



2009-10

Annual report

Inspection of sale of
OTC medicines in retail sale



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1. Background and the rules in brief

In this report, we have chosen to focus primarily on deficiencies that have caused us to file police reports. We have done so to focus on reducing the most serious finable deficiencies.

The annual report covers only statements of inspection results of retail outlets and over-the-counter (OTC) outlets primarily in 2008, 2009 and 2010. Based on the feedback we have received on our previous reports, we have concentrated on providing absolute figures. At the same time, we have limited the use of statements in percentages. Unlike our previous reports, we have also chosen a graphical presentation for some of the data.

Danish Medicines Agency, April 2011

1.1. Types of over-the-counter (OTC) medicines

Medicines that are permitted for sale outside pharmacies in retail outlets and OTC outlets are placed in the dispensing groups HF, HX and HV.

The dispensing groups signify:

- HF = OTC medicines permitted for sale outside pharmacies, for human use
- HX = OTC medicines permitted for sale outside pharmacies, for human use, with dispensing limitations
- HV = OTC medicines permitted for sale outside pharmacies, for veterinary use

Medicines for human use:

- **HF** (e.g. smoking cessation products and medicines to remedy a sore throat, cough, colds or allergies, etc.)

- **HX** (e.g. medicines for cold sores and painkillers)

Medicines for animals:

- **HV** (e.g. flea repellents).

A **retail outlet** is a retail distributor who has been authorised by us to sell medicines outside pharmacies. This authorisation may cover all medicines of dispensing groups HF and HX or of dispensing group HV. Retail outlets are found in for example supermarkets, chemists, petrol stations, kiosks and pet shops.

An **OTC outlet** is a retail shop that receives OTC medicines from a pharmacy with which it has entered into an agreement. Therefore, these shops do not have to be authorised by the Danish Medicines Agency.

OTC outlets are permitted to sell the medicines placed in the above-mentioned dispensing groups HF, HX and HV. In addition, an OTC outlet is permitted to dispense sealed bags containing other medicines ('medicine bags') that have been processed and packed at the pharmacy with which the OTC outlet has an agreement.

OTC outlets are often found in small supermarkets and kiosks. The pharmacies are obliged to supervise their OTC outlets twice a year.

1.2. Common rules

Retail outlets and OTC outlets are governed by a number of common rules, regardless of the assortment of products they carry:

- The sale of medicines to persons under the age of 15 is prohibited,
- Medicines must not be freely accessible to customers,
- Medicines cannot be exchanged,
- Medicines whose expiry date has exceeded, whose packaging has been opened or whose quality is otherwise questionable must be removed from the shelves.

Outlets that sell OTC products (dispensing groups HF and HX) are required to carry at least a basic range of OTC products covering nine different product groups.

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

The Danish Medicines Agency inspects retail distributors pursuant to the legislation:

- 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*').

1.3. Age limit of 18 years imposed on the sale of painkillers

The Danish Government has decided to make it more difficult for young people under the age of 18 to gain access to painkillers that are available over the counter. The purpose is to reduce the number of suicides and suicide attempts with mild painkillers sold over the counter.

On 7 March 2011, the new dispensing limitations for OTC painkillers entered into force. The limitation applies to the dispensing of oral painkillers from retail outlets, OTC outlets and pharmacies. The rules have been implemented by way of a new dispensing group for OTC medicines in retail sale: HX 18.

If young people under the age of 18 need to buy OTC painkillers, e.g. tablets, they need a prescription from a doctor or dentist, and they can therefore only buy them at a pharmacy.

In late February 2011, the Danish Medicines Agency sent out information to all retail outlets, OTC outlets and pharmacies in Denmark to prepare them for the new administrative rules. Information in English and Danish is available on our website.

Signs with the age limits 15 and 18 have also been sent out to shops.



Image: Sign with the age limits of 15 and 18 years for OTC medicines.

2. Inspections

Table 1. Number of inspections in the period 2005 to 2010

(The table shows all inspections, including companies with no pharmaceutical activity)

	2005	2006	2007	2008	2009	2010
Authorisation of new retail outlets	159	155	143	277	249	200
Retail outlets	340	492	705	580	533	639
OTC outlets	64	76	80	75	85	82
Total	563	723	928	932	867	921

'Companies with no pharmaceutical activity' covers either of the following possibilities:

- Approval inspections of new retail outlets
- Unannounced inspections of retail outlets which do not utilise an obtained authorisation for retail sale
- Inspections of companies due to relocation
- Inspections of OTC outlets which have closed down without our knowledge.

Before a company is granted an authorisation for retail distribution of medicines, the Danish Medicines Agency performs an on-site approval inspection. During an approval inspection, the retail distributor's facilities for the storing of the medicines are checked, and we go over the applicable rules with the applicant's responsible person.

We subsequently carry out unannounced inspections (reinspections) to check how the products are stored and review the handling of medicines. We endeavour to carry out the first reinspection within the first 12 months after the authorisation has been granted. The next inspection is scheduled based on the outcome of the reinspection. In general, all shops are inspected at least every three to four years. If a shop receives 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. We check the individual pharmacy's level of compliance with its supervisory duty when we inspect the pharmacy. 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 uses the five ratings below for the inspection results:

- Very satisfactory = inspection identified no deficiencies
- Satisfactory = inspection identified a few non-serious deficiencies
- Less satisfactory = inspection identified one single serious deficiency
- Unsatisfactory = inspection identified serious or many deficiencies
- Unacceptable = inspection identified unacceptable deficiencies

The tables below show the results of our inspections carried out in 2009 and 2010 by sales outlet.

Table 2a. Inspection results for 2009

(excluding approval inspections and unannounced inspections of companies with no pharmaceutical activity)

	Very satisfactory	Satisfactory/less satisfactory	Unsatisfactory	Unacceptable
Sales outlets in total	115	345	73	67
Selling HF and HX only	75	231	43	37
Selling HF, HX and HV	18	31	1	10
Selling HV only	16	38	7	10
OTC outlets	6	45	22	10

Calculation basis:

600 inspections distributed between 517 retail outlets and 83 OTC outlets. Of the 67 that were rated 'Unacceptable' in 2009, 46 companies were reported to the police, which corresponds to 7.6 % of the total number of inspections in 2009.

Table 2b. Inspection results for 2010

(excluding approval inspections and unannounced inspections of companies with no pharmaceutical activity)

	Very satisfactory	Satisfactory/less satisfactory	Unsatisfactory	Unacceptable
Sales outlets in total	180	380	66	72
Selling HF and HX only	101	247	32	39
Selling HF, HX and HV)	43	50	13	8
Selling HV only	28	38	6	15
OTC outlets	8	45	15	10

Calculation basis:

698 inspections distributed between 620 retail outlets and 78 OTC outlets. Of the 72 that were rated 'Unacceptable' in the second half of 2010, 42 companies were reported to the police, which corresponds to 6.0 % of the total number of inspections in 2010.

As can be read from the text below tables 2a and 2b, 7.6 % of the inspected companies were reported to the police in 2009, whereas it was only 6.0 % in 2010. This is a handsome fall of 1.6 percentage points on 2009, which is a fine result.

In sections 2.4 and 2.5, we look closer at the deficiencies which caused us to report it to the police.

2.2. Is the trend the same for retail outlets and OTC outlets?

Tables 3a and 3b show the results of the inspections carried out in retail outlets and OTC outlets, respectively (in percentage) over the past four years. We have chosen to display the two types of outlets separately to illustrate differences and similarities.

Table 3a. Inspection results of retail outlets

(excluding approval inspections and unannounced inspections of companies with no pharmaceutical activity)

	Very satisfactory	Satisfactory/less satisfactory	Unsatisfactory	Unacceptable
2010	28 %	54 %	8 %	10 %
2009	21 %	58 %	10 %	11 %
2008	18 %	56 %	8 %	18 %
2007	20 %	63 %	9 %	8 %



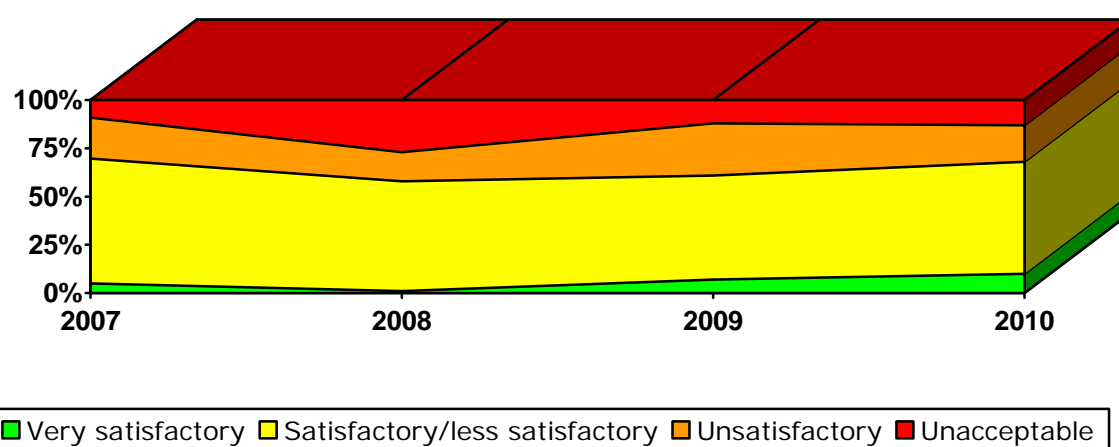
Figure 1: Graphical presentation of the inspection results of retail outlets from 2007 to 2010 in percentage terms.

Table 3b. Inspection results of OTC outlets

(excluding unannounced inspections of companies with no pharmaceutical activity)

	Very satisfactory	Satisfactory/less satisfactory	Unsatisfactory	Unacceptable
2010	10 %	58 %	19 %	13 %
2009	7 %	54 %	27 %	12 %
2008	1 %	57 %	15 %	27 %
2007	5 %	64 %	21 %	9 %

* The percentages for 2008 have been adjusted compared to table 2b in the 2008-2009 report, due to a counting error before the percentage calculations.

**Figure 2:** Graphical presentation of the inspection results of OTC outlets from 2007 to 2010 in percentage terms.

The figures in tables 3a and 3b show that the retail outlets do better than the OTC outlets, percentage-wise.

But if we look at how the figures have developed from 2009 and 2010, the OTC outlets have seen the greatest favourable development.

In 2010, we found no deficiencies in 10 % of the inspected OTC outlets. This is more than a two-fold increase compared to 2007.

In 2010, we found no deficiencies in 28 % of the inspected retail outlets, which is an improvement of 7 percentage points compared to 2009.

2.3. How are the OTC outlets managing?

During the inspections carried out by the Danish Medicines Agency in 2010, we noted that some pharmacies have made new handbooks for the OTC outlets and informed them of the applicable rules as part of the pharmacies' biannual reviews. Our perception is that the staff of the OTC outlets has generally welcomed the pharmacies' measures.

In the new handbooks, the pharmacies have gathered all the information that an OTC outlet needs, including staff instructions, relevant Danish executive orders, guidelines, the pharmacy's inspection reports, etc.

It turns out that for those pharmacies that have taken the time to make handbooks and ensured that the staff of the OTC outlet understands the content, there has been a positive rub-off effect on the quality, which again has reduced the number of deficiencies.

In other outlets, where time had not been allocated for this purpose or where the required understanding of the principles was otherwise inadequate, a similar positive rub-off effect was not observed.

2.4. Sanctions and notifications to the police

The rating 'Unacceptable' and in some cases the rating 'Unsatisfactory' imply that we 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. When we consider one or several deficiencies or offences to be very serious, we report it to the police for imposition of a fine.

Table 4 – Number of notifications to the police

(excluding approval inspections and unannounced inspections of companies with no pharmaceutical activity)

	2008	2009	2010
Number of inspections of retail outlets	564	517	620
– of which reported to the police	75	41	41
Broken down by type of authorisation:			
1) sale of OTC medicines (HF & HX)	59	26	24
2) sale of OTC medicines (HF & HX) and veterinary medicines (HV)	9	9	8
3) sale of veterinary medicines (HV)	7	6	9
Number of inspections of OTC outlets	74	83	78
– of which reported to the police	3	5	1

Table 4 shows the number of reports to the police in connection with unannounced inspections and the distribution of notifications between various retail outlets and OTC outlets.

The Danish Medicines Agency is quite content with the development and the total fall in the number of cases punishable by a fine for both retail and OTC outlets, but the Agency will still endeavour to increase the companies' awareness of its own self-inspection of medicine handling to reduce the number of serious deficiencies.

Retail outlets

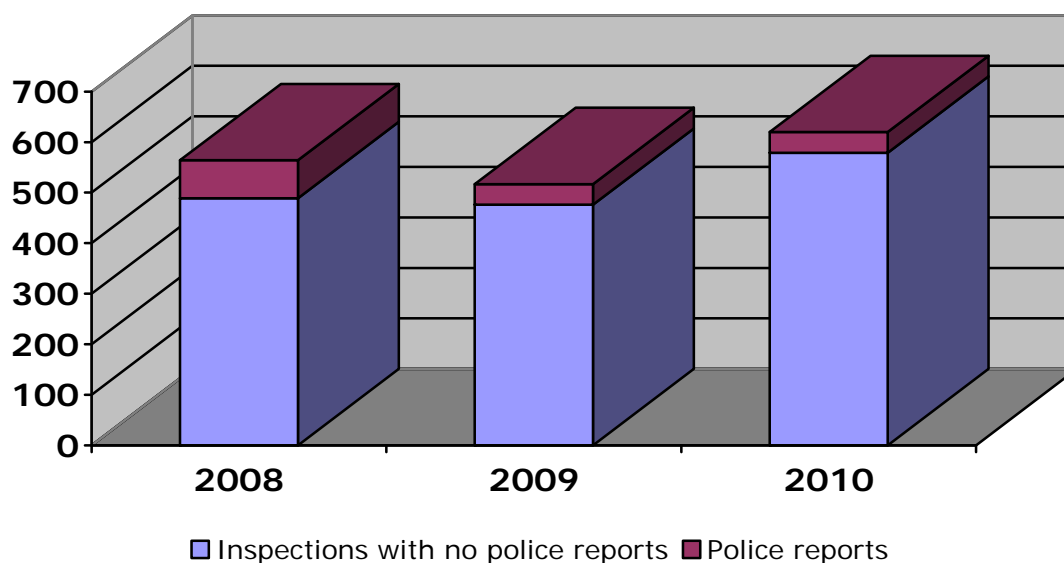


Figure 3: Number of inspections of retail outlets and notifications to the police for imposition of a fine.

Overall, the number of police notifications resulting from inspections at retail outlets has fallen markedly from 2008 to 2009. The figures from 2010 show that this positive decline continues.

Distribution broken down by the retail outlets' type of authorisation

The majority of retail outlets exclusively sell OTC medicines (HF & HX). Therefore, it is not surprising that most police notifications were made in this segment. The number of companies reported to the police in 2010 is down by two compared to 2009, but since we inspected more companies in 2010, this is a step in the right direction.

The number of police reports of retail outlets selling OTC medicines (HF & HX) and veterinary medicines (HV) is unchanged from 2008 to 2009 with one less police report in 2010. However, seen in the light of how many companies were inspected, the fall is significant.

After previous years' positive downward trend, retail outlets that exclusively sell veterinary medicines (HV) have now taken a disturbing turn for the worse. There were three more police reports than in 2009, which is a considerable increase.

OTC outlets

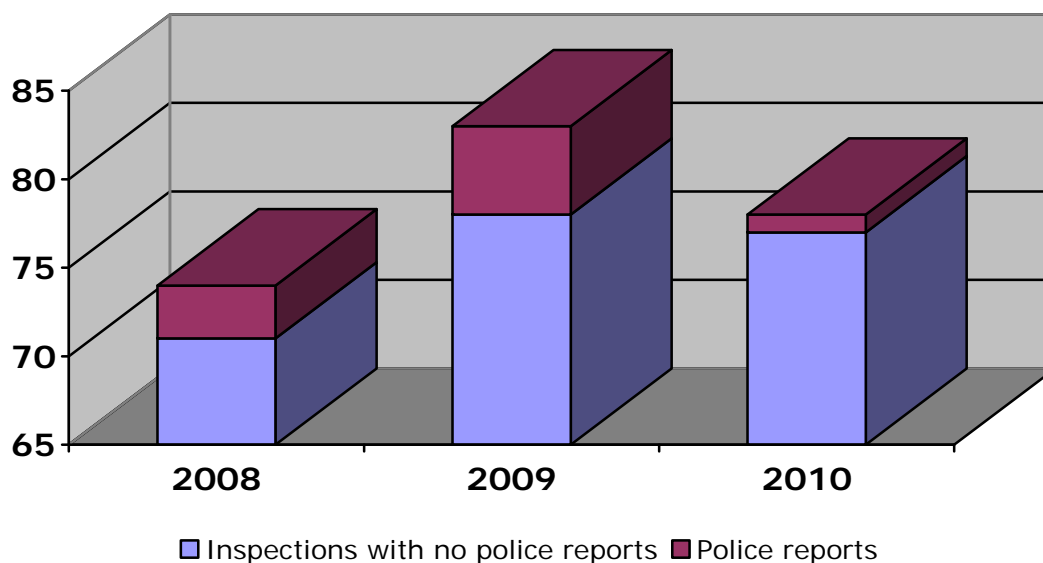


Figure 4: Number of inspections of OTC outlets and police notifications for imposition of a fine.

The OTC outlets show a somewhat different development. After a large increase in the number of police notifications from 2008 to 2009, it is gratifying to see that only one OTC outlet was reported to the police in 2010 out of 78 inspected OTC outlets.

2.5. Causes of police notifications

Causes that may lead us to recommend that a fine be imposed:

- Detection of expired medicines
- Possibility for self-service
- Opened packages
- Sale without a valid licence
- Repeated deficiencies where prescribed corrective actions have not been complied with
- Sale of illegal medicines
- Sale of pharmacy-only medicines

The majority of incidents we reported to the police were caused by detection of expired medicines. The other offences occur only rarely. Thus in 2010, there were no incidents where the placing of medicines caused us to report it to the police due to the possibility of self-service.

Table 5 – Overview of police notifications broken down by type of outlet and type of deficiency in the period 2008 to 2010

(excluding approval inspections and unannounced inspections of companies with no pharmaceutical activity)

	Number of police notifications	Type of deficiencies that have led to a police notification		
	Total	Self-service	Expired medicines – date exceeded by more than six months	Other
2010				
Retail outlets	41	-	39	3
OTC outlets	1	-	-	1
2009				
Retail outlets	41	5	32	4
OTC outlets	5	2	2	1
2008				
Retail outlets	75	6	61	9
OTC outlets	3	-	2	1

One police notification may cover more than one offence, which explains why the number of reports to the police may be lower than the total number of deficiencies.

2.6. Expired medicines

Since 2008, we have recommended that a fine be imposed whenever we found medicines at the sales outlets with shelf-lives that had expired by more than six months. Previously, we did so when the shelf-life had expired by more than 12 months.

Figure 5 shows a favourable development in fines triggered by detection of medicines expired by more than six months as the number of cases punishable by a fine in 2009 has decreased almost two-fold compared to 2008. It shows that the Danish Medicines Agency's actions against expired medicines in retail sale have paid off positively.

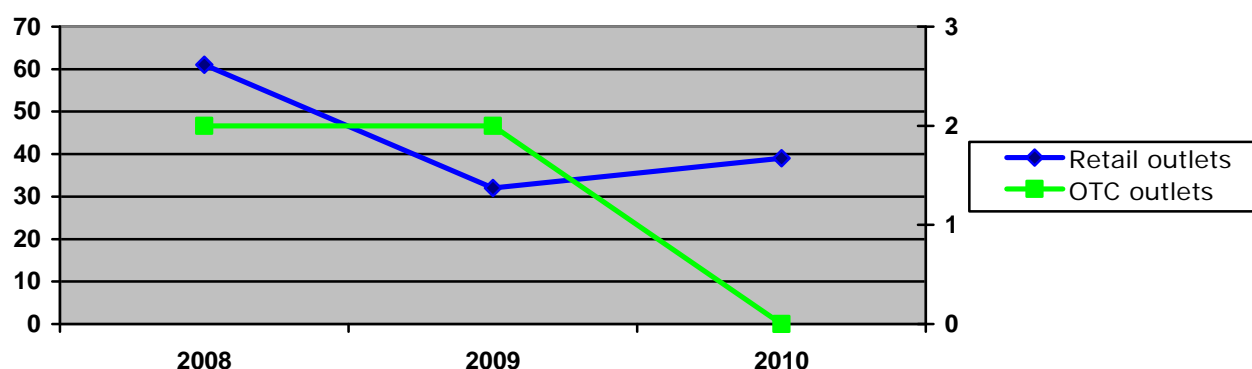


Figure 5: The chart above illustrates the movements in the number of fines issued for expired medicines through 2008-2010 for retail outlets and OTC outlets. The left-hand scale from 0-70 reflects retail outlets, and the right-hand scale from 0-3 reflects OTC outlets.

The OTC outlets' development is favourable with only one police report in 2010.

But, we have also found medicines whose shelf-lives had expired by less than six months. The distribution for 2008, 2009 and 2010 is broken down by retail outlets and OTC outlets in tables 6a, 6b and 6c.

When our inspectors go on approval inspections, they stress the importance of good routines, but it regrettably turns out at the subsequent inspections that not all manage the routines. It is unfortunate that during our inspection visits, we find so many medicines with expired shelf-lives. It must be safe for consumers to buy OTC medicines in retail sale. Consumers must be confident that the medicines are effective.

Table 6a – Detection of expired medicines in 2010

(excluding approval inspections and unannounced inspections of companies with no pharmaceutical activity)

	Retail outlets			OTC outlets
	<i>HF-HX</i>	<i>HF-HX & HV</i>	<i>HV</i>	
Shelf-life expired by up to three months	16	11	4	5
Shelf-life expired by up to six months	4	7	3	2
More than six months (police report)	22	8	9	0
Total	42	26	16	7
<i>Total number of inspections</i>	<i>419</i>	<i>114</i>	<i>87</i>	<i>78</i>

Table 6b – Detection of expired medicines in 2009

(excluding approval inspections and unannounced inspections of companies with no pharmaceutical activity)

	Retail outlets			OTC outlets
	<i>HF-HX</i>	<i>HF-HX & HV</i>	<i>HV</i>	
Shelf-life expired by up to three months	27	8	6	5
Shelf-life expired by up to six months	23	5	4	3
More than six months (police report)	20	8	4	2
Total	70	21	14	10
<i>Total number of inspections</i>	<i>386</i>	<i>60</i>	<i>71</i>	<i>83</i>

Table 6c – Detection of expired medicines in 2008

(excluding approval inspections and unannounced inspections of companies with no pharmaceutical activity)

	Retail outlets			OTC outlets
	<i>HF-HX</i>	<i>HF-HX & HV</i>	<i>HV</i>	
Shelf-life expired by up to three months	48	12	4	7
Shelf-life expired by up to six months	15	2	5	1
More than six months (police report)	53	7	1	2
Total	116	21	10	10
<i>Total number of inspections</i>	<i>380</i>	<i>116</i>	<i>68</i>	<i>74</i>

3. Focus on chain stores

In response to our annual reports, some chain stores have contacted us with comments and follow-up questions to the content of the report. We appreciate this interest.

A few chain store head offices have requested the Danish Medicines Agency to send a copy of the report on their shops. We have honoured these requests. We are thus happy to support the chain stores' endeavours to continuously raise the quality of the way their shops handle medicines.

The Danish Medicines Agency has also written to a couple of chain stores if inspections of several shops in the same chain led to the finding of the same type of deficiency. In response, the chains have adjusted their guidelines for medicines in their shops.

When we go out on shop inspections, we sometimes hear that a shop in a chain has limited possibilities compared to the instructions given by the head office on the placement of goods. Therefore, in future, we will expand and strengthen cooperation with the chain stores' head offices.

4. New format for inspection reports

The Danish Medicines Agency is continuously improving the format of our inspection reports. We are presently working to thoroughly change the report format. We have made them shorter and made it easier to communicate more clear and simple messages about any identified deficiencies with suggestions for improvements.


We want the new reports to be quick to read in a busy workday. The reports will span one or maximum two A4 sheets. We will limit or shorten references to rules etc., as it is presumed that retail outlets and OTC outlets can look up the rules through guidelines on our website, www.laegemiddelstyrelsen.dk (most of which is in Danish only).

In the process of creating the new templates, we sent out a number of the old and the new reports concurrently to a number of randomly picked retail outlets. We then interviewed them on their experience with reading and using the reports in their daily work with medicine handling. We will base our development of the new report format on the experience and feedback we have received.

We have already experienced that the new templates improve dialogue during our inspections and speed up the on-site inspection.

In future, the rating system will also be simplified for the benefit of the companies. The following ratings will now be used. We have compared it to the old system below.

New rating system	Corresponds to rating in old system:
1 = No deficiencies	<ul style="list-style-type: none"> Very satisfactory = inspection identified no deficiencies.
2 = Deficiencies	<ul style="list-style-type: none"> Satisfactory = inspection identified a few non-serious deficiencies. Less satisfactory = inspection identified one single serious deficiency. Unsatisfactory = inspection identified serious or many deficiencies.
3 = Fine/police report	<ul style="list-style-type: none"> Unacceptable = inspection identified unacceptable deficiencies.


HOF Reg. nr. 9028

Inspektionsrapport

X:
X:
X:
Att.:

Resultat af inspektion:	1	Ingen afvigelser
	2	Afvigelser
	3	Bede/politianmeldelse
	*	Bilag vedlagt
	#	Skriftlig tilbagemelding

Inspektionsdato:	
Sags nr.:	LMST-
Virksomhedsnummer:	
Rapport udsendt:	
Lægemiddelansvarlig:	
Deltagere ved inspektionen:	

Kontrollen omfatter:

1 = Ingen afvigelser 2 = Afvigelse 3 = Bede/politianmeldelse * = Bilag vedlagt # = Skriftlig tilbagemelding	
1. Opbevaring a. Placering (bl.a. utilgængeligt for kunder) b. Orden og tilstrækkelig plads til lægemidlerne c. Rengøring omkring lægemidlerne d. Adskilt fra andre varegrupper e. Lagerforhold (udenfor butikskøleket) 2. Lægemiddelsortiment a. Basissortiment (sevejligst for HF/HK) b. Brudte, ulovlige, skadede pakninger	3. Egenkontrol a. Udløbne lægemidler b. Temperatur 4. Dokumentation a. Indkøb b. Reklamationer c. Tilbagekaldelser 5. Personale a. Kendskab til reglerne

Inspektørens bemærkninger:

Lægemiddelstyrelsen anbefaler:

☐ At der foretages regelmæssig dokumenteret temperaturkontrol

☐ At der foretages regelmæssig dokumenteret udløbskontrol

☐ At der oprettes en lægemiddelmappe (til fakturaer, leveringer, bilag mv.)

☐ At der udarbejdes interne instruktioner, der beskriver rutiner for håndtering af lægemidler

Lægemiddelstyrelsen fører løbende kontrol med virksomheder der har tilladelse til at forhandle lægemidler efter lægemiddellovens § 39, stk. 1, § 44, stk. 1-2. Jeres virksomhed er nu udtaget til periodisk kontrol. Formålet med kontrollen er at vurdere om jeres virksomhed lever op til kravene i bekendtgørelsen.

Virksomhedstilladelsen omfatter salg af:

☐ Håndkøbslægemidler udenfor apotek, (HF/HK lægemidler) efter bekendtgørelse nr. 108 af 9. februar 2011 om forhandling af håndkøbslægemidler uden for apotek (Bkg. nr. 108)

☐ Veterinære lægemidler, (HV lægemidler) efter bekendtgørelse nr. 1241 af 12. december 2005 om forhandling af visse jern- og vitaminpræparater samt visse antiparasitære lægemidler til dyr uden for apotek (Bkg. nr. 1241)

Fra Lægemiddelstyrelsen:

Inspektør:

Side 1 af 1

Example of one of our new templates used for inspections