Essay

Shall it Be Must or Shall it Be Should? Analysis of How the Term Shall Is Understood and Application to the EU-HTA Regulation

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Shall it Be Must or Shall it Be Should? Analysis of How the Term *Shall* Is Understood and Application to the EU-HTA Regulation

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Abstract: The authors have observed several uninformed discussions in Health Technology Assessment (HTA) forums, conferences and conventions regarding the mandatory or voluntary application of the EU-HTA regulation from both the perspectives of Member States (MS) and health technology developers (HTD). The systematic use of the verb "shall" in the EU HTA regulation has caused confusion among audiences unfamiliar with legal terminology.

Keywords: Corporate Governance; European Union; European Health Technology Assessment; European Health Technology Assessment Regulation; Health Technology Assessment; Health Technology Developers; Joint Clinical Assessment; Member States

Introduction

In everyday language, "shall" often doesn't imply obligation like "must" does. Saying "I shall go to the market" isn't about obligation, whereas "I must go to the market" implies a mandatory requirement from oneself or someone else.

In legal and regulatory texts, the term “shall” is traditionally used to denote an obligation or duty. Unlike the permissive “may,” which implies discretion, “shall” generally indicates that an action is mandatory [1]. Black’s Law Dictionary notes that *“shall” is generally imperative or mandatory in legal contexts*, effectively meaning “must” – yet it cautions that sometimes a “shall” may be construed as permissive or directive, or as simply a future-tense, depending on context [2]. The interpretation of "shall" can differ depending on jurisdiction and context. Modern drafting practices have increasingly examined the term due to its ambiguities, as experts have identified several different usages of "shall" in legal texts.

This paper aims to clarify the term "shall" from general legal texts, EU legislation and the EU-HTA Regulation. It examines whether using "shall" makes a provision legally binding and enforceable, including the consequences of non-compliance. This document clarifies the use of "shall" in legal policy documents, distinguishing it from its everyday usage to avoid confusion. It is not a research paper or a legal opinion, but represents an authorized opinion based on references and the authors' expertise. The authors are not liable for their good faith opinions and readers cannot hold them responsible for decisions made based on this manuscript. They should seek professional legal advice when necessary.

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Interpretation of "Shall" in Ex-EU Jurisdictions

In U.S. law, "shall" denotes a mandatory duty, while "may" is permissive. The Supreme Court confirmed this in *Kingdomware Technologies, Inc. v. United States* (2016), clarifying that "shall" imposes a requirement [3].

Courts sometimes interpret "shall" as permissive rather than mandatory if it aligns with legislative intent [1]. Recent U.S. legal drafting prefers "must" over "shall" for clarity. Style guides recommend this change because "shall" has multiple meanings. Bryan Garner identified at least eight distinct interpretations of "shall" in US legal documents [4].

In the United Kingdom, "shall" has traditionally been used in legislation to signify mandatory obligations.

In recent decades, the UK (and other Commonwealth jurisdictions like Canada, Australia and New Zealand) have moved away from using "shall" in new legislation, viewing it as archaic and potentially confusing. The Office of the Parliamentary Counsel (UK) now has an explicit policy to avoid the legislative "shall." The official drafting guidance states: *"Office policy is to avoid the use of the legislative 'shall'."* [5].

In international law, "shall" is used in treaties to convey binding obligations. When a country ratifies a treaty, it must adhere to *pacta sunt servanda* (Article 26 of the Vienna Convention), meaning treaty terms are binding and must be executed in good faith. Thus, any "shall" clause in a treaty is legally enforceable internationally [6,7].

"Shall" in European Union Law

In the European Union's legal texts, "shall" is understood as imposing a legal obligation – effectively equivalent to "must" [8]. EU legislative drafting conventions use "shall" in the English versions of regulations and directives to indicate mandatory provisions. In contrast, many English-speaking jurisdictions have adopted the term "must" for clarity [8]. For example, the EU's *English Style Guide* explicitly notes that in EU legislation *"shall means the same as must"*, and it gives examples like *"The following products shall be clearly labelled…"* as binding requirements [8]. Likewise, prohibitions are phrased as "shall not" (never "may not") to avoid any ambiguity – e.g. *"Food shall not be placed on the market if it is unsafe."* [8]. This stylistic choice reflects that the EU treats "shall" as the language of command in its legal acts.

EU drafting manuals, like the Joint Practical Guide, stress clarity and consistent terminology, reserving "shall" for obligations. Though some suggest using "must" instead, the Interinstitutional Style Guide still uses "shall" for normative provisions [4]. In EU regulations, "shall" signifies an imperative, legally binding requirement for its addresses.

EU Health Technology Assessment Regulation

The new EU Health Technology Assessment Regulation (Regulation (EU) 2021/2282) [9] contains numerous provisions using "shall" to mandate actions by Member States and EU bodies. Shall appears 209 times in the EU-HTA regulation. For instance, it provides that *"Member States shall appoint members and representatives"* to the coordination group, among other duties [10]. Such phrasing is not merely aspirational – it creates a binding legal duty for Member States. In EU law, a regulation is directly applicable in all Member States, so a clause stating that *"Member States shall do X"* means they are obliged to perform X by force of EU law. There is no discretion to opt out or delay; failure to comply constitutes a breach of EU law.

EU legal interpretation benefits from multilingual consistency – the obligation conveyed by "shall" in English is mirrored by terms in other EU languages that unequivocally signal duty. For example, in EU-HTA Regulation in French texts, *"les États membres sont tenus de"* is used as a translation of shall, meaning *"Member States are obliged to"*. It is consistent with several other languages, such as Spanish, German, Italian as observed by the authors using automated traduction.

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Participation in EU-HTA R is mandatory and legally binding for MSs and HTDs must submit a high-quality JCA dossier. Below are excerpts from EU-HTA R [9] in italic to highlight examples of duties for MSs and HTD with associated short explanations.

"This Regulation shall be binding in its entirety and directly applicable in all Member States". MSs must comply with EU-HTA R and fulfill their duties under the law. Non-compliance is a violation of EU law.

"*Member States must designate their members to the Coordination Group and inform the Commission of any changes*". Participation is mandatory, not voluntary.

"*The members of the Coordination Group shall designate their national or regional authorities and bodies as members of subgroups of the Coordination Group*." Upon their appointment, the members of the Corporate Governance (CG) committee have several legal obligations as outlined by statutory regulations.

"*The health technology developer shall submit the dossier to the Commission in accordance with the submission request made pursuant to paragraph 1*". It is a legal enforceable requirement to submit a JCA dossier for HTD.

"*The dossier shall meet the following requirements*:

- *the submitted evidence is complete with regard to the available studies and data that could inform the assessment;*
- *the data has been analysed using appropriate methods to answer all research questions of the assessment;*
- *the presentation of the data is well structured and transparent, thereby allowing for an appropriate assessment within the limited timeframes available;*
- *it includes the underlying documentation in respect of the submitted information, thereby allowing the assessor and co-assessor to verify the accuracy of that information.*
- *The dossier for medicinal products shall include the information set out in Annex I."*

HTD must submit a dossier and meet all legal requirements. They need to show the JCA subgroup they have complied with these five stipulations.

"*Where the Commission finds that the dossier fails to meet the requirements laid down in Article 9(2), (3) and (4), it shall request the missing information, data, analyses and other evidence from the health technology developer (second request). In such a case, the health technology developer shall submit the requested information, data, analyses and other evidence in accordance with the timeframe established pursuant to Article 15*". The HTD is required to address missing information analyses or any other evidence requested by the commission.

"*The health technology developer shall not provide any comments on the results of the draft assessment*". HTD are not associated to the scoping nor to the JCA review.

Implications of Non-Compliance

If a Member State does not follow an obligation stated with "shall" in an EU regulation, it violates EU law. The European Commission can enforce these obligations and start an infringement procedure against the non-compliant Member State [11]. This process may lead to referral to the Court of Justice of the EU, which can impose financial penalties on a state that does not comply [11]. In EU regulations, "shall" signifies a legal obligation for Member States, enforceable by EU institutions. Non-compliance can result in court judgments and fines [11]. Regulations are directly applicable, so affected parties can invoke them in national courts if the provisions are clear and unconditional. This leaves room to escalate at EU relevant court. Essentially, "shall" is binding in EU law, with non-compliance leading to legal consequences.

While the law does not specify legal consequences for failing to submit a JCA dossier, the EU Commission can refer the matter to the EU Court of Justice, which may result in legal consequence for an HTD including fine.

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“Should” in the EU HTA Regulation

In the EU context, including in the EU-HTA Regulation, "shall" imposes obligations, while "should" appears in recitals or non-binding guidances, indicating political or ethical preferences, but not legal duties. "Should" suggests best practices or advisable actions, but is neither legally required nor binding. The term "should" is used frequently in the EU HTA regulation. "Should" appears 87 times in the EU-HTA regulation.

“May” in EU HTA Regulation

In the context of the EU, including in the EU-HTA Regulation, "shall" is used to impose obligations, whereas "may" typically indicates discretion or permission. It characterizes an optional or permissive action. "May" grants the power or authority to do something but does not require it. This term appears rarely (19 times) in the EU-HTA regulation.

EU Law Corpus

A law in the EU context is a broader term that refers to all binding legal acts adopted by EU institutions, including regulations, directives, and decisions. EU law is made up of primary law (the Treaties) and secondary law (such as regulations, directives, and decisions). While regulations are immediately applicable once in force, other forms of EU law, like directives, require Member States to achieve certain results but allow them to choose the means of implementation [12]. They become part of national law and can be enforced through the national courts of each member state from the time they come into force.

A **regulation** in the EU is a binding legislative act that is directly applicable and enforceable in all Member States as soon as it enters into force. It does not require any national legislation to be implemented and applies in its entirety across the EU. Regulations override any conflicting national laws and ensure uniformity in their subject matter throughout the Union [12]. Regulations become part of national law and can be enforced through the national courts of each member state from the time they come into force [12].

EU-HTA regulation is therefore in force from 12th January 2025 it is a binding legislative act, directly applicable in all EU Member States automatically and uniformly. It overrides national laws.

Conclusion

The term "shall" may sometimes carry some ambiguity in legal contexts, but it is generally equivalent to "must". It defines obligations and should not be considered as optional or discretionary. Due to the potential multiple meanings of "shall" identified in legal and regulatory corpus, lawmakers have increasingly substituted "shall" with "must".

However, within the European Union's legal texts, “shall” remains the reference and is understood to impose a legal obligation effectively equivalent to “must”. There is no ambiguity regarding this interpretation. Consequently, participation in all EU-HTA requirements is mandatory and legally binding for Member States (MSs) and Health Technology Developers (HTDs). Non-compliance exposes MSs and HTDs to legal enforcement and penalties.

EU-HTA Regulation display all attributes of regulation and is enforceable immediately up on entry in force. So EU-HTA regulation is opposed to MS and HTD from 12th of January 2025.

No doubt is permissible for the enforcement of EU-HTA Regulation on MS and the legal liability for not applying the regulation.

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Abbreviations

The following abbreviations are used in this manuscript:

CG	Corporate Governance
EU	European Union
EU-HTA	European Health Technology Assessment
EU-HTA R	European Health Technology Assessment Regulation
HTA	Health Technology Assessment
HTD	Health Technology Developers
JCA	Joint Clinical Assessment
MS	Member States

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