SÚKL
Státní ústav pro kontrolu léčiv

Státní ústav pro kontrolu léčiv
Šrobárova 48, 100 41 Praha 10

tel.: +420 272 185 111
fax: +420 271 732 377

e-mail:posta@sukl.cz
web: www.sukl.cz

INFORMATION FOR MARKETING AUTHORISATION HOLDERS

OTC Medicinal Products Subject to Sales Restriction - Implementation of a New Category

The State Institute for Drug Control (SÚKL) has been preparing the implementation of a new category of supply of medicinal products, **"OTC medicinal products subject to sales restriction"** on the grounds of provisions of Section 39 (3) of the new Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, as amended ("Act on Pharmaceuticals"). Under the provisions of the Act on Pharmaceuticals the possibility to place sales restrictions on supply of a medicinal product available without prescription shall apply from 1 January 2009.
The introduction of the new category of supply of medicinal products (hereafter "OTC with sales restriction") into day-to-day practice requires close cooperation of all stakeholders, i.e. marketing authorisation holders, healthcare professionals, health insurance companies and patients. In support of the above SUKL has prepared a public communication campaign targeted first on professionals and afterwards also on the general public. Within this campaign targeted questions will be used to collect information needed for further action to be taken by SUKL in the area of changes in supply of medicinal products and in the same way the new category of medicinal products will be presented to the public.

Please find below for your comments the criteria for inclusion of medicinal products in the category "OTC with sales restriction", conditions for supply and links to medical care, and a list of ATC groups which in the opinion of SUKL experts may be placed in the new category of supply. Thanks to the perfect knowledge of your own portfolio the proposed category OTC with sales restriction may be amended including appropriate restrictions.

The new system is aimed (among others) at the harmonisation of conditions governing supply of medicinal products which contain the same active substance, which have the same pharmaceutical form and strength, and also at the harmonisation of conditions for supply of interchangeable medicinal products with similar efficacy and risk/benefit ratio in therapeutic use.
To achieve this aim, also the possibility laid down by law to institute administrative proceedings *ex offo* will be applied, however, medicinal products authorised by mutual recognition procedure (MRP) where the Czech Republic is not a RMS will be excluded in the first phase of this exercise.

Proposed general criteria for inclusion of medicinal products into OTC with sales restriction category

SÚKL experts have set criteria that will be taken as grounds for the assessment of supply categories for individual medicinal products. In the table below, the basic criteria which will be considered in applications for inclusion of a medicinal product into the category OTC with sales restriction are listed in the left column. These criteria will be applied also in situations when SUKL initiates proceedings on inclusion of a product into this category on its own motion.
In the right column, situations that may occur in relation to the criterion on the left and in case of supply without prescription are described and explained.

Indication	**Acute conditions** – possibility of correct self-diagnosis by patient **Chronic indications** – diseases where "stable course is presumed, without a necessity for frequent consultations with doctor, self-monitoring by patient *(patient able to identify in time his/her need for medical consultation)* **Need for medical "supervision" during treatment** – frequent laboratory controls, adjustment of posology, where applicable

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Active substance	**Risk** – substance falls into a group subjected to close monitoring for safety reasons; risk management plans in place; need for close pharmacovigilance supervision **"New substance"** – little experience with adverse reactions, interactions, restrictions **Interactions** – high interactivity with other active substances, food supplements, yet unknown or expected but yet not described interactions **Efficacy** – supplementary, supportive versus causal treatment
Strength of medicinal product	Need for restrictions, suitability in relation to indications, Risk factors – restrictions in relation e.g. to the stage of the chronic disease, intoxication, abuse
Package size	Need for restrictions, suitability in relation to indications, Risk factors – restrictions in relation e.g. to the stage of the chronic disease, intoxication, abuse
Pharmaceutical form, route of administration	Suitability in relation to indications
Impact on use in relation to advertising	Risk assessment, safe use, economic impact on public healthcare system
Impact on use in relation to the health insurance system	Assessment of impact on the balance of public health insurance system
„Public demand"/interest	Evaluation of issues raised by patients, health professionals, marketing authorisation holders, health insurance companies

Below please find the **"Positive List"**, which contains ATC groups included in the new category as well as the proposed/relevant restrictions for supply.

ATC groups and proposed restrictions are submitted for comments within this public consultation exercise and may be amended or modified on the grounds of new information gained within marketing authorisation activities. Please not that this is not the final list.

Decisions taken within regulatory activities in the field of marketing authorisation will include possible limitations, namely the restricted number of packages supplied without medical prescription, supply of the product after diagnosis has been established by a doctor (the first package is subject to medical prescription), age restriction (e.g. children under specified age, elderly patients above 65 years of age), pharmacist's warning upon supply of the product (risks, interactions, limited period of use etc.), verification of patient's data upon supply (age, diagnosis, concomitant therapy). Information on supply of medicinal products will be registered in the Central Data Repository, which will allow pharmacists to control the established restrictions when supplying medicinal products from the category OTC with sales restriction. In the case of a restricted number of packages per purchase it will be possible to control e.g. the number of packages and date of purchase of the medicinal product in question by the given person.
Labelling and package leaflets of medicinal products placed in the category OTC with sales restriction will have to be modified in line with the requirements set for medicinal products available without medical prescription.

The "Positive List" of ATC groups

ATC Code	Name of ATC code	Indication	Restriction
A03A	Drugs for functional bowel disorders	Irritable bowel syndrome	For detailed information see the Proposed Sales Restrictions section
A03BB01	Butylscopolamine	Irritable bowel syndrome	For detailed information see the

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			Proposed Sales Restrictions section
C02AB	Methyldopa	Hypertension	For detailed information see the Proposed Sales Restrictions section
C02AC	Imidazoline receptor agonists	Hypertension	For detailed information see the Proposed Sales Restrictions section
C02CA	Alpha-adrenoreceptor antagonists	Hypertension	For detailed information see the Proposed Sales Restrictions section
C04AE01	Ergoloid mesylates	Peripheral vascular diseases, cerebrovascular insufficiency in the elderly	For detailed information see the Proposed Sales Restrictions section
C05A	Antihemorrhoidals for topical use	C05AA* Antihemorrhoidals containing corticosteroids	
C10AA*	HMG CoA reductase inhibitors (statins)		
C10AB *	Fibrates	Hypercholesterolaemia, hyperlipidaemia	
C10AC *	Bile acid sequestrants	Primary hypercholesterolaemia for which statins cannot be used	
C10AX *	Other cholesterol and triglyceride reducers		
G03A *	Hormonal contraceptives for systemic use		
H03C *	Iodine therapy	Prophylaxis and treatment of struma in case of iodine shortage in diet or after partial strumectomy	
M01AB01	Indometacin		
M01AE51	Ibuprofen, combinations containing pseudoephedrine		For detailed information see the Proposed Sales Restrictions section
M04 *	Antigout preparations		
N02BA51	Acetylsalicylic acid, combinations excl. psycholeptics containing pseudoephedrine		For detailed information see the Proposed Sales Restrictions section
N02BE71	Paracetamol, combinations with psycholeptics containing pseudoephedrine		For detailed information see the Proposed Sales Restrictions section
N02CC *	Selective serotonin agonists (triptans)	Treatment of migraine	
N03 *	Antiepileptics		
N04 *	Anti-Parkinson drugs		
N07AA *	Anticholinesterases	Treatment of myasthenia gravis	
N07C *	Antivertigo preparations	Treatment of Meniere's disease	
R03A *	Adrenergics, inhalants	Prevention and treatment of asthma bronchiale	
R03B *	Other drugs for obstructive airway	Obstructive airway diseases	

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	diseases, inhalants (glucocorticoids, anticholinergics, nedocromil)		
R03CC *	Selective beta-2-adrenoreceptor agonists	Prevention and long-term bronchodilatation therapy in asthma bronchiale, chronic obstructive bronchitis and pulmonary emphysema	
R03D *	Other systemic drugs for obstructive airway diseases (xanthines, leukotriene receptor antagonists)	Obstructive airway diseases	

Note: Suggestions of sales restrictions will yet be considered in the ATC groups marked with an asterisk (*).

Proposed Sales Restrictions

Note: If more indications are approved for a product, OTC supply with sales restrictions relates only to the indication listed in the table. In other indications, the product will remain subjected to medical prescription (this does not apply to products containing pseudoephedrine).

Preparations/ indications	ATC codes	Maximum number of packs supplied within a single supply	Conditions for supply
Products containing pseudoephedrine (PE)	M01AE51 N02BA51 N02BE71	24 units (tablets, capsules etc.) (corresponds to 720mg PE)	– The pharmacist has to verify in the Central Data Repository, if a person asking for a product has obtained any product containing PE within the last seven days. If he/she has, the pharmacist must not supply such product. – The pharmacist shall be obliged to send a report on the realised supply to the Central Repository within the scope laid down by SUKL. – The next supply of any product containing PE to the same person is possible only after 7 days of the previous supply. – Products containing PE cannot be mail-ordered.
Irritable bowel syndrome	A03AA04 A03AB06 A03AD02 A03AX58 A03BB01	1 pack	– The irritable bowel syndrome diagnosis has been verified by a doctor (i.e. the doctor has given the patient a prescription). – The pharmacist will verify the diagnosis, ask a patient about the course of the disease and possible changes in symptoms. He/she will also verify the supply of the medicinal product on prescription within 6 months. – The pharmacist will supply the product only after verification of the diagnosis and prescription within the last 6 months has been verified and only if the symptoms have not changed.
Hypertension	C02AC05 C02AC06 C02CA04 C02CA06	for 3-month treatment	– The diagnosis of hypertension has been verified by a doctor (i.e. the doctor has given the patient a prescription). – The pharmacist will measure the patient's blood pressure on the arm and by asking the patient targeted questions he/she will determine whether the patient has diabetes mellitus, renal disease or has ever had a heart attack or stroke

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			– The pharmacist will supply the product only if all of the following conditions are fulfilled: a) Blood pressure is less than 130/80mmHg in persons with obesity, diabetes mellitus, renal disease, history of heart attack or stroke, or less than 140/90mmHg in other persons; b) Blood pressure is not less than 100/60mmHg; c) Heart rate does not exceed the physiological range of 60-90 pulses/min; d) Hypertension is treated with monotherapy; e) The report on the supply of the product on a medical prescription is not older than 12 months.
Methyldopa / hypertension	C02AB01	for 3-month treatment	– The diagnosis of hypertension has been verified by a doctor (i.e. the doctor has given the patient a prescription). – The pharmacist will measure the patient's blood pressure on the arm and by asking the patient targeted questions he/she will determine whether the patient has diabetes mellitus, renal disease or has ever had a heart attack or stroke – The pharmacist will supply the product only if all of the following conditions are fulfilled: a) Blood pressure is less than 130/80mmHg in persons with obesity, diabetes mellitus, renal disease, history of heart attack or stroke, or less than 140/90mmHg in other persons; b) Blood pressure is not less than 100/60mmHg; c) Heart rate does not exceed the physiological range of 60-90 pulses/min; d) Hypertension is treated with monotherapy; e) The patient uses the product for more than 3 months f) The report on the supply of the product on a medical prescription is not older than 6 months.
Peripheral vascular diseases, cerebrovascular insufficiency in the elderly	C04AE01	for 3-month treatment	– The pharmacist will measure the patient's sitting blood pressure on the arm. – The pharmacist will supply the product only if all of the following conditions are fulfilled: a) Blood pressure is be less than 100/60mmHg; b) Heart rate does not exceed the physiological range of 60-90 pulses/min; c) The report on the supply of the product on a medical prescription is not older than 12 months.

For easier orientation, SÚKL has also created a "Negative list" containing the ATC groups which pursuant to the Act on Pharmaceuticals cannot be classified as "OTC supply with sales restrictions" due to the nature of the active substance, the pharmaceutical form or indication (narcotic and psychotropic substances, products used parenterally, products with a risk of substance abuse, with serious adverse drug reactions or those necessitating further investigation).
The negative list will be continuously revised and other ATC groups will be added as necessary.

The "Negative list" of ATC groups

ATC Code	Name of ATC code	Indications**
A01AC	Corticosteroids for local oral treatment	Decubitus and ulceration resulting from mechanical irritation, stomatitis aphthosa, pemphigus vulgaris, allergic mucosal reaction, lichenoid lesion, mucosal reactions and defects due to chemotherapy and irradiation
A03D	Antispasmodics in	Before and after instrumental examination, pain in non-

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	combinations with analgesics	extensive surgeries
A03E	Antispasmodics and anticholinergics in combination with other drugs	Spastic pain of smooth muscles, enteric, biliary and renal colic, urinary bladder tenesmus, spastic dysmenorrhoea, before and after instrumental examination
A07E	Intestinal antiinflammatory agents	Treatment of colitis ulcerosa and Crohn's disease
A08	Antiobesity preparations	Only for patients who do not respond adequately to a weight reduction programme (they are unable to maintain or achieve weight reduction by 5% within 3 months)
A10	Drugs used in diabetes	All indications
A14	Anabolic agents for systemic use	Conditions associated with negative nitrogen balance, therapy of osteoporosis, metastatic breast cancer, anaemia related to bone marrow failure
B01	Antithrombotic agents	All indications
B02	Antihemorrhagics	All indications
B05	Blood substitutes and perfusion solutions	All indications
B06	Other hematological agents	Surgery, orthopaedics: therapy of acute and chronic periarticular inflammation of the shoulder, arm and knee. Local anaesthesia: acceleration of action of local anaesthesia, enhancement of desensitized area Ophthalmology: for decreasing motility of ocular muscles during eye surgery. Internal medicine: acceleration of resorption of injected drugs. Obstetrics: for increasing flexibility of soft tissues of birth canal during labour
C01	Cardiac therapy	C01A Cardiac glycosides, C01B Antiarrhytmics, C01C Cardiac stimulants, C01D Vasodilators used in cardiac diseases, C01E Other cardiac preparations
C03	Diuretics	C03C High-ceiling diuretics, C03D Potassium-sparing agents, C03E Diuretics and potassium-sparing agents in combination
C07	Beta blocking agents	All indications
C08	Calcium channel blockers	All indications
C09	Agents acting on the renin-angiotensin system	All indications
D01B	Antifungals for systemic use	Onychomycosis, tinea capitis, cutaneous mycotic infections (tinea corporis, tinea cruris, tinea pedis), cutaneous candidosis where systemic use is appropriate due to infection site, severity, and scope
D07	Corticosteroids excl. weak corticosteroids	All indications
D10B	Anti-acne preparations for systemic use	Retinoids – treatment of severe acne resistant to antibiotics
G01	Gynecological antiinfectives and antiseptics	G01A Antiinfectives and antiseptics, excl. combinations with corticosteroids – only antibiotics
G02	Other gynecologicals	G02A Oxytocics, G02B Contraceptives for topical use (intrauterine, intravaginal), G02CA Sympathomimetics, labour repressants, G02CB Prolactine inhibitors
G03	Sex hormones and modulators of the genital	G03B Androgens, G03C Estrogens, G03D Progestogens, G03E Androgens and female sex hormones in

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	system	combinations, G03F Progestogens and estrogens in combinations, G03G Gonadotropins and other ovulation stimulants, G03H Antiandrogens, G03X Other sex hormones and modulators of the genital system
G04BD	Urinary antispasmodics	All indications
G04C	Drugs used in benign prostatic hypertrophy	G04CA Alfa-adrenoreceptors antagonists, G04CB – Testosterone–5-alpha reductase inhibitors
H	Systemic hormonal preparations, excl. sex hormones and insulins	H01 Pituitary and hypothalamic hormones and analogues, H02 Corticosteroids for systemic use, H03B Antithyroid preparations, H05 Calcium homeostasis
J	Antiinfectives for systemic use	All indications
L01	Antineoplastic agents	All indications
L02	Endocrine therapy	All indications
L03	Immunostimulants	Excl. L03AX
L04	Immunosuppresive agents	All indications
M01AH	Coxibs	All indications
M01C	Specific antirheumatic agents	All indications
M03	Muscle relaxants	All indications
M05	Drugs for treatment of bone diseases	All indications
N01	Anesthetics	Excl. transdermal and oral
N02A	Opioids	All indications
N02CA	Ergot alkaloids	Treatment of attacks of migraine
N05	Psycholeptics	All indications
N06	Psychoanaleptics	Excl. N06BX Other psychostimulants and nootropics and N06DA Anticholinesterases (treatment of dementia)
N07BB	Drugs used in alcohol dependence	All indications
N07BC	Drugs used in opioid dependence	All indications
N07X	Other nervous system drugs	All indications
P01	Antiprotozoals	All indications
R01BA	Sympathomimetics	Nasal decongestants for systemic use (they contain pseudoephedrine)
R05DA	Opium alkaloids and derivatives	All indications
R05FA	Opium derivatives and expectorants	All indications
R07AA	Lung surfactants	All indications
R07AX01	Nitric oxide	All indications
S01A	Ophthalmologicals - Antiinfectives	All antibiotics and antivirals
S01B	Antiinflammatory agents	All indications
S01C	Antiinflammatory agents and antiinfectives in combination	All indications
S01E	Antiglaucoma preparations and miotics	All indications
S01F	Mydriatics and cycloplegics	All indications
S01L	Substances for treatment of age related macular degeneration	All indications

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S02B	Corticosteroids	All indications
S02C	Corticosteroids and antiinfectives in combination	All indications
S02DA	Analgesics and anesthetics	Treatment of otitis

*** Note: The "Indications" column „contains indications for which the supply is subject to medical prescription. The medicinal products in the same ATC group with other indications are already OTC products or can be classified as OTC or OTC with sales restriction.*

Relations between supply regulation and reimbursement
The switch to OTC with sales restriction does not present a risk of losing the option to determine the level and conditions of reimbursement for the medicinal product. If a patient, after a consultation with his/her doctor, collects his/her medicine from a pharmacy with a medical prescription (first diagnosis of condition or repeated medical consultation due to chronic condition), he/she will receive the medicinal product and reimbursement from health insurance will also be granted.
This category will allow patients to purchase the medicinal product also without medical prescription; in such case, however, they will have to pay the full price.

Relations between supply regulation and advertising
As regards the promotion of OTC medicinal products subject to sales restriction, **direct-to-consumer advertising will be allowed**. The impact of direct-to-consumer advertising will be always evaluated as one of the criteria when suitability of inclusion of a medicinal product in the OTC with sales restriction category is assessed.

Dynamics of the system and regular reviews
Medicinal products placed in the OTC with sales restriction category will be subjected to ongoing monitoring from the pharmacovigilance point of view with a particular emphasis on the safety and potential risks of use, and with a of view of the impact of advertising on proper use. When a negative impact is found (e.g. increased number of cases of misuse having potential effect on human health, complications of chronic conditions, need for more frequent medical consultations) the medicinal product will be placed in a category preventing the occurrence of such events.
The marketing authorisation holders' statutory obligation to perform regular monitoring and review the quality, safety and efficacy of medicinal products applies also to this category.

You are invited to send your comments and proposals to the following address: posta@sukl.cz before September 15 2008. Please indicate "OTC s omezením/OTC with Sales Restriction" as the subject of your message.

Thank you for your cooperation and your comments.

MUDr. Ivana Koblihová
Deputy Director for Regulatory Affairs
State Institute for Drug Control