– WHITE PAPER –

Reimbursement-Linked Incentives for the Development of the Medical Industry

The Reimbursement Mode for Economic Development (RMED) and the Favourable Medical Industry (FMI) Framework

Edited by: Krzysztof Łanda, Lieven Annemans, Mark Parker & Tanja Novaković

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Editorial Team

Name	Affiliation	Email
Krzysztof Łanda	Watch Health Care Foundation, Warsaw, Poland	kl@krislanda.eu
Lieven Annemans	Faculty of Medicine & Health Science, Department of Public Health, Heymanslaan 10, 4K3, Ghent, Belgium	Lieven.Annemans@Ugent.be
Mark Parker	ZEM Solutions d.o.o., Belgrade, Serbia	mark@zem-solutions.com
Tanja Novaković	ZEM Solutions d.o.o., Belgrade, Serbia	tanja@zem-solutions.com

Contributing Authors

Name	Affiliation	Email
Gérard De Pouvourville	ESSEC Business School and Research Director of the National Centre for Scientific Research, Paris, France	b00072308@essec.edu
Maarten Postma	Department of Health Sciences, University of Groningen, University Medical Center Groningen, Groningen, the Netherlands; Department of Economics, Econometrics & Finance, University of Groningen, Faculty of Economics & Business, Groningen, the Netherlands; Department of Pharmacology & Therapy, Universitas Airlangga, Surabaya, Indonesia; Center of Excellence in Higher Education for Pharmaceutical Care Innovation, Universitas Padjadjaran, Bandung, Indonesia.	m.j.postma@rug.nl
Michael Schlander	Institute for Innovation & Valuation (InnoVal-HC), Wiesbaden, Germany; German Cancer Research Center (DKFZ), Heidelberg, Germany; Alfred Weber Institute (AWI), University of Heidelberg, Germany	m.schlander@dkfz-heidelberg.de
Nick Verhaeghe	Department of Public Health, Interuniversity Centre for Health Economics Research (ICHER), Ghent University, Ghent, Belgium; Department of Public Health, Interuniversity Centre for Health Economics Research (ICHER), Vrije Universiteit Brussel, Brussels, Belgium	Nick.Verhaeghe@ugent.be
Oriol Solà-Morales	Fundació HiTT, Barcelona, Spain	osola@hittbcn.com
Tomáš Doležal	Institute of Health Economics and Technology Assessment (iHETA), Prague, The Czech Republic	dolezal@iheta.org
Ulf Persson	The Swedish Institute for Health Economics, IHE, Lund, Sweden	ulf.persson@ihe.se
Marcin Czech	Institute of Mother and Child, Warsaw, Poland; Warsaw University of Technology Business School, Warsaw, Poland	Marcin.Czech@pw.edu.pl
Khalid Saeed Khan	Department of Preventive Medicine and Public Health, University of Granada, Spain	profkkhan@gmail.com
Dominik Dziurda	HTA Formedis	dominik.dziurda@htaformedis.pl
Monika Duszynska	Law for Lifesciences	monika.duszynska@md-law.pl
Joanna Lis	Polskie Towarzystwo Farmakoekonomiczne	Joanna@fraktal.com.pl
Omar Ali	Head of Payers Verpora & Former Adviser NICE	Omar.Ali@verpora.com
Prof. Robert Gwiazdowski	Professor, Lazarsky University, Warsaw, Poland	robert@gwiazdowski.pl

REFERENCE

List of Abbreviations

Abbreviation	Meaning	Abbreviation	Meaning
API	Active Pharmaceutical Ingredient	**MFG**	Medizinforschungsgesetz (German Medical Research Act)
DNUR	Duża Nowelizacja Ustawy o Refundacji (Major Amendment to Drug Reimbursement Act)	**NHF**	National Health Fund
EEA	European Economic Area	**NHSA**	National Healthcare Security Administration (China)
EU	European Union	**NRDL**	National Reimbursement List (China)
FMI	Favourable Medical Industry (classification system)	**NVBP**	National Volume-Based Procurement (China)
GLI	Global Legal Insights	**PANSOL**	Pan-European Solidarity Reimbursement List
ICER	Institute for Clinical and Economic Review	**Profarma**	Spanish pharmaceutical support programme
ICUR	Incremental Cost-Utility Ratio	**QALY**	Quality-Adjusted Life Year
IQVIA	IQVIA (research and consulting organisation)	**R&D**	Research and Development
IVDR	*In Vitro* Diagnostics Regulation	**RMED**	Reimbursement Mode for Economic Development
MDR	Medical Device Regulation	**RTR**	*Refundacyjny Tryb Rozwojowy* (Polish: RMED)

OVERVIEW

Key Features of the RMED Framework

- **Rationale for Reimbursement-Based Instruments:** System-level instruments linked solely to marketing authorisation have limited impact on the localisation of the medical industry within a given economic area. To compete effectively in the global landscape, policy tools must instead leverage pricing and reimbursement (P&R) mechanisms within publicly financed health systems, i.e. within basic benefits packages (BBP).
- **Product-Linked Rather Than Company-Linked Incentives:** Unlike conventional industrial policy tools – such as tax concessions, grants, or generic investment incentives – which reward the mere presence of a manufacturer in a given jurisdiction, the RMED is directly linked to the value of specific medicinal products and medical devices manufactured by a producer within a given jurisdiction.
- **Favourable Medical Industry (FMI) Classification System:** Companies are evaluated against six monetised criteria – including employment, taxation, export–import balance, intellectual property acquisition, non-R&D investment, and domestic production value – and assigned to one of five FMI categories (A through E), with higher categories reflecting progressively greater economic partnership with the host country.
- **Graduated and Proportional Incentive Structure:** RMED provides tiered benefits primarily across three areas – fiscal advantages, pricing conditions for generics and biosimilars, and Incremental Cost-Utility Ratio (ICUR) adjustments for innovative therapies – proportionate to a manufacturer's FMI category.
- **Built-In Feedback Mechanism and Automatic Adjustment Mechanism:** The framework incorporates an automatic feedback loop whereby greater investment in the host economy yields progressively more favourable reimbursement conditions, creating a virtuous cycle that incentivises continuous and escalating domestic engagement without requiring ad hoc political decisions.
- **Permanent, Flexible, and Adaptive Design:** Rather than functioning as a one-off support mechanism, the RMED establishes a permanent system of long-term incentives whose criteria and weightings can be modified over time to reflect shifting industrial policy.
- **Scalability Across Company Types and Sizes:** The instrument applies equally to innovative pharmaceutical companies, generic and biosimilar manufacturers, and medical device producers, and is scalable to both large multinational corporations and smaller domestic entities.
- **Full Compliance with the EU Legislation:** RMED is designed to operate within existing EU legal frameworks, ensuring that its mechanisms are consistent with European rules on reimbursement and state support.
- **Improved Cost-Effectiveness Position for Innovative Medicines:** For innovative therapies, RMED applies coefficients to the ICUR, effectively improving the likelihood that a medicine will meet reimbursement thresholds if its manufacturer demonstrates stronger economic partnership with the country.
- **Strengthening of Drug Sovereignty and Supply Chain Resilience:** By incentivising domestic production, RMED reduces reliance on global supply chains, supports local active pharmaceutical ingredient (API) manufacturing despite cost disadvantages, and strengthens healthcare system resilience to external disruptions.

SECTION 01

Introduction and Conceptual Overview

The fragmentation of reimbursement systems across European Union Member States continues to limit both equitable patient access to medicines and the efficient allocation of public healthcare resources. In response to these structural challenges, the Pan-European Solidarity Reimbursement List (PANSOL), as introduced in prior work by the present authors, proposes a coordinated, solidarity-based mechanism for the joint reimbursement of selected medicinal products across participating countries [1]. Conceived as a flexible framework that may be implemented either at the level of the entire EU or through enhanced cooperation among a subset of Member States, PANSOL establishes the institutional foundation for more integrated and strategically aligned reimbursement policy across Europe [1].

Building upon this foundation, the Reimbursement Mode for Economic Development (RMED[1]), as presented in this paper, is conceived as a complementary policy instrument designed to align reimbursement decisions with broader industrial policy objectives. Whereas PANSOL addresses the collective financing and equitable distribution of medicines across participating countries [1], the RMED introduces a system of incentives that rewards manufacturers in proportion to their tangible economic contribution to the European economy. In this sense, the full realisation and effectiveness of the RMED is contingent upon the coordinated reimbursement architecture that PANSOL is intended to provide. Unlike conventional industrial policy tools – such as tax concessions, direct grants, or generic investment incentives – which typically reward the mere presence of a manufacturer within a given jurisdiction, the RMED framework establishes a direct and proportional relationship between the clinical and economic value of the products manufactured by a company and the reimbursement benefits that company may receive from public funds [2, 3].

It should be emphasised, however, that the RMED can also function as a standalone national instrument: while PANSOL enhances its scale and strategic impact, it does not constitute a formal precondition for the implementation of the RMED. Three complementary pathways for the introduction of the RMED may therefore be distinguished. The first, a long-term action, envisages the RMED as a criterion for reimbursement and pricing decisions for medicines included in PANSOL at the level of the entire EU; this represents the most ambitious option and is unlikely to be achieved in the short term, as it requires political will and a lengthy agreement process. The second, a medium-term action, envisages the RMED as a criterion for reimbursement and pricing decisions for medicines included in PANSOL within a group of EU Member States cooperating under the enhanced cooperation procedure; this can be achieved within a much shorter timeframe, as it requires the consent of only a limited number of Member States. The third, a short-term action, would see the European Commission encourage individual EU Member States to adopt the RMED as a reimbursement criterion at national level, with shared core criteria (for example, the high importance of active pharmaceutical ingredient (API) production in the EU or in neighbouring countries) and weightings recommended by the European Commission, while individual Member

[1] in Polish: *Refundacyjny Tryb Rozwojowy*, RTR. The RMED concept was originally developed in Poland under the name RTR and advanced through draft legislation in 2016–2017. The present paper proposes the RMED as a novel instrument for the benefit of the EU as a whole, or for the group of countries participating in PANSOL under the enhanced cooperation procedure [1].

States retain the discretion to adapt the RMED to their specific industrial policy priorities. Taken together, these three pathways underline that the RMED is best understood as a flexible instrument for stimulating the development of the medical industry in Europe – covering both medicines and medical devices – through reimbursement and pricing levers, and as a credible response that could help the EU compete more effectively in the global contest for the location of the medical industry.

A considerable number of government programmes across EU Member States are predicated upon tax relief, capital grants, or broadly targeted investment incentives that bear no intrinsic connection to the clinical effectiveness or therapeutic merit of the products that the medical industry produces at a given location. Such instruments may be characterised, in essence, as "rewards for existence" – forms of support that are wholly disconnected from the fundamental purpose of pharmaceutical and medical device enterprises, namely the development and manufacture of medicinal products and devices that serve to preserve and improve the health of society [3]. Tax breaks and grants are directed at producers on the basis of their geographic location, and are therefore related to the company *per se* rather than to the value or quality of its output.

> *The RMED is not confined to one-off support mechanisms; rather, it establishes a permanent, yet flexible and modifiable, system of long-term incentives that flow from the maintenance and expansion of the medical industry in a given country.*
>
> – Adapted from Łanda (2019)[3] and Góra & Jagliński (2020)[2]

The RMED, by contrast, is directly linked to specific medicinal products or medical devices. It rewards entrepreneurs in a given location, but only insofar as they have developed and produce something of demonstrable value, and the reward is proportional to the value of products manufactured by medical industry enterprises within that jurisdiction. Moreover, the RMED establishes a permanent, yet flexible system of long-term incentives [2]. In this manner, the instrument effectively combines pharmaceutical and medical device policy with the broader industrial policy objectives of a given jurisdiction (i.e. EU as proposed here).

Despite advanced conceptual and legislative preparatory work carried out between 2016 and 2017, the RMED has not been fully implemented in Poland to date, but due to the turmoil in the international market and the change in US policy regarding the medical industry, the RMED may become a strong card, a very attractive incentive and an adequate response of the European Union to the United States' proposals for the medical industry. The following analysis refers to the original concept as articulated in the draft legislation of 2016 [4], which has only been partially transposed into law as part of the 2023 amendment to the Drug Reimbursement Act in Poland. The present white paper sets out the rationale, structural principles, and anticipated benefits of the RMED in its complete form, whilst also examining analogous instruments employed in other jurisdictions and assessing their implications for EU-wide industrial and health policy.

SECTION 02

Purpose and Significance of the RMED

The RMED constitutes a mechanism that recognises and rewards producers who undertake local manufacturing activities, invest in research and development, and actively strengthen local supply chains. Under this instrument, coefficients are assigned to participating manufacturers that reflect the degree of their economic partnership with the host territory, i.e. the European Union or the group of participating Member States. These

coefficients translate into more favourable reimbursement conditions – including preferential cost-effectiveness thresholds, exemptions from payback mechanisms and other predefined mechanisms [2, 3].

The principal objective of the RMED is to foster the development of long-term production capacity and research capability within the medical sector in Europe. By linking reimbursement decisions to the tangible economic contribution of manufacturers, the instrument provides a powerful incentive for companies to make sustainable investments in infrastructure, to expand manufacturing plants, and to deepen their engagement in research and development activities. In so doing, the RMED contributes to the strengthening of pharmaceutical supply security and the reinforcement of the resilience of the healthcare system to external shocks – including global health crises, pandemics, and supply chain disruptions [2, 3].

It is noteworthy that the RMED framework was developed with particular attention to the strategic vulnerabilities exposed by international supply chain dependencies. As Góra and Jagliński [2] have argued, the concept of "state drug sovereignty" – that is, the capacity of a nation to ensure the availability of essential medicines through domestic production and secure supply chains – is of increasing relevance in an era characterised by geopolitical instability and the demonstrated fragility of global pharmaceutical supply networks.

SECTION 03

Structural Principles of the RMED

3.1 Design Philosophy and Scope of Application

The RMED was designed as a flexible mechanism capable of adaptation to the evolving objectives of the state's industrial policy within the pharmaceutical and medical device sectors. The instrument applies equally to innovative companies and to manufacturers of biosimilar, generic, and me-too products [3].

A central design principle is the provision of an automatic consideration mechanism of a manufacturer's economic activity by the relevant Ministry, e.g. the Ministers of Health or European Commission. The framework incorporates a feedback mechanism whereby greater investment yields more substantial benefits under the RMED, creating a virtuous cycle of investment and reward [3].

CORE ELEMENTS OF THE RMED FRAMEWORK

1. Assessment of the extent to which a given pharmaceutical company constitutes a partner of the economy, as expressed through its FMI designation;
2. Assignment of specific FMI categories to individual companies applying for reimbursement;
3. Attribution of specific benefits to individual types of medicines and medical devices on the basis of the FMI category of their manufacturer; and
4. Voluntary participation mechanism: Companies may opt into the RMED framework in order to obtain preferential treatment linked to FMI classification; non-participating entities remain subject to standard pricing and reimbursement procedures without disadvantage.

Under the RMED, the reimbursement of new preparations takes into account the measurable partnership with the European economy – expressed through the Favourable Medical Industry (FMI) designation – of individual companies applying for the financing of their products from public funds [4].

3.2 Criteria for the Evaluation of Partnership with the European Economy (FMI)

RMED should be entirely voluntary. If a company wants to receive the benefits associated with being assigned to higher RMED categories, that will be welcomed However, if it doesn't (i.e., it's not a partner of the European economy), it doesn't have to apply for RMED, and its reimbursement and pricing applications will be processed as before, without the preferences and benefits associated with RMED. The RMED mechanism therefore operates not on the dividing line between EU Member States, but on the dividing line between the EU and the world. In this manner, the RMED enhances the EU's strategic position in the global pharmaceutical landscape by incentivising companies worldwide to anchor greater economic activity within Europe. All criteria are expressed in monetary values, and each is assigned a weighting reflecting the prevailing priorities of industrial policy [3].

For example, should drug safety considerations – specifically, domestic API production – become strategically important, a criterion such as "the value of API production in the preceding year" may be introduced with a correspondingly high weighting [2, 3].

Table 1. Criteria for the evaluation of partnership with the domestic economy (FMI assessment).

No.	Evaluation Criterion	Scope of Evaluation	Weights
1.	Employment	Value of income tax advance payments; total remuneration including social security contributions	*Per policy*
2.	Contract-based employment	Coefficient of intellectual property acquisition costs from creators conducting business activity within the territory of the host state	*Per policy*
3.	Export–import balance	Exports minus imports	*Per policy*
4.	Taxation	Corporate income tax paid	*Per policy*
5.	Non-R&D investments	Capital expenditure outside R&D (investments in fixed assets, intangible and legal assets)	*Per policy*
6.	Local production minus exports	Value of reimbursement of products manufactured domestically (packaging and release alone are insufficient)	*Per policy*

Source: Adapted from Łanda (2019)[3] and the Major Amendment to the Reimbursement Act (2016)[4].

3.3 Categories of "Friendliness" with the European Economy: The FMI Classification

Within the draft legislation of 2016 [4], five FMI categories were established. Companies assigned to Category N are classified as non-FMI entities. The highest category – Category D – is not assigned at inception but serves as an aspirational target, incentivising continuous advancement [3].

Table 2. FMI categories and their corresponding levels of economic impact.

Impact on the Economy	FMI Category
Neutral	**N**
Small	**A**
Medium	**B**
Large	**C**
Initially "empty box"	**D**

Source: Adapted from the Major Amendment to the Reimbursement Act (2016)[4] and Łanda (2019)[3].

The RMED is a scalable instrument, applicable to large corporations and smaller entities alike, provided production volume or company value is considered when assigning categories [3].

3.4 Differentiation of Benefits According to Manufacturer Economic Activity

The RMED provides a graduated system of benefits, whereby higher FMI categories confer access to progressively greater advantages. This tiered structure is designed to ensure that the benefits received by a given manufacturer are directly proportional to its demonstrated contribution to the European economy (as used throughout this paper, "European" refers to the whole EU or to the group of Member States participating in the PANSOL framework under the enhanced cooperation procedure, as described in the previous paper [1]), thereby reinforcing the feedback mechanism at the core of the RMED. The differentiation of benefits spans three distinct domains – general fiscal advantages, pricing conditions for restorative medicines, and cost-effectiveness adjustments for innovative therapies – each calibrated to incentivise sustained and deepening economic partnership [2, 3].

3.4.1 General Benefits

Furthermore, companies in these categories are entitled to exemptions or reductions in social security contributions for highly qualified employees, thereby reducing the cost burden associated with maintaining a skilled workforce in research, development, and manufacturing roles. These general benefits are intended to improve the overall operating environment for companies that have made meaningful investments in the host economy, making it more attractive to locate and retain high-value employment within the jurisdiction [4].

The set of benefits described herein is proposed as a common baseline applicable across all participating countries within the RMED framework. Individual Member States may, however, introduce additional benefits beyond this commonly agreed package, tailored to their specific industrial policy priorities. The full range of RMED benefits – including those applicable to innovative pharmaceuticals, innovative medical devices, generics, biosimilars, and me-too products – warrants further development and will be elaborated in a subsequent version of this paper.

3.4.2 Benefits for Restorative (Generic/Biosimilar) Medicines

For manufacturers of restorative medicines – including generic, biosimilar, and me-too products – the RMED provides for modified pricing conditions that apply to the first counterpart product, to subsequent counterpart products, and to price renegotiation processes. Companies in higher FMI categories are afforded the possibility of raising the price of their products to a defined limit, thereby improving margins and supporting continued investment in domestic production capacity. However, should a price increase be granted during the renegotiation process, any subsequent request for a price reduction will first reduce the "virtual" limit before affecting the actual reimbursement price – a safeguard designed to prevent abuse of the pricing flexibility whilst still rewarding sustained economic partnership [3].

3.4.3 Benefits for Innovative Medicines

The benefits afforded to manufacturers of innovative (therapeutically novel) medicines under the RMED are of particular significance, as they operate directly upon the health economic evaluation that determines whether a given product is eligible for reimbursement from public funds. Under the applicable legislation, any reimbursement application for a therapeutic innovation drug must be accompanied by a formal economic analysis that includes the calculation of

the Incremental Cost-Utility Ratio (ICUR) – a measure that expresses the additional cost per unit of health gain (typically per quality-adjusted life year, QALY) associated with the new therapy relative to the existing standard of care. The ICUR is a legally mandated component of the reimbursement dossier, and the value it yields is a decisive factor in determining whether a positive reimbursement decision is issued [3].

The RMED introduces a system of coefficients that are applied to the ICUR calculation, effectively adjusting the numerator of the cost-effectiveness ratio in favour of manufacturers that have demonstrated a higher degree of economic partnership with the host country. Two variants of the coefficient are provided – a "mild" variant, representing a more conservative policy approach, and an "aggressive" variant, reflecting a higher level of ambition in incentivising domestic investment. Table 3 presents the RMED coefficients applicable to each FMI category under both variants [3].

Table 3. RMED coefficients for innovative medicines by FMI category.

Impact on the Economy	FMI Category	RMED Coefficient (Mild)	RMED Coefficient (Aggressive)
Neutral	N	1.00	1.00
Small	A	0.90	0.75
Medium	B	0.80	0.50
Large	C	0.70	0.25
Initially "empty box"	D	0.50	0.10

Source: Łanda (2019)[3].

To illustrate: should a company be assigned to FMI Category C, it would be entitled to apply an RMED coefficient of 0.70 (mild variant) or 0.25 (aggressive variant) in its ICUR calculation. The application of this coefficient substantially reduces the effective ICUR, thereby enhancing the probability of the product falling below the cost-effectiveness threshold and obtaining a favourable reimbursement decision. Conversely, a company in Category N receives a coefficient of 1.00, meaning its ICUR remains unadjusted and it receives no preferential treatment. The graduated nature of this system ensures that the incentive to invest domestically is both continuous and proportional. The specific coefficients ultimately adopted were to be determined through the parliamentary legislative process, with the two variants designed to illustrate the range of policy options available to policymakers [3, 4].

Table 4 further illustrates the effect by presenting the resulting ICURs, expressed in euros, for each FMI category under both variants. The differential is substantial: under the aggressive variant, a company in Category D benefits from a ratio of 5,000, compared with 50,000 for Category N – a tenfold difference reflecting the framework's intention to create a powerful reward for the highest levels of economic partnership [3].

Table 4. Illustrative ICURS by FMI category under mild and aggressive RMED policy variants.

FMI Category	ICUR (Mild)	ICUR (Aggressive)
N	50,000	50,000
A	45,000	37,500
B	40,000	25,000
C	35,000	12,500
D	25,000	5,000

Values in € (illustrative values; final thresholds in EUR to be determined by participating Member States).

3.4.4 Innovative medical devices

For innovative medical devices, the RMED should adopt a benefit structure distinct from that used for innovative medicines. Within the EU, access for devices is shaped not by a single reimbursement threshold alone, but by the interaction of conformity assessment, procurement practice, hospital financing, and evolving EU-level HTA-related procedures. Medical technologies also differ from medicines in that innovation is highly iterative and product cycles are short, with many devices undergoing iterative improvement within 18 to 24 months [5]. For that reason, the common RMED baseline for participating countries should

combine evidentiary, procurement, and financing advantages, rather than simply replicate the ICUR-based approach proposed for innovative medicines.

The European Commission's December 2025 proposal acknowledges that the MDR/IVDR transition "led to the discontinuation of certain devices intended for small groups of patients" because compliance costs made conformity assessment economically difficult [6, 7]. Its proposed breakthrough and orphan device pathways, together with fee reductions for micro and small manufacturers, confirm the need for innovation-friendly measures [6, 7]. RMED could complement these reforms by adding reimbursement-based incentives for manufacturers that develop and produce innovative devices in Europe.

A common RMED EU package could include four benefits.

First, manufacturers in higher FMI categories should receive priority access to joint scientific consultations and coordinated evidence dialogue at national level, so that evidentiary expectations are clarified earlier and market-entry timelines become more predictable.

Second, participating countries should apply innovation-oriented procurement and reimbursement rules for eligible devices, permitting purchasers and payers to consider lifecycle value, service and maintenance obligations, training, interoperability, cybersecurity, and measurable patient outcomes, rather than lowest acquisition price alone.

Third, innovative devices that demonstrate meaningful clinical or organisational benefit should be eligible for temporary add-on reimbursement, dedicated hospital payments, or ring-fenced innovation budgets for a defined introductory period.

Fourth, such access should be linked to coverage with evidence development, including registry-based follow-up and rapid reassessment once real-world evidence mature. The third and fourth elements are proposed here as an RMED-specific adaptation to the device sector, inferred from the EU policy direction toward faster, more predictable and more innovation-supportive pathways, together with the sector's unusually short innovation cycle.

This approach would be consistent with current EU policy priorities. Recent EU materials emphasise both the economic importance of the medical devices sector and the need for a more competitive, innovative, and predictable regulatory and procurement environment. Accordingly, the common RMED baseline for innovative medical devices should be available across all participating countries, while Member States may add additional national supplements – for example, faster coding decisions, implementation grants for hospitals, digital integration support, or national innovation procurement pilots – on top of the shared EU package.

SECTION 04

Compliance with European Union Law

Tax concessions have previously been considered as instruments for pharmaceutical industry development, and targeted grants have been practised on an *ad hoc* basis. Tax relief is difficult to implement owing to the risk of non-compliance with EU competition and state aid law [3, 8].

The RMED is intended to operate within, and be compatible with, the EU legal framework. This interpretation is supported by available legal opinions and relevant precedents from Member States. The key arguments may be summarised as follows [4, 8]:

1. **Sovereignty over reimbursement expenditure:** The Treaty on the Functioning of the European Union

expressly reserves to the Member States the authority to determine how public funds are spent on the reimbursement of medicines and to define the composition of the health services package available to their populations. It is noteworthy that the only regulation common to the entire EU in this domain is the Transparency Directive, which governs the procedural transparency of pricing and reimbursement decisions but does not prescribe the substantive criteria that Member States must apply – and which, accordingly, does not contradict the RMED in any respect. In practice, there is no common list of reimbursed medicines for the entire EU; each Member State follows its own distinct rules and priorities for the creation of such a list, reflecting national epidemiological needs, budgetary constraints, and industrial policy objectives [4].

2. **Absence of fiscal redistribution:** There exists no system of fiscal redistribution within the EU that would permit the economic benefits arising from the pharmaceutical industry's presence – including tax revenues, employment, export earnings, and knowledge spillovers – to be distributed evenly across Member States, irrespective of the industry's geographic location. In other words, only the country in which the manufacturer is established and operates derives direct fiscal and economic benefit from the taxes paid, the wages disbursed, and the medicines exported from its territory. This structural asymmetry provides a compelling justification for individual Member States to adopt instruments such as the RMED that seek to attract and retain pharmaceutical manufacturing and research activity within their borders [8].
3. **Established precedents:** A considerable number of EU Member States already support their domestic pharmaceutical industries through reimbursement-linked mechanisms and informal pricing arrangements. Most notably, a formal support system closely analogous to the RMED has been in operation in Spain under the Profarma programme, which classifies pharmaceutical companies into categories based on their investment in research and development, local production, exports, and employment, and awards corresponding benefits in terms of public procurement scoring, tax concessions, and preferential financing [9, 10]. No information has been identified suggesting that the Spanish Profarma system is in breach of EU law or has been subject to infringement proceedings. A comparable system is also in place in Belgium, and its compliance with EU law has not been called into question by either the European Commission or the Court of Justice of the European Union [8].

A further consideration concerns the relationship between the RMED and the EU Joint Clinical Assessment (JCA) under the Health Technology Assessment Regulation. The position of the present authors on the design of EU-level clinical assessment is developed separately in companion work, in which a light-touch approach to the JCA is advocated rather than the current procedurally heavy model. The RMED is conceived as compatible with such a light-touch approach: it operates on reimbursement and pricing decisions, which remain within Member State competence, and does not interfere with, override, or modify the relative clinical assessment of medicinal products carried out at EU level. The interaction between the two instruments – and the precise legal architecture under which an RMED could

operate alongside a reformed JCA – would, in line with the comments received during peer review, benefit from a dedicated legal analysis to be undertaken as part of the further work programme.

SECTION 05

Anticipated Benefits of the RMED

The full implementation of the RMED is anticipated to yield substantial benefits [2, 3]:

- An increase in European production, with industrial development accelerating as the RMED's weight as a reimbursement criterion increases.
- Enhanced pharmaceutical supply security, including the possibility of initiating domestic API production even where price competitiveness with China or India is not achievable.
- Strengthened industrial impact through synergy with investment grants and tax concessions, creating a coherent system of incentives.
- A transparent, permanent, automatic, yet flexible linkage between pharmaceutical policy and the industrial policy of the state.

Were the RMED to become a principal criterion, its advantages would be apparent across three dimensions [3]:

1. **The size of funds:** Within the EU, substantial public expenditure is already directed towards the reimbursement of medicines and medical technologies. Across EU Member States, public expenditure on reimbursed outpatient pharmaceuticals alone exceeded €185 billion in 2024 [11], while total pharmaceutical expenditure – including hospital-administered medicines – is estimated to range between €250-€340 billion [12]. In parallel, expenditure on medical technologies is estimated at approximately €136 billion across the EU, based on their share of total healthcare spending [5]. Taken together, these figures illustrate the very significant scale of public financial flows associated with reimbursement systems. Were the RMED to be formally adopted as a reimbursement criterion, this scale would confer upon it a powerful capacity to influence both the development trajectory and the geographic localisation of the medical industry within the EU.
2. **The temporal dimension:** If the medical industry is compelled to expend resources on the system as a whole without targeted direction, such spending is inefficiently allocated and yields diminished returns. By contrast, if the RMED enables predictable and foreseeable reimbursement revenues, the industry is empowered to plan for sustained growth over the long term, thereby optimising its investment decisions regarding manufacturing capacity, research infrastructure, and workforce development.
3. **Repeatability and continuation:** In the context of stable reimbursement revenues and the predictability of FMI evaluation criteria over time, the RMED provides the conditions necessary for pharmaceutical companies and manufacturers of medical devices to implement long-term development strategies within the EU – a degree of strategic certainty that one-off grants or time-limited tax concessions are inherently unable to provide [2].

SECTION 06

RMED-Analogous Instruments in Other Jurisdictions

Several countries have implemented instruments broadly analogous to the RMED to stimulate investment in local pharmaceutical and medical device production.

Spain: The Profarma Programme

PROFARMA 2025–2026

The Profarma programme evaluates pharmaceutical companies against criteria including R&D investment, local production, exports, and employment. Companies are classified into categories (A, B, C) determining access to rebate concessions, preferential loans, and investment support [9, 10]. It has contributed to:

- Sustained increase in exports of medicinal products from Spain.
- Increased employment in R&D and manufacturing sectors.
- Improved innovativeness, particularly in biotechnology [10].

In July 2025, the Profarma 2025–2026 Plan was presented to establish Spain as a European leader in pharmaceutical production [9].

Germany: Regulatory and Economic Instruments

MEDIZINFORSCHUNGSGESETZ (MFG) 2024

In 2024, Germany introduced the *Medizinforschungsgesetz* (Medical Research Act), permitting confidential reimbursement pricing for medicines meeting specified conditions [13]:

- At least 5% of phase III participants must be from German research centres.
- The manufacturer must provide, *inter alia*, a 9% discount on the reimbursed product.
- The mechanism applies exclusively to medicines entitled to data exclusivity.

The procedure operates as follows: upon obtaining a reimbursement decision, the manufacturer has five days in which to request price confidentiality, and must demonstrate that it satisfies the requisite conditions. This change was introduced to address the problem whereby German reference prices for reimbursed medicines, used as reference prices in other jurisdictions, led to unfavourable pricing in other markets, which in turn prompted some companies to withdraw from the German market. The mechanism was introduced on a provisional basis and is subject to review to assess whether it has contributed to its intended objectives, including encouraging clinical trials in Germany, creating new employment opportunities, and accelerating patients' access to the most recent therapies [13]. API production within the EU or EEA is also to be considered in public procurement of non-patented antibiotics [14].

China: NHSA and National Volume-Based Procurement

NVBP / NRDL SYSTEM

Under China's reformed system, the National Healthcare Security Administration (NHSA) conducts centralised price negotiations. The National Volume-Based Procurement (NVBP) programme provides guaranteed hospital supply contracts to competitive manufacturers. Medicines on the NVBP are listed on the National Reimbursement List (NRDL), substantially enhancing their market share. Priority for entry onto the NRDL is accorded to medicines that meet stringent quality requirements and whose manufacturers offer competitive pricing, whilst

also reflecting a degree of economic patriotism, inasmuch as the majority of reimbursed medicines are sourced from domestic manufacturers. The rigorous requirements pertaining to production location and quality standards encourage foreign companies to invest in manufacturing plants and research and development facilities within China [15, 16]. The system, though blunt, has proven highly effective [16]. Guaranteed volumes of drugs included in the NVBP reimbursement list stimulate domestic pharmaceutical expansion [15].

SECTION 07

Discussion and Policy Implications

The RMED represents a sophisticated approach to aligning pharmaceutical reimbursement with industrial development objectives [2, 3].

A practical question that the RMED must address is how it can be implemented in a setting in which EU Member States already compete with one another to attract pharmaceutical and medical device investment. The German Medical Research Act, the Spanish Profarma programme, the Belgian arrangements referred to in Section 04, and incentive elements present in the French pricing and reimbursement system illustrate that several Member States already deploy reimbursement-related instruments oriented towards the localisation of the medical industry. Any new framework cannot be designed in isolation from these existing mechanisms; rather, it must be conceived in a manner that is interoperable with them and that limits the risk of intra-EU regulatory arbitrage. The European comparators (Germany, Spain, Belgium, France) are therefore the most directly relevant reference points for RMED implementation, whereas the Chinese NVBP system – which uses guaranteed procurement volumes and pricing leverage to incentivize domestic manufacturing – is referred to as an illustrative example of the leverage that volume-based reimbursement and procurement can exert on industrial location, rather than as a model to be transposed into the European context. On this basis, the implementation of the RMED – whether through PANSOL, through enhanced cooperation, or at national level – should explicitly take into account the existing landscape of Member State incentives and seek to align them under shared principles, in order to avoid duplicative competition and to direct the combined effect of these instruments towards strengthening the medical industry within the EU as a whole.

The international examples provide compelling evidence of legal viability and practical effectiveness. Spain's Profarma has contributed to increased exports, employment, and innovation [9, 10]. Germany's Medical Research Act illustrates growing recognition that reimbursement-linked instruments can encourage research and strengthen production [13, 14]. China's NVBP demonstrates the potency of volume-based guarantees [15, 16].

> *The compliance of the RMED with EU law – confirmed by three independent legal opinions and further reinforced by the partial introduction of a "mini" RMED in 2023 – removes a significant potential barrier to full implementation.*
>
> – Based on the Major Amendment to the Reimbursement Act (2016)[4] and IQVIA (2019)[8]

The experience of Spain and Belgium provides further reassurance [4, 8]. Full implementation would represent a transformative step towards European pharmaceutical sovereignty [2].

SECTION 08

Risks and Mitigations : A Framework for Further Development

The present white paper intentionally scopes risks and mitigations as a topic for further work; a dedicated subsection addressing these issues is essential for the framework's policy robustness. Such an analysis should identify foreseeable risks – including, but not limited to, the potential for intra-EU competition for industrial location, exposure to state aid and competition-law challenges, administrative burden in operationalising FMI categorisation, the risk of price increases in higher FMI categories outpacing demonstrable economic returns to the host economy, and possible unintended effects on access for products supplied by manufacturers in lower FMI categories. Each identified risk should be paired with proportionate mitigation measures, including transparent and auditable FMI evaluation criteria, periodic recalibration of weightings and coefficients, safeguards against abuse of pricing flexibility (as already outlined in Section 3.4.2 for restorative medicines), and explicit alignment with the existing reimbursement-linked instruments operating in Germany, Spain, Belgium and France. The development of this subsection is proposed as a deliverable for a subsequent version of the white paper.

SECTION 09

Conclusions

The RMED, together with its FMI classification framework, constitutes a unique policy instrument bridging pharmaceutical reimbursement and industrial development strategy. It rewards manufacturers for the tangible, measurable value they generate – through employment, investment, production, exports, taxation, and intellectual property creation.

The instrument's flexibility, scalability, automatic consideration mechanism, and built-in feedback mechanism ensure adaptation to evolving priorities. International evidence from Spain, Germany, and China confirms that reimbursement-linked instruments are legally permissible and practically effective.

Full implementation merits serious consideration by policymakers, not only for national industrial development, but as a model for other EU Member States seeking to strengthen their pharmaceutical manufacturing base, enhance supply chain resilience, and secure long-term drug sovereignty.

The FMI classification system outlined in this paper provides a robust starting point for linking reimbursement policy with industrial development objectives; however, its full potential will depend on its continued evolution. Expanding the scope of the framework to capture a wider range of economic contributions – including strategic manufacturing, supply chain resilience, and high-value innovation activities – would strengthen its capacity to support EU-level policy goals. Such development would also facilitate greater alignment with broader European priorities, including competitiveness, innovation, open strategic autonomy, the security of supply of critical medicines and medical technologies, and industrial resilience. The progressive refinement and expansion of the FMI framework therefore represent an important next step, to be advanced through ongoing collaboration and policy dialogue.

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