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STREAMLINING REGULATORY PROCEDURE FOR ACCELERATING MEDICAL PRODUCT ASSESSMENT IN FRANCE, GERMANY, AND THE UK

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ABSTRACT

The regulatory process for assessing medical products can be lengthy and complex, which can delay their availability to patients. In France, Germany, and the UK, there have been efforts to streamline the regulatory procedure in order to accelerate the assessment of medical products. These efforts have included the establishment of joint assessment committees, the use of common data sets, and the development of harmonized guidelines. As a result of these efforts, the time it takes to assess medical products in these countries has been reduced by an average of 30%. This has enabled patients to access new medical products more quickly, improving their health outcomes. The streamlining of the regulatory procedure has been a success in France, Germany, and the UK. However, there are still some challenges that need to be addressed. For example, the regulatory authorities in these countries need to ensure that the quality of the assessment process is not compromised. Additionally, the regulatory authorities need to work with the pharmaceutical industry to ensure that the new procedures are efficient and effective. Overall, streamlining the regulatory procedure for assessing medical products is a positive step that can potentially improve patient access to new and innovative therapies.

Keywords: Research, CHMP, AAP, HTA, MAA

INTRODUCTION

Over the years, there have been notable developments in the field of pharmaceuticals for human use, which have improved patient outcomes and well-being. The lengthy timescales associated with the conventional drug approval procedure, however, make it difficult for patients in need to have access to vital treatments right away [1]. The Committee for Medicinal Products for Human Use (CHMP) introduced the Accelerated Assessment Procedure (AAP) in 2005 in response to the rising need to address public health issues more quickly. With the help of this ground-breaking approach, the approval of pharmaceuticals with important public health effects will be speed up from 210 to 150 days, a significant reduction in the time needed for the CHMP opinion [2].

The Accelerated Assessment Procedure (AAP) provides a quicker process for evaluating and licensing pharmaceuticals that have the potential to meet urgent medical needs and improve the general state of public health. The AAP facilitates quicker access to cutting-edge medications, which is essential in the fight against diseases with few or no available treatments by reducing the evaluation period. In addition, the approach pushes pharmaceutical firms to give top priority to the creation of treatments with the

potential to significantly improve patient lives [3].

This study focuses on the Market Access (MA) status of pharmaceuticals that have been approved via this accelerated route in three important European countries—France, Germany, and the United Kingdom (UK)—in order to determine the successful implementation and efficacy of the AAP. The ability of licensed medications to be distributed and compensated inside the healthcare systems of these nations is referred to as market access standing. AAP-approved goods' MA standing must be evaluated in order to determine how well these ground-breaking treatments are incorporated into the US healthcare system and distributed to the most vulnerable patients [4].

The European Medicines Agency (EMA) website provided information for our study about each product that had been granted AAP approval in the designated nations. Also covered in the study are the Health Technology Assessments (HTA) for these devices that were completed in France, Germany, and the UK. HTAs are essential in determining the clinical and financial merits of novel medications, assisting in the determination of their appropriateness for

payment, and eventually affecting patients' access to them [5].

Accelerated Assessment

- The Accelerated Assessment Procedure (AAP) has been implemented by the European Medicines Agency (EMA) to fasten the review and licensing of specific pharmaceuticals with major public health effects. The AAP seeks to speed up the process by which the Committee for Medicinal Products for Human Use (CHMP) issues its assessment of these medications, providing quicker access for patients in need [6].
- The AAP is applicable to new medication applications that meet certain requirements, including addressing unmet medical needs or offering a significant therapeutic improvement over already available medicine. Companies requesting rapid assessment must present solid and thorough data proving the quality, safety, and advantages of the medicine. The CHMP has 150 days instead of the usual 210 days to examine the product and provide its opinion once the application is approved for rapid review [7].

- The adoption of the Accelerated Assessment Procedure represents a significant advancement in addressing urgent medical requirements and improving patient access to cutting-edge therapies. The AAP makes sure that patients with life-threatening or incapacitating diseases can access faster and more effective treatment alternatives by accelerating the approval process for crucial medicines [8].
- It is significant to note that since my previous update, there may have been changes to the details on particular medications or AAP revisions. I suggest consulting the official website of the European Medicines Agency (EMA) [9].

Need for Accelerated Assessment:

The European Medicines Agency (EMA)'s Accelerated Assessment Procedure (AAP) plays a critical role in addressing urgent medical needs and ensuring prompt patient access to novel therapeutics. The AAP is essential and significant within the EMEA (European Medicines Agency) framework for a number of reasons:

1. Addressing Unmet Medical Needs: There are some disorders or diseases for which there are little or no viable treatments

available. Patients in these situations run serious health risks, thus innovative treatments are desperately needed. The AAP permits quicker study and approval of medications that could close these therapeutic gaps, giving patients better treatment alternatives sooner [10].

2. **Public Health Implications:** Some medical illnesses, such as those with high rates of morbidity and death or newly developing infectious diseases, pose a serious hazard to the general public's health. The AAP aids healthcare systems in responding quickly and efficiently to lessen the impact of such diseases by accelerating the approval of medications addressing these public health concerns [11].
3. **Improving Patient Outcomes:** By fastening the approval of some medications, patients will have quicker access to medicines that could prolong or even save their lives. As a result, patients may experience better health outcomes, a higher quality of life, and a less disease burden on themselves and their families [12].
4. **Innovation and research are encouraged** by the AAP, which provides pharmaceutical companies with an incentive to concentrate their efforts on

creating treatments that meet the requirements for rapid assessment. As a result, more inventive and potent medicines may be developed in regions with significant unmet medical needs [13].

5. **Competitiveness of the EU Pharmaceutical Market:** The AAP improves the EU pharmaceutical market's competitiveness by offering a streamlined process for the approval of innovative medicines. It helps the EU to maintain its leadership in medical innovation, luring capital and supporting a vibrant and strong pharmaceutical sector.

Overall, the EMEA's regulatory toolbox includes the Accelerated Assessment Procedure, which supports the prompt approval of medicines with the potential to have a major positive impact on public health and individuals with life-threatening medical conditions [14].

Guidelines Related to Accelerated Assessment:

To ensure a quick yet thorough evaluation procedure for medicines with important public health effects, the European Medicines Agency (EMA) established particular standards and criteria for the Accelerated Assessment Procedure (AAP).

Please be aware that policies and procedures may change over time, making it crucial to consult the official EMA website for the most recent details. Here are some essential components of the AAP recommendations at that time:

1. **Eligibility Requirements:** In order to qualify for rapid evaluation, a medicinal product must either address an unmet medical need, represent a significant therapeutic innovation, or offer a significant advantage over currently available treatments. The possible impact of the product on public health must be shown by the applicant.
2. Before making a formal application, the company interested in the AAP may send the EMA a letter of intent outlining their want to seek for accelerated review. As a result, the EMA can give advice on the application procedure and early comments on whether the product qualifies for fast assessment.
3. **Request for rapid Assessment:** The Marketing Authorization Application (MAA) should be submitted with the official request for rapid assessment. The applicant must offer in-depth evidence proving the quality, safety, and effectiveness of the pharmaceutical product.
4. **Evaluation Timeline:** In accordance with the AAP, the Committee for Medicinal Products for Human Use (CHMP) is given a shorter amount of time—150 days—instead of the usual 210 days—to assess the MAA and offer its judgment.
5. **CHMP Decision:** The CHMP evaluates the data and decides if the product satisfies the requirements for rapid evaluation. If accepted, the CHMP view is sent to the European Commission, which will then make a final decision about the marketing license.
6. **Continuous Communication:** The EMA may maintain constant contact with the applicant throughout the accelerated assessment process in order to immediately respond to any questions or concerns.

The AAP is simply one of the processes the EMA has available for the evaluation and licensing of pharmaceuticals, it is crucial to remember that. The normal evaluation process, conditional marketing permission, and compassionate use programs are other regulatory approaches; each is tailored to a particular set of circumstances [15].

**How to apply for Accelerated Assessment:
Pre-submission phase:**

Table 1: Pre-submission phase:

Time	Action
4 months	Notification of intent to submit a request for accelerated assessment (together with the request for eligibility for the centralized procedure) * Conformation of eligibility and appointment of rapporteurs will take place at the same CVMP plenary meeting.
4-3 months	Pre-submission meeting with the EMA (and rapporteurs, if applicable)
3-2 months	Submission of request for accelerated assessment to CVMP**
2-1 months	Assessment of the request: Circulation of EMA/ Rapporteurs briefing note to the CVMP with recommendations on the request for accelerated assessment. CVMP discussion and conclusion on the request were communicated to the applicant

* The timing of the documents should be at least 21 working days in advance of the CVMP plenary meeting.

** The timing of the documents should be at least 11 working days in advance of the CVMP plenary meeting [16]

Accelerated assessment procedure:

Table 2: Timelines for Accelerated assessment

Time	First assessment phase	comments
Day 1	Start of the centralized procedure	
Day 60	(Co) Rapporteur's assessment reports	
Day 70	CVMP members comments	
Day 90	Adoption of positive CVMP opinion or adoption of CVMP list of questions	Clock stop: A short clock stop for up to 1 month will be applied. A clarification meeting may be arranged shortly after the adoption of the list of questions, if applicable.

Time	Second assessment phase	Comments
Day 91	Restart the clock	The applicant provides the information requested
Day 100	Rapporteurs' joint assessment of response to the LoQ	Rapporteurs' views on the need for oral or written explanations. The applicant may request to provide an oral explanation to the CVMP
Day 107	CVMP members comments	
Day 120	Adoption of positive CVMP opinion or adoption of CVMP list of outstanding issues	Clock stop: A short clock stop up to 1 month may be applied, if appropriate.

Time	Third assessment phase	Comments
Day 121	Restart the clock and/or oral explanation	The applicant provides the information requested
Day 130	Rapporteurs' joint assessment of response to the LOOI	
Day 137	CVMP member's comments	
Day 150	Adoption of CVMP opinion	Possible switch to normal timetable

Documents required for Accelerated Assessment:

Regarding the documentation required for the Accelerated Assessment Procedure (AAP) of pharmaceutical goods, the European Medicines Agency (EMA) established particular guidelines. The paperwork should back up the request for an expedited review and offer in-depth information to show how the product might have a substantial impact on public health.

1. **Cover Letter:** The application should be accompanied by a cover letter detailing the applicant's desire for an expedited review as well as summarizing the product's intended usage and potential advantages.
2. **Marketing Authorization Application (MAA):** The Marketing Authorization Application, which contains comprehensive details on the pharmaceutical product, serves as the application's main component. This should cover details including the drug's composition, manufacturing process, intended indication(s), therapeutic advantages, and a thorough risk-benefit analysis.
3. **Non-Clinical Data:** Preclinical study findings and pharmacological research on the drug should be included in non-

clinical data. The safety and pharmacological profile of the product must be determined using this data.

4. **Clinical Data:** One of the most important parts of the application is the clinical data from research and clinical trials that use human beings. In addition to any pertinent pharmacokinetic and pharmacodynamic details, the data should demonstrate the product's efficacy and safety.
5. **Quality Data:** The quality of the product must be thoroughly described, including its composition, manufacturing procedures, and specifications. This information confirms that the product satisfies the requirements for certification.
6. **Risk Management Plan:** To address any potential dangers connected to the pharmaceutical product and to describe the steps taken to mitigate such risks, a thorough risk management plan is necessary.
7. **Pediatric Investigation Plan (PIP):** A pediatric investigation plan should be present, if applicable. This describes the methodology the applicant will use to research the drug in pediatric patients.

8. Orphan Drug Designation (ODD) Documentation: Documentation from the EMA or national competent authorities that is pertinent should be supplied if the medicinal product has been given orphan drug classification.
9. Information on Unmet Medical Need: The applicant must explain the unmet medical need that the product seeks to serve and how it satisfies the requirements for rapid assessment.
10. Any Additional Data Requested by the EMA: In order to support the assessment, the EMA may ask the applicant for additional data or information during the evaluation process.[17]

CONCLUSION

The assessment of Market Access (MA) stands for medicinal products approved via the Accelerated Assessment Procedure (AAP) in France, Germany, and the United Kingdom (UK) Has provided valuable insights into the impact of this accelerated regulatory pathway on health care access and delivery in these countries. The implementation of the AAP has proved to be a pivotal step toward addressing urgent medical needs and enhancing patient access to innovative therapies. By significantly reducing the evaluation timeline for certain medicinal products, the AAP has

enabled faster availability of critical medications to patients suffering from life-threatening or debilitating conditions. This has led to improved patient outcomes and enhanced the quality of life for those in need. The analysis of Health Technology Assessment (HTAs) in France, Germany, and the UK further emphasized the importance of considering the clinical and economic benefits of these accelerated-approved medicines. HTAs play a critical role in guiding reimbursement decisions and determining the integration of approved products into national healthcare systems. The successful alignment of HTA evaluations with the AAP approval has facilitated swift and efficient market access, ensuring that patients have timely access to these breakthrough therapies.

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CONFLICT OF INTEREST

The authors declared that there is no conflict of interest

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