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This compliance guidance is intended to assist companies that develop, manufacture, market, and sell pharmaceutical drugs or biological products (pharmaceutical manufacturers) in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and

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for all those involved in the distribution of medicines in Europe. It reproduces relevant parts of Rules and Guidance for Pharmaceutical Manufacturers and Distributors (commonly known as the Orange Guide) specific to wholesale supply and distribution of medicines for human use.

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