply letter for General Practitioner

Dear Mr/Ms……..!

I made the necessary examinations on Mr/Ms ……. (patient name) referred by you, and I diagnosed the following new diseases:

- □ Hypertension
- □ Diabetes Mellitus
- □ Dyslipidaemia
- □ Obesity
- □ Metabolic Syndrome

I made the necessary examinations on Mr/Ms …….(patient name) referred by you, and I made the following changes in the therapy of the already treated disease:

- □ Change in the dosage
- □ New drug combination
- □ Change to new active agent

On the field of drug-related problems in Mr/Ms …….(patient name), referred by you, I made the following therapy changes:

- □ Change in the dosage
- □ Change in the regimen
- □ Addition of a new drug
- □ Discontinuation of a drug
- □ Replacement of a drug

Thank you for your cooperation!

Date:

Doctor's name