



Quality and Safety

for Redcare Pharmacy N.V.

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1. Striving for the highest quality standards and customer safety

Redcare Pharmacy is Europe's online one-stop pharmacy of the future with a vision to continue until every human has their health. The organisation is committed to being recognised by its customers as the most trusted brand within the e-pharmacy industry. This trust is based on and enabled by a comprehensive understanding of quality and (customer) safety throughout the entire organisation. As a people-first online pharmacy, Redcare Pharmacy constantly strives to provide excellent quality and safety of products and services to its customers. Ensuring high quality and safety of products and services to our customers is considered a top priority and is therefore an important objective of the organisation's strategy. This document describes what measures Redcare Pharmacy has developed and implemented to deliver this objective.

2. Quality Management System as foundation

Within Redcare Pharmacy, an extensive customer-centric Quality Management System (QMS) has been developed/implemented to safeguard and to continuously improve the quality and safety of products and processes. The QMS of our organisation contains the coherent overall set of organisational structures, responsibilities, procedures, processes and resources that are necessary to implement the quality policy, to achieve the predetermined quality objectives and to ensure excellent quality of care. The Plan-Do-Check-Act (PDCA) cycle for continuous improvement possesses a central role in this system. Overall, it is a management system for steering and controlling an organisation with regard to quality. All our products and services are subject to the processes defined by our QMS.

Our QMS has the following objectives:

- Continuously monitoring and improving the performance of the organisation by providing insight and overview on relevant quality topics, facilitating and improving all processes within the organisation.
- Ensuring the quality and (customer) safety of the products and services that are delivered.
- Providing control- and steering information in the areas of quality and safety.



3. Meeting high quality and safety standards

Redcare Pharmacy guarantees the safety and quality of all our products and services by continual compliance to international and national regulations/standards. Table 1 provides an overview of the standards and licenses for which Redcare Pharmacy is certified. Redcare Pharmacy does not possess any minor and/or major observations in its certifications and licenses.

Table 1

Overview of certifications and licenses

Certificate	Scope	Certification body
Good Distribution Practice (GDP) for Human Medicines	Specifies the requirements to ensure that quality and integrity of medicines is maintained throughout the supply chain	Dutch Health and Youth Care Inspectorate (IGJ)
ISO 9001:2015	Specifies the requirements for an organisation's Quality Management System	TÜV Nord
ISO 27001:2013	Specifies the requirements for an organisation's Information Security Management System	TÜV Rheinland
European Standard for Organic Products	Specifies the requirements for safe handling and storage of organic products throughout the supply chain	Skal Biocontrole (NL BIO 01), CCPB Srl (IT BIO 009)
Prequalification Pharmacy	Qualification which specifies the requirements for sufficient, appropriate manufacture, dispensing and adaptation of medical aids	German Society for Prequalification in Healthcare (DGP)
Pharmacist Registration	Registration which allows for the distribution of prescription medicines to patients	Dutch Health and Youth Care Inspectorate (IGJ)
Wholesale License	License for sourcing medicines from within the EEA (European Economic Area) and dispensing them	Ministry of Health, Welfare and Sport (CIBG)
Veterinary Medicines License	License for the manufacture, import, wholesale - and/or retail sale of veterinary drugs	Medicines Evaluation Board (CBG)
Animal Feed License	Licence for trade, storage and transport of animal feed products	Dutch Food and Consumer Product Safety Authority (NVWA)



4. Guaranteeing the (chemical) safety of our products

4.1. Accurate checks on falsified medicines

As an e-pharmacy and wholesaler of medicinal products, it is our duty to contribute to the safe distribution of medicinal products in the European market. The Falsified Medicine Directive¹ (FMD) has been implemented to prevent false medication from entering the supply chain. Falsified medicines are becoming more sophisticated and therefore the risk of counterfeit medication reaching patients increases¹. According to the FMD, each medicinal product needs to be verified and decommissioned in a European database. In our organisation all products that are subject to this directive, are both verified and decommissioned in the system. Based on the alerts that we receive from the database, continuous actions are taken to (even better) assure the safe distribution of medicinal products towards our customers. A real-time dashboard has been developed which shows the trends with respect to the number of alerts and the number of successful scans.

4.2. Timely and proper handling of recalls and quality defects

Daily checks are performed on notifications and on information regarding products with defects or quality issues. When Redcare Pharmacy is informed about a defect or a quality issue with one of our products, the product is recalled and a strict predefined recall procedure is initiated. In order to guarantee the safety and quality of our products, recalls are being handled with the highest priority and are documented, managed and controlled adequately. In case of a recall, the stock is directly checked, customers are contacted and authorities are informed. Furthermore, specific notifications with regard to recalls are being published on the website.

Moreover, adverse effects and unforeseen side effects of products that are reported by customers are carefully checked, handled and directly communicated to manufacturers and appropriate authorities. This is being done to prevent the delivery of unsafe products to customers.

4.3. Strict requirements for returning products to saleable stock

Returned products to Redcare Pharmacy are handled with utmost care. In order to guarantee product safety within our saleable stock, returns are being carefully documented and checked on all legally determined requirements before being replaced in saleable stock. Returned products that do not meet these requirements are physically separated from saleable stock and professionally destroyed. The return rate within the organisation is also closely monitored as a performance measure.

4.4. Product assessment and product release of our assortment

The safety of (new) products in the complete assortment we offer to our customers is guaranteed by the Pharma Compliance department, which assesses each product on strict quality standards and on compliance with external guidelines and regulations. For each country separately, assessments are being performed on the allowance to sell products on the basis of national guidelines considering several check points like dosage, maximum quantity, language and label/product

¹European Commission. (n.d.). Falsified medicines. Retrieved June 27, 2023, from https://ec.europa.eu/health/medicinal-products/falsified-medicines_en



information. Amendments to existing legislation are monitored on a daily basis in order to prevent important adjustments from being missed. Furthermore, Redcare Pharmacy assesses products through regularly requiring charge analyses of products from suppliers of for example food products, to check correctness of product content and to ensure product safety.

4.5. Medication management

All medication orders for customers are double-checked and assessed on possible interactions between medications. The organisation's system is professionalised by a fully automatic warning system that identifies interactions between products, products with possible problematic effects for specific customers or that have a low therapeutic range. Furthermore, maximum quantity restrictions are applied based on legislation and automated within the system. In case of severe interactions, contra-indications or ambiguities about e.g. dosage, the customer or prescribing doctor is always being actively contacted by colleagues of our pharma team to discuss the matter.

4.6. Providing reliable product information to our customers and responsible marketing

With regard to product information, all products are assessed on required, allowed and reliable information that should be provided to our customers about the product and the safe usage of the product. This results in our customers being extensively informed about the content of products (e.g. ingredients, additives, allergens etc.), the usage of medication, possible interactions and new prescriptions in forms of general product information, information on the web shops including a product detail page, first-user letters and package inserts. Next to written product information, Redcare Pharmacy offers an always-accessible pharmaceutical advisory service consisting of trained pharmaceutical staff and an online doctor service for customers who require advice.

Redcare Pharmacy complies to the various regulations that apply to the responsible marketing and advertising of products. Moreover, regular internal audits (supported by external consultants for further objectivation) are executed to assess our available product information on correctness and compliance with European and national regulations.

5. Adequately managing risks

Redcare Pharmacy is on a consistent basis exposed to various opportunities and risks. As an organisation, Redcare Pharmacy believes it is important to have an extensive and systematically updated overview of the risks we face as an organisation and of how these risks can be mitigated. A complete Enterprise Risk Management (ERM) framework has been developed and implemented in order to effectively manage strategic, operational, compliance and financial risks. Risks related to quality and safety as well as risks related to pharma compliance form an important cornerstone within the ERM framework. Risks that could lead to negative effects with respect to quality and safety of products and services are identified at an early stage from both a bottom-up and top-down perspective. The identified risks that require attention are prioritised by so called 'domain owners'. Consequently, these prioritised risks are proactively mitigated to minimise its



potential negative consequences and to ensure the delivery of safe, high-quality products and services and the achievement of objectives.

6. Prevention and handling of errors

Within Redcare Pharmacy, a professional system for the identification and handling of (potential) errors, that resulted or could have resulted in customer harm, has been implemented. Information on the amount of errors made in the organisation is well documented and analysed. Moreover, a dashboard has been established to permanently track and analyse the amount of errors within the organisation. The main goal of this error management system is to continuously improve our processes, enhance customer safety and ensure quality of our services. The error management system is based on the Healthcare Quality, Complaints and Disputes Act. Through error management, failures/weaknesses in our processes are identified and investigated. Based on the analysis, appropriate corrective and preventive actions (CAPA) are taken to reduce and prevent reoccurrence and bring the quality and safety of our processes to a higher level. For instance, we are in close cooperation with a pioneering external Artificial Intelligence consultancy firm to further reduce the possibility of errors and thus improve the safety of our customers.

7. Quality along the supply chain

As an e-pharmacy platform and wholesaler, Redcare Pharmacy interacts with a variety of suppliers. Redcare Pharmacy applies strict control measures in order to maintain and ensure the quality of products and substances throughout the complete supply chain. Redcare Pharmacy only procures from qualified suppliers who meet desired quality conditions and comply with organisational and legal requirements. For instance, suppliers should be able to provide relevant insight in their quality processes and should possess all required licenses and certifications (e.g. WDA/MIA/GDP/GMP/Organic etc.) for the goods and/or services that they sell to Redcare Pharmacy. This means that without the right licenses/certificates, no goods and/or services can be purchased from the respective supplier. Suppliers who fulfil the demanded requirements are deemed to be qualified for contracting and the procurement of goods and/or services. All necessary supplier licenses and certificates are up to date and are continuously re-requested if they expire in the near future.

As our suppliers are in possession of required licenses and certificates, this further implies that all of Redcare Pharmacy's suppliers are trained and regularly inspected (by corresponding authorities) with respect to these standards. For example, the GDP guideline requires that all employees involved in wholesale distribution activities are trained on the GDP requirements and they should receive initial and continual training that is relevant to their role².

In addition, Redcare Pharmacy regularly assesses and evaluates the performance of suppliers based on predefined evaluation criteria. This is for example being done by the performance of (risk-based) supplier audits. This enables us to determine the strengths and weaknesses of potential suppliers and is an incentive for quality and performance improvement.

Moreover, when products from eligible suppliers arrive at our warehouse, they are strictly checked on all quality aspects. These include amongst others checking that

² European Commission. (2013). Good Distribution Practice. *Official Journal of the European Union*.



products are undamaged and that temperatures and expiry dates are within the approved range.

8. Applying safe storage conditions

Safe and appropriate storage conditions of products are key to guarantee product safety. Medicinal products should not be exposed to any contamination which could affect its quality and safety. Based on the Warehouse Management System (WMS) at Redcare Pharmacy, products are automatically allocated to different storage locations in the warehouse. Hereby we assure physical separation of different product types and therefore minimise the risk of contamination. Further, only trained employees have access to the storages.

The storage of products in the right temperature conditions is an important issue for Redcare Pharmacy due to its high influence on quality and safety. As Redcare Pharmacy is both a wholesaler and an online pharmacy, the products need to be stored and transported in the right conditions. There are several measures in place to ensure appropriate temperature conditions throughout the processes of Redcare Pharmacy. The complete warehouse of Redcare Pharmacy is qualified and state of the art temperature controlled. The temperature control system allows the temperature to be continuously controlled at a level within precisely defined limits. A multitude of calibrated data loggers are placed throughout the storage areas. These data loggers capture temperature and humidity and thus enable for the continuous temperature and humidity monitoring of storage areas. In case of deviations from predefined limits, a strict predefined alarm protocol is in place which ensures that temperature deviations are immediately and appropriately handled by responsible employees. In addition, the responsible employees are trained to adequately determine whether the quality of products is affected. In this way, the quality and safety of products is continuously guaranteed.

9. Quality indicators to assess performance

Redcare Pharmacy is committed to reach its own established internal Key Performance Indicators (KPIs) with respect to quality and safety within the organisation. These are the so-called minimum standards of the organisation and is aimed at eliminating all potential harm to our customers and at maximising customer satisfaction. A variety of indicators are available for real-time monitoring.

Next to internal determined KPIs, Redcare Pharmacy, as an e-pharmacy, provides an annual overview of important quality and safety indicators to the Royal Dutch Pharmacists Association (KNMP). Through digitalisation of these indicators, continuous insight and data about the quality and safety level of our pharmaceutical services is available and used to continuously improve the care provided by our pharmacy. The quality indicator results are publicly published by the KNMP³.

10. Learning from our customers

10.1. Tracking customer satisfaction

By actively and continuously measuring our Net Promoter Score (NPS), insight is gained into customer satisfaction and customer experience. The NPS is obtained through asking our customers how likely they are to recommend the services of Redcare Pharmacy to others. Further follow-up questions are asked to our

³ KNMP. (n.d.). Meting Kwaliteitsindicatoren Farmacie. Retrieved July 7, 2023, from <https://www.knmp.nl/bedrijfsvoering/kwaliteit-zorgverlening/meting-kwaliteitsindicatoren-farmacie>



customers to identify relevant feedback. The NPS score including customer feedback is continuously being shared on dashboards within the entire organisation. Based on the received customer feedback, improvement actions are being determined and implemented in order to ensure the highest quality of products and services to our customers. Furthermore, regular questionnaires are being sent by the pharmaceutical advisory to our customers for more detailed and focused insights in their customer experiences. The NPS score of Redcare Pharmacy is regularly publicised and is steadily above 70, indicating an excellent score.

10.2. Careful handling of customer complaints

At Redcare Pharmacy we constantly wish to improve our customer satisfaction and therefore also the quality and safety of our products, services and processes. The adequate managing of complaints within the organisation is an instrument that facilitates the achievement of these objectives. Complaints received from customers are registered, documented, handled, analysed, and evaluated with care and structure. Recurrence of specific complaints can be prevented in the future through the correct processing of incoming complaints. The managing of complaints relates to one of the most important principles of our QMS, namely the customer centricity. Complaints are seen as useful input for continuous quality improvement within Redcare Pharmacy. Based on this information, the organisation is able to initiate appropriate actions that will raise the quality of products, services and processes to a higher level.

11. Safeguarding food safety

Redcare Pharmacy stores and distributes a wide range of food products, received from various suppliers. As Redcare Pharmacy continually strives to provide excellent safety of products, safety with regard to the storage and distribution of food products is crucial. In order to be able to maintain a high level of food safety, a regularly trained Hazard Analysis and Critical Control Points (HACCP) team is established that continuously identifies possible hazards and monitors the level of food safety within the organisation. Furthermore, an HACCP system is in place which is in accordance with the principles of HACCP that are identified and described in the Codex Alimentarius of the World Health Organization. This HACCP system ensures the identification, monitoring and handling of hazards and critical control points within an extensive, well-considered hazard analysis.

12. Appropriate training for employees

The appropriate training of employees is a significant theme within the organisation. At Redcare Pharmacy, the aim is to go beyond what is required by law and regulations when it comes to the training of employees. Trainings are conducted to ensure employees throughout the entire organisation are aware of and trained on the highest safety and quality levels. At the onboarding of Redcare Pharmacy, each employee receives a standard Quality, Safety & Security training to ensure a baseline level of knowledge. This training is accompanied by a test that has to be passed before the first working day, in this way it is ensured that all employees are not only trained on the basic Quality, Safety & Security aspects, but they really understand it. More detailed and specific trainings are customised for the appropriate functional groups and roles. For example, we have established amongst others a GDP advanced training for specific employee groups and an audit training based on ISO 9001:2015 for specific employee functions.



An annual training overview is present within Redcare Pharmacy. This annual training overview describes the by Redcare Pharmacy offered training initiatives for our employees that are considered internally necessary or are externally required by law. The annual training overview contains an overview of mandatory trainings for the entire organisation, specific functional groups, as well as functional roles. It summarises information on the training content, required frequency, assigned obligation, targeted employee groups, and executing department. Next to providing a necessary overview, the annual training overview is an organisational tool that supports the continuous development of all our employees and enables us to keep up to date with latest developmental trends and requirements. The status of the trainings listed in the annual training overview is accurately documented in the existing integrated training overview. This document records which employee completed which training.

13. Continuous insights in performance and improvement possibilities

13.1. Execution of audits as daily business

A comprehensive policy for conducting audits has been established within Redcare Pharmacy. Risk-based internal audits are conducted regularly throughout the organisation to determine the extent to which our products and services meet set internal and external guidelines, protocols and/or standards. Different types of audits like mystery calls, mystery orders, departmental audits as well as in-depth audits are performed to get a good insight in the quality of our processes and services. Performing audits contributes to creating a culture based on safety and quality awareness, improvement and learning throughout the organisation. Internal audits are a useful instrument to identify defects and opportunities for improvement. In addition, the measures required to maintain and/or improve the required safety and quality become visible and tangible.

Next to internal audits, Redcare Pharmacy is regularly being inspected on several international and national standards by external authorities. These inspections provide useful insights on compliance to quality standards and identify important risks and opportunities for improvement. Compliance to international standards is considered crucial within Redcare Pharmacy and helps the organisation to maintain a high level of safety and quality, and improve performance.

13.2. Quarterly management review on all quality and safety aspects

The periodically executed management review indirectly contributes to improving quality and safety of products and services at Redcare Pharmacy. The management review is a quarterly internally developed and published report describing the recent developments of every aspect within the QMS of the organisation. The purpose of the review is to continuously improve the QMS and make sure that it is suitable, adequate and effective. It is a method of regular communication and alignment in which shortcomings become apparent. The main goal of this review is to contribute to quality improvement instead of merely justifying.



14. Management of changes and deviations

A framework for change and deviation management is implemented within Redcare Pharmacy. This framework enables us to successfully overcome deviations, to develop corrective and preventive actions and to implement changes in a risk-oriented and effective manner. Corrective and preventive actions (CAPA) are applied to adequately deal with deviations. Based on the CAPA system, non-conformities and quality problems can be identified, analysed, investigated and effective actions can be taken to prevent their reoccurrence. Furthermore, change control is implemented within Redcare Pharmacy to control and deal with changes in an effective manner. The main goal is to ensure that all changes within Redcare Pharmacy that might potentially affect the quality of our products and services or the reproducibility of processes, are carefully evaluated, documented, reviewed and controlled. With respect to change management, a clear and straightforward procedure is predefined and followed by trained employees at all times. Through the appropriate controlling and handling of deviations and changes, potential risks that might have a negative effect on the quality and safety of our products and services are identified and minimised by Redcare Pharmacy.