



MedicinesComplete User Guide

# The MHRA Orange and The MHRA Green Guide



The reference source for manufacturers and distributors of medicines



Available through





## Overview and Access

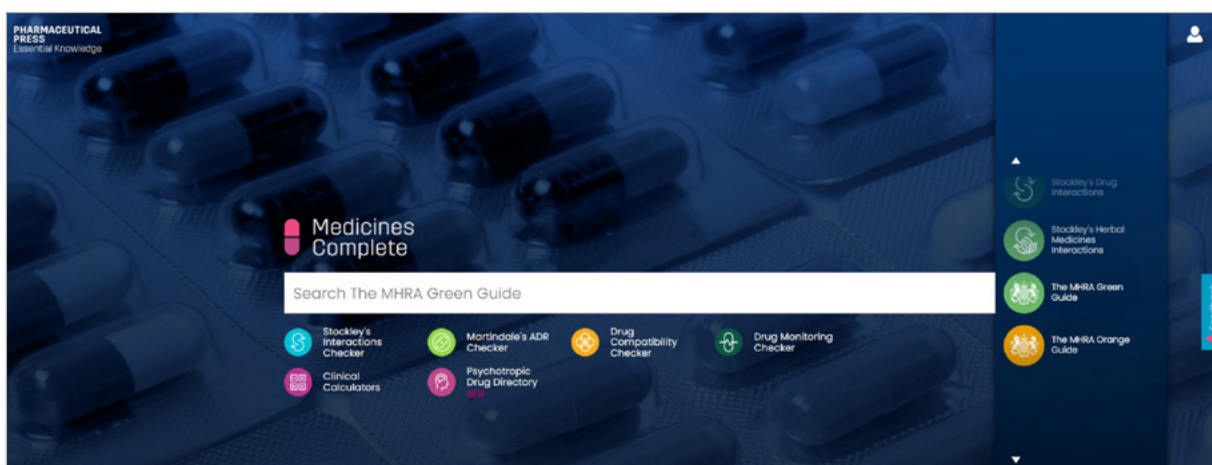
On the home page, you can access the guides directly by selecting **The MHRA Orange Guide** (Rules and Guidance for Pharmaceutical Manufacturers and Distributors) or **The MHRA Green Guide** (Rules and Guidance for Pharmaceutical Distributors) from the publication list.

## Searching for regulatory guidance

- Located at the top of the screen. Enter your keywords related to the directives, regulations, or legislation you are researching.

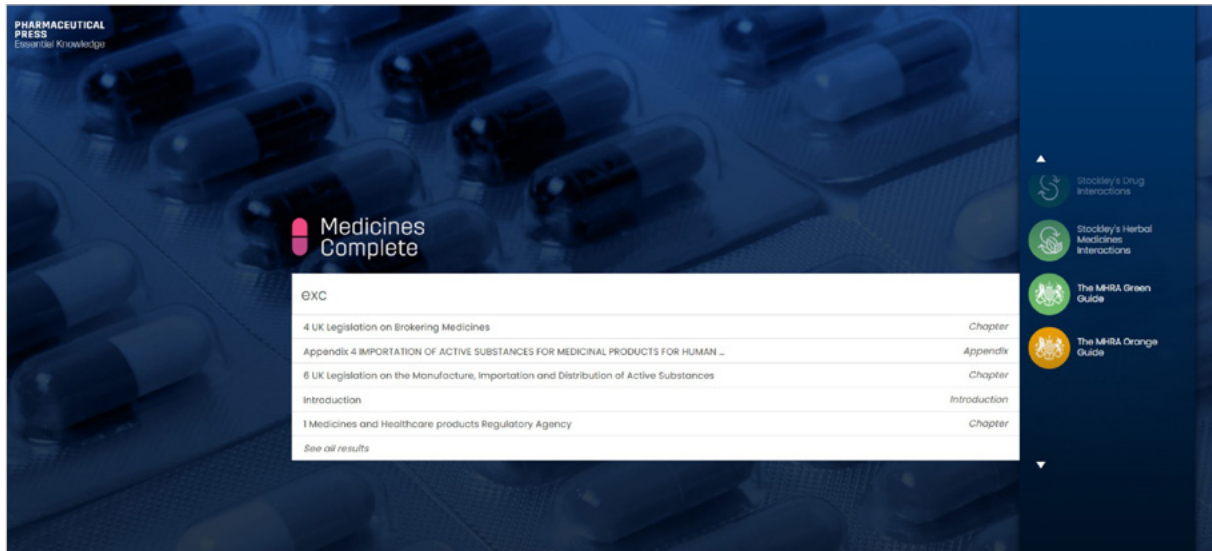


- To restrict your search strictly to manufacturing and distribution rules, use the drop-down menu next to the search bar and select either **The MHRA Orange Guide** or **The MHRA Green Guide** before pressing Enter.





- As you type your query, the platform will suggest relevant regulatory terms to help you find the precise legislation or guidance document quickly.



## Navigating the content

- Once inside either guide, you can use the left-hand navigation panel to browse through the hierarchical table of contents. This is particularly useful for reading through entire chapters or specific annexes in sequence.





## Refining search results

- If your initial search yields too many results, use the filter panel on the left side of the search results page.
- You can filter your findings by specific chapters, annexes, or updates to ensure you are viewing the most relevant and current guidelines for manufacturers and distributors.

The screenshot shows the MedicinesComplete interface. The search bar contains '2 EU Guidance on Good Manufactu'. The left sidebar shows a list of sub-sections under 'The MHRA Orange Guide', including 'PART I: Basic Requirements for Medicinal Products', 'Introduction', '1 PHARMACEUTICAL QUALITY SYSTEM', 'Principle', 'Pharmaceutical Quality System', 'Good Manufacturing Practice for Medicinal Products', and 'Quality Control'. The main content area displays the text of the 'Pharmaceutical Quality System' section, including paragraphs and numbered points (1.5, 1.6, 1.7) detailing the responsibilities of senior management and the requirements for a Quality Manual.

## Cross-referencing

- Because these guides are hosted within MedicinesComplete, you can easily cross-reference manufacturing and distribution guidelines with other legal and regulatory publications (such as **Dale and Appelbe's Pharmacy and Medicines Law**) by expanding your search scope using the drop-down menu.

The screenshot shows the MedicinesComplete interface with the same search query. The left sidebar now includes additional search results from other sources, such as 'Dale and Appelbe's Pharmacy and Medicines Law' and 'Drug Administration via Enteral Feeding Tubes'. The main content area displays the text of the 'Good Manufacturing Practice for Medicinal Products' section, including a numbered point (1.8) detailing the requirements for GMP, such as consistent production, quality standards, and specific manufacturing processes.



## The MHRA Orange Guide

The reference source for manufacturers and distributors of medicines from Medicines and Healthcare Regulatory Agency (MHRA). Based on current regulation, and regularly updated to reflect changes in best practices, legal requirements, and emerging technologies.



## The MHRA Green Guide

The MHRA Green Guide is the essential reference for all distributors, brokers of human medicines, importers, and distributors of active substances in Europe and the UK.



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### Disclaimer

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