LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

2026

Danish Medicines Agency

Annual OMCL Report 2025

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1
Organisation of the Danish OMCL

This section provides a short description of the Danish Medicines Agency, the Danish Official Medicines Control Laboratory (OMCL) and its staff, our quality management system and status of accreditation.

1.1 General structure of the Danish Medicines Agency

The Danish Medicines Agency has around 650 employees, and the four largest professional groups in the organisation are pharmacists, administrative assistants, doctors, lawyers and masters of social science (organisational chart next page, Figure 1). The Agency perform most of the tasks in close collaboration with colleagues from regulatory authorities and organisations in the other EU countries.

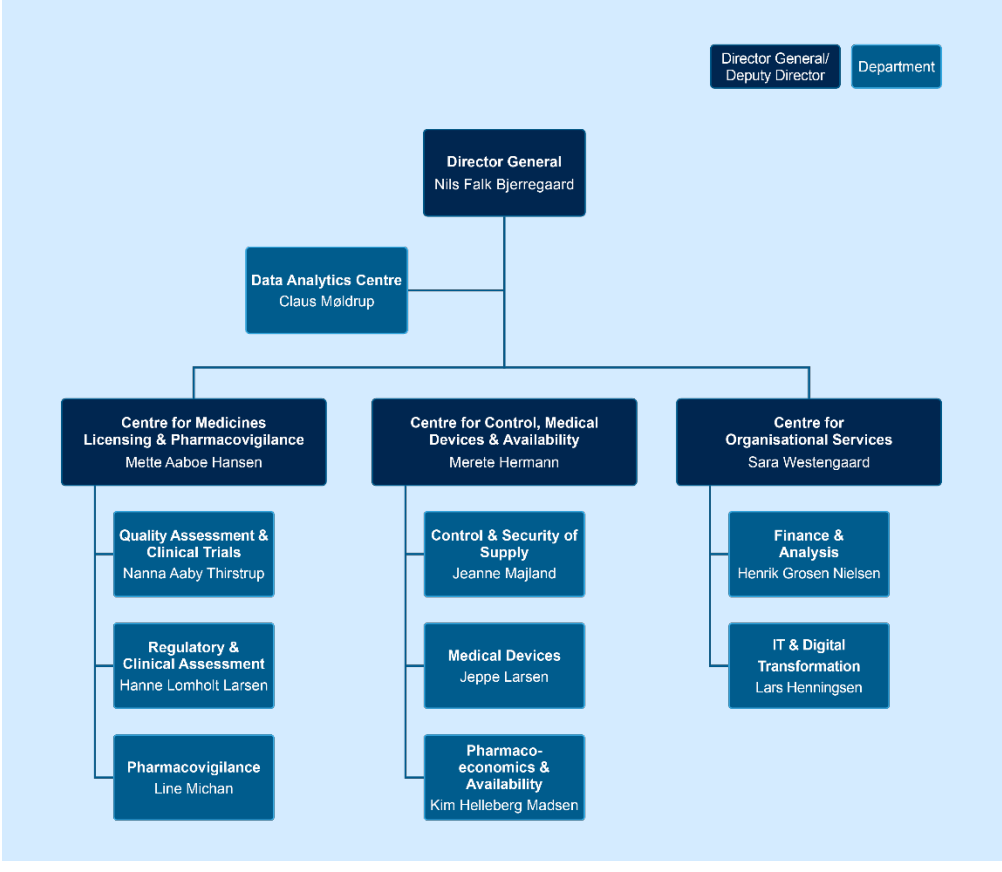
The Danish Medicines Agency

- authorises and inspects pharmaceutical companies and licenses medicinal products in the Danish market
- monitors adverse reactions from medicinal products
- authorises clinical trials
- decides which medicines are eligible for reimbursement
- monitors medical devices available in Denmark and supervises adverse incidents involving medical devices
- appoints proprietary pharmacists, organises the pharmacy structure and supervises pharmacies and retailers.

The Danish Medicines Agency mission, vision and strategy 2022-2026 is described at the webpage together with the statements that we live by

- The Danish Medicines Agency mission, vision and strategy 2022 - 2026

FIGURE 1
ORGANISATIONAL CHART OF THE DANISH MEDICINES AGENCY



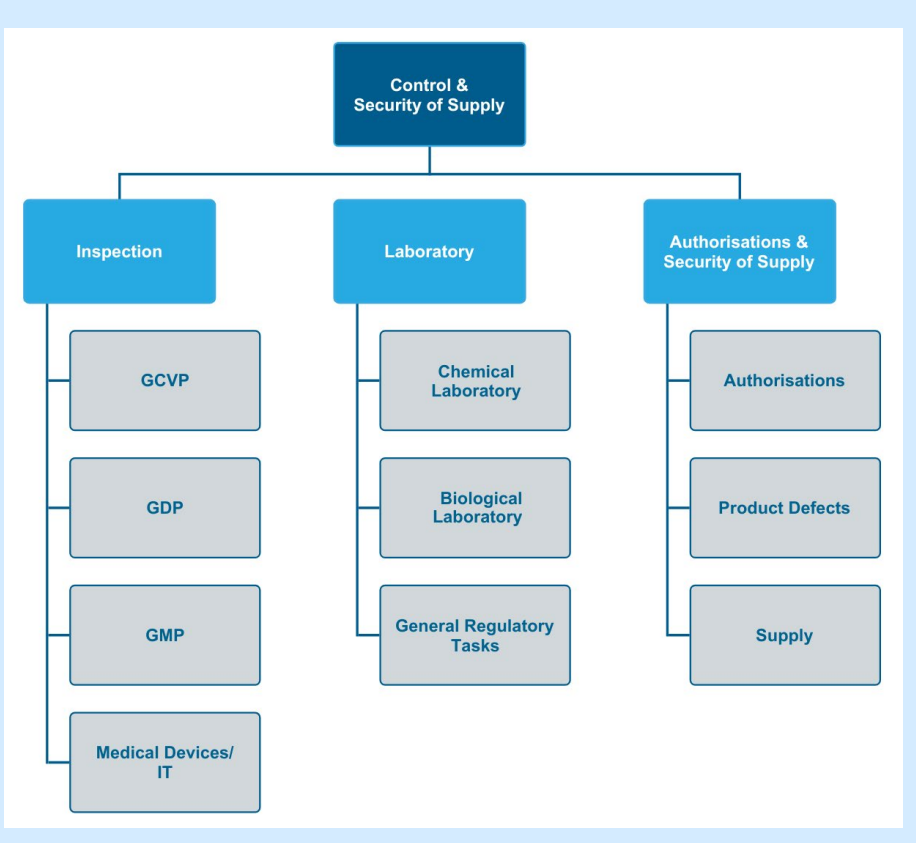
Source: Organisation (December 2025)

1.1.1 Department of Control and Security of Supply

The department “Control and Security of Supply” is responsible for the Danish Medicines Agency's regulatory duties with respect to laboratory testing and monitoring of medicinal products. The Danish inspectorate is also in this department of the Danish Medicines Agency. The Unit “Authorisations & Security of Supply” handles complaints and reports about quality defects in medicinal products as well as any related recalls. This Unit also supervises company authorisations for handling and manufacturing medicinal products and monitor the supply of medicinal products.

The laboratory Unit contains the Danish OMCL. In addition to OMCL activities, the laboratory performs tasks in connection with the elaboration, testing and perform verification of monographs for The European Pharmacopoeia (Ph. Eur.). The National Pharmacopoeia secretariat is also placed in the Laboratory.

FIGURE 2
ORGANISATIONEL CHART OF THE DEPARTMENT OF CONTROL & SECURITY OF SUPPLY



Laboratory: The Danish Official Medicines Control Laboratory (OMCL)
GCVP: Good Clinical & Vigilance Practice
GDP: Good Distribution Practice
GMP: Good Manufacturing Practice

A separate Annual Report on OCABR activities is provided.

Risk-based model for the selection of new control projects
When taking a medicinal product in for a control it is not possible to check every control point every time for all products controlled. This is a consequence of the complexity and the number of control points.

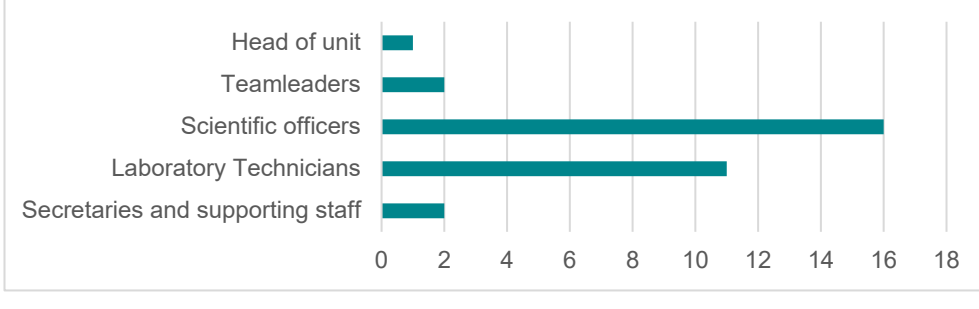
For selection of new control projects for medicinal products and active substances for testing, the Danish OMCL has developed a risk-based model based on OMCL documents including "Incorporation of a risk-based approach in Market Surveillance testing at OMCLs, PA/PH/OMCL (06) 3 R11" as well as risk factors from HMA pre-authorisation risk assessment model and inputs from other countries. Consequently, the OMCL have worked extensively in 2025 to revise the risk model together with the Agency's computational resources at DAC (Data Analytics Centre).

The Danish OMCL are now utilising a risk model database which has defined many different risk parameters based on available electronic data sources. These parameters are such as time elapsed since last control, consumption, complaints from patients as well as medical professionals, findings during previous controls and inspections along with different characteristics of the product. The different risk parameters have been ranked, and therefore the risk model database gives an automatic risk scoring. Moreover, we carry out risk-based control adjusted to the individual situation. Therefore, from this risk model database, different projects are extracted depending on the scope for example elderly products, formulation as vaginal products. The result is an updated list of prioritised medicines selected for control of products.

1.2 Personnel Matters of the Danish OMCL

The Danish OMCL was in 2025 divided in three teams: Chemical Laboratory, Biological Laboratory and General Regulatory Tasks. In total, the Laboratory accounted for 32 full-time equivalents (FTEs) with the 34 employees. The distribution of FTEs by role is presented in Table 1.

TABLE 1
2025 STAFF DISTRIBUTION (FTE) BASED ON ROLES AT THE DANISH OMCL



1.3 Quality management system

Since 1995, the Danish OMCL has been accredited according to the requirements of ISO 17025 and has been subject to a regular independent surveillance programme. In 2006, the accreditation included a flexible scope accreditation. The accreditation of the Danish OMCL was renewed in April 2022; next renewal is in January 2026.

The scope of the accreditation is testing of pharmaceutical products and active ingredients and is linked to a specific list of methods mainly from Ph. Eur. and list of methods/techniques authorised by the accreditation board.

Our national accreditation body for the Danish OMCL is DANAK.

Types of testing:

- **Biological and biochemical**
- **Chemical testing**

The Danish OMCL received the first MJA attestation in February 2011. The specified field of activity for the OMCL is “Testing of pharmaceutical products and API (biological and chemical); Market surveillance testing and screening for illegal products; Elaboration of standards and reference materials to Ph. Eur.; Participation in PTS, CAP, BSP, CRS and MSS”. The most recent MJA in 2023 was successfully carried out as a joint audit with DANAK.

Work is ongoing with focus on evaluation of measurement uncertainty, data security and computerised systems.

1.4 Internal collaboration

The GXP-inspectors, quality assessors and OMCL work in the same organisation and geographical location. The quality assessors, GMP/GDP inspectors and OMCL staff have access to the same databases, and all data are available to enable quality assessors to make decisions on the acceptability of manufacturers nominated on applications for marketing authorisations as well as post-marketing control. The inspectors are obliged to update the common database after inspections including the inspection result as a score, and for GMP inspections, the information about issued GMP certificate. Information on conducted lab controls on specific medicinal products are shown in the same database via a link to the ECM-system. Marketing authorisations are included and linked to data on company authorisations and inspections.

Competence teams – several multidisciplinary teams are organised across the Agency, which cover topics including grey zone products with blood, cells and tissues, pharmacovigilance, parallel imports and radiopharmaceuticals. All members contribute with relevant subject for discussion during meetings and risks can be identified and handled accordingly.

Triggered inspections can be requested by assessors, OMCL and other stakeholders. Scientific officers from OMCL, Licensing, Clinical trials and others, have a standing invitation to participate in all types of inspections, and are sometimes requested formally for expert knowledge in special circumstances. Inspectors have authority in law to sample during inspections and bring samples to the OMCL for testing. If decided before the inspection details on the sampling are agreed in advance.

Hand over meetings between inspectors and OMCL staff or quality assessors are planned when needed (to make the understanding between inspectors and assessors better). A yearly meeting before finalising the OMCL activity is usually planned.

The collaboration between quality assessors, inspectors and OMCL, is formalised and the advantage of being under the same roof is of huge importance; the inspector can go to the assessors or OMCL and discus any issue with the chemists, as well as the opposite way.

Also located in the department is the unit “Authorisations and Security of Supply” who handles complaints and reports about quality defects in medicinal products as well as any related recalls. When any systematic defects are detected, the OMCL may be informed to trigger a control, or the Inspectors may be informed to trigger an inspection.

2
Activities related to the national market

This section gives an overview of the Danish OMCL sampling approach, results of testing and workload on both the legal and illegal supply chain to the Danish market.

2.1 Legal Supply Chain (authorised medicines)

The Danish OMCL carries out analyses on a range of medicinal products both according to the authorised dossier of the marketing authorisation holder (MAH) as well as in-house (validated and non-validated) methods. In general, selected testing which typically includes appearance, physical tests such as uniformity of mass and hardness, assay of active ingredient(s) and impurities is performed.

Furthermore, the OMCL performs supplementary tests for specific products or drug substances. Where possible investigations review the labelling and the documentation such as batch protocol, certificate of analysis (CoA) and/or specification compliance. Some investigations only review the labelling and/or documentation without the typical analysis performed in the laboratory.

2.1.1 Sampling approach

As mentioned in 1.1.1 the Danish OMCL use a risk-based model for the process of selecting medicines for control. This risk-based model utilises powerful computational resources to include several parameters, such as time elapsed since last control, novelty, complaints from patients as well as medical professionals, and findings during previous controls. Liaising with DAC, has enabled the Danish OMCL to establish updated lists of prioritised medicines or groups of medicines for control.

2.1.2 Results

As described in 2.1 for every control either one test or various tests are conducted on the finished product, API or suspected, illegal substance. The workload for each product has increased as the analyses get more complex and more tests are conducted per product than previous years. For some products multiple batches of the finished product or API are controlled when relevant for the control project.

For most finished products more than one type of control (laboratory analysis, documentation review, labelling control) was performed and some finished products and API’s had multiple batch numbers investigated. For products where more than 3 controls or laboratory analyses are performed a complexity factor are added to give the final control count.

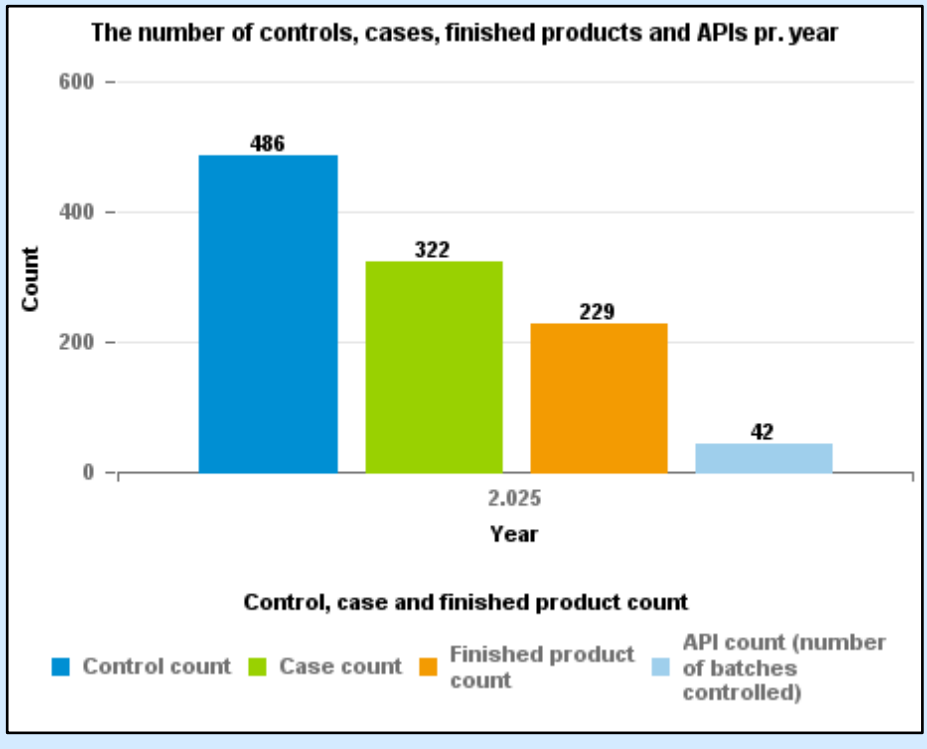
The workload of the Danish OMCL is best described by the control count which in 2025 was 486. The key performance indicator (KPI) for the control count is 350.

A total count of 229 different finished products was called in for control in 2025. The KPI's for the number of finished products is 150 different products. Furthermore, 42 different batches of API were controlled.

The case count refers to the registration of the control cases in our ESDH-system for registration and journalising of data and results.

The statistics for the work performed in the Danish OMCL for 2025 are shown in figure 3.

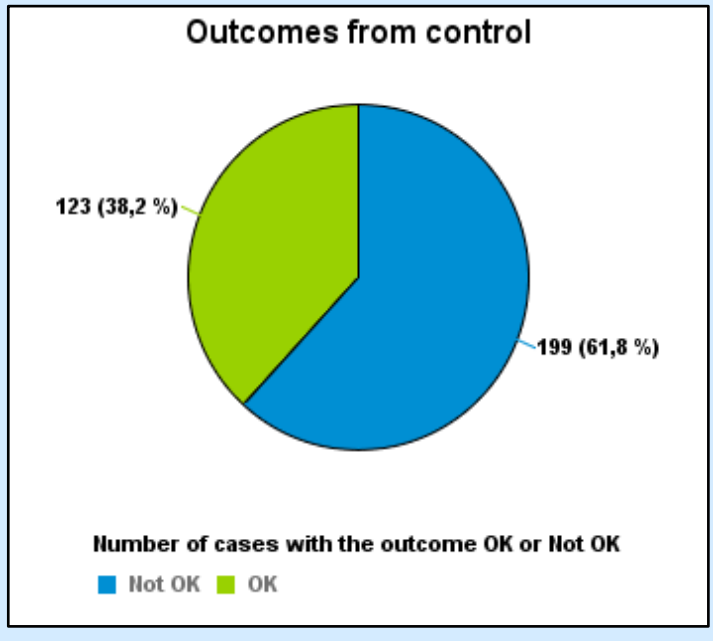
FIGURE 3
OVERVIEW OF THE WORKLOAD FOR THE DANISH OMCL IN 2025



Source: SAB BI report "OMCL Årsrapport", "Figur, pr år"
Data extracted: 20260408

The outcome distribution of the controls performed is shown in figure 4. As mentioned, each control may cover more than one test. In this figure the worst outcome of the tests performed for each control is reported. The outcome is divided in OK (all tests complies) and Not OK (minimum one test does not comply = lead to remarks, enforcement notices or evaluation of recalls).

FIGURE 4
OVERVIEW OF THE CONTROL RESULTS IN 2025



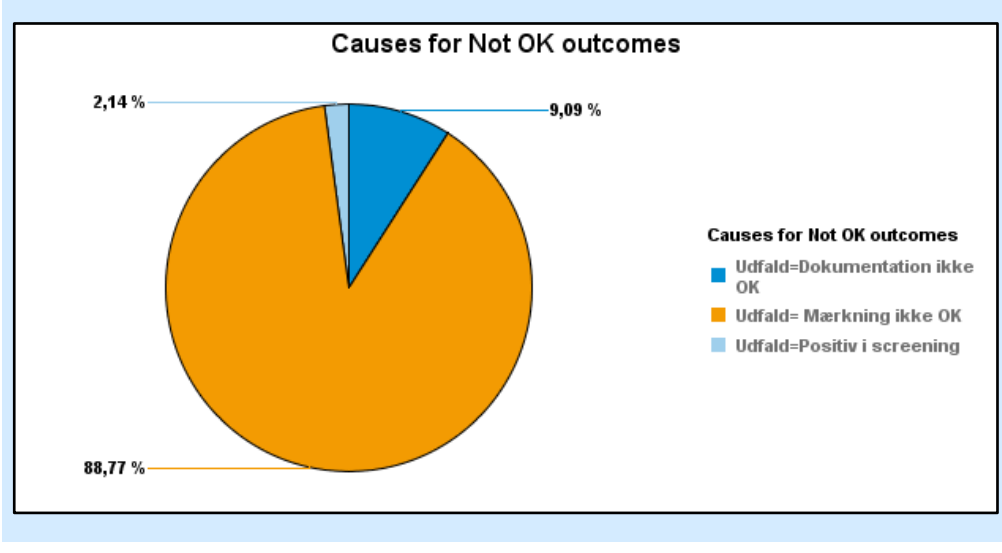
Source: SAB BI report ”OMCL Årsrapport”, “Diagram of outcomes”
Data extracted: 20260408

If the case outcome results in an evaluation of recall, the case will be forwarded to the unit of Authorisations & Security of Supply for further evaluation. The evaluation of the need for a recall includes an assessment of the non-compliance also considering the security of supply to the Danish marked.

Of the 61.8 % controls in 2025 which were “Not OK” most of the noncompliance were related to labelling comments. The second most common cause of noncompliance relate to comments to the documentation. This year no noncompliance was related to the laboratory analyses. The distribution of causes for noncompliance for 2025 is shown in figure 5. The distribution of noncompliance does not vary significant from former years.

The results “positive hit in the screening of suspected illegal samples are also represented in Figure 5. Further explanation of these results is given in chapter 2.4.

FIGURE 5
OVERVIEW OF THE TYPES OF NONCOMPLIANCE DETECTED IN 2025



Source: SAB BI report ”OMCL Årsrapport”, “Diagram of outcomes”
Data extracted: 20260408

Explanatory note:
Udfald=Dokumentation ikke OK = Documentation review was not in compliance
Udfald=Mærkning ikke OK = Labelling was not in compliance
Udfald=Positiv i screening = Positive hit in the screening of suspected illegal samples

2.1.3 Details/technical issues

For a list of the finished products analysed by the Danish OMCL see “*2025 OMCL Annual Report Annex 1”*. This annex will not be published on the website of the Danish Medicines Agency for public consultation. Any findings have been discussed with and are corrected by the MAH.

2.2 Legal Supply Chain (medical devices)

The control of medical devices on the Danish marked is not in the scope of the Danish OMCL. The market surveillance and user safety are managed by the department for Medical Devices within the Danish Medicines Agency.

2.2.1 Sampling approach

Medical devices could be anything from crutches, wheelchairs and glasses to diagnostic analyses, pacemakers, mobile phone apps and state-of-the-art surgical devices and appliances used in hospitals. If these devices start malfunctioning, fail or are used in the wrong way, the consequences can be serious to the patients, healthcare professionals or others. That is why it is important that manufacturers and authorities are informed if a medical device does not work as intended or if errors or other problems occur.

Manufacturers, healthcare professionals, and entities with operational responsibility for public and private hospitals are obliged to report serious incidents or suspected serious incidents (device malfunction, failure and deficiencies) to the competent authority, i.e. the Danish Medicines Agency in Denmark.

Others e.g., users, patients, authorised representatives, distributors, and importers also have the possibility to report incidents to the Danish Medicines Agency.

2.2.2 Results, details/technical issues

No testing of medical devises was performed by the Danish OMCL in 2025.

2.3 Legal Supply Chain (suspected samples)

The Danish Medicines Agency did not carry out any analysis on counterfeit medicines during 2025 (see Table 2).

2.4 Illegal Supply Chain

The Danish OMCL laboratory continues to analyse products suspected of containing undeclared APIs. However, the number of products received at the laboratory has fallen considerably in the last few years. Samples are primarily analysed by liquid chromatography coupled to a high-resolution mass spectrometer (LC-HRMS). The products are usually in the dosage form of either tablets, capsules or powder.

In 2025, six products were tested at the OMCL. Four of the products were found to contain undeclared active pharmaceutical ingredients.

The number of samples analysed by the Danish OMCL is presented in Table 2.

TABLE 2
TOTAL NUMBER OF SUSPECTED COUNTERFEIT SAMPLES TESTED FROM THE LEGAL AND ILLEGAL SUPPLY CHAIN

		2025
Total number of suspected counterfeit samples in the legal supply chain	a	0
Total number of confirmed counterfeit samples of licensed medicines in the legal supply chain	b	0
Total number of suspected illegal samples tested	g	6
Total number of illegal samples identified (other than counterfeit samples in the legal supply chain - b)	c+d+e+f	unknown

Case outcome applicable for *g* is available in "*2025 OMCL Annual Report Annex 1"*. This annex will not be published at the Danish Medicines Agency website.

Project with the Danish Veterinary, Food, Agriculture and Fisheries Agency

In 2025, the Danish OMCL participated in a collaborative project between the Danish Medicines Agency and the Danish Veterinary and Food Administration. The surveillance project included selected registered dietary supplements for sleep-regulation. In total, 24 products were sampled and were screened by LC-MS for undeclared pharmaceutical ingredients, such as melatonin. The samples included tablets, capsules and powders. None of the samples were found to contain undeclared active pharmaceutical ingredients.

3
Activities related to the network

In this section some of the highlights from the OMCL's activities related to the network is reported.

3.1 Proficiency Testing Studies

For the purpose of quality assurance, the Danish OMCL have analysed the following PTS-samples in 2025: PTS254, PTS255, PTS256, PTS257, PTS258, and PTS259.

A few of the PTS's were analysed by both laboratory teams (Chemical and Biology).

All PTS results was considered satisfactory.

Furthermore, the biological laboratory participated in a PTS for ILC particulate contamination. This test resulted in an OOS. During the following deviation management an acceptable result was obtained.

Collaborative studies for reference materials

The chemical laboratory participated inter-laboratory analysis of CRS batch 4 for Ivermectin for Ph. Eur. The test methods performed was Related and GC-FID. Also, CRS batch 6 for Labetalol hydrochloride was analysed for Loss on drying. All test results were accepted to be incorporated in the determination of the CRS values. Furthermore, for CRS batch 3 for Sitagliptin phosphate monohydrate, Karl Fischer was performed as part of the inter-laboratory analysis, but the final results from EDQM have not yet been distributed with the participants.

The biological laboratory participated in a collaborative study (BSP169) for the calibration of replacement batches for the Ph. Eur. Heparin sodium BRP. Two candidates were found suitable to be used as reference preparations for the chromogenic anti-IIa and anti-Xa assays as well as the Sheep plasma clotting assay. Results from this study was considered satisfactory.

SUP014 – Analysis of Suspicious Unknown Products

28 OMCLs participated in SUP014. Participants are asked to identify the substance present in the unknown sample provided (test sample SUP014, one vial containing 4 tablets), using the method(s) of their own choice. In addition, participants were invited to provide quantitative results if they so wished together with the measurement uncertainty.

The Danish OMCL used our own validated method: *K0939-MET-LC-MS Targeted Screen* for identification and successfully identified the compound as Doxycycline. For quantification the validated method: *K0945-MET-LC-UV* was used, and the reported result was considered satisfactory within the range of ±10% of the consensus value.

3.2 Chemical Laboratory

Participation in marked surveillance studies (MSS)
In 2025 the Danish OMCL participated in two Market Surveillance Studies (MSS studies), which were initiated and coordinated by the EDQM.

MSS065 Disintegration of Alendronic acid tablets

The Danish OMCL participated in the MSS065 Disintegration of Alendronic acid tablets.

All tablets containing Alendronic acid available on the Danish marked (6 products) were included in the study. 4 of the products had a minimum requirement for disintegration time according to the finished product specification, the requirements ranging from 30 seconds to 1 minute. All 6 samples complied with their specification.

In addition to disintegration time all 6 samples from the Danish marked were also tested according to Ph. Eur. 2.9.5 (uniformity of mass). Some samples were further tested according

to Ph. Eur. 2.9.8 (Hardness) and Ph. Eur. 2.9.7 (Friability), for internal use only. All samples tested conformed to the requirements stated in Ph. Eur.

MSS066 Lenalidomide

The Danish OMCL participated in the MSS0066 of Lenalidomide APIs and capsules. From the Danish market 29 finished products and 23 APIs, were requested from 6 different MAHs.

The finished products were analysed for Appearance, Identification, Assay, Uniformity of Dosage Unites (only lowest dosage samples), Related substances and Dissolution (only highest dosage samples). For all finished products a full labelling control was performed.

The API samples were tested according to the draft versions of the Ph. Eur. monographs for Lenalidomide, Lenalidomide hemihydrate and Lenalidomide hydrochloride monohydrate. They were analysed for Appearance, Identification, Water (only Lenalidomide hydrochloride monohydrate samples), Assay and Related substances. All samples conformed to the specification limits, and all results were reported to EDQM.

All findings, and the outcome of the laboratory analysis were reported to the MAHs.

As all products were collected directly from the MAH, the MSS066 was combined with the sampling of extra API for the MSSFP006 Lenalidomide. The API samples were shipped to EDQM for the MSSFP006 study, planned to be performed in 2026.

MRP/DCP collaboration

As part of the MRP/DCP collaboration and mutual agreement on the testing of medicinal products, the Danish OMCL submitted 6 finished products for analytical testing at other OMCLs.

When MRP/DCP approved medicinal products are sampled from the Danish marked, an extra sample is requested to perform the labelling check in parallel with the analytical test.

CAP sampling and label check

For centrally authorised products CAP sampling and label check were performed for packages on the Danish marked. Samples were collected from wholesaler level.

In 2025, 5 centrally authorised products were sampled. No non-compliance was detected for these 5 products.

No generic products were sampled in 2025.

8 parallel-distributed products were sampled with the same non-compliance found for two products from the same parallel distributor. For both products the anti-tampering device could be removed without any visual signs of tampering. The MAH was informed of the findings.

Verification of Ph. Eur. Draft monographs

Niketamide

The method for related substances in the monograph Nikethamide was in draft updated from a TLC method to HPLC method.

The Danish OMCL performed a fully second verification including investigated stability, linearity, S/N level, LOD and LOQ, accuracy, recovery and correction factors for the nine impurities and the active substance (API) in the draft method.

Furthermore, eight batch samples were controlled for content of related substances and the limits in the monograph draft were updated according to these results. A report including our comments on the method was created and sent to the EDQM and the method has been updated and published in the Pharmeuropa,

National market surveillance studies
Several different control projects were performed on the national market.

Signal-based control: Control of products from one specific finished product manufacture, requested by DKMA inspectors

DKMA inspectors requested a laboratory control of products from one specific finished product manufacture based on signals of non-compliance for this manufacture. Two products from the Danish marked were included in the control.

The analytical results for both products were within the specification limits; therefore, the quality of the products was satisfactory. The documentation needed to be updated for both products.

For one of the products, an analytical method needed re-validation due to a necessary change to the method description. The reference standard could not be fully dissolved in the described amount of solvent, as the solution was saturated. Therefore, the amount of solvent used to dissolve the reference standard needed to be doubled. In the approved validation report, the incorrect amount of solvent was used, and thereby the data was based on a saturated reference standard solution, resulting in an incorrect validation of the method.

The quality control (QC) laboratory had already initiated this change in their release testing, without having it approved by the authorities. Thereby, the actually used amount of solvent in the reference standard preparation, had also not been validated.

Eye preparations

A project about eye preparations was started in 2025. The project included 5 different original products of eye drops. Parallel imported products of all 5 original products were also included in the project. A total of 12 products were analysed for a variety of analytical methods.

The control of two of the original products, including one parallel imported product, was finalised in 2025. The outcome of this control was that all analytical results were within the specification limits, while the documentation of the original products needed to be updated according to requirements in ICH guidelines.

Signal based control: initiated by the Danish regulatory department

In 2024 the laboratory was contacted by the regulatory department (REG), at DKMA. Difficulties with one specific MAH were encountered, as the MAH had bought numerous finished products from other companies. These difficulties resulted in REG suggesting that the

laboratory performed a spot check for full documentation and laboratory control on some of the products from this specific MAH.

First part of the project, the DKMAnet database for leaflets, was scanned. For one product, an incorrect document was uploaded, instead of the leaflet. This case was handled by REG.

In 2025 a full documentation and laboratory control were performed on two finished products. The laboratory control included Assay by Potentiometric titration, Assay by HPLC, Related substances by HPLC, Dissolution, Uniformity of content and Uniformity of mass. All results were in compliance with the specification.

A comment regarding difficulties of the Assay by Potentiometric titration, was reported to the MAH. The main finding was in the control of documentation. During method transfer changes were made in the analytical methods Assay by Potentiometric titration and the HPLC methods. These changes have not been approved by DKMA, via a variation change to the documentation, before implemented in the QC laboratory analytical procedures.

The outcome of the control was that MAH will have their dossier updated according to the findings in the control and perform an additional robustness-study.

Dabigatran Etexilate Mesilate

A project was setup to analyse the API Dabigatran Etexilate Mesilate acquired from 8 MAH of the finished products on the Danish marked. Analysis of related impurities on HPLC and GCMS was performed as well as documentation control of the methods, validations, specifications and certificate of analysis.

The outcome of the laboratory analysis was they all comply to the requirement of the Ph. Eur. monograph. Regarding the documentation control, comments were given and acknowledged.

Biological Laboratory

CAP testing
The Danish OMCL participated in two studies in the 2025 CAP program where one study was finalised in 2025, and one study will be continued in 2026. Two studies were continued from the 2024 CAP program and finalised in 2025.

The Danish OMCL preformed different tests on the samples including potency by different cell assays, capillary Electrophoreses, different HPLC methods (SE- and CEX- HPLC), as well as total protein and dose accuracy. Results were reported to the EDQM.

Verification of Ph. Eur. Draft monographs
Adalimumab

The biological laboratory participated in the verification study of the Ph. Eur. draft monograph for Adalimumab. Four methods were verified for 6 different products (two from each MAH) of adalimumab.

The methods were: strength by UV-detection, impurities by capillary electrophoresis (non-reduced and reduced CE-SDS), as well as Capillary Isoelectric focusing (cIEF), and potency determination by TNF-alpha Neutralisation assay (Ph. Eur. 2.7.26 method D). The monograph has been published in Pharmeuropa.

Complaints

Opening of ampoules

A complaint concerning a problem encountered when opening ampoules. During routine opening of the ampoules, healthcare professionals had on several occasions experienced that the ampoule appeared brittle and crumbled. In one instance, this resulted in a minor cut injury caused by glass shards.

The laboratory investigation also showed difficulties in opening the ampoules and advised the MAH to inform the user on how to open the ampoules.

3.3 General Regulatory Tasks

National Market Surveillance study

Project on Patient information leaflets

A leaflet in Danish must be uploaded at “Indlaegsseddel.dk” for all products marketed on the Danish marked. In 2025 the Danish OMCL continued a control project to check:

- Whether the package leaflet is uploaded?
- Whether the package leaflet is printable?
- Whether the package leaflet is readable when printed out?
- Whether the electronic package leaflet contains a date of latest revision?

10 % of the leaflets for ATC code B01-B06 controlled were flawed. 490 searches on “Indlaegsseddel.dk” were made. B01-B06 covers Blood and blood-forming organs.

3 % of the leaflets for ATC code J07 controlled were flawed. 60 searches on “Indlaegsseddel.dk” were made. J07 covers Vaccines.

Further ATC groups were selected for continued control projects.

Contribution to the European Pharmacopoeia (Ph. Eur.)
Three delegates from Denmark are appointed to the Ph. Eur. Commission and participate in the tree yearly meetings. Two of these delegates are from the Danish OMCL, and the third delegate is an assessor from the DKMA.

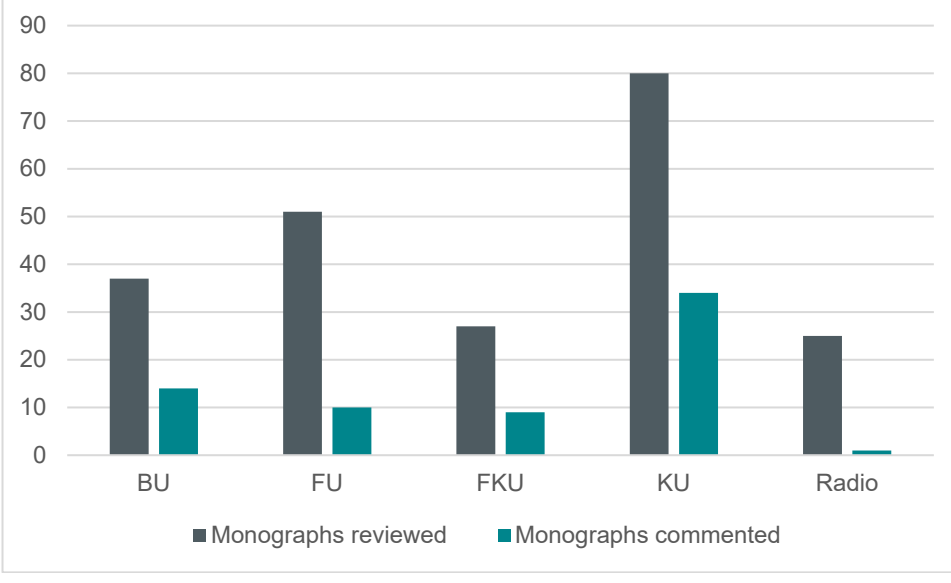
The Danish OMCL contributed with active experts in several expert groups to the Ph. Eur.:

- CST WP: Chromatographic separation techniques
- CTP WP: Cell Therapy Products
- MAB WP: Monoclonal Antibodies

A substantial part of the Danish activities concerning development of pharmacopoeial monographs (e.g. “Pharmeuropa” evaluation) takes place in the 4 subcommittees of the Danish Pharmacopoeia Commission; Biology Subcommittee (BU), Chemistry Subcommittee (KU), Pharmacy Subcommittee (FU) and Pharmacognosy Subcommittee (FKU). The Internal Subcommittee Radiopharmaceuticals (Radio) have also handled relevant monographs.

The committees consist of participants primarily from industry and academia combined with assessors, regulators and laboratory experts from the Danish Medicines Agency. This composition of participants assures that both purely technical as well as legislative aspects of the monograph proposals are addressed. The committees commented on all four editions of Pharmeuropa in hearing during 2025. The number of monographs reviewed and commented is illustrated in Table 3.

TABLE 3
MONOGRAPHS REVIEWED AND COMMENTED BY THE DANISH COMMITTIEES



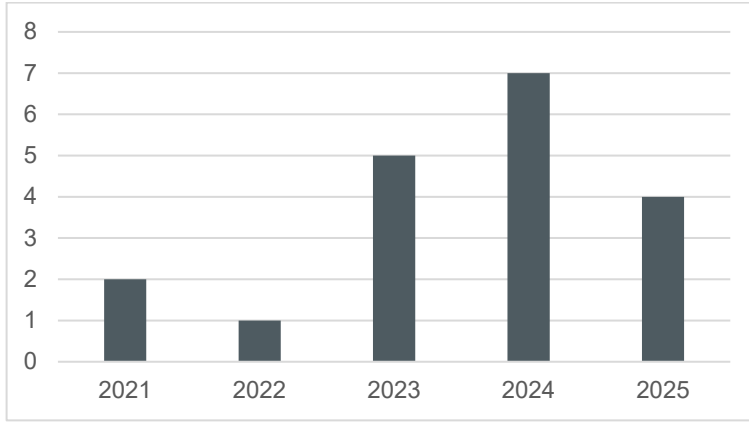
Source: "Optælling af monografier i høring og kommenteret / 2025"

Explanatory note:
BU: Biology Subcommittee
KU: Chemistry Subcommittee
FU: Pharmacy Subcommittee
FKU: Pharmacognosy Subcommittee
Radio: The Internal Subcommittee Radiopharmaceuticals

The Danish secretariat of the National Pharmacopoeia Authority (NPA) 4 Requests for Revision (RfR). In Table 4 the number of RfR handled by the Danish secretariat for the last 5 years is shown.

TABEL 4

NUMBER OF REQUESTS FOR REVISION VIA THE DANISH NPA FOR THE LAST 5 YEARS



Source: "Optælling af monografier i høring og kommenteret / 2025"

The Danish NPA furthermore handled 7 questions related to The European Pharmacopoeia (Ph. Eur.) or the Danish legislation for quality standards on medicinal compounds and products (Danske Lægemiddelstandarder).

4
Method related activities

In this section, we report some of the highlights from the OMCL's method related activities from 2025.

Method for the control of indelible labelling

The Danish Inspectorate have requested the in-house method for the testing of indelible labelling to be published. Therefore, the Danish OMCL published the method on the webpage in both Danish and English to make our work more transparent.

The inhouse test for indelible labelling was described to standardise the test performance by the DKMA staff as no standardised test is published elsewhere.

Link: Control of indelible labelling in the laboratory

Upgraded software for analytical equipment

To assure the stability of some of the larger analysis in the laboratory, two major software updates have been accomplished. Chromeleon™ Chromatography Data System for the (U)HPLC analysis and Openlab, Agilent, for the GC-MS analysis.

Polarimeter

For the analysis of the API products, a new polarimeter have been purchased.

GLP-1 analogues - LCMS screening method for GLP-1 analogues as Semaglutide

An LC-MS screening method (K0995-MET) was developed and validated. The method is a targeted screen at LC-MS for selected substances focusing on GLP1 analogues as well as other substances of large molecules. A qualitative determination is made by comparing retention time, molecular masses and molecular charge state using an internal library created by reference standards. For the identification of a substance, at least three molecular charge-states should be demonstrated with mass accuracy < 10 ppm and retention time comparison if the substance is in the library. In case of missing reference material, identification is not precise but is indicated as most likely.

The method has been applied in two cases, both cases with unknown labelling, and the content could be identified as Semaglutide.

Workshop of OMCL guideline Validation of Computerised Systems

The Danish OMCL has in October 2025 together with EDQM, Croatia, Sweden and the Netherlands contributed to the planning and execution of a 4-day online workshop in the guideline: Validation of computerised systems.

5
Public relation activities

In this section, we report some of the highlights from the OMCL's public related activities from 2025.

The Danish Medicines Agency are working on our communication as one of our four strategic benchmarks "*We will invest in dialogue and communication with the public and society to become the primary source of knowledge on medicines and medical devices*."

The Danish OMCL had in 2025 increased focus in to communicate about the outcome and learning from finalised control project and standard practice for different control parameters.

In 2025 the OMCL published the following news about control projects at the DKMA webpage: News (laegemiddelstyrelsen.dk)

- Electronic leaflets for veterinary medicinal products have too small font size
- Pharmaceutical companies must ensure that the labelling on the medicine packages cannot disappear

We reposted and promoted the following news from EDQM:

- The new online version of The European Pharmacopoeia and the associated webinar to the new website with new functionalities: https://www.linkedin.com/posts/laegemiddelstyrelsen_unlocking-the-potential-of-the-european-pharmacopoeia-activity-7343562973203869698-vghy?utm_source=share&utm_medium=member_desktop&rcm=ACoAACOOAI8BfGlUZ_ntb93KT5VhZUzXOZWDJxU
- Cannabis flower monograph open for comments: Changes to the Cannabis Flower Monograph – Now Open for Public Consultation
- The news about The European Pharmacopoeia removed the rabbit pyrogen test and replaced it with alternative non-animal methods. This news was also shared on LinkedIn and Facebook. (In Danish) En milepæl i arbejdet med at reducere brugen af forsøgsdyr i lægemiddelindustrien

All titles to the European monographs are translated into Danish. For herbal drug preparations, this process occasionally results in unusual naming considerations. In the case of *Epimedium leaf*, the decision stood between a direct translation of the Chinese name, "*horny goat herb*", or a translation of the European name, "*bishop's hat leaf*". (In Danish)

- https://www.linkedin.com/posts/laegemiddelstyrelsen_bispehueblad-eller-liderlig-gedeurt-activity-7368636544183656448-IL-6?utm_source=share&utm_medium=member_desktop&rcm=ACoAACOOAI8BfGlUZ_ntb93KT5VhZUzXOZWDJxU

A complaint about AI reading the braille correct on the medicinal packages of one patient's medicines, was controlled in a small labelling project. All labelling in braille was correct, and the conclusion was made that AI not just yet are able to read braille correct. A news item on LinkedIn was published about the results. (In Danish)

- https://www.linkedin.com/posts/kan-ai-l%C3%A6se-medicinpakker-en-lidt-share-7380910835205910528-QnFT?utm_source=share&utm_medium=member_desktop&rcm=ACoAACOOAI8BfGlUZ_ntb93KT5VhZUzXOZWDJxU

the Danish OMCL continuously check that even older medicines meet modern quality standards through controls of documentation and lab testing, ensuring patient safety. An example was acetazolamide, approved in 1953 and still in use today. This news was published to encourage companies to go over the documentation for their older medicines marketed on the Danish marked. (In Danish)

- https://www.linkedin.com/posts/tilbage-til-1950erne-n%C3%A5r-l%C3%A6gemidler-share-7382358294860021761-moRw?utm_source=share&utm_medium=member_desktop&rcm=ACoAACOOAI8BfGlUZ_ntb93KT5VhZUzXOZWDJxU

To facilitate the strategy on being transparent and open we let the public get to know our staff and work opportunities in the Danish Medicines Agency by sharing presentations of the staff on the LinkedIn profile.

- After suffering a stroke, Lene Holt made a remarkable comeback to the labour marked taking a part-time role at the Danish Medicines Agency's lab. Her expertise in pharmaceutical regulation makes her a valued employee in the field of pharmaceutical quality assurance: https://www.linkedin.com/posts/laegemiddelstyrelsen_lene-genfandt-sit-faglige-fodf%C3%A6ste-i-laboratoriet-activity-7302954671952785408-fkcD?utm_source=share&utm_medium=member_desktop&rcm=ACoAACOOAI8BfGlUZ_ntb93KT5VhZUzXOZWDJxU

The Danish Medicines Agency participated in the Career Days event at Øksnehallen and had prepared a brochure about the work conducted in the Danish OMCL. The aim was to attract new employees and students. The brochure is not published on our webpage.

6
Future planning

In this section some of the future national projects and Network related activities will be enumerated.

In 2026 the Danish OMCL will participate in multiple governmental corporations in the Strategic Sector Cooperation (SSC).
SSC is a government-to-government cooperation within a specific sector. It is a central instrument for the Danish foreign and security policy and development cooperation and paves the way for Denmark's economic diplomacy. The cooperation is between Danish public authorities and national partner authorities and promotes equal partnerships.
In 2026 the Danish OMCL will share our experiences with delegations from Ukraine and China.

6.1 National

The Danish OMCL expect to focus on the following projects on the national marked:

- Follow-up on previous controls to check if the MAH have corrected our findings
- Ear preparations
- Medicinal products that have been approved a very long time ago.
- Signal based control
- Antibiotics

6.2 Network

The Danish OMCL expect to participate in the following testing:

- MSS FP006
- PTS265, PTS266, PTS267, PTS268, PTS269 and PTS274
- Expert work in Ph. Eur. expert groups 10A and MAP WP.

7
Difficulties encountered

The OMCL's difficulties related to testing activities and organisation.

Nothing to report.