

Serendipidade, Conformidade

&

GDP

Good distribution practices (GDP) ⁽¹⁾

Good distribution practices are that part of quality assurance that ensures that the **quality** of a **pharmaceutical products** is **maintained** by means of adequate control of the numerous **activities** which occur throughout the **distribution process**.

Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)

Good distribution practices (GDP) ⁽²⁾

That part of quality assurance that ensures that the **quality** of a **pharmaceutical product** is **maintained** by means of adequate control of the numerous **activities** which occur during the **distribution process** as well as providing a tool to **secure** the **distribution system** from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products.

WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)

Good storage practices (GSP)

(Good storage practices are) that part of quality assurance that ensures that the **quality** of **pharmaceutical products** is **maintained** by means of adequate control throughout the **storage** thereof.

Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)

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WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)

Good trade and distribution practices (GTDP)

(Good trade and distribution practices are) that part of quality assurance that ensures that the **quality of pharmaceutical products is maintained** by means of adequate control throughout the numerous activities which occur during the **trade** and the **distribution process**.

Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)

(Good trade and distribution practices are) that part of quality assurance that ensures that the **quality of pharmaceutical products is maintained** by means of adequate control throughout the numerous activities which occur during the **trade** and the **distribution process**.

WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)

Deliberação n.º 017/CD/2015

O Decreto-Lei n.º 176/2006, de 30/08 prevê no seu Capítulo IV, Secção IV as regras aplicáveis à distribuição por grosso de medicamentos, estabelecendo o artigo 100.º que o titular de autorização de distribuição por grosso deve, entre outras obrigações, cumprir com as boas práticas de distribuição.

O artigo 59.º n.º 10 do mesmo diploma legal prevê que as Boas Práticas de Distribuição são aprovadas por regulamento do INFARMED, I.P., tendo em consideração as diretrizes aprovadas pela Comissão Europeia.

Importa, por isso, proceder à regulamentação das Boas Práticas de Distribuição.

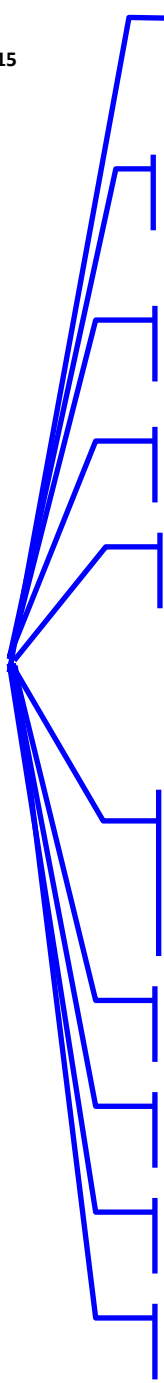
No âmbito da preparação da presente regulamentação foi promovida a audição pública, em particular, da indústria farmacêutica cuja atividade incide no exercício da distribuição por grosso, tendo sido acolhidas a larga maioria das suas sugestões.

Assim, ao abrigo do disposto no n.º 10 do artigo 59.º do Decreto-Lei n.º 176/2006, de 30 de Agosto, e tendo em consideração a Diretriz de 5 de Novembro de 2013 (2013/C 343/01) publicada no Jornal Oficial da União Europeia de 23 de Novembro de 2013, o Conselho Diretivo do INFARMED- Autoridade Nacional do Medicamento e Produtos de Saúde delibera o seguinte:

- 1- É aprovado o Regulamento relativo às Boas Práticas de Distribuição previsto no n.º 10 do artigo 59.º do Decreto-Lei n.º 176/2006, de 30 de agosto, que constitui o anexo à presente deliberação e dela faz parte integrante.
- 2- A presente deliberação entra em vigor no primeiro dia útil do mês seguinte ao da sua publicação.

PRESENTE À SESSÃO DO	
C.D. DE 19.03.2015	
O Presidente	
O Vice-Presidente	
A Vogal	
ATA N.º 011/CD/2015	

**Boas Práticas de
Distribuição de
Medicamentos
para uso humano**



1 — GESTÃO DA QUALIDADE

- 1.1. Princípio
- 1.2. Sistema de qualidade
- 1.3. Gestão das atividades subcontratadas
- 1.4. Revisão e monitorização pela administração
- 1.5. Gestão dos riscos para a qualidade

2 — PESSOAL

- 2.1. Princípio
- 2.2. Pessoa responsável
- 2.3. Outro pessoal
- 2.4. Formação
- 2.5. Higiene

3 — INSTALAÇÕES E EQUIPAMENTO

- 3.1. Princípio
- 3.2. Instalações
- 3.2.1. Controlo da temperatura e do ambiente
- 3.3. Equipamento
- 3.3.1. Sistemas informáticos
- 3.3.2. Qualificação e validação

4 — DOCUMENTAÇÃO

- 4.1. Princípio
- 4.2. Observações gerais

5 — OPERAÇÕES

- 5.1. Princípio
- 5.2. Qualificação dos fornecedores
- 5.3. Qualificação dos clientes
- 5.4. Receção de medicamentos
- 5.5. Armazenamento
- 5.6. Destruição de medicamentos obsoletos
- 5.7. Seleção
- 5.8. Fornecimento
- 5.9. Exportação para países terceiros

**6 — RECLAMAÇÕES, DEVOLUÇÕES,
SUSPEITAS DE MEDICAMENTOS
FALSIFICADOS E RETIRADAS DE
MEDICAMENTOS**

- 6.1. Princípio
- 6.2. Reclamações
- 6.3. Medicamentos devolvidos
- 6.4. Medicamentos falsificados
- 6.5. Recolha de medicamentos

7 — ATIVIDADES SUBCONTRATADAS

- 7.1. Princípio
- 7.2. Entidade Contratante
- 7.3. Entidade Contratada

8 — AUTOINSPEÇÕES

- 8.1. Princípio
- 8.2. Autoinspeções

9 — TRANSPORTE

- 9.1. Princípio
- 9.2. Transporte
- 9.3. Contentores, embalagens e rotulagem
- 9.4. Produtos que necessitam de condições especiais

**10 — DISPOSIÇÕES ESPECÍFICAS
APLICÁVEIS AOS INTERMEDIÁRIOS**

- 10.1. Princípio
- 10.2. Sistema de qualidade
- 10.3. Pessoal
- 10.4. Documentação

Yomeimon gate

The **Yomeimon Gate** (a National Treasure), is breathtakingly beautiful; the exquisite sculptural decoration is amazing in its color, detail and different techniques. It has over 508 sculptures. Of these 194 are imaginary animals, called Reiju (Holy, or spiritual animals). Truly a wonderful monument to the artistic skill of the craftsmen.

Yomeimon-Gate-Toshogu-Shrine Nikko

The Yomeimon (Sunlight Gate, so called because it faces south) is named after one of the twelve gates of the imperial court in Kyoto. It is also popularly called "Higurashi-no-mon" (Twilight Gate) because it is believed a person can stand from dawn to dusk looking at all its sculptures and beauty.

Built in 1636, Yomeimon Gate is 11.1 meters high, 7 meters wide, and 4.4 meters deep. It has twelve pillars colored in white pigment and carved with scrolling patterns.

Despite its appearance of perfection, Yomeimon Gate is not perfect. It has a famous pillar called Mayokeno-sakabashira (Inverted pillar for amulet). This inverted pillar was so placed in order to avoid angering the gods with a presumption of perfection, as only the gods acquire perfection. It is located on the left side of the Yomeimon gate and was deliberately placed upside down. A fact not so well known, is that there are two more inverted pillars in the Honden and the Haiden.



“In everything, no matter what it may be, **uniformity is undesirable. Leaving something incomplete makes it interesting, and gives one the feeling that there is **room for growth**.”**

Someone once told me, "Even when building the imperial palace, they always leave one place unfinished." In both Buddhist and Confucian writings of the philosophers of former times, there are also many missing chapters.”

— Yoshida Kenkō, Essays in Idleness: The Tsurezuregusa of Kenko –
Written sometime between 1330 and 1332

ESSAYS IN IDLENESS
THE TSUREZUREGUSA OF KENKŌ



Translated and with a new preface by DONALD KEENE

Regulations, Directives and other acts

The aims set out in the EU treaties are achieved by several types of legal act. Some are binding, others are not. Some apply to all EU countries, others to just a few.

Regulations

A "regulation" is a **binding legislative act**. It must be applied in its entirety across the EU. For example, when the EU wanted to make sure that there are [common safeguards on goods imported from outside the EU](#), the Council adopted a regulation.

Directives

A "directive" is a legislative act that **sets out a goal that all EU countries must achieve**. However, **it is up to the individual countries to devise their own laws** on how to reach these goals. One example is the [EU consumer rights directive](#), which strengthens rights for consumers across the EU, for example by eliminating hidden charges and costs on the internet, and extending the period under which consumers can withdraw from a sales contract.

Decisions

A "decision" is **binding on those to whom it is addressed** (e.g. an EU country or an individual company) and is directly applicable. For example, the Commission issued a decision on the [EU participating in the work of various counter-terrorism organisations](#). The decision related to these organisations only.

Recommendations

A "recommendation" is **not binding**. When the Commission issued a recommendation that EU countries' law authorities improve their use of [videoconferencing to help judicial services work better across borders](#), this did not have any legal consequences. A recommendation allows the institutions to make their views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.

Opinions

An "opinion" is an instrument that **allows the institutions to make a statement in a non-binding fashion**, in other words without imposing any legal obligation on those to whom it is addressed. An opinion is not binding. It can be issued by the main EU institutions (Commission, Council, Parliament), the Committee of the Regions and the European Economic and Social Committee. While laws are being made, the committees give opinions from their specific regional or economic and social viewpoint. For example, the Committee of the Regions issued an [opinion on the clean air policy package for Europe](#).

GMP Inspection Deficiencies 2013

Review of Deficiencies Observed in 2013





Data Integrity (DI)

DI issues, both as a result of bad practise and to a significantly lesser extent intentional fraud, have been observed across all geographical locations and sectors of the industry with some very high profile cases being observed recently.

There will therefore be a focus on this area during inspections in the near future. In addition; – the MHRA has communicated an expectation that companies will carry out a **routine effectiveness review of their governance systems** to ensure **data integrity** and **traceability** are maintained

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Yomeimon-Gate Toshogu-Shrine Nikko