comeo·check

Instructions for Use

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History of Changes

Version	Date	Change Description
1.0	31/03/2025	Initial version
1.1	22/12/2025	• Some texts have been slightly reworded for more clarity; • The table of content has been reordered; • A new section 3.1.1 Overall architecture is provided, including a graphical aid; **The following revisions were issued for safety reasons:** • The Intended Use, General principle of operations, and Clinical benefits to be expected have been reworded for more clarity; • The warnings and precautions have been rewritten with mention of the residual risks and their potential consequences, and how to reduce them as far as possible; • Information on the following additional residual risks have been added: data errors, alert fatigue, overreliance on alerts, and inaccessibility of the eIFU. • The limitations have been rewritten and reorganized to align with Drug-Drug Interactions, Drug-Condition Interactions (including list of supported conditions) and Drug-Drug Therapeutic Duplications.

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1 Introduction

1.1 Purpose

This documentation aims at guiding the users for the safe use of the ComeoCheck software.

It delivers important notices, limitations, contraindications, precautions, and warnings, regarding the use of ComeoCheck, that must be considered carefully by all users before any use.

1.2 Scope

This document is meant to deliver general information, precautions, and warning and limitations for the Healthcare Professionals.

This document is part of the ComeoCheck User Guides series whose reading is mandatory in function of the person's roles:

- Healthcare Professionals who are using ComeoCheck through their Computerized Physician Order Entry (CPOE) system.
- Any stakeholder interested in medication appropriateness check and medicines information.

1.3 Applicability

The information in this document applies to the versions of ComeoCheck mentioned on the first page of this document, for all markets where it is distributed, unless specifically mentioned otherwise in the text. When a certain chapter or subchapter is limited to a version, this is the case for all paragraphs within this section and its subsections.

1.4 Audience

Intended audience of this guide are:

- Healthcare Professionals that are users of ComeoCheck;
- Any other person in charge of- or making use of the application.

Technical staff and developers can refer to the [REL1] ComeoCheck - Integration Manual available from the manufacturer (see section 1.6).

1.5 Paper copy

The present Instructions for Use deliverable is distributed electronically and is accessible through the link in the "About" page of the application. In conformity with the (EU) 2021/2226 Regulation on Electronic Instructions for Use of Medical Devices, it will be available from the manufacturer for 15 years after the last device has been placed on the market.

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Users requiring a paper copy can submit a request to:

E-mail:	Online: https://support.comeo.com E-mail: support@comeo.com

The requester shall receive the requested paper copy no later than seven (7) calendar days after submission of the request.

1.6 Support and Incident Reporting

Any question or request for clarification regarding ComeoCheck or the present Instructions for Use may be addressed to the manufacturer.

Any **complaint** concerning ComeoCheck, or any **incident** that has occurred in relation to its use, should be reported without undue delay to the manufacturer.

Contact details:

Region	**Support**
[BE] Belgium	Online: https://support.comeo.com E-mail: support@comeo.com

Functional and technical support are available through the same contact point. To facilitate understanding and resolution, please describe the circumstances and observed conditions.

Any **serious incident** that has occurred in relation to ComeoCheck must be reported without undue delay to both the manufacturer and the Competent Authority of the country where the user and/or patient is established.

Serious incident reporting	
Manufacturer	support@comeo.com
[BE] Belgium	FAGG Portal in Dutch: https://www.fagg.be/nl/MENSELIJK_gebruik/gezondheidsproducten/medische_hulpmiddelen_hulpstukken/materiovigilantie/wat_0 AFMPS Portal in French: https://www.afmps.be/fr/humain/produits_de_sante/dispositifs_medicaux/materiovigilance/que_notifier/professionnel_de_la

To assist in the investigation and resolution of any serious incident, please include a description of the circumstances and observed conditions.

1.7 Related documents

ID	Reference	Description
REL1	CCK-ITM	ComeoCheck - Integration Manual

1.8 Glossary of terms

Term	Definition
Alert	Information signal notifying the User of a condition of the Patient and the Prescription providing contextual awareness that is intended to improve the clinical workflow or understanding of the Patient condition, the awareness not being intended by the need to take immediate action but to prevent further implications.
Aid	In this documentation, the term “aid” is used to denote the provision of patient-specific medical information intended to reinforce healthcare professionals’ clinical judgment, without automating, replacing, or constraining clinical decision-making.
Alert fatigue	A usability phenomenon in which frequent or repetitive alerts reduce the user’s attention or responsiveness to warnings. Alert fatigue may cause healthcare professionals to ignore or overlook relevant alerts due to desensitization, perception of low value, or cognitive overload.
Analysis	Technical processing performed by ComeoCheck on prescription-related data received from the CPOE system, consisting of applying predefined computational rules and logic to identify potential medication-related situations (e.g., interactions or contraindications) and to generate corresponding alert information. The analysis does not constitute a clinical decision, does not validate the prescription, and aids – without replacing – the Healthcare Professional’s judgement. In this documentation, the term ‘analysis’ refers to the technical processing performed by ComeoCheck, while the term ‘check’ refers to the medication appropriateness checking activity performed by Healthcare Professionals.

Term	Definition
APB	The Belgian Pharmacists Association. (French) Association Pharmaceutique Belge: https://www.apb.be/fr/corp/Pages/default.aspx (Dutch) Algemene Pharmaceutische Bond: https://www.apb.be/nl/corp/Pages/default.aspx This association represents Belgian retail pharmacists and provides its members with services and tools to support them in their daily work.
API	Application Programming Interface. Software component that can be re-used by an application system programmatically though a documented interface.
ATC	Anatomical Therapeutic Chemical. The Anatomical Therapeutic Chemical (ATC) Classification System is a drug classification system that classifies the active ingredients of drugs according to the organ or system on which they act and their therapeutic, pharmacological, and chemical properties. It is controlled by the World Health Organization Collaborating Centre for Drug Statistics Methodology (WHOCC). See structure and principles here: https://www.whocc.no/atc/structure_and_principles/
BMUC	Belgian Meaningful Use Criteria. The BMUC (Belgian Meaningful Use Criteria) is a Belgian public incentive system to promote the use of medical software systems within hospitals: https://www.health.belgium.be/en/node/28866

Term	Definition
CAS Number	Chemical Abstracts Service. The Chemical Abstracts Service (CAS) Registry Number, also referred to as CASRN or CAS Number, is a unique numerical identifier assigned by the CAS to every chemical substance described in the open scientific literature (currently including all substances described from 1957 through the present, plus some substances from the early or mid 1900s), including organic and inorganic compounds, minerals, isotopes, alloys and non-structural materials (UVCBs, substances of unknown or variable composition, complex reaction products, or biological origin).
Check of Medication Appropriateness	The validation of the medication treatment of patients at risk for potentially inappropriate medication (PIM), including drug-related problems (DRPs) and ADEs by combining structured data available from the hospital information system (HIS) and by using standardized algorithms, also referred to as clinical rules.
Clinical relevance	The clinical relevance defines the meaning and severity of the Drug-Drug Interaction. There are 7 levels defined by DelphiCare (contraindicated, severe, moderately severe, weak, warning from the producer, no expected inaction, no advice possible).
Cloud software	A software that runs on remote servers and is accessed over the Internet, rather than being installed on a user's local device.
CNK	(French) Code National / (Dutch) Nationale Kode. This national code number is used for identifying unequivocally all the different packages of products available in pharmacies open to the public.
CPOE system	Computerized Physician Order Entry system
Computerized Physician Order Entry system	The physician's use of computer assistance to directly enter medication orders from a computer or mobile device. The order is also documented or captured in a digital, structured, and computable format for use in improving safety and organization.
DelphiCare	DelphiCare is a scientific database over Belgian and foreign medicines, as well as parapharmaceutical products labeled by the APB. The "Centre d'Information Pharmaceutique (CIP) - Centrum voor Farmaceutische Informatie (CFI)" of the APB publishes DelphiCare.

Term	Definition
Drug-Condition Interaction	An event in which a drug that is intended for therapeutic use causes some harmful effects in a patient because of a disease or condition that the patient has. This can be true for both prescription and over-the-counter drugs.
Drug-Drug Interaction	A change in a drug's effect on the body when the drug is taken together with a second drug. A Drug-Drug Interaction can decrease or increase the action of either or both drugs or cause adverse effects.
eIFU	Electronic Instructions for Use
Healthcare Professional	Any member of the medical, pharmacy or nursing professions who, in the course of their professional activities, may prescribe, administer or dispense to a patient a medicinal product.
FAMHP	Federal Agency for Medicines and Health Products. https://www.famhp.be/en The Belgian competent authority for the quality, safety and efficacy of medicines and health products.
IFU	Instructions for Use
Intervention class	The intervention class defines the type of action to take in case of Drug-Drug Interaction. There are 8 intervention classes defined by the legacy DelphiCare (from the most critical (1) to the weakest (8)). The intervention class is now obsolete and supported in the backward compatible mode only of API v1, it has been replaced by the clinical relevance concept. Refer to section 4.5 for more information.
Magistral preparation	A medication specially prepared by a pharmacist because an appropriate medicine is not readily available. Also called 'Extemporaneous preparation'.
Monograph	The monograph is an exhaustive documentation on an interaction between two drugs. It contains the essential information about the interaction but also data on the type of interactions (pharmacokinetic or pharmacodynamics) and the substances affected by these interactions. On the other hand, it also describes the pharmacological effects, mechanisms, comments and contains the corresponding bibliography.

Term	Definition
Overreliance	A usability risk in which users place excessive trust in a computerized system or its outputs, leading to reduced personal verification or clinical judgment. Overreliance may result in users accepting system results without adequate critical assessment of the patient's specific situation.
SAM Database	The Authentic Source of Medicines (SAM) is the Belgian reference database of medicinal products made available as an open source database by medicines competent authorities. More information: https://www.famhp.be/en/human_use/medicines/medicines/information_about_medicines/authentic_source_of_medicines_sam
SMD or SaMD	Software as a Medical Device.
SPC	Summary of Product Characteristics.
Therapeutic Duplication	The practice of prescribing multiple medications for the same indication without a clear distinction of when one agent should be administered over another – for example, pain, nausea and vomiting, and constipation.
WHOCC	World Health Organization Collaborating Centre.

2 Intended Application

2.1 Intended use

ComeoCheck is a cloud software application programming interface designed for integration into computerized physician order entry systems. It is intended to aid healthcare professionals as they perform their check of medication appropriateness. It retrieves information from recognized medication knowledge sources in order to return real-time alert data on potential medication interactions and contraindications that are above a customizable level, for consideration by healthcare professionals within the ordering workflow.

2.2 Intended indications

ComeoCheck is indicated to aid during the check of medication prescriptions appropriateness involving all or part of the following aspects: **Drug-Drug Interactions**, **Drug-Condition Interactions** and **Drug-Drug Therapeutic Duplications**.

For details on the scope and limitations of the analysis, including the list of conditions supported, please refer to section 4.5.

2.3 Intended use environment

ComeoCheck is intended to be used as an integrated component within a CPOE system, deployed exclusively for use by Healthcare Professionals.

Information regarding qualified combinations with CPOE systems and the conditions for their safe use is provided in section 3.4.

Restrictions on locations or environments of use:
ComeoCheck is intended to be integrated into a CPOE system operated in a clinical environment by Healthcare Professionals. Validation of the integrated system in the customer's specific environment is outside the scope of ComeoCheck and remains the responsibility of the Healthcare Institution (see section 4.4.3).

2.4 Intended user profiles

ComeoCheck is intended to be used exclusively by Healthcare Professionals that have been trained for using the CPOE system integrated with ComeoCheck.

2.5 Target population

ComeoCheck targeted population encompasses any human patient being treated in a Healthcare Institution under the control of a Healthcare Professional.

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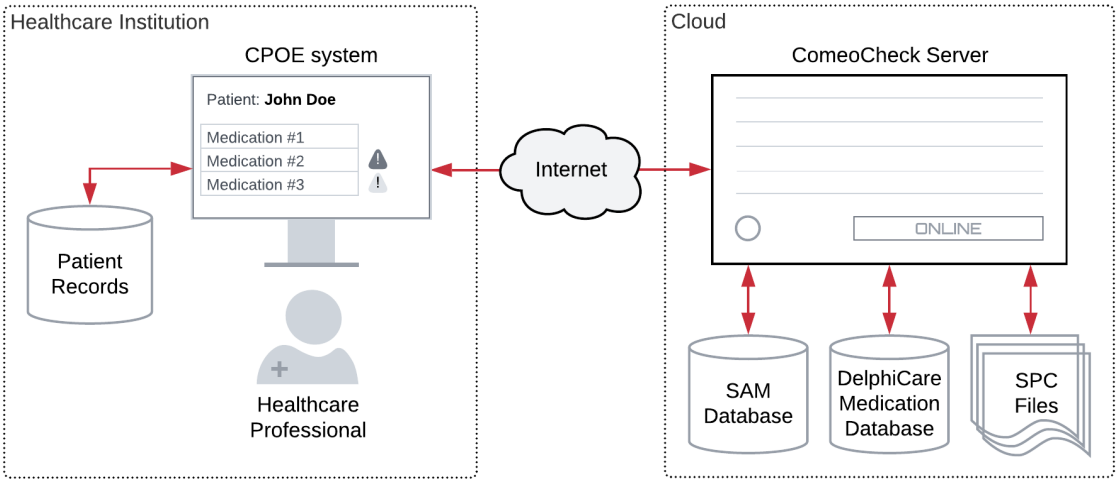
3 Device Description

3.1 How ComeoCheck achieves its intended use

3.1.1 Overall architecture

ComeoCheck is available in the cloud as a software application programming interface (API) to be used exclusively through software integration from the CPOE system to delivers potential interaction and contraindication alerts for a medication prescription about to be confirmed by a Healthcare Professional.



ComeoCheck does not provide any user interface for the Healthcare Professional. The Healthcare Professional is entirely using ComeoCheck from/through the user interface of the CPOE system, that must have been enhanced for this purpose by its manufacturer.

Therefore, in case the CPOE system becomes unavailable, then ComeoCheck will also become unavailable preventing the Healthcare Professionals to be aided for their Check of Medication Appropriateness.

ComeoCheck relies on several data sources, i.e., the DelphiCare database provided by the APB, the SAM database, and files from the FAMHP.

3.1.2 General principle of operations

ComeoCheck is a software API invoked by the CPOE system whenever a user is about to prescribe medications for a patient.

The CPOE system transmits to ComeoCheck the list of medications about to be ordered and the patient's known ongoing medications and conditions, together with the desired clinical relevance

level of alerting threshold (see section 3.1.3). Based on this information, ComeoCheck retrieves information from the following recognized medication knowledge sources:

- The **DelphiCare** database for Drug-Drug Interactions, Drug-Condition Interactions, and Drug-Drug Therapeutic Duplication, including their clinical relevance, essential information and monograph;
- The **SAM** database for CNK mapping information regarding specific hospital packages;
- The Summary of Product Characteristics (**SPC**) files provided by the FAMHP.

ComeoCheck performs technical data transformations only (formatting, layout normalization, indexing, and combination of source data for efficient retrieval). It does not modify, interpret, or enrich the medical content of the underlying sources, and it does not generate additional medical information.

ComeoCheck returns the alerts that are above or equal to the requested alerting threshold to the CPOE system regarding:

- **Drug-Drug interactions**: potential adverse interaction(s) that may arise from the simultaneous use of medications. When an interaction is identified, scientific contextual information may be provided in the form of essential (concise) information or a detailed monograph.
- **Drug-Condition interactions**: potential adverse effect(s) that may result from a specific patient condition or physiological state (i.e., disease, hyper-sensibility to a substance, pregnancy, breastfeeding, …). When such an interaction is identified, concise scientific contextual information may be provided.
- **Drug-Drug therapeutic duplication**: potential adverse effect(s) linked to duplicative therapeutic actions across medications. When a therapeutic duplication is detected, a reference to the common active substance is provided.

Once the alerts and related information have been returned to the CPOE system, ComeoCheck's role ends. The CPOE system is solely responsible for displaying and managing these alerts according to its own user interface and workflow. ComeoCheck has no direct interaction with the user and is not informed of how the alerts are handled nor of the prescribing decisions made by the Healthcare Professional in the ordering workflow.

3.1.3 Alerts

The alerts are delivered reflecting the DelphiCare scale based on the clinical relevance:

Clinical relevance	Description and meaning
Contraindicated	The interaction partners cannot be combined with each other, that is, they are contraindicated.

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Clinical relevance	Description and meaning
Severe	The interaction could be mortal or have serious, sometimes irreversible consequences for the patient.
Moderately severe	The interaction can have therapeutically significant consequences for the patient.
Weak	The interaction has no clear therapeutic consequences but should be monitored under certain circumstances.
Warning from the producer	For this interaction, only specific information from a pharmaceutical company is available, most often from the SPC.
No expected interaction	There are indications in the literature that no interactions occur or that no interactions are to be expected on the basis of structure, pharmacokinetics or pharmacodynamics.
No advice possible	An assessment based on the available literature is not possible.

This scale may be adapted by the CPOE system manufacturer (e.g., by reducing/merging the number of levels, by using specific denominations, or by using specific color coding).

Depending on the implementation choice within the CPOE system, the clinical relevance is used as an alert filter as needed and might be the basis for different displaying (more or less intrusive, non-blocking or blocking, requiring bypass justification or not, etc.).

Frequency (probability) of occurrence

> **Version note:** frequency is not supported by API v1.

It is not always straightforward to assess a reported interaction solely based on clinical relevance. Therefore, DelphiCare also mentions the frequency of occurrence: very common (≥ 1/10), frequent (≥ 1/100 to < 1/10), uncommon (≥ 1/1.000 to < 1/100), rare (≥ 1/10.000 to < 1/1.000), very rare (< 1/10.000) or not known.

Assessment of the sources and nature of the sources

DelphiCare indicates the quality of the data available (unknown, insufficient, poor, sufficient, good) and the nature of the sources consulted for the interaction (clinical studies, case observations, summary of product characteristics).

Interaction direction

The direction of the interaction describes whether one interaction partner influences the other (one-way interaction), whether the action of the two interaction partners is changed (two-way interaction) or whether the effect cannot be defined more precisely (without direction).

Side effects and symptoms

Adverse reactions and symptoms that may result from them are listed in a dedicated section. The use of layman's language by DelphiCare supports the user in communicating with the patient.

Risk factors

The risk factors that may influence the occurrence of certain interactions are recorded in a structured manner.

Interaction monitoring

If patient follow-up is required when managing the interaction, this information is available in a structured way: parameters for follow-up, start of follow-up, duration of follow-up and any follow-up data after stopping one of the interacting substances.

Adjustment of the dose as part of the management of the interaction

This also applies to any adjustments to the dose or to the dosing schedule, which are necessary when considering certain interactions: taken or administered over time, adjustment of the dose and the dose interval, recommendations for short-term treatment and other recommendations.

3.1.4 Illustrative example

A patient receiving chronic treatment with Marcoumar 3 mg tablets and Lanoxin 0,125 mg tablets should take Brufen 400 mg tablets.

CNK code	ATC code	Description
0119065	B01AA04	Marcoumar (c) 3mg
4524237	C01AA05	Lanoxin (c) 0,125mg
3607462	M01AE01	Brufen (c) 400mg

The way the CPOE system detects an interaction is system specific but basically consist in raising an alert notification.

In this example, two drug interactions are reported:

Interaction code	Clinical relevance	Interaction drug 1	Dir	Interaction drug 2
009904	Severe	Lanoxin (c) 0,125mg	←	Brufen (c) 400mg
000706	Severe	Marcoumar (c) 3mg	–	Brufen (c) 400mg

The first interaction is unidirectional. It is here represented by an arrow to the left (←) between the two interacting specialties. The right specialty influences the left.

The second interaction is directionless, which implies mutual reinforcement of adverse effects. This is indicated by a dash (–) between the names of the specialties.

The two reported clinical interactions are of "severe" clinical relevance.

3.1.5 Information

As side features, ComeoCheck is also able to:

- Provide **informative textual posology guidelines** including usual and max doses – provided by DelphiCare.
- Provide access to the official medicine's **Summary of Product Characteristics (SPC)** – provided by FAMHP.

3.2 Clinical benefits to be expected

No direct clinical benefit, understood as a positive impact of the device on the health of individual, is expected from the use of ComeoCheck. ComeoCheck is not intended to supplant the decision-making role of the physician, nor provide pivotal information to justify the adequacy of prescribed medication plans.

The indirect clinical benefit of the software lies in providing real-time alert data and information on potential Drug-Drug Interactions, Drug-Condition Interactions and Drug-Drug Therapeutic Duplications, as documented in recognized medication knowledge sources.

Additionally, ComeoCheck applies alert thresholds that are configured within the CPOE system, enabling healthcare professionals to tailor notifications to the specific needs of different clinical settings.

3.3 Performance characteristics of the device

The following table lists the device performance characteristics:

Feature	Characteristics description
Medication Alerting Service	
Drug-Drug Interactions Alerting	• Medication identification by APB CNK medication coding scheme. • Medication identification by WHO ATC medication coding scheme. • Filtering out by Clinical Relevance on 7 levels. • Provide Essential Information and Monograph for each reported interaction.
Drug-Condition Interactions, Advice and Precautions Alerting	• Medication identification by APB CNK medication coding scheme. • Condition identification by APB DelphiCare condition coding scheme. • Support alerting for the conditions as listed in section 4.5.2. • Filtering out by Risk Level.

Drug-Drug Therapeutic Duplications Alerting	• Medication identification by APB CNK medication coding scheme.
	• Support alerting for the following situations of duplications:
	  ○ Two or more medications having the same active substance in common;
	  ○ Two or more medications having the same ATC level 5 class.

Medication Information Service	
Drug Contraindications, Advice and Precautions Information	• Medication identification by APB CNK medication coding scheme. • Information delivered for the same conditions as for the alerting service.
Drug Composition Information	• Medication identification by APB CNK medication coding scheme. • Substances identification by CAS registry number.
Consult Drug Posology Guidelines	• Medication identification by APB CNK medication coding scheme. • Deliver unstructured text posology guidelines.
Summary of Product Characteristics Document	• Medication identification by APB CNK medication coding scheme. • Deliver summary of product characteristics documents in PDF.

3.4 Software systems that can be used together with ComeoCheck

The table below lists the information flows that are supported by ComeoCheck and the software systems that can be used together to provide extra functions.

Integration	System	Details
Medication Appropriateness Service	CPOE system	**Intended purpose:** Provide alerts intended to aid the Healthcare Professionals while checking the appropriateness of their patient medication prescription. **Supported protocols:** Specific JSON REST protocol **Qualified software for safe combination:** The qualification of a safe combination includes technical integration, interoperability testing, and agreement on responsibilities between the CPOE system manufacturer and Comeo. Healthcare institutions shall ensure that ComeoCheck is used only with CPOE systems that are officially supported and qualified for this purpose. An up-to-date list of CPOE systems qualified for use with ComeoCheck, as well as relevant integration information, is made available by the manufacturer upon request or via the manufacturer's support channels (see section 1.6). For a more detailed technical view on how to integrate a CPOE system with ComeoCheck, please refer to the [REL1] ComeoCheck - Integration Manual. **Known restrictions or constraints:** Requires a valid license token and Internet connectivity (see section 5).

3.5 Configuration

For ComeoCheck to function properly, the CPOE system must be configured with the license token allowing the use of ComeoCheck.

ComeoCheck can be configured by the means of a clinical relevance filter threshold influencing the way alerts are filtered out.

4 Important Notices

4.1 Contraindications

The following are known contraindications preventing Healthcare Professionals to rely on ComeoCheck for performing a check of medication appropriateness.

The use of ComeoCheck is contraindicated for any of the following conditions:

a. For patients taking medicines that have been prescribed outside Belgium and/or are imported from another market and not reimbursed in Belgium and therefore not supported by the APB DelphiCare database.
b. For patients taking medicines that are unknown to the CPOE system. Reasons for this situation typically include but are not limited to:
    - One or several previous prescriptions have been performed using a different CPOE system in the same Healthcare Institution whose data are not shared or accessible to the CPOE system integrated with ComeoCheck.
    - One or several previous prescriptions have been performed in a different Healthcare Institution whose data are not shared or accessible or copied into the CPOE system integrated with ComeoCheck.
    - One or several previous prescriptions have been performed by one or several open care prescribers whose data are not shared or accessible or copied into the CPOE system integrated with ComeoCheck.
c. The CPOE system is permanently or temporarily not connected to the Internet preventing to establish a reliable access to the cloud ComeoCheck services.

The use of the ComeoCheck Drug-Condition Interactions detection service is contraindicated for any of the following conditions:

d. For patients whose conditions are not encoded or available in the CPOE system using a structured coding scheme compatible with ComeoCheck.

4.2 Side effects

There are no known side effects from the use of ComeoCheck.

4.3 Warnings

The following is a non-exhaustive list of important attention points to be reviewed and understood by Healthcare Professionals before considering using ComeoCheck within their Healthcare *Institution.*

4.3.1 Ensure reliability of network connectivity

ComeoCheck is an online service that relies on the healthcare institution's network and Internet connectivity for proper operation.

The service is delivered via the Internet, and the manufacturer has implemented hosting and monitoring measures to ensure high availability. However, as with any online service, temporary interruptions may occur, which can result in short periods during which the service is unavailable. In such situations, a non-analysis error message is displayed.

Healthcare institutions should ensure that their IT infrastructure supports reliable network connectivity, for example by implementing appropriate network-availability monitoring or redundancy, in order to maintain continuous access to ComeoCheck.

4.3.2 Ensure vigilance for potential software failures

ComeoCheck, the connected CPOE system, and the connector between them are software components. As with any software-based system, defects ("bugs") or security vulnerabilities may occur and could affect system behavior or performance.

The manufacturer has conducted extensive verification and testing and has implemented security measures to protect the service against cyber-attacks and malware.
However, software malfunctions may still occur and could result in the following situations:

a) Display of irrelevant alerts (false positives);
b) Failure to display relevant alerts (false negatives);
c) Display of incomplete or corrupted alert information.

Healthcare institutions should therefore ensure appropriate operational vigilance, including:

- Implementing complementary verification or consistency checks within the CPOE system;
- Ensuring that the CPOE system and its integration components are kept up to date, and contacting support in case of doubt;
- Maintaining effective protection of digital equipment against malware and viruses in accordance with institutional IT policies;
- Encouraging healthcare professionals to review alerts carefully, taking into account their clinical relevance, and to avoid overreliance on automated outputs (see section 4.3.6).

4.3.3 Ensure vigilance for potential data errors

ComeoCheck analyses rely on large, continuously updated datasets originating from external scientific and pharmaceutical sources and forming the DelphiCare database.

The Belgian Pharmacists Association (APB) maintains and verifies the DelphiCare database using structured processes. However, as with any data-driven system relying on multiple sources, data inaccuracies or inconsistencies may occur.

Data errors may occur at various levels, including:

- Errors or omissions in the scientific or pharmaceutical data provided by third parties, e.g., Drug-Drug Interactions, dug-conditions interactions, or medication details (see also 4.5.3);
- Incorrect or incomplete data integration or formatting during import into ComeoCheck;
- Data tampering;
- Errors or omissions in the local product master file, within the Healthcare Institution;
- Incorrect or inconsistent identifiers transmitted by the CPOE system.

Such data issues could result in:

a) Missing or outdated alerts;
b) Alerts of incorrect clinical relevance or scope;
c) Incomplete or misleading information displayed to the user.

Healthcare institutions should therefore maintain appropriate operational vigilance, including:

- Ensuring regular updates of their local product master data and configuration;
- Verifying correct mapping of medicines identifiers (e.g., CNK codes) between systems;
- Monitoring for and reporting any unexpected or inconsistent alert behavior or any suspected data anomaly to the manufacturer via the support channel (see section 1.6);
- Encourage healthcare professional to pay attention to all alerts and their level of clinical relevance, avoiding overreliance on ComeoCheck outcome (see section 4.3.6).

4.3.4 Ensure accessibility to the labelling and instructions for use

The Instructions for Use (IFU) and labelling information (available through the "About" page) of ComeoCheck are provided electronically (eIFU) and are accessible online within the ComeoCheck service.

The manufacturer provides the labelling and eIFU in electronic form and ensures that the information made available is the latest approved version. However, as with any digital content, temporary unavailability or display issues may occur and may prevent healthcare professionals from accessing this information for a limited period of time.

Such situations may result in the following consequences:

a) The healthcare professional may be unable to consult the IFU and thus misinterpret alerts or outcomes provided by ComeoCheck;
b) The healthcare professional may be unable to access the support contact information to submit a complaint or incident report;

c) The healthcare professional may remain unaware of their right to request a paper copy of the eIFU.

Healthcare institutions and CPOE system manufacturers should therefore ensure that users have reliable access to the ComeoCheck documentation, including:

- Providing users with reliable access to the latest version of the Instructions for Use, Terms of Use, and Labelling (About page);
- Linking exclusively to the manufacturer-hosted documentation to avoid uncontrolled or outdated copies;
- Maintaining secure and stable connectivity to the documentation resources (see also 4.3.1);
- Ensuring the CPOE system supports the display of standard document format (PDF).

4.3.5 Avoid alert fatigue

ComeoCheck may generate multiple alerts depending on the prescription complexity and configuration of the CPOE system.

A high volume of alerts can, over time, reduce user attention or lead to desensitization – a phenomenon commonly referred to as alert fatigue. This may result in clinically relevant alerts being overlooked or disregarded.

ComeoCheck presents alerts in a structured and prioritized manner based on their level of clinical relevance (see section 3.1.3). However, the way alerts are displayed and managed within the clinical workflow depends on the configuration and use of the CPOE system.

Healthcare institutions should therefore take appropriate steps to manage alert presentation within their clinical context, for example by:

- Adjust the alert threshold to the clinical practice and context (e.g., patient population, criticality of care, etc.);
- Periodically reviewing alert thresholds configured in the CPOE system;
- Encouraging users to report patterns of excessive or irrelevant alerts for continuous improvement.

4.3.6 Avoid user overreliance on alerts

ComeoCheck is intended to aid healthcare professionals during their Check of Medication Appropriateness.

As with any clinical decision-support technology, users may be tempted to place excessive trust in automated outputs and give less attention to their own clinical evaluation or to contextual patient information.

Healthcare professionals should therefore:

- Critically assess all recommendations or alerts considering the complete clinical situation and available patient data;
- Verify that prescriptions remain appropriate even in the absence of alerts;
- Understand that ComeoCheck complements, but does not replace, professional expertise and responsibility for the final medication decision.

ComeoCheck is intended to aid the healthcare professional by providing analysis of their medication prescription but does not replace the healthcare professional's judgment. Healthcare professionals must therefore exercise clinical judgment and remain ultimately responsible for all prescribing and dispensing decisions.

4.4 Precautions

ComeoCheck may partially or completely malfunction if it is not integrated, configurated, maintained, operated, and used in accordance with the complete Instruction set, consisting in this documentation and the [REL1] ComeoCheck - Integration Manual. To ensure that the product always operates properly and safely, it must be operated and used in accordance with the instructions provided in these documentations.

Besides the guidelines in the instruction set, this section contains a mandatory but non-exhaustive list of precautions to be taken by Healthcare Professionals in the integration and deployment of ComeoCheck within their Healthcare Institution.

4.4.1 Ensure adequate usability of CPOE alert management

ComeoCheck is designed to integrate with the CPOE system without providing any direct user interaction or user interface.

Consequently, usability depends on the user interface and user experience implemented by the CPOE system's alert management. The way alerts are displayed, prioritized, acknowledged, or overridden is entirely under the control of the CPOE manufacturer.

The manufacturer provides documentation and technical support to the CPOE system manufacturer. Nevertheless, inadequate usability or poor integration of alert management in the CPOE system may occur, which could lead to delayed, missed, or misunderstood alerts, potentially compromising the optimal composition or execution of prescribed medications.

To support safe and effective use of the integrated system, healthcare professionals should, before deploying the service within their institution:

- Verify that alert management is usable and effective within the clinical workflow;

- Confirm that alerts originating from or relevant to medication prescriptions are clearly presented and distinguishable from other notifications;
- Confirm that non-analysis error messages are clearly presented and distinguishable from other messages (see section 4.3.1);
- Ensure that alert handling does not require excessive user actions or context changes (see section 4.3.4).

The manufacturer provides interface specifications and recommendations to support safe integration but does not control or validate the usability of third-party CPOE systems. Healthcare institutions remain responsible for assessing and ensuring the safe and effective use of the combined system.

4.4.2 Ensure healthcare professional's awareness of CPOE system configuration

The ComeoCheck features may be implemented in full or in part by the manufacturer of the CPOE system.

ComeoCheck offers flexibility to CPOE manufacturers in their integration and does not require the CPOE system to forcibly request every possible type of analysis of prescription appropriateness.

For example, a CPOE system manufacturer may choose to request analysis of Drug-Drug Interactions but not of Drug-Condition Interactions or Drug-Drug Therapeutic Duplications, due to technical constraints such as data availability or format. In such cases, healthcare professionals should not assume that those additional analyses are covered by the system.

As a result, healthcare professionals may assume a system configuration different from the actual one, which could lead to incorrect interpretation of the analysis outcome.

To support correct understanding and appropriate use of the integrated system, Healthcare Professionals should, before accessing the service in the CPOE system:

- Be informed of the configuration and scope of the ComeoCheck integration within their CPOE system;
- Verify which analysis types and clinical relevance filters are active, and which conditions are supported;
- Understand how alert filters (see section 3.1.3) affect which alerts are displayed;
- Request clarification from their local support team or the CPOE system manufacturer in case of doubt.

4.4.3 Ensure validation of the integrated system in the local environment

ComeoCheck is provided as a software component intended for integration into a third-party CPOE system. While the manufacturer verifies the correct functioning of ComeoCheck according to

its specifications and provides integration requirements to CPOE system manufacturers, validation of the integrated system in the customer's specific environment is outside the scope of ComeoCheck.

Local validation activities may be necessary to account for customer-specific configuration, infrastructure, data sources, user roles, and clinical workflows. A lack of such validation may result in unexpected or incorrect system behavior, including misinterpretation of alerts or analysis results.

Healthcare institutions should, prior to clinical use of the integrated system:

- Validate the behavior of the integrated CPOE-ComeoCheck system in an environment representative of the production environment;
- Verify that local configuration, workflows, and data sources are compatible with the intended use of ComeoCheck;
- Confirm that alerts and analysis results are correctly displayed and understood in the context of local clinical practice;
- Ensure that any local changes to configuration, infrastructure, or workflows are assessed for their potential impact on the behavior of the integrated system.

Responsibility for validation of the integrated system in the customer's specific environment remains with the Healthcare Institution.

4.5 Limitations

The following is a non-limitative list of relevant factors that may affect the device's performance or safety.

4.5.1 Limitations regarding the Drug-Drug Interactions analysis

The ComeoCheck service provides an aid in checking the potential Drug-Drug Interactions but shall not be considered as comprehensive or deterministic in the prescription process.

The service may not detect all possible Drug-Drug Interactions as:

a) It's scope is limited to medicines commercialized on the Belgian market and officially identified by the APB using the Belgian CNK code.
b) It does not take into account situations where a magistral preparation or radiopharmaceutical preparation is involved in the prescription with no tracing to the original product and/or substance CNK or ATC code.
c) On average every month, as soon as published, the new DelphiCare data snapshot is loaded in ComeoCheck. However, the Drug-Drug Interaction may not have been documented in the DelphiCare database by the APB, as the data are collected and assembled through a publication process involving collection, identification, verification, curation, localization, translation, review and publication delays, meaning that information that could already have

been published within the scientific community might not yet be available through the publication process.

For the above reasons, ComeoCheck does *not* provide a comprehensive analysis encompassing the detection of *all* Drug-Drug Interactions but is limited to a subset.

The APB and the manufacturer have taken extensive mitigation measures ensuring that:

a) In case of prescription of medicines commercialized outside Belgium, the ATC code can be provided by the CPOE system, so that if a similar medicine with the same ATC code is commercialized in Belgium, the analysis can be performed through substituting the provided ATC code by the Belgian equivalent CNK code, increasing the likeliness of detection.
b) In case of magistral preparation preserving the traceability to the original product and/or substance CNK or ATC code, the detection is performed.
c) A close follow-up of medication packages upon market introduction is performed by the APB to ensure a timely inclusion of every medication and related known Drug-Drug Interactions in the DelphiCare database.

Healthcare professionals should take these limitations into account and use ComeoCheck as a decision-support tool, in combination with their clinical judgment and other available information sources. Additional guidance regarding appropriate use and avoidance of overreliance is provided in section 4.3.6.

4.5.2 Limitations regarding the Drug-Condition Interactions analysis

The ComeoCheck service provides an aid in checking the potential Drug-Condition Interactions but shall not be considered as comprehensive or deterministic in the prescription process.

The service does not encompass all possible Drug-Condition Interactions, but is limited to the following defined list of illnesses, hyper-sensibilities, and physiological states:

- Asthma;
- Hypersensitivity to rifamycins;
- Hypersensitivity to polymyxins;
- Hypersensitivity to nitrates;
- Hypersensitivity to imidazole derivatives;
- Hypersensitivity to barbiturates;
- Hypersensitivity to an ACE inhibitor;
- Photodermatosis (history of ...);
- Hypersensitivity to NSAIDs;
- Parkinson's disease;
- Renal insufficiency;
- Hepatic insufficiency;
- Neuroleptic malignant syndrome (history);

- Hypersensitivity to iodine;
- Contact lenses;
- Diabetes;
- Hypersensitivity to cephalosporins;
- Heart failure;
- Open-angle glaucoma;
- Hypertension;
- Hypersensitivity to sulfonamides;
- Prostatic hypertrophy;
- Narrow-angle glaucoma;
- Hypersensitivity to penicillins;
- Hypersensitivity to tetracyclines;
- Hypersensitivity to lincosamides;
- Aminoglycoside hypersensitivity;
- Phenylketonuria;
- Quinolone hypersensitivity;
- Macrolides hypersensitivity;
- Sulfite hypersensitivity;
- Epilepsy;
- Carbapenem hypersensitivity;
- Depression;
- Pregnancy;
- Breastfeeding;
- Glucose-6-phosphate dehydrogenase deficiency;
- Benzodiazepine hypersensitivity.

Drug-Condition Interactions related to conditions not included in this list are not evaluated by ComeoCheck and will therefore not be reported

The scope of the analysis performed (i.e. which conditions are covered) is intended to be communicated to the healthcare professional through the connected CPOE system, allowing correct interpretation of the results.

Healthcare professionals should take these limitations into account and use ComeoCheck as a decision-support tool, in combination with their clinical judgment and other available sources of patient information. Additional guidance on appropriate use and avoidance of overreliance is provided in section 4.3.6.

4.5.3 Limitations regarding the Drug-Drug Therapeutic Duplication analysis

The ComeoCheck service provides an aid in checking potential Drug-Drug Therapeutic Duplications but shall not be considered as comprehensive or deterministic in the prescription process.

The service does not detect all possible Drug-Drug Therapeutic Duplications, but is limited to identify:

- Two or more medications having the same active substance in common;
- Two or more medications having the same ATC level 5 class.

Consequently, therapeutic duplications of drugs that:

- Have in common a substance and one of its derivatives (e.g., ester, analogs, isomeric forms, etc.),
- Have different substances but duplicate by a common indication,

…will not be detected by the Service for potential duplication.

For these reasons, ComeoCheck performs a subset-based analysis of Drug-Drug Therapeutic Duplications and does not cover all possible duplication mechanisms.

Healthcare professionals should take these limitations into account and use ComeoCheck as a decision-support tool, in combination with their clinical judgment and other available information sources. Additional guidance regarding appropriate use and avoidance of overreliance is provided in section 4.3.6.

4.5.4 Limitations regarding patient data

ComeoCheck analyzes medication appropriateness solely on the basis of the medications transmitted at the time of analysis.

It has no awareness of the patient's historical, contextual, or external medical data.

The following limitations apply to the ComeoCheck service with respect to patient data:

a) ComeoCheck has no access to any patient administrative or medical records and is not connected to any third-party medical data vault, hub, or network. It has no means of identifying individual patients and does not collect any personal data, including cookies.
b) ComeoCheck retains no record of previous analysis for the same patient and is unable to correlate successive analysis with each other.
c) ComeoCheck does not differentiate between medications already being taken and medications about to be prescribed. Consequently, it cannot determine whether an alert relates to previously prescribed medicines, newly prescribed medicines, or a combination of both.

d) ComeoCheck is not informed of prior clinical decisions or of any alert bypasses previously established by a prescriber. Therefore, subsequent analysis that include the same medicines combinations will trigger the same alerts again (see also 4.3.4).

4.6 System, error and fault messages

Medication alerts messages are meant to be self-explanatory to Healthcare Professionals and displayed according to their clinical relevance as described in section 3.1.3.

Technical error messages are meant to be caught by the CPOE system and are described for developers in the [REL1] ComeoCheck - Integration Manual.

4.7 Lifetime, decommissioning and disposal of ComeoCheck

4.7.1 Device lifetime

The device lifetime is defined to 3 years after the release date of the version to the market. The release date is mentioned on the device About page.

4.7.2 Decommissioning and disposal

ComeoCheck is a cloud software system that has no local components installed within the Healthcare Institution infrastructure, network or user local machine. It can be safely decommissioned at any time by stopping to call the service, with no specific measure to be taken for disposal.

4.8 Compatibility Notices

Version notes

ComeoCheck is fully compatible with the software MedCheck v3.* (*) for both the API v1 and API v2 versions.

The below section describes the changes brought by the API v2 compared to the API v1. Healthcare Institutions using the API v2 can ignore this section. Refer to the manufacturer of the CPOE system to understand which API version is being used by your CPOE system.

(*) MedCheck is a product of Pfizer Inc., 400 Webro Rd, Parsippany, New Jersey 07054, United States

4.8.1 Change in the principle of operation

Interactions by pair of substances

The conceptual modification brought by API v2 is that it better reflects the new DelphiCare database from the APB:

- Previous versions of DelphiCare database provided the description of interactions at the level of the class or group of substances. By consequence, the interaction text was often relating to several substances belonging to these classes. This may have made it more difficult to find information about the specific interaction reported by the CPOE system.
- In the new version of DelphiCare database leveraged by API v2, interactions between substances are individually described with – if necessary – a specific interaction text and clinical relevance. The action information therefore only deals with the specific combination of interacting substances, which makes consideration of the interaction more accurate.

For example:

- In the new version, ritonavir and itraconazole, ketoconazole, miconazole or posaconazole are individually described;
- In the previous version, interactions were grouped into a single common interaction between HIV protease inhibitors and azole derivatives.

4.8.2 How backward compatibility is ensured

Despite the above change, the API v1 remains supported, so that any CPOE system that was integrated successfully with API v1 will continue to operate.

Note that to fully benefit from the new DelphiCare database, the CPOE system must be adapted by its manufacturer to API v2. Inquire to the manufacturer of the CPOE system for upgrade information.

When the CPOE system has not been upgraded to be compatible with the new DelphiCare database through API v2, it is by default running in backward compatible mode.

In this mode, the following adjustments are automatically provided:

The intervention class can continue to be used

The intervention class is mapped to the following levels of clinical relevance as follow:

Intervention class [API v1]	**Clinical relevance** [API v2]
Contraindicated	Contraindicated
Contraindicated in case of risk factors	
Contraindicated for caution	Severe
Concomitant use not recommended	

Intervention class [API v1]	**Clinical relevance** [API v2]
Follow-up / adaptation(s)	Moderately severe
Follow-up / adaptation(s) required in certain cases	
Follow-up by caution	Weak
No measures to take	Warning from the producer
	No expected inaction
	No advice possible

Please note that the intervention class and the clinical relevance are different concepts, therefore this mapping is only an approximation.

Fields are adapted in the essential information

The essential information data set contains short information that, in most cases, will be sufficient to manage the interaction. It is adapted as follows:

Information fields [API v1]	**Backward compatible content** [API v2]
Left interaction group	This field content will be populated with the more specific left interaction substance.
Right interaction group	This field content will be populated with the more specific right interaction substance.
Intervention class	As the intervention class isn't existing anymore, this field content is populated by recreating the intervention class based on the clinical relevance as described in the mapping table above.
Effect	No change, the effect field content is preserved.
Management	This field content is populated with the measures to take field that contains the same information.
Pharmacologic effect	No change, the pharmacologic effect field is preserved.
Unlikely substance	This field is not existing anymore and will remain empty.

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Fields are adapted in the monograph

The monograph data set contains detailed scientific information. It is adapted as follows:

Information fields [API v1]	**Backward compatible content** [API v2]
Left interaction group	This field content will be populated with the more specific left interaction substance.
Right interaction group	This field content will be populated with the more specific right interaction substance.
Intervention class	As the intervention class isn't existing anymore, this field content is populated by recreating the intervention class based on the clinical relevance as described in the mapping table above.
Effect	No change, the effect field is preserved.
Comments	This field content is populated with the important remarks field that contains the same information.
Management	This field content is populated with the measures to take field that contains the same information.
Bibliography	No change, the bibliography field is preserved.
Pharmacologic effect	No change, the pharmacologic effect field is preserved.
Pharmacokinetic effect	This field is not existing anymore and will remain empty.
Pharmacodynamic effect	This field is not existing anymore and will remain empty.
Other interaction type	This field is not existing anymore and will remain empty.
Interaction substance described	This field is not existing anymore and will remain empty.
Interaction substance expected	This field is not existing anymore and will remain empty.
Interaction substance any	This field is not existing anymore and will remain empty.
Interaction substance unlikely	This field is not existing anymore and will remain empty.

5 User Device Technical requirements

5.1 Minimum Hardware Requirements

There are no specific hardware requirements for the user device other than the compliance with the CPOE system hardware requirements.

5.2 Minimum Software Requirements

On top of the CPOE system software requirements, using the ComeoCheck Public API requires the support of the display of standard document format (PDF) and a configuration of the network infrastructure as described below.

The communication middleware is fully based on HTTPS requests/responses and does not differ from regular browser-based integrations with Internet web sites. The responses are formatted in simple JSON or HTML format that can be natively handled by most of the programming languages and/or frameworks.

In case of proxy and/or outbound routing rules are in place, we recommend that the CPOE system codebase gets access to:

URL	https://*.comeocheck.net/*
Port	443

Regarding the coding aspects, please refer to the [REL1] ComeoCheck - Integration Manual for technical details and coding guidelines about the integration of the ComeoCheck Public API in the CPOE system.

5.3 Security considerations

When using ComeoCheck though the CPOE system, it is essential to follow security best practices to ensure the safety of patient data and the proper functioning of the system. The next table contains a non-exhaustive list of general security considerations:

Topic	Considerations
Secure Access to the CPOE system	• Always use unique login credentials and never share them with others. • Ensure multi-factor authentication (MFA) is enabled and complete the authentication process for every login. • Do not allow unauthorized individuals to view or access the application while it is in use.

	• Lock your device or application screen if you step away from your workstation • Log out of the system when not in use
Use of Approved Devices	• Access ComeoCheck only from devices that are approved and compliant with your organization's security policies. • Keep your devices updated with the latest operating system and security patches.
Data Handling and Export	• Avoid exporting sensitive patient data unless strictly necessary and authorized. • Ensure exported data is stored securely, encrypted, and deleted when no longer required. • Use data anonymization techniques to remove identifiable information before exporting or sharing data, in compliance with privacy regulations. • Do not transfer sensitive data using unsecured channels such as email
Responding to Alerts	• Take all system alerts and notifications seriously. • If you encounter a security alert, follow the recommended action steps provided by the system or notify your IT/security team immediately.
Reporting Suspicious Activity	• Report any suspicious activity, such as unexpected account logins or data anomalies, to your organization's IT/security team promptly. • Use the incident reporting system designated by your organization to log potential breaches or concerns.
Compliance with Organizational Policies	• Follow your organization's security policies and guidelines while using ComeoCheck. • Participate in regular security awareness training to stay informed about potential risks and best practices.
Keep Personal Information Secure	• Do not save passwords or sensitive information in unsecured locations (e.g., sticky notes, text files). • Use password managers if needed, ensuring they comply with organizational security requirements.

6 Regulatory information

	**Comeo sa/nv** Rue Boulvint 54 1400 Nivelles, Belgium
CE 2797 	ComeoCheck is a Medical Device