Towards Device-Focused Joint Clinical Assessment: Comparing Submission Templates for Medical Devices and Medicinal Products

HTA407

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INTRODUCTION

The EU Health Technology Assessment (HTA) Regulation introduces Joint Clinical Assessments (JCAs), requiring health technology developers (HTDs) to generate robust and harmonized clinical evidence. While the JCA framework provides a common structure for evidence submission, medical devices (MDs) present distinct characteristics, including iterative technological development and user-dependent performance, that may require specific considerations[1-2].

OBJECTIVE

To compare the JCA submission templates for MDs and medicinal products (MPs), identify device-specific considerations and potential gaps, and inform proactive evidence planning for HTDs.

METHOD

A structured comparative framework was applied to JCA submission templates for MDs and MPs. The analysis focused on:

1) clinical evidence expectations;
2) PICO (patient, intervention, comparator, outcome) definitions and flexibility for device-specific pathways; and
3) literature review methodology and data standards.

Differences were thematically analyzed to understand how MD-specific evidence considerations, are reflected in the templates.

RESULTS

1. Strong methodological alignment between MD and MP JCAs

Core JCA methodology is largely harmonized across MDs and MPs, with comparable requirements for PICO-based assessment, systematic evidence identification, evidence synthesis, indirect comparisons, and assessment of uncertainty. **Table 1** summarizes the comparative overview of MD and MP JCA submission templates.

2. The MD template explicitly captures technology-specific characteristics

The MD template explicitly captures user training and organizational requirements; however, the implications of operator experience and learning curves for comparative effectiveness are not explicitly operationalized within the core evidence synthesis framework.

3. Distinct regulatory evidence sources

Both templates require systematic evidence retrieval, but their regulatory sources differ: the MD template explicitly includes Clinical Evaluation Reports (CERs) and medical device registries, while the MP template specifies clinical safety and efficacy data from the EMA submission file.

Table 1: Comparative Overview of Medical Device and Medicinal Product JCA Submission Templates

Domain	MD template	MP template	Key finding / implication
Core JCA structure	PICO-based	PICO-based	Highly aligned
Comparative effectiveness	Required	Required	Common methodological foundation
Indirect comparison	Detailed requirements	Detailed requirements	Highly aligned
Technology characterization	Model, UDI, EMDN, versions, software, lifetime	Substance, formulation, ATC, dose	More technology/lifecycle-specific for MDs
Use requirements	Procedures, training, equipment, facilities, supplies	Personnel, equipment, supplies	Greater operational detail for MDs
Evidence sources	CER + MD/patient registries	EMA submission data + patient registries	Different regulatory evidence ecosystems
Technology evolution	Previous versions and changes explicitly reported	Not similarly structured	Relevant for evidence interpretation
Learning/user effects	Training/user requirements captured	Less specifically characterized	Potential implications for effectiveness
Evidence synthesis	Meta-analysis, indirect comparison, sensitivity/subgroup analyses	Same	Strong methodological alignment
Device-specific evidence challenges	Partially reflected	N/A	Potential need for additional interpretation/guidance

ATC, Anatomical Therapeutic Chemical Classification; CER, Clinical Evaluation Report; EMA, European Medicines Agency; EMDN, European Medical Device Nomenclature; JCA, Joint Clinical Assessment; MD, medical device; MP, medicinal product; N/A, not applicable; PICO, Population, Intervention, Comparator, Outcome; UDI, Unique Device Identification.

CONCLUSIONS

The JCA framework is substantially harmonized for both MPs and MDs, but the challenge is translating MD-specific characteristics captured at the descriptive level into the methodological assessment of comparative effectiveness.

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