LÆGEMIDDEL STYRELSEN

DANISH MEDICINES AGENCY

Annual report on the inspection of retail saleof OTC medicines 2008-9

Contents

1. Background

This annual report presents the results of the inspections carried out by the Danish Medicines Agency in 2008 in the retail distribution chain (excluding pharmacies), i.e. supermarkets, chemists, petrol stations and pet shops, etc. The report covers both the pharmacies' OTC outlets and companies that have been granted an authorisation for retail distribution by the Danish Medicines Agency.

A number of medicinal products have been licensed for retail distribution outside pharmacies, for example in supermarkets, kiosks, chemists, and petrol stations. For humans, this includes products such as smoking cessation products, cough and cold remedies, skin products and painkillers. For animals it includes flea products and certain iron and vitamin products.

Medicinal products allowed for sale outside pharmacies are classified in either of the following three dispensing groups: HF[1] (e.g. cough and cold remedies and skin products) or HX[2] (e.g. painkillers) or HV[3] (flea products for animals).

Retail distributors who would like to sell medicinal products must obtain an authorisation from the Danish Medicines Agency. This authorisation covers all medicinal products of dispensing groups HF and HX or dispensing group HV.

[1] HF = Over-the-counter medicine. Human medicinal product sold in non-pharmacy outlets.

[2] HX = Over-the-counter medicine. Human medicinal product sold in non-pharmacy outlets. Maximum 1 package/customer/day.

[3] HV = Over-the-counter medicine. Veterinary medicinal product sold in non-pharmacy outlets.

In addition to retail distributors who hold an authorisation, so-called OTC outlets also sell over-the-counter products. An OTC outlet is a retail shop that receives over-the-counter medicines from a pharmacy with which it has entered into an agreement. These shops therefore do not need authorisation from the Danish Medicines Agency. OTC outlets are permitted to sell the medicinal products that are placed in the dispensing groups HF, HX and HV. In addition, OTC outlets may dispense sealed bags containing other medicinal products ('medicine bags') that have been processed and packed at a pharmacy with which the OTC outlet has an agreement.

1.1. The rules in brief

Distributors of medicinal products are governed by a number of common rules regardless of the assortment of products they carry:

- The sale of medicinal products to persons under the age of 15 is prohibited,
- Medicinal products must not be freely accessible to customers,
- Medicinal products cannot be taken back for exchange,
- Medicinal products whose shelf life has expired, whose packaging has been opened or whose quality is otherwise questionable must be removed from the shelves.

With the exception of outlets that only sell smoking cessation products, distributors of OTC products (dispensing groups HF and HX) are required to carry at least a basic range of over-the-counter products covering nine different product groups.

The sale of medicinal products of dispensing group HX (painkillers) is limited to one package a day per customer for products containing the same active ingredient.

The Danish Medicines Agency inspects retail distributors pursuant to the following legal framework:

- Executive order on distribution of over-the-counter medicinal products outside pharmacies (Danish title '*Bekendtgørelse om forhandling af håndkøbslægemidler uden for apotek'*),
- Executive order on distribution of over-the-counter medicinal products from OTC outlets ('*Bekendtgørelse om forhandling af håndkøbslægemidler fra håndkøbsudsalg*) and executive order on pharmacies and pharmacy staff (*bekendtgørelse om apoteker og apotekspersonale*),
- Executive order on distribution of certain iron and vitamin products and certain antiparasitic medicinal products for animals outside pharmacies ('*Bekendtgørelse om forhandling af visse jern- og vitaminpræparater samt visse antiparasitære lægemidler til dyr uden for apotek'*).

1.2. Development in the number of companies distributing over-the-counter medicines

In October 2001, OTC medicines were admitted for sale in ordinary retail outlets (in addition to the pharmacies' OTC outlets), and since then the number of authorised sales outlets has grown from 950 to nearly 2,000. In addition, there are around 630 OTC outlets and 208 delivery facilities dispatching medicine from pharmacies.

At the end of 2006, it became possible to apply for an authorisation to sell smoking cessation products only.

Since 2006, altogether 17 sales outlets have applied for and have been granted an authorisation to sell smoking cessation products. The figures show that only five of these sales outlets have maintained their authorisation and that the remaining 17 have terminated their authorisation.

2. Inspections

Table 1 below displays the number of inspections carried out from 2005 until end-June 2009.

Table 1. Number of inspections from 2005 until end-June 2009

	2005	2006	2007	2008	2009 first half
Authorisation of new retail distributors	159	155	143	277	159
Retail distributors (excluding OTC outlets)	340	492	705	580	235
OTC outlets	64	76	80	75	15
Total	**563**	**723**	**928**	**932**	**409**

Before the granting of an authorisation for retail distribution of medicinal products, the Danish Medicines Agency must perform an approval inspection on site. During an approval inspection, the retail distributor's facilities for the storing of the medicinal products are checked, and we go over the applicable rules with the applicant's responsible person.

We subsequently carry out reinspections to check how the products are stored and review the handling of medicinal products. The first reinspection normally takes place 12 months after the authorisation has been granted. The next inspection is scheduled based on the outcome of the inspection. In general, all shops are inspected at least one time within a three year period. If a shop has achieved an inspection result with serious deficiencies, the next inspection will be advanced.

The pharmacies are obliged to supervise their OTC outlets at least twice a year. The Danish Medicines Agency checks the pharmacy's level of compliance with this supervisory duty during the pharmacy inspections. This is the reason why we only check the OTC outlets on a random basis and not according to a fixed schedule.

2.1. Inspection results

The Danish Medicines Agency classifies inspections based on the following five ratings:

1. Very satisfactory = inspection identified no deficiencies.
2. Satisfactory = inspection identified a few non-serious deficiencies.
3. Less satisfactory = inspection identified one single serious deficiency.
4. Unsatisfactory = inspection identified serious or many deficiencies.
5. Unacceptable = inspection identified unacceptable deficiencies.

As the inspection result 'less satisfactory' was introduced in 2008, the figures for 2008

and 2009 have been placed in separate tables as they are not fully comparable with previous years. The table for the first six months of 2009 also include total figures.

Table 2a. Inspection results in the first six months of 2009 (excluding approval inspections)

	Very satisfactory		Satisfactory / Less satisfactory		Unsatisfactory		Unacceptable	
	2009							
	Total	%	Total	%	Total	%	Total	%
Sales outlets in total	**55**	**22.4**	**139**	**56.7**	**27**	**11.0**	**17**	**6.9**
- Sales outlets selling products in HF and HX and possibly HV.	47	23.4	117	58.2	23	11.4	14	7
- Sales outlets selling HV products only	8	27.6	14	48.3	4	13.8	3	10.3
OTC outlets	0	0	8	53.3	6	40	1	6.6
Calculation basis: 245 inspections distributed on 230 retail distributors and 15 OTC outlets								

Of the 17 that were rated 'Unacceptable' in 2009, 14 have been reported to the police, which corresponds to 5.7%.

Table 2b. Inspection results in 2009 (excluding approval inspections)

	Very satisfactory	Satisfactory / Less satisfactory	Unsatisfactory	Unacceptable
	2008			
Sales outlets in total	**16 %**	**56 %**	**9 %**	**19 %**
- Sales outlets selling products in HF and HX and possibly HV.	17 %	57 %	8 %	18 %
- Sales outlets selling HV products only	22 %	62 %	6 %	10 %
OTC outlets	1 %	72 %	23 %	4 %

Table 3. Inspection results in 2005, 2006 and 2007 (excluding approval inspections)

	Very satisfactory	Satisfactory	Unsatisfactory	Unacceptable
	2007			
Sales outlets in total	**18 %**	**63 %**	**10 %**	**8 %**
- Sales outlets selling products in HF and HX and possibly HV.	19 %	64 %	9 %	7 %
- Sales outlets selling HV products only	21 %	56 %	10 %	13 %
OTC outlets	5 %	64 %	21 %	9 %
	2006			
Sales outlets in total	**20 %**	**59 %**	**7 %**	**14 %**
- Sales outlets selling products in HF and HX and possibly HV.	20 %	60 %	7 %	13 %
- Sales outlets selling HV products only	16 %	54 %	9 %	21 %
OTC outlets	1 %	79 %	1 %	19 %
	2005			
Sales outlets in total	**15 %**	**62 %**	**15 %**	**8 %**
- Sales outlets selling products in HF and HX and possibly HV.	15 %	63 %	16 %	6 %
- Sales outlets selling HV products only	16 %	56 %	10 %	18 %
OTC outlets	2 %	53 %	22 %	23 %

The number of inspections rated 'Unacceptable' has risen drastically on 2007. This increase is a result of the Danish Medicines Agency's choice in 2008 to impose fines on sales outlets that were found to carry medicinal products whose shelf life had expired by more than six months. In the first half of 2009, the number of deficiencies and police notifications associated with medicinal products that had passed their shelf life by more than six months had fallen again. This indicates that the efforts to eliminate expired medicinal products in the retail distribution chain have rubbed off positively on retail distributors who have become much more keen on removing expired medicine.

2.2. Sanctions

The rating 'Unacceptable' and in some cases the rating 'Unsatisfactory' means that the Danish Medicines Agency will ask the retail distributor to submit a written report possibly with the inclusion of documentation to prove that the deficiencies identified have been corrected.

Violation of the rules is punishable by a fine. In 2008, the Danish Medicines Agency reported 77 cases to the police for imposition of a fine, of which 82% were motivated by medicinal products which had passed their shelf life by more than six months. In the first half of 2009, 14 cases resulted in police notifications.

In 2008/2009, the size of fines recommended for imposition ranged from DKK 2,000 to DKK 12,000.

The nature of breaches that lead to police notifications are often associated with improper storing of medicinal products and shelf-life expiry, but also cases involving medicines that have been stored freely accessible to customers, unauthorised sale, and opening of packages and relabelling of medicinal products are subject to police notification.

In 2008, 13% of reinspections gave rise to police notifications.

In case of serious or repeated contraventions, the Danish Medicines Agency may revoke the authorisation for retail distribution of medicinal products. However, the Danish Medicines Agency has never found cause to impose this sanction on retail distributors.

2.3. The pharmacies' OTC outlets

As a result of the shortcomings identified by the inspection of a small share of the pharmacies' OTC outlets in 2007, the Danish Medicines Agency chose to inspect 75 of the approximately 630 OTC outlets that existed in 2008.

These inspections were a direct result of the actuality that 30% of the OTC outlets inspected in 2007 were rated either 'Unsatisfactory' or 'Unacceptable'.
In 2008, 27% of the OTC outlets were rated 'Unsatisfactory' or 'Unacceptable'.

Overall, the Danish Medicines Agency finds that the occurrence of deficiencies is too high, in particular with respect to missing products in the basic range of OTCs and the staff's lack of knowledge about the rules that apply to the dispensing of medicinal products, where the number of deficiencies were 43% and 64%, respectively.
The Danish Medicines Agency also finds it worrying that 24% of the inspected OTC outlets had stored the medicinal products improperly, meaning that they are displayed freely accessible to the customers contrary to the rules.
Actually, the shelf life is the only area where the pharmacies' OTC outlets match the level of the other distributors of over-the-counter medicines.
The Danish Medicines Agency has ordered the companies concerned to correct the situation.

2.4. Deficiencies

Table 4a through 4c show the deficiencies identified for three types of retail distributors in 2007 and 2008.

Table 4a. Identified deficiencies as a percentage of the companies inspected in the first half of 2009

Deficiencies, first half of 2009	HF-HX (possibly HV 2009)		Only HV 2009		OTC outlet 2009	
	Number	%	Number	%	Number	%
Self-service	2	0,8	3	1,2	1	0,4
Basic range of OTCs	78	31,8	-	-	6	2,5
Purchase documentation	17	10	2	0,8	1	0,4
Mixed with other products	66	27	10	4	14	5,7
Temperature documentation	11	(4,5)	9	,07	-	-
Illegal medicinal products	1	0,4	-	-	-	-
Staff's lack of knowledge about the rules	71	29	9	3,7	7	2,9
Other deficiencies	41	16,7	8	3,3	3	1,2
Temperature cold room documentation	-	-	-	-	2	0,8
Publication of information	-	-	-	-	4	1,6
Pharmacy's inspection file	-	-	-	-	6	2,5
Medicine bags > 14 days	-	-	-	-	1	0,4
Shelf life expired by	50	20,4	3	1,2	6	2,5
- up to 3 months	24	9,8	-	-	4	1,6
- between 3 months and 6 months	16	6,5	-	-	1	0,4
- more than 6 months	10	4	3	1,2	1	0,4

Calculation basis: 245 inspections

Table 4b. Identified deficiencies as a percentage of the companies inspected in 2008

	HF-HX (possibly HV 2008) %	Only HV 2008 %	OTC outlet 2008 %
Self-service	2	0,7	24
Basic range of OTCs	27	-	43
Purchase documentation	6	3	15
Mixed with other products	33	6	80
Temperature documentation	(9)	45	-
Illegal medicinal products	0,2	-	1
Staff's lack of knowledge about the rules	34	3	64
Other deficiencies	25	2	25
Temperature cold room documentation	-	-	37
Publication of information	-	-	31
Pharmacy's inspection file	-	-	40
Medicine bags > 14 days	-	-	25
Shelf life expired by	40	16	13
- up to 3 months	19	8	9
- between 3 months and 6 months	6	7	1
- more than 6 months	15	1	3

Table 4c. Identified deficiencies as a percentage of the companies inspected in 2007

	HF-HX (possibly HV 2007) %	Only HV 2007 %	OTC outlet 2007 %
Self-service	5	8	16
Basic range of OTCs	30	-	38
Purchase documentation	5	15	18
Mixed with other	37	43	86

products			
Temperature documentation	(13)	52	-
Illegal medicinal products	1	1	4
Staff's lack of knowledge about the rules	23	15	33
Other deficiencies	18	17	19
Temperature cold room documentation	-	-	40
Publication of information	-	-	19
Pharmacy's inspection file	-	-	43
Medicine bags > 14 days	-	-	33
Shelf life expired by	35	21	12
- by up to six months	27	11	11
- between six and 12 months	5	6	1
- by more than 12 months	3	4	0

2.5. Types of deficiencies identified by inspections in 2008/2009

Medicinal products stored in a self-service area
The pharmacies' OTC outlets more often tend to place medicinal products in an area accessible to customers than do pet shops, grocery shops, kiosks and chemists. Since medicinal products are to be stored without the possibility of self-service, this is not allowed. In case of serious contraventions, retail distributors, OTC outlets and responsible pharmacies have been reported to the police.

The mixing of medicinal products with other goods
In most of the pharmacies' OTC outlets, medicinal products are placed on the shelves together with other goods, typically food supplements, herbal medicinal products, personal care products (shampoo, lotion and razor blades) and tobacco products. Medicinal product must be stored separately from other goods.

Often, the OTC outlets display all the products they receive from the pharmacy on the same shelve. But not all products delivered by the pharmacy are medicinal products, which is probably an indication that the pharmacies have not informed the OTC outlets sufficiently.

Staff's lack of knowledge about the rules
Too often, the Danish Medicines Agency's inspectors experience that the distributor's staff which handles and sells the medicinal products is not familiar with the contents of the applicable executive orders.

It is a requirement that the distributors have appointed a responsible person who must ensure that the rest of the staff is familiar with the governing law.

It is ultimately the responsibility of the pharmacy to see to it that the staff of the OTC outlet is familiar with the legislation governing medicinal products.

Documentation for temperature inside refrigerator – human medicinal products
The pharmacies' OTC outlets must store medicinal products at cool temperatures (2-8° C). For example, this is necessary with respect to medicine bags containing insulin. More than one third of the inspected OTC outlets failed to document the temperature inside the refrigerator, and in a few cases the Danish Medicines Agency discovered that the temperature inside refrigerators and cold rooms deviated from the stipulated temperature by several degrees.

Temperature – documentation – veterinary medicinal products
In December 2005, a requirement was imposed on retail distributors who sell over-the-counter veterinary products to measure and document the temperature where the medicinal products are kept. Still many distributors have not established routines for such documented control.

Publication of information
OTC outlets must have a visible sign with the Danish text "Håndkøbsudsalg fra…" (in English: OTC outlet from [*name of the pharmacy*]). In 2008, such a sign was missing at more than one fourth of the companies inspected. In 2009, the corresponding figure was four out of 15 inspected premises.

Pharmacy's inspection file
A copy of the pharmacy's reports on the biannual supervision of the pharmacy sale must be compiled in an inspection file. A copy must be available at the OTC outlet. From among the inspections carried out in 2008, 40% had no such copy at the OTC outlet, and in some cases it was not clear whether the pharmacy had obliged with its supervisory duty. In the first half of 2009, the corresponding figure was six out of 15 OTC outlets.

The knowledge obtained about the pharmacies' level of compliance with their duty to supervise their OTC outlets is used to select pharmacies for future inspections.

The return of medicine bags to the pharmacy within 14 days
No later than 14 days after a medicine bag has been delivered to the OTC outlet, unclaimed medicine bags must be returned to the pharmacy. In 2008, 25% of all inspected OTC outlets had exceeded this rule of 14 days.

In 2009, the corresponding figure was one out of 15 inspections, indicating that the pharmacies have become more aware of the problem.

Shelf life expired
In 2008, medicine products with an expired shelf life were once again found on the shelves of authorised distributors. This problem is much smaller for the pharmacies' OTC outlets, which not only reported a decrease in the number of shops with expired medicinal products, but also a reduction in the number of days by which the shelf life

had been passed. This is most likely a result of the pharmacies' biannual supervisory visits to the OTC outlets.

2008 recorded that 1% of the inspected pet shops, cereals and animal feed companies (only sale of veterinary products) had medicinal products that were more than six months too old. The corresponding figure for other sales outlets (HF-HX and possibly HV) was 15%. In all of these cases, the Danish Medicines Agency has reported the company to the police.

In the first half of 2009, 10 cases involving medicinal products that had expired by more than six months were identified among retail distributors, three among OTC veterinary outlets and one among 15 pharmacy OTC outlets. This reflects a positive trend that retailers have become much more aware of removing expired medicinal products from the shelves.

Purchase documentation
The pharmacies' OTC outlets often fail to keep adequate documentation of purchased medicinal products at the premises of the OTC outlet (e.g. invoices of delivering notes). On the part of the OTC outlets, this is often because it has not been established with the pharmacy that it is the OTC outlets that must keep the documentation.

Compared with 2007, the distributors of OTC veterinary medicine have become decisively better to document their purchases. In 2007, 15% were unable to document where they had purchased their products, but in 2008, this figure had decreased to 3%.

Illegal sale of medicinal products
The discovery of pharmacy-only medicines or the sale of medicinal products of unauthorised companies was very limited in 2008 and the first half of 2009.

Missing products in the OTC basic range
Companies selling OTC medicines must at least carry a so-called basic range of OTC products. The OTC basic range covers nine groups of OTC products. In 2008, 43% of the OTC outlets did not comply with this requirement. In 2009, six out of 15 inspected premises did not comply with this requirement.

Other deficiencies
Other deficiencies generally include deficiencies in cleaning, hygiene and order. Also, the inspectors often find medicine packages that have either been opened or squeezed or otherwise damaged.

Medicine packages must no be opened, and the packaging must not be damaged. Any such medicinal products must be returned for destruction.