

## EFPIA Position Paper

### Optimizing Marketing Authorization Renewals for Efficiency and Sustainable Access

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#### Executive Summary

Currently, there is a highly divergent approach to the marketing authorization (MA) renewal process globally, with requirements of varying complexity across countries. While many authorities still require marketing authorizations (MAs) to be renewed continuously after a defined period (usually every five years), others only request a one-time renewal five years after the initial marketing authorization, and some have adopted simplified approaches such as auto-renewals or unlimited MAs.

The complexity of international renewal requirements often leads to duplication of efforts, unnecessary administrative burden for both industry and regulators, and inefficiencies that can jeopardize product supply and hinder continuous access to safe, effective, and high-quality medicines for patients.

This paper recommends that National Regulatory Agencies (NRAs) to simplify renewal requirements and ultimately transition toward unlimited MAs to support more efficient oversight and reliable medicine supply where the maturity of the regulatory system allows.

#### Background

Traditionally, companies must submit renewal applications—often every five years—to keep their marketing authorization valid. The intention behind repeated renewals is to ensure that a product's safety, quality, and efficacy continue to meet the standards established by NRAs through periodic reassessment of its benefit-risk balance.

However, over the past two decades, the regulatory systems have evolved considerably. Today, comprehensive pharmacovigilance systems, GMP inspections, and post-approval change management frameworks are operated to continuously ensure the quality, safety, and efficacy of marketed medicines. In addition, regulators have the power to suspend or revoke permanent MA in case of serious risks established during post-approval management. As a result, periodic reassessments have



become redundant since their objectives are now effectively achieved through strong post-marketing regulatory mechanisms.

### Current Renewal Practices

After the initial MA, various post-marketing regulatory mechanisms—such as pharmacovigilance activities, GMP inspections, post-approval variations, and ongoing obligations—ensure continuous evaluation of the product’s benefit-risk profile. However, renewal practices differ widely:

- **Permanent MA:** In countries such as the US, Canada, and Japan, the initial MA remains valid indefinitely, and no renewal process is required. Although marketing authorizations are presently subject to a single renewal, the revised General Pharmaceutical Legislation will introduce indefinite validity across all Member States.
- **Single renewal and reliance-based renewal:** In jurisdictions such as Switzerland, an initial marketing authorisation typically becomes indefinite following a first renewal —conducted five years after the first issuance—without requiring a full re-assessment of safety, efficacy and quality dossier. Some authorities such as MHRA in the UK rely on assessments and renewals by trusted regulatory authorities to make their own regulatory decisions.
- **Auto-Renewal:** In countries such as Singapore with a mature post-marketing framework the renewal process is purely administrative and maintained through annual fees without dossier submission.

Despite these advancements, many countries (>40) still require companies to resubmit unchanged Modules 3 including testing requirements every five years (and sometimes between 1-5 years). These partial or full dossier resubmissions replicate data already reviewed and updated through ongoing pharmacovigilance reports and approved variations. This practice provides no additional benefit but significantly increases workload, review timelines, and the risk of MA expiry and supply interruption.

### Challenges with the Current System

- **Redundant Data and Document Collection:** Rebuilding and resubmitting unchanged clinical, nonclinical, and quality data not only create a huge administrative burden for industry but also represent inefficient use of resources for regulators as they must review repeated information.
- **Resource Deviation:** Regulators spend time on administrative reviews rather than on activities that have safety implications, such as pharmacovigilance, GMP inspections, or emerging health priorities.
- **Supply Disruption:** In some countries, companies cannot submit or implement variations to update safety or quality information until the renewal is approved resulting in constraining supply-chain flexibility. Long renewal review timelines contribute to an increase in the backlog of submission reviews, resulting in outdated information / renewal approvals. Unexpected delays in renewal approvals can impact supply planning, resulting in disruption of product supply and continuous treatment which can be critical for patients.



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- **Fragmented Global Landscape:** Different expectations and renewal periods across countries lead to complexity for submission management and supply planning. Marketing authorization holders must create multiple renewal strategies, customized to local requirements, often duplicating effort and slowing the pace of updates.

In essence, the current renewal system has become misaligned with today’s continuous oversight throughout the lifecycle of the products. Modernizing it is crucial to focus public health by ensuring that regulatory systems remain efficient, risk-based, and resilient.

## Recommendations

Enabled by a more efficient lifecycle oversight that ensures continuous product availability, EFPIA recommends regulators to adopt a, risk-based approach to the renewal process. The following recommendations outline practical options that can be implemented individually or in sequence, depending on national regulatory priorities.

### A. Transitioning Toward Permanent Authorization or Administrative Renewal

#### 1- Implement permanent MA or administrative renewals

Regulators with established post-marketing oversight systems such as robust pharmacovigilance, risk-based GMP supervision, and post-approval change controls—may transition to permanent marketing authorization or administrative renewal. or. These models replace routine dossier submissions with targeted surveillance, re-allocating resources to high-value priorities like as signal detection, anti-counterfeiting, and improved access pathways.

#### 2- Introduce reliance mechanisms in renewal process

Authorities can leverage decisions or assessments from trusted regulatory authorities or WHO-listed authorities. Reliance enables informed decision-making while optimizing limited resources and avoiding duplication of work.

### B. Strengthening Renewal Processes as Part of the Transition Pathway

For regulators aiming to enhance elements of their To strengthen post-marketing surveillance systems, regulators can adopt measures that streamline current renewal activities while laying the groundwork for permanent renewal models: **Simplify renewal documentation requirements**

Streamline renewals by targeting assessments on emerging safety data, updated GMP information, and critical CMC updates, rather than re-reviewing unchanged data (e.g., Modules 3-5). This approach reduces administrative burden without compromising benefit-risk oversight



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### **1- Allow submissions for variations independent from renewals**

Allow post-approval changes to proceed independently from renewal cycles, ensuring greater flexibility, avoiding supply disruptions, and supporting equitable patients access worldwide to state-of-art technologies and new or extended indications.

### **2- Digital enablement and capacity building**

Investing in structured regulatory information management systems and digital dossier platforms to automate submission tracking, stakeholder notifications and real-time insights into product status will accelerate the transition toward efficient, data-driven oversight that does not depend on the renewal process.

### **3- Reinvestment in surveillance**

Redirecting regulatory capacity from repetitive renewal reviews can enable NRAs to strengthen post-marketing oversight, including pharmacovigilance signal detection, risk-based GMP inspections, and timely responses to emerging public health threats.

## **Conclusion**

Marketing authorization renewals were traditionally designed to ensure continued product oversight. However, with the development of robust pharmacovigilance and lifecycle oversight (including GxP inspections, and post-approval change management), these objectives are met continuously throughout the product's lifecycle.

Simplifying or eliminating periodic renewals through risk-based, reliance-enabled, and digitally supported approaches in line with WHO Good Regulatory Practices and OECD's outcome focused regulation guidance will enhance regulatory agility, enable patients to access to the highest standards of patient protection, and secure uninterrupted patient access to medicines.

## **Appendix**

### **1. List of countries requiring Module 3**

## **References**

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- 4) Medicines and Healthcare Products Regulatory Agency (MHRA) UK, 2025- Guidance on International Recognition Procedure
- 5) Health Sciences Authority (HSA) Singapore 2025, Renew or Cancel a License
- 6) National Institute of Drug and Food Surveillance (INVIMA) Colombia 2023, Decree Number 1474 of 2023
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- 8) Rodriguez and De Lucia 2021, A Proposal of a Combined Convergence Regulatory Strategy Applied to Post-approval Changes by Latin American Countries, Reducing Workload and Allowing Continuous Improvement to Guarantee the Quality, Safety and Efficacy of Medicines, Volume 8, Article 768376
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## Appendix 1- Countries Requiring Module 3 Data for Renewal Submissions

Countries Requiring Module 3 Data for Renewal Submissions			
1	Albania	41	Kuwait
2	Algeria	42	Kyrgyzstan
3	Angola	43	Malaysia
4	Aruba	44	Mali
5	Azerbaijan	45	Mauritania
6	Bahrain	46	Moldova
7	Bangladesh	47	Morocco
8	Belarus	48	Mozambique
9	Benin	49	Myanmar
10	Bolivia	50	Nepal
11	Bosnia and Herzegovina	51	Nicaragua
12	Botswana	52	Nigeria
13	Burkina Faso	53	Oman
14	Cambodia	54	Palestine
15	Cameroon	55	Panama
16	Cabo Verde	56	Paraguay
17	Chile	57	Peru
18	Congo	58	Philippines
19	Costa Rica	59	Qatar
20	Côte D'Ivoire	60	Rwanda
21	Cuba	61	Saudi Arabia
22	Curaçao	62	Senegal
23	Dominican Republic	63	Sierra Leone
24	Egypt	64	Sint Maarten
25	El Salvador	65	South Africa



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26	Ethiopia	66	Sri Lanka
27	Gabon	67	Sudan
28	Georgia	68	Syria
29	Ghana	69	Tanzania
30	Guatemala	70	Thailand
31	Guinea	71	Togo
32	Haiti	72	Türkiye
33	Honduras	73	Turkmenistan
34	India	74	Ukraine
35	Indonesia	75	United Arab Emirates
36	Iraq	76	Uruguay
37	Israel	77	Uzbekistan
38	Jordan	78	Venezuela
39	Kenya	79	Yemen
40	Kosovo	80	Zimbabwe



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