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# EXPERT OPINION

# on Proposed Article 50 MDR of the Commission's Proposal Amending the MDR and IVDR

**(Article 1(40) of the Commission's Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I, of December 16, 2025, COM(2025) 1023 final, 2025/0404 (COD), on replacing Article 50 MDR)**

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# EXECUTIVE SUMMARY

This Opinion examines whether Article 50 of the Commission's Proposal amending the MDR and IVDR is compatible with Union law. Proposed Article 50 would require notified bodies to grant mandatory fee reductions to micro and small enterprises and to orphan-device applicants, to allow micro and small enterprises to defer payment until completion of the relevant conformity-assessment activity, and, in certain circumstances, to accept requests for conformity assessment on instruction from the responsible authority. Proposed Article 50(3) would also empower the Commission, by implementing act, to specify the structure and level of notified-body fees.

The Opinion concludes that Article 50, in its proposed form, gives rise to **serious interferences** with the freedom to conduct a business protected by **Article 16 CFREU**. The mandatory fee reductions interfere directly with notified bodies' pricing autonomy. The payment-deferral requirement interferes with the financial conditions of service provision and shifts liquidity and default risk onto notified bodies. The compelled-acceptance mechanism interferes with negative contractual freedom. Taken together, those mechanisms produce a still more serious cumulative interference: notified bodies may be required to charge less, receive payment later, bear greater financial risk, and accept the very engagement that generates those burdens. Article 50(3) may further intensify that effect by restricting their ability to offset those burdens through autonomous fee structuring.

The **objectives** pursued by the Proposal are **legitimate** and **weighty**. The Union may seek to improve the functioning of the medical-device regulatory framework, reduce burdens on SMEs and orphan-device manufacturers, preserve innovation and competitiveness, secure access to conformity assessment, and protect device availability and public health. Nor is Article 50 manifestly inappropriate for those purposes. In a limited sense, the proposed measures are capable of contributing to the objectives pursued.

The decisive difficulty lies in the **means chosen**. Article 50 does not merely regulate notified bodies in the public interest. It **uses private notified bodies as the financing mechanism for a policy designed to relieve selected categories of manufacturers**. That design is **not necessary**. The same objectives could have been pursued by less intrusive means, including public compensation, reimbursement or voucher schemes, secured payment-deferral mechanisms, stricter enforcement and standardisation of existing fee-transparency duties, cost-based legislative criteria for any fee regulation, public coordination mechanisms for access problems, targeted use of the existing derogation regimes under Article 59 MDR and Article 54 IVDR, and compensated public-service obligations.

In any event, Article 50 imposes an **excessive burden** on notified bodies. The burden is **concentrated** on a limited class of private undertakings, imposed **without compensation**, **insufficiently calibrated to actual costs**, and cumulative in its operation. It is also institutionally **asymmetric**: notified bodies remain private, for-profit undertakings, yet Article 50 would make them carry burdens resembling public-service obligations without the public financing, cost-recovery safeguards or institutional status that normally accompany such obligations. The comparison with Union pharmaceutical law is particularly instructive. In that field, fee relief for SMEs and orphan products is embedded in a public, cost-based and institutionally secured framework. Article 50 transposes some of the visible instruments of that model, but omits its financing logic.

The Opinion therefore concludes that Article 50 of the Proposal constitutes a **disproportionate** interference with Article 16 CFREU and **violates** the notified bodies' fundamental right to conduct a business. This conclusion does not deny the Union legislature's broad discretion in regulating medical devices, supporting SMEs, or protecting public health. It turns on a narrower point: the Union may not pursue those objectives by **reallocating a public-interest burden to a limited class of private undertakings through a mechanism that is uncompensated, cost-blind, and insufficiently safeguarded**.

If enacted in that form, the offending provisions would therefore be **invalid** and **unenforceable**. They **could not lawfully be relied upon by Union institutions, Member State authorities or manufacturers to require notified bodies to grant the mandatory fee reductions, defer payment, or accept requests for conformity assessment.**

Article 50(3) raises a further and independent problem under **Article 291 TFEU**. Implementing acts may be used to ensure uniform conditions for implementing rules already laid down by the legislature. They may not be used to determine essential normative choices. Yet Article 50(3) would empower the Commission to specify the structure and level of private notified-body fees without laying down a cost-based methodology, rules on cost recovery, limits on Commission discretion, or safeguards for notified bodies' economic viability. That power concerns one of the central elements of the interference with Article 16 CFREU: the remuneration which notified bodies may receive for their services.

For that reason, large parts of the matter **should be determined by the Union legislature** itself. A narrower implementing power concerning fee templates, reporting formats, technical comparability, or publication mechanisms would likely be unobjectionable. The power actually proposed is broader. In the absence of legislative criteria securing cost recovery, economic viability, and an appropriate balance between SME support and notified-body autonomy, Article 50(3) risks transferring essential distributive and rights-sensitive choices to the Commission. It is therefore vulnerable both as a matter of Article 291 TFEU and as part of the fundamental-rights problem under Article 52(1) CFREU.

If enacted in its proposed form, Article 50(3) would be **invalid** and **unenforceable**. It would **not validly empower the Commission to specify the structure and level of notified-body fees by implementing act**. **Any implementing act adopted on that basis would therefore be vulnerable because its legal basis would be defective**.

# I. Mandate and Scope

TÜV Verband has instructed me to prepare an expert opinion on **proposed Article 50 MDR**, as it would be inserted into Regulation (EU) 2017/745 by Article 1(40) of the Commission Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices, and amending Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I, dated 16 December 2025, COM(2025) 1023 final, 2025/0404 (COD) (hereinafter "the Proposal"). Proposed Article 50 would regulate both manufacturers' access to notified bodies and the fees charged by notified bodies, by imposing on notified bodies fee-transparency duties, mandatory fee reductions, payment deferral for micro and small enterprises, possible Commission specification of the structure and level of fees, non-discriminatory access duties, response obligations, and, in certain cases, compelled acceptance of conformity-assessment requests.

The present Opinion assesses **whether those proposed rules are compatible with Union law**. It focuses, in particular, on the freedom to conduct a business protected by Article 16 CFREU, the conditions for limitations of Charter rights under Article 52(1) CFREU, and the limits on the conferral of implementing powers under Article 291 TFEU. It does not examine the Proposal as a whole, but is confined to the rules concerning notified bodies contained in proposed Article 50 MDR and, where relevant, the corresponding amendments to the IVDR.

# II. Regulatory Background, the Role of Notified Bodies, and Proposed Article 50

This section sets out the regulatory context in which proposed Article 50 must be assessed. Its purpose is not to determine, at this stage, whether the proposed measure is compatible with Union law. Rather, it identifies the structure of the MDR/IVDR framework, the role of notified bodies within that framework, the concerns invoked by the Commission in support of the Proposal, and the legal mechanisms by which proposed Article 50 would intervene in the relationship between manufacturers and notified bodies. That background is relevant in particular to the later assessment of legitimate objectives, appropriateness, necessity and proportionality under Article 52(1) CFREU, and to the separate question whether Article 50(3) remains within the limits of Article 291 TFEU.

Notified bodies occupy a distinctive position in that framework. They are not Union institutions, Member State authorities or public agencies. They are bodies designated and supervised under Union law and national law to perform conformity-assessment activities within their scope of designation. Their assessments are indispensable for the placing on the market of many medical devices and in vitro diagnostic medical devices and therefore serve an important public-interest function within the Union regulatory system. At the same time, notified bodies remain, in most cases, private undertakings operating for remuneration in a regulated market. That dual character is central to the present Opinion. The fact that notified bodies perform functions of public importance does not make them public authorities; conversely, the fact that they are private economic actors does not remove them from the

regulatory framework of the MDR and IVDR. The legal questions raised by Article 50 arise precisely from that institutional position.

Against that institutional background, the Commission describes the European medical-technology market as economically significant and identifies a number of weaknesses in the operation of the existing MDR/IVDR framework. According to the Commission, the European medical-technology market was worth approximately EUR 170 billion in 2024,[1] making it the second largest medical-technology market in the world.[2] For that market, Regulations (EU) 2017/745 on medical devices ("MDR") and (EU) 2017/746 on in vitro diagnostic medical devices ("IVDR") established a regulatory framework designed, first, to ensure the smooth functioning of the internal market in medical devices, secondly, to secure a high level of protection for the safety and health of patients and users, and, thirdly, to support innovation.[3]

The MDR and the IVDR replaced the earlier legislative framework, which had consisted of three Directives in force since the 1990s.[4] That reform was prompted by several concerns, including shortcomings in the safety of certain medical devices, obstacles to the functioning of the internal market, and deficiencies in the availability, coherence and reliability of data and information relating to medical devices.[5] The Regulations sought to address those problems by strengthening the Union framework, in particular through a more robust regulatory infrastructure and enhanced safeguards.

At the same time, however, the current framework has also been the subject of substantial criticism. A range of actors, including stakeholders, several Member States, the European Parliament and the Commission itself, have identified a number of weaknesses in the operation of the MDR and the IVDR. These include implementation delays, increased administrative burdens, longer certification timelines, higher costs of achieving market access, inconsistent application of regulatory requirements, and an unduly complex governance structure.[6] Against that background, the Commission presented, on 16 December 2025, a proposal to amend both Regulations.[7]

The Proposal retains the basic architecture of the existing regime, in particular its decentralised structure with responsibilities distributed among the Member States and the

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[1] Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I, of December 16, 2025, COM(2025) 1023 final, 2025/0404 (COD), at 1.

[2] Commission Staff Working Document, Evaluation on the Targeted evaluation of Regulation (EU)2017/745 on Medical Devices and Regulation (EU)2017/746 on In vitro Diagnostic Medical Devices, SWD(2025) 1051 final, at 48.

[3] Recitals (1) and (2) of both MDR and IVDR.

[4] Council Directive 90/385/EEC, OJ L 189, 20.7.1990, pp. 17-36; Council Directive 93/42/EEC, OJ L 169, 12.7.1993, pp. 1-43; Council Directive 98/79/EC, OJ L 331, 7.12.1998, pp. 1-37.

[5] Evaluation, SWD(2025) 1051 final (supra note 2), at 4 et seq.

[6] Ibid, 50-52. See also European Parliament resolution of 23 October 2024 on the urgent need to revise the Medical Devices Regulation, 2024/2849(RSP), OJ C, C/2025/485, 29.1.2025, and Joint Paper of Croatia, Finland, France, Germany, Ireland, Luxembourg, Romania, Malta and Slovenia on necessary reforms in MDR and IVDR: priorities/main points, Council of the European Union, 28.11.2024, 15380/24.

[7] Proposal, COM(2025) 1023 final (supra note 1).

continued involvement of notified bodies in the conformity-assessment process. At the same time, it seeks to render that framework leaner and more cost-effective, with a view to enhancing the competitiveness and innovative capacity of the Union market for medical devices. A central element of that objective is the position of small and medium-sized enterprises ("SMEs"), which play a significant role in innovation but which, in the Commission's view, are disproportionately affected and disadvantaged by the burdens and costs generated by the current regulatory framework.[8]

According to the Commission's targeted evaluation, the current framework has had ambivalent effects on notified bodies. On the one hand, notified bodies have faced substantially increased costs, in particular in connection with designation procedures and joint assessments. On the other hand, they have also benefited from increased revenues, though only at the price of heightened pressure, intensified scrutiny and more demanding regulatory oversight.[9] The Commission's targeted evaluation further found that the designation, supervision and performance of notified bodies vary considerably across the Member States. National authorities and manufacturers alike pointed to significant divergences in the way notified bodies conduct conformity assessments, including inconsistencies in the manner in which their fees are presented. The evaluation indicates, moreover, that most notified bodies do not appear to follow the template list of standard fees developed by the MDCG.[10] Such inconsistencies are said to affect SMEs, orphan devices and low-risk products in particular.[11] At the same time, fee levels also vary according to the size of the manufacturer; by way of example, the Commission notes that large manufacturers pay 165 % more than SMEs for the last certificate obtained.[12]

The Proposal seeks to respond to those difficulties in two principal ways. First, it proposes to simplify and accelerate the process for the assessment and designation of applicant notified bodies, while at the same time tightening the rules governing their oversight. Secondly, with specific regard to the fee burden borne by SMEs and orphan-device manufacturers, it proposes a series of direct interventions in the legal relationship between manufacturers and notified bodies. In particular, the Proposal provides that notified bodies must apply reduced fees for conformity-assessment activities in the case of micro and small enterprises and in the case of orphan devices (proposed Article 50(2)). In addition, it requires notified bodies to grant micro and small enterprises the possibility of deferred payment (also proposed Article 50(2)). With a view to increasing the predictability of conformity-assessment fees and preventing fee levels regarded as excessive, the Proposal further empowers the Commission to adopt implementing acts specifying the structure and level of those fees (proposed Article 50(3)). Finally, it empowers the Member State authorities responsible for notified bodies, in certain circumstances, to require a notified body to accept a manufacturer's request for conformity-assessment activities (proposed Article 50(6)).

The combined effect of these provisions is therefore not merely to increase transparency as regards the fees charged by notified bodies, but to subject both the economic terms and, in certain respects, the contractual accessibility of conformity assessment to a significantly more intensive regulatory framework. The Commission justifies those measures on the basis that,

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[8] Evaluation, SWD(2025) 1051 final (supra note 2), at 23, 24, 25, 26, 27, 28, 34, 35, 36, 42, 45, 49; Proposal, COM(2025) 1023 final (supra note 1), at 2, 3, 10.

[9] Evaluation, SWD(2025) 1051 final (supra note 2), at 37-8.

[10] Ibid, at 22.

[11] Ibid, at 25, 26, 36.

[12] Ibid, at 35.

although most notified bodies are private, for-profit entities, they nevertheless exercise their function in the public interest.[13]

Article 1(40) of the Proposal would amend the MDR by inserting the following provision:

*Article 50*
***Access to notified bodies and fees***

1. Notified bodies shall establish lists of their fees for the conformity assessment activities that they carry out and shall make those lists publicly available. They shall notify the lists to the Commission, which shall make references to them available to the public on a dedicated website.
2. Notified bodies shall apply at least a 50 % fee reduction for manufacturers that are micro enterprises within the meaning of Recommendation 2003/361/EC and at least a 25 % fee reduction for small enterprises within the meaning of that Recommendation. They shall apply at least a 50 % fee reduction for manufacturers that apply for conformity assessment of an orphan device referred to in Article 52a(3). Notified bodies shall provide manufacturers that are micro or small enterprises within the meaning of Recommendation 2003/361/EC the possibility to defer the payment of fees until the relevant conformity assessment activity is finalised.
3. The Commission, in consultation with the MDCG, may adopt implementing acts to specify the structure and level of the fees referred to in paragraph 1, taking into account the need to:
   (a) establish and maintain high standards of quality and safety of devices;
   (b) ensure the availability of devices;
   (c) protect the interests of micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC;
   (d) support innovation and competitiveness.
4. Notified bodies shall ensure that manufacturers, which are micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC, have access to their conformity assessment activities in a manner that is not less favourable than the manner in which access is provided to other manufacturers.
5. Notified bodies shall deal with any request for conformity assessment activities from a manufacturer and, within 15 days of receipt of the request, inform the manufacturer accordingly.
6. When duly justified in the interest of public health or patient health or safety, the authority responsible for notified bodies may instruct a notified body to accept a manufacturer's request for conformity assessment activities falling within that notified body's scope of designation.'

[13] Proposal, COM(2025) 1023 final (supra note 1), recital (27).

# III. Fundamental Rights Analysis Under Article 16 CFREU

A central question in assessing the compatibility of proposed Article 50 with Union law is whether the obligations it would impose on notified bodies constitute unjustified interferences with their **fundamental rights**. The European Union is founded on the rule of law, and compliance with fundamental rights is a condition of the legality of Union action. Measures adopted by the Union institutions cannot be regarded as lawful if they are incompatible with the fundamental rights protected by Union law.[14]

The relevant point of departure is the Charter of Fundamental Rights of the European Union (CFREU). Pursuant to Article 6(1) TEU, the Charter has the same legal value as the Treaties and therefore forms part of primary Union law. It follows that the legality of legislative and regulatory action adopted by the Union institutions must be assessed, where appropriate, by reference to the Charter. Article 51(1) CFREU confirms the same proposition in institutional terms: the provisions of the Charter are addressed, first and foremost, to the institutions, bodies, offices and agencies of the Union, which are required to respect the rights, observe the principles, and promote their application in all their action. Where, therefore, the Commission proposes a legislative measure and the Union legislature enacts it, both act within a legal framework fully bound by the Charter.

It equally follows that private undertakings affected by Union action may rely on the Charter for protection where a Union measure interferes with rights guaranteed to them by Union law. Notified bodies are not public authorities, but private, for-profit entities operating within a regulatory framework established by Union law. As such, they are not excluded from the personal scope of Charter protection. If a Union measure adversely affects their protected legal sphere, they may invoke the Charter against that measure in the ordinary way.

In the present context, the principal provision is **Article 16 CFREU**, which recognises the freedom to conduct a business. That is the right most directly engaged by Article 50 of the Proposal. The measures there envisaged concern, in particular, the level of fees charged for conformity-assessment activities, the timing of payment, and, in certain circumstances, the freedom of notified bodies to decide whether they will enter into a contractual relationship at all. Those are matters which go to the core of entrepreneurial autonomy. It is therefore Article 16 CFREU that provides the central standard against which the legality of the proposed regime must be examined.

## 1. Scope of Article 16 CFREU and Interference

Article 50 of the Proposal contains three distinct operative measures which engage the freedom to conduct a business guaranteed by Article 16 CFREU. First, Article 50(2) requires notified bodies to grant mandatory fee reductions of at least 50 % for micro enterprises, at least 25 % for small enterprises, and at least 50 % for orphan devices. Secondly, the same

[14] Joined Cases C-402/05 P and C-415/05 P *Yassin Abdullah Kadi and Al Barakaat International Foundation v Council and Commission*, 3 September 2008, ECLI:EU:C:2008:461, para 284.

provision requires notified bodies to grant micro and small enterprises the possibility of deferring payment of fees until the relevant conformity-assessment activity has been finalised. Thirdly, Article 50(6) empowers the authority responsible for notified bodies, where duly justified in the interest of public health or patient health or safety, to instruct a notified body to accept a manufacturer's request for conformity-assessment activities falling within that body's scope of designation.

Each of those measures is, in itself, capable of interfering with entrepreneurial autonomy. The mandatory fee reductions affect the price which a notified body may receive for its services. The payment-deferral requirement affects the timing of remuneration and shifts liquidity pressure and default risk onto the notified body. The compelled-acceptance mechanism affects the notified body's freedom to decide whether it will enter into the relevant contractual relationship at all. All three therefore concern matters which may fall within the protected sphere of Article 16 CFREU.

Taken together, however, those measures do more than create three parallel restrictions. They interact and reinforce one another. The notified body may be required to charge less, to wait longer for payment, and, in certain circumstances, to accept the very engagement which generates those burdens. Their cumulative effect is therefore to restructure the economic terms on which notified bodies must operate in relation to selected categories of manufacturers. In that sense, Article 50 of the Proposal gives rise not only to three individual interferences, but also to a fourth, composite interference formed by the combined operation of all three. That cumulative regime may be particularly intrusive and is liable, in a direct and substantial manner, to interfere with the freedom to conduct a business guaranteed by Article 16 CFREU.

## a) Scope of the Freedom to Conduct a Business

### *(1) Contractual and entrepreneurial autonomy*

Article 16 CFREU provides that "[t]he freedom to conduct a business in accordance with Union law and national laws and practices is recognised."

A central component of that freedom is **freedom of contract**. That follows already from the Explanations relating to Article 16, to which due regard must be given pursuant to Article 52(7) CFREU and Article 6(1), third subparagraph, TEU. Those Explanations state that Article 16 is based on the Court's case-law recognising freedom to exercise an economic or commercial activity and freedom of contract, and on Article 119(1) and (3) TFEU, which recognises free competition. Freedom of contract is thus not external to Article 16. It forms part of its recognised content.

The same point emerges from the general principles of Union law. As Advocate General Kokott observed, contractual freedom predates the Charter and is one of the general principles of Union law. It is rooted in personal freedom of action and inseparably linked to the freedom to conduct a business. In a legal order committed to an open market economy with free competition, contractual freedom must therefore be guaranteed. When exercising public

powers in the economic sphere, the Union institutions must take account of both contractual freedom and the freedom to conduct a business.[15]

The Court of Justice, sitting as Grand Chamber, has itself confirmed, in clear terms, that freedom of contract forms an integral part of Article 16 CFREU. In its own words, the protection afforded by that provision covers "the freedom to exercise an economic or commercial activity, freedom of contract and free competition".[16] It further stated that "the freedom of contract includes, in particular, the **freedom to choose with whom to do business** … and the **freedom to determine the price of a service**".[17] The Court later reiterated the same proposition in substantially identical terms.[18]

That case-law defines the protected scope of Article 16 in concrete terms. It shows, first, that the protected sphere extends to the essential elements of contractual autonomy; secondly, that those elements include the freedom to determine the economic terms of a service relationship; and, thirdly, that the freedom to choose one's counterparty likewise falls within the protected domain. The legal and economic structuring of business relationships is therefore not external to Article 16. It forms part of its core content. That is so even in a sector already characterised by dense regulation. At the level of scope, there can accordingly be no serious doubt that rules concerning remuneration, contractual choice, the economic architecture of service provision, and the legal structuring of market relationships belong, in principle, to the sphere protected by Article 16.

The Court has also made clear that Article 16 is not confined to price-setting and counterparty choice in the narrow sense. It includes "the right for any business to be able to freely use, within the limits of its liability for its own acts, the economic, technical and financial resources available to it".[19] Article 16 therefore protects not merely the formal act of contract formation, but also the undertaking's control over the economic resources through which its business activity is organised and financed. That element of the case-law is of evident importance wherever legislation regulates not only the amount of remuneration, but also the financial framework within which services must be supplied.

The same understanding is reflected in Advocate General Szpunar's analysis. He explained that, although freedom of contract is not expressly named in Article 16, it is clear from the Charter Explanations that it forms a constituent part of the freedom to conduct a business. He further observed that Article 16 codifies the Court's case-law in which freedom of contract had already been recognised as part of EU law.[20] As to its content, he stated that freedom of contract comprises at least the freedoms to conclude a contract, to choose the counterparty, and to determine the content of the contractual relationship, including the amount of the

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[15] Opinion of Advocate General Kokott, Case C-441/07 P *Commission v Alrosa*, 17 September 2009, ECLI:EU:C:2009:555, paras 224 and 225.

[16] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, para 42.

[17] Ibid, at para 43.

[18] Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, para 79; Case C-277/16 *Polkomtel*, 20 December 2017, ECLI:EU:C:2017:989, para 50.

[19] Case C-134/15 *Lidl*, 30 June 2016, ECLI:EU:C:2016:498, para 27; Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, para 78.

[20] Opinion of Advocate General Szpunar, Case C-261/20 *Thelen Technopark Berlin*, 15 July 2021, ECLI:EU:C:2021:620, paras 78 to 80.

mutual prestations and, in particular, the price or remuneration for the other party's services.[21] That analysis accurately articulates the logic already present in the Court's own judgments.

### *(2) Article 16 CFREU as a subjective right*

The distinctive wording of Article 16 ("in accordance with Union law and national laws and practices") does not deprive it of the character of a subjective right. It is true that the Court has emphasised that the freedom to conduct a business "does not constitute an absolute prerogative, but must be viewed in relation to its function in society".[22] It is equally true that the Court has explained that the distinctive wording of Article 16 is reflected "in the way in which Article 52(1) of the Charter requires the principle of proportionality to be implemented".[23] But that means that Article 16 is open to limitation in accordance with Article 52(1) CFREU; it does not mean that the provision is merely programmatic or normatively weak.

On the contrary, the Court consistently treats Article 16 as a **genuine standard of legality**. In *Sky Österreich*, it subjected the legislative arrangement at issue to a full Charter analysis under Articles 16 and 52(1) CFREU.[24] In *Polkomtel*, it held that a requirement to update prices annually and to submit them for prior verification constituted an "interference in the exercise of the right guaranteed by Article 16 of the Charter", and therefore had to satisfy Article 52(1) CFREU.[25] In *Bank Melli Iran*, the Court again treated Article 16 as a right requiring structured review under Article 52(1), including the conditions of legal basis, essence, legitimate objective and proportionality.[26] That line of authority leaves no room for the suggestion that Article 16 is merely decorative or of reduced normative force.

Advocate General Szpunar expressly drew the same conclusion. He stated that the wording of Article 16 "does not imply either a reduction in the level of protection guaranteed by that right or that it has the status of a principle or of a 'second-class' right".[27] The reference in Article 16 to Union law and national laws and practices therefore concerns the regulatory setting within which the right is exercised; it does not strip the right of its status as a right. On the contrary, the principle of freedom of contract acquires a constitutional dimension through Article 16 CFREU.

That point matters here because notified bodies are **private, profit-oriented undertakings** operating within a Union regulatory framework. They are not public authorities. As such, they may rely on Article 16 where Union legislation affects their protected legal sphere. In their case, that sphere is not exhausted by a general liberty to remain economically active. It includes, more concretely, the legal and economic conditions under which they organise the provision of their services, the structuring of remuneration, the use of their financial resources, and the terms on which contractual relationships are formed and maintained. That is sufficient, at the level of scope, to bring the present legislative setting within the ambit of

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[21] Ibid, paras 82 and 83.

[22] Case C-277/16 *Polkomtel*, 20 December 2017, ECLI:EU:C:2017:989, para 50; see also Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, para 80.

[23] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, paras 46 and 47.

[24] Ibid, paras 41 to 66.

[25] Case C-277/16 *Polkomtel*, 20 December 2017, ECLI:EU:C:2017:989, paras 50 to 55.

[26] Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, paras 77 to 91.

[27] Opinion of Advocate General Szpunar, Case C-261/20 *Thelen Technopark Berlin*, 15 July 2021, ECLI:EU:C:2021:620, para 89.

Article 16, without prejudging the analytically distinct question whether the specific mechanisms under consideration amount to a limitation of that right.

That conclusion is consistent, by analogy, with the Court's reasoning in the pharmacy field. In *Apothekerkammer des Saarlandes*, the Grand Chamber expressly proceeded on the basis that even an operator entrusted with a public-health function remains an economic actor pursuing profit; it observed that a pharmacist, "like other persons", pursues "the objective of making a profit", even though that interest is tempered by professional training, experience and responsibility.[28] The judgment therefore confirms that regulatory integration into a public-interest framework does not, as such, deprive a private undertaking of its economic character or of the relevance of its own commercial interests.

At the same time, the Court's insistence that Article 16 must be viewed in relation to its **social function** should not be misunderstood in a one-sided way. One aspect of that social function undoubtedly lies in the fact that entrepreneurial activity is carried on within a regulated economic order and may therefore be subject to extensive regulation in the public interest. But the social function of Article 16 does not consist solely in its openness to regulation. It also lies in the role of the freedom to conduct a business as a legal guarantee of market-based economic autonomy. In that sense, the provision both permits regulation and protects the entrepreneurial freedom that regulation presupposes. The task is therefore one of balance, not of simple subordination.

### *(3) Article 16 CFREU and free competition*

The Court's interpretation of Article 16 extends beyond contractual autonomy in the narrow sense and encompasses the dimension of free competition. That aspect is of particular importance in the present context. Competition is not merely one policy objective among others within the Union legal order. It is one of the structural principles on which that order is built. This is reflected, inter alia, in the allocation of competences under Article 3(1)(b) TFEU, in the internal-market objective set out in Article 3(3) TEU, and in Article 119(1) TFEU, which commits the Economic and Monetary Union to an open market economy with free competition. The Explanations relating to Article 16 expressly refer, among other provisions, to Article 119 TFEU. The freedom protected by Article 16 must therefore be understood within that constitutional setting.[29]

The significance of the Court's case-law lies in the fact that it does not treat free competition merely as an objective principle of the Treaties. Within the context of Article 16 CFREU, the Court gives it a **rights-related dimension**. Entrepreneurial freedom is thus not confined to the abstract liberty to pursue an economic activity; it also includes participation in a competitive market order. In that sense, Article 16 has not only an individual-autonomy dimension, but also a structural market dimension.[30]

That broader dimension should not be understated. In Union law, contractual freedom does not operate in a vacuum. It is embedded in the wider constitutional framework of the internal market and of an open market economy with free competition. The connection is explicit in

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[28] Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others*, 19 May 2009, ECLI:EU:C:2009:316, para 37.

[29] *Kühling & Drechsler* in Pechstein et al GRCh Art. 16 para 17.

[30] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, para 42; Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, para 79.

the Treaties themselves and is reflected in the Explanations to Article 16. It follows that the freedom protected by Article 16 is not merely a private-law freedom in isolation. It is also a market freedom: a freedom to act, compete, negotiate, and structure one's economic relations within a competitive order.

This has analytical consequences for the later stages of the examination. If Article 16 encompasses participation in a competitive market order, then the right cannot be interpreted as if its internal logic were one of preferential legal protection for selected market actors. The principle of competition protected through Article 16 is directed, in essence, towards **participation on market terms**. That does not make targeted support for small and medium-sized enterprises or for other favoured categories legally impossible. Union law may plainly pursue objectives such as innovation, device availability, or the support of SMEs. But once Article 16 is understood as having a free-competition dimension, it follows that support for one class of market actors cannot simply be treated as self-justifying from the internal perspective of Article 16 itself. Rather, where the legislature seeks to benefit one class of market participants by imposing corresponding burdens on another, narrower class of private undertakings, that distributive choice calls for particular care at the later stages of justification and proportionality.

That is why the free-competition dimension of Article 16 must remain fully visible from the outset. It informs the normative weight of entrepreneurial freedom and helps explain why legal measures that selectively reallocate economic burdens and advantages within a market cannot be analysed solely in terms of ordinary regulatory discretion. If the right protected by Article 16 includes participation in a competitive market order, then measures which reshape the competitive conditions under which a small class of private undertakings must operate are capable of engaging the right in a particularly direct way. That is especially so where several mechanisms (such as mandatory fee reductions, mandatory payment deferrals and mechanisms to accept requests from SMEs) operate in combination and thereby alter not merely one bilateral contractual term, but the broader legal and economic setting in which competition takes place. At this stage, the point is that such arrangements fall within the conceptual horizon of Article 16; the separate question whether, and with what intensity, they interfere with the right belongs to the next subsection.

The same understanding is consistent with the broader constitutional role of contractual freedom within Union law. As Advocate General Szpunar observed, freedom of contract underpins the operation of the Union legal order, above all in the context of the fundamental freedoms. The internal market and the commitment to a highly competitive social market economy would be difficult to conceive without it.[31] The protection of contractual freedom under Article 16 must therefore be understood not in isolation, but in light of the competitive market framework in which that freedom operates.

For present purposes, three propositions follow. First, Article 16 protects **freedom of contract** and the essential legal and economic terms of entrepreneurial activity. Secondly, it does so as a **genuine subjective right**, not merely as a programmatic principle. Thirdly, it includes a **free-competition dimension**, with the consequence that entrepreneurial freedom must be understood not only as individual autonomy, but also as participation in a competitive

[31] Opinion of Advocate General Szpunar, Case C-261/20 *Thelen Technopark Berlin*, 15 July 2021, ECLI:EU:C:2021:620, paras 76 and 80.

market order. That is the framework within which the question of interference must now be examined.

## b) Serious Interferences with Article 16 CFREU

Having identified the content and scope of the freedom to conduct a business guaranteed by Article 16 CFREU, the next question is whether Article 50 of the Proposal interferes with that freedom and, if so, with what intensity. That question must be addressed in a differentiated manner. The Proposal does not affect entrepreneurial freedom in only one respect. It concerns, first, the price which notified bodies may charge for conformity-assessment activities; secondly, the time at which payment for those activities may be required and the corresponding allocation of liquidity and default risk; thirdly, the freedom of notified bodies to decide whether they will enter into a contractual relationship at all; and, finally, the cumulative legal and economic effect of those three mechanisms taken together.

The Court's case-law makes clear that measures affecting those matters fall within the notion of an interference with Article 16 CFREU. The Court has held that the protection afforded by Article 16 covers "the freedom to exercise an economic or commercial activity, freedom of contract and free competition".[32] It has further stated that the freedom of contract includes, in particular, "the freedom to choose with whom to do business" and "the freedom to determine the price of a service".[33] The Court has also recognised that Article 16 protects "the right for any business to be able to freely use, within the limits of its liability for its own acts, the economic, technical and financial resources available to it".[34] Finally, the Court expressly held that the possibility for a regulatory authority to require an operator to update its prices annually and to submit them for periodic monitoring constitutes an "interference in the exercise of the right guaranteed by Article 16 of the Charter".[35] Against that background, each of the four interferences must be examined separately.

### *(1) Mandatory fee reductions*

The first interference lies in the mandatory fee reductions laid down in the first and second sentences of Article 50(2) of the Proposal. Those provisions require notified bodies to grant at least a 50 % reduction for micro enterprises, at least a 25 % reduction for small enterprises, and at least a 50 % reduction in the case of orphan devices. The measure therefore does not merely regulate the environment in which notified bodies operate. It directly determines a central element of the service relationship itself, namely the remuneration which notified bodies may receive for conformity-assessment activities.

That constitutes an interference with Article 16 CFREU in a particularly **direct** sense. The Court has expressly recognised that the freedom protected by Article 16 includes the freedom

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[32] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, para 42.

[33] Ibid, para 43; Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, para 79.

[34] Case C-134/15 *Lidl*, 30 June 2016, ECLI:EU:C:2016:498, para 27; Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, para 78.

[35] Case C-277/16 *Polkomtel*, 20 December 2017, ECLI:EU:C:2017:989, paras 50 to 55.

to determine the price of a service.[36] In *Sky Österreich*, the Court held that Article 16 was interfered with because the holder of exclusive rights could not "decide freely on the price to be charged".[37] The same logic applies here with even greater force. The Proposal does not merely limit the circumstances in which notified bodies may set prices, nor does it simply subject their prices to ex post supervision. It requires them, by force of law, to surrender a fixed share of the remuneration otherwise payable for their services.

The Court's judgment in *Polkomtel* is instructive by comparison. There, the Court held that a requirement to update prices annually and to submit them for prior regulatory verification already constituted an interference with Article 16 CFREU.[38] The mechanism at issue here goes substantially further. It does not merely subject prices to review or control. It compels the undertaking to reduce them by law. The interference is therefore qualitatively more intrusive than the regulatory arrangement considered in *Polkomtel*. It does not leave pricing autonomy formally intact while surrounding it with supervision; it directly displaces it.

The intensity of that interference is **considerable**. First, the percentages are high in absolute terms. A compulsory reduction of 25 % or 50 % is not a marginal adjustment, but a very substantial diminution of the remuneration otherwise payable for the service. Secondly, the effect is amplified by the breadth of the categories covered. The Proposal is directed in particular at micro and small enterprises, which account for the overwhelming majority of undertakings in the medical-device sector: the Commission itself proceeds on the basis that SMEs constitute around 90 % of the relevant sector, the majority of them being micro and small enterprises.[39] The practical significance of the measure is therefore not confined to a narrow subset of exceptional cases. It reaches a very large portion of the market in which notified bodies operate. A measure of that kind cannot plausibly be described as a minor limitation on entrepreneurial freedom.

The interference is aggravated by the way in which the Proposal is framed. The mandatory reductions of 25 % and 50 % are not linked to any discernible methodology based on the actual costs of the relevant conformity-assessment activity. They are fixed as abstract percentages and apply irrespective of the complexity of the file, the resource intensity of the assessment, the staffing and expertise required, the overheads associated with the notified body's activity, or the investment made by the notified body in maintaining designation and carrying out the procedure. The practical consequence is obvious: the mandatory reduction may well exceed the undertaking's profit margin and may therefore force notified bodies to perform conformity-assessment activities on terms that are not merely less profitable, but insufficient even to cover their costs. The interference is therefore not only weighty in economic effect; it is also crude in legal design. It is imposed in flat-rate terms and **detached from the actual cost burden** borne by the undertaking required to absorb it.

That matters for intensity. The interference with Article 16 is more serious where the legal rule does not merely limit commercial discretion in a calibrated way, but severs the normal connection between the remuneration for a service and the economic burden of providing it. The Proposal does exactly that. It does not require a notified body to justify its fees by reference to objective criteria, nor does it merely set a ceiling by reference to a cost-based methodology. It requires the notified body to provide a significant part of its service at a

[36] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, para 43; Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, para 79.

[37] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, para 44.

[38] Case C-277/16 *Polkomtel*, 20 December 2017, ECLI:EU:C:2017:989, paras 50 to 55.

[39] Proposal, COM(2025) 1023 final (supra note 1), at 1.

discount whose level is fixed independently of the cost of the activity in question. This goes well beyond ordinary price regulation. It amounts to a **legally mandated transfer** of part of the economic burden of certification from the protected manufacturer to the notified body.

Nor can it be assumed that the notified body will remain free to offset that burden elsewhere by autonomous pricing decisions. Article 50(3) of the Proposal empowers the Commission, in consultation with the MDCG, to adopt implementing acts specifying the structure and level of the fees. That means that the Proposal does not merely impose mandatory rebates while otherwise leaving notified bodies free to reorganise their fee structure. On the contrary, it subjects the broader structure and level of fees to regulatory determination. In those circumstances, notified bodies cannot assume that they will remain free to offset the losses resulting from the mandatory rebates by increasing fees in other parts of their activity. The interference with pricing autonomy is therefore **not only immediate, but also systemic**. It deprives notified bodies not merely of a portion of their remuneration, but of the ordinary market-based means by which such losses might otherwise be absorbed.

Recital 28 of the Proposal reinforces that conclusion. By preserving the potential application of Articles 101 and 102 TFEU to notified bodies' price-setting and economic activities, the Proposal itself recognises that the fees at issue form part of the economic conduct of private undertakings. Article 50(3) therefore concerns a competitive price parameter, not merely the technical presentation of administrative information.

Similarly, Article 50(3) does not correct the problem that the level of the reduction is entirely independent of the actual investments and costs associated with the relevant conformity-assessment activity. The criteria to which the Commission must have regard when specifying the structure and level of fees are: (a) the establishment and maintenance of high standards of quality and safety of devices; (b) the availability of devices; (c) the protection of the interests of micro, small and medium-sized enterprises; and (d) the support of innovation and competitiveness. The provision does not require the Commission to take account of the costs incurred by notified bodies, their economic viability, or their interest in cost recovery. For that reason, the implementing power conferred by Article 50(3) cannot remedy the underlying defect. It provides no basis on which the Commission could compensate, in any meaningful sense, for the notified bodies' loss of their freedom to determine the price of their services.

For those reasons, the mandatory fee reductions in Article 50(2) must be characterised as a **serious interference** with Article 16 CFREU. They directly affect the notified body's freedom to determine the price of its services; they do so by imposing significant fixed reductions across a broad part of the market; and they do so without any meaningful cost-based calibration.

### *(2) Mandatory payment deferral*

The second interference lies in the requirement that notified bodies provide micro and small enterprises with the possibility to defer payment of fees until the relevant conformity-assessment activity has been finalised. This measure differs from the first in one important respect: it does not reduce the nominal amount of the fee. Its target is not the level of remuneration, but the time at which remuneration becomes due. Even so, it interferes with Article 16 CFREU in an independent and serious way.

That is so because the time of payment forms part of the legal and economic structure of the service relationship. The Court has made clear that Article 16 protects not only contractual

choice and price, but also the undertaking's right freely to use its economic, technical and financial resources.[40] A rule which obliges a notified body to provide its service first and to receive payment only at the end of the procedure affects exactly that dimension of entrepreneurial freedom. It constrains the undertaking's ability to structure the financial conditions of its activity and to deploy its resources according to its own commercial judgment.

The interference is again **direct**. The payment-deferral requirement is not simply a background factor that might, as a matter of economic reality, influence cash flow. It is a legal obligation to carry the financing burden of the conformity-assessment procedure for a longer period than the undertaking would otherwise choose. The notified body must, in substance, extend liquidity to the manufacturer until the relevant activity has been finalised. It must therefore absorb the time-gap between performance and payment from its own resources.

That affects the undertaking in several distinct ways. First, it places **liquidity pressure** on the notified body by postponing the inflow of funds which would otherwise finance the performance of the service. Secondly, it shifts **financing costs** onto the notified body, because the undertaking must carry the value of the deferred payment during the intervening period. Thirdly, it increases exposure to **credit and default risk**. If payment is pushed to the end of the process, the notified body bears the risk that recovery may become more difficult, that the commercial position of the manufacturer may deteriorate, or that payment disputes may arise only after the service has been largely or entirely performed. In economic terms, the deferred-payment mechanism therefore transforms the service relationship into one that is materially more burdensome and materially more risky for the notified body.

This is not a trivial modification of contract administration. It is a legal displacement of a part of the financial burden of certification. The manufacturer's immediate liquidity burden is reduced; the notified body's financing burden is increased. The economic significance of that shift is especially clear in a regulatory setting where conformity assessment is resource-intensive, where staff and expertise must be maintained over time, and where cash-flow predictability matters to the viability of the undertaking. A rule of deferred payment therefore affects not merely one incidental contractual detail, but the financial architecture of the business relationship itself.

The intensity of the interference is further increased by the fact that the Proposal does **not** attach **any compensatory mechanism** to the deferral. There is no statutory interest, no public guarantee, no escrow mechanism, and no reimbursement of the financing costs thereby imposed on notified bodies. The notified body must bear the burden from its own resources. The resulting effect is that the undertaking is not merely asked to tolerate a later payment date; it is required to finance, without compensation, a part of the manufacturer's regulatory access costs.

The Court's case-law confirms that an interference with Article 16 need not take the form of a prohibition on carrying on business as such. It is sufficient that the legal measure materially constrains the undertaking's control over the essential financial conditions of its activity. That is plainly the case here. The payment-deferral requirement therefore constitutes a **serious interference** with Article 16 CFREU. It directly affects the notified body's control over the

[40] Case C-134/15 *Lidl*, 30 June 2016, ECLI:EU:C:2016:498, para 27; Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, para 78.

financial conditions of service provision, the use of its own resources, and the allocation of financing and credit risk within the contractual relationship.

The seriousness of that interference is reinforced by a further consideration internal to the MDR itself. Article 53(5) MDR and Article 49(5) IVDR provide that notified bodies and their personnel "shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities". The payment-deferral mechanism sits uneasily with that requirement. By obliging notified bodies to carry the financing burden of the conformity-assessment process until completion, it is capable of generating precisely the kind of financial pressure from which Article 53(5) seeks to shield them. The point is not that every deferred payment will in fact distort an assessment. The point is more structural: where a notified body must perform a resource-intensive assessment without receiving payment until the end of the procedure, its economic exposure to delay, non-payment, and loss increases. That exposure may create incentives, at least at the margins, to accelerate procedures, to favour files likely to be completed and paid more quickly, or to manage assessments under a form of liquidity pressure that Article 53(5) MDR and Article 49(5) IVDR appear designed to exclude. A legislative regime which itself creates financial pressure on notified bodies therefore does not merely burden their entrepreneurial freedom under Article 16 CFREU; it also risks undermining the institutional logic of Article 53(5) MDR and Article 49(5) IVDR, which assume that conformity assessment must be carried out under conditions of financial independence from precisely such pressure.

The same point is supported, by analogy, by the Court's judgment in *Apothekerkammer des Saarlandes*. There, the Grand Chamber accepted that, in a public-health field, the law may seek to ensure that the relevant activity is carried out under conditions of "genuine professional independence" and may adopt measures capable of eliminating or reducing the risk that such independence will be prejudiced, because that would affect the reliability and quality of the service provided.[41] The Court further recognised that private operators remain influenced by the pursuit of profit and that economic incentives may matter for the independence with which a regulated public-interest function is exercised.[42] By the same logic, a Union measure which itself generates liquidity pressure and payment-related risk for notified bodies cannot be treated as neutral from the standpoint of independence. On the contrary, it creates the very type of economically induced pressure from which Article 53(5) MDR and Article 49(5) IVDR seek to protect the conformity-assessment process.

For that additional reason, the payment-deferral mechanism should be regarded as a **particularly serious interference**.

### *(3) Compelled acceptance of requests*

The third interference lies in Article 50(6), which empowers the authority responsible for notified bodies, where duly justified in the interest of public health or patient health or safety, to instruct a notified body to accept a manufacturer's request for conformity-assessment activities falling within that body's scope of designation.

That mechanism interferes with Article 16 CFREU because it affects negative contractual freedom, that is, the freedom *not* to conclude a contract. The Court has expressly identified

[41] Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others*, 19 May 2009, ECLI:EU:C:2009:316, para 35.

[42] Ibid, paras 37, 39 and 40.

the freedom to choose with whom to do business as part of the freedom of contract protected by Article 16.[43] That proposition necessarily includes the freedom not to enter into a contractual relationship where the undertaking does not wish to do so. A power conferred on a public authority to compel a private undertaking to accept a contractual request therefore strikes directly at one of the core elements of entrepreneurial autonomy.

The seriousness of the interference should not be understated. Article 50(6) does not merely oblige notified bodies to deal with requests or to respond within a certain time. That is already addressed separately in Article 50(5). Article 50(6) goes further: it authorises the competent authority to override the notified body's own decision on whether the requested conformity-assessment activity will be taken on at all. In substance, it displaces the undertaking's own commercial and organisational judgment and substitutes a public decision for it.

That is a severe intrusion into negative contractual freedom. The notified body may have good reasons—commercial, organisational, capacity-based, or risk-based—for declining a particular request. It may, for example, regard the file as economically unattractive, operationally difficult, or incompatible with the efficient management of its resources. When notified bodies refuse conformity assessment procedures for manufacturers, this is usually because they have already exhausted their capacity or because the manufacturer does not sufficiently meet the requirements of the MDR or IVDR. Even a procedure following an instruction by the authority responsible for the notified body would then fail. The MDR and the IVDR already contain provisions for such products in Articles 59 and 54 respectively. Even so, Article 50(6) allows the authority, in the circumstances specified, to compel the undertaking to accept that request nonetheless. The notified body is therefore no longer master of the basic decision whether the contractual relationship comes into existence.

This is not altered by the fact that the notified body operates in a regulated field and performs a public-interest function. That context is undoubtedly relevant to later justification. But at the level of interference, the decisive point is simpler: the Proposal removes from the notified body, at least in certain circumstances, the freedom to refuse a contractual engagement. Measured against the Court's case-law in *Sky Österreich* and *Bank Melli Iran*, that is a **direct** interference with one of the paradigmatic incidents of Article 16 CFREU.

Its intensity is increased by the practical significance of the decision whether to refuse or accept a file. The choice whether to enter into a conformity-assessment engagement is not merely symbolic. It is one of the few remaining market-based means by which a notified body can protect itself against economically disadvantageous, operationally overburdensome, or strategically unsuitable transactions. Once that choice is removed or narrowed by public compulsion, the notified body loses a central instrument of entrepreneurial self-organisation.

The seriousness of the interference becomes still more apparent once the measure is viewed in institutional terms. So far as can be seen, Union conformity-assessment law contains no close example of a private, for-profit notified body or conformity-assessment body being placed under a statutory duty to enter into a certification contract with an applicant. On the contrary, the existing MDR/IVDR architecture presupposes a consensual contractual relationship, while access problems in exceptional cases are addressed, if at all, through **public-law mechanisms operated by competent authorities**, notably the derogation regimes in Articles 59 MDR and 54 IVDR, rather than through a duty to contract imposed on private notified bodies. By

[43] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, para 43; Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, para 79.

contrast, EU law does recognise duties to deal for private undertakings in other fields, but those examples are categorically different. In **competition law**, such duties arise only exceptionally, above all for dominant undertakings controlling an indispensable facility or input, and only under very strict conditions.[44] In **sectoral regulation**, comparable duties are imposed ex ante on operators of regulated networks or infrastructures, such as private telecom undertakings; thus, in *Polkomtel*, the Court treated price-control and access-related obligations imposed on a private telecom operator as an interference with Article 16 CFREU[45]. Those regimes, however, concern dominance, bottleneck control, or network regulation. They do not provide a genuine precedent for compelling private notified bodies, in the ordinary conduct of conformity assessment, to conclude contracts with manufacturers.

In the pharmaceutical regime, by contrast, EMA is required to deal with applications and requests falling within its statutory remit because it is a **public authority** entrusted by Union law with the administration of a regulatory authorisation system. Any obligation to entertain such procedures is therefore a **public-law procedural duty** attached to the exercise of public functions. Notified bodies, by contrast, are not public authorities, but private, for-profit undertakings operating in a market environment. If Article 50(6) nevertheless empowers the competent authority to require them to accept a manufacturer's request, the Proposal treats them, in that respect, like public administrative bodies while leaving them economically in the position of private market actors.

The Court's reasoning in *Apothekerkammer des Saarlandes* also points in the same direction. It accepted that, in a highly regulated health sector, the law may protect professional independence against external economic influence because such influence may affect the reliability and quality of the service provided.[46] In particular, the Court considered that external operators driven by profit may compromise the independence of the relevant professionals by encouraging conduct shaped by commercial rather than professional considerations.[47] By analogy, a mechanism under which the competent authority may override a notified body's own judgment whether it can responsibly take on a file risks subjecting conformity assessment to an external pressure incompatible with the idea of genuinely independent professional assessment. That is especially so where the compelled engagement is combined with mandatory rebates and deferred payment.

That is precisely what makes the **interference particularly serious**: quasi-public duties are imposed, but without the institutional status, public financing, or public-law framework that would ordinarily accompany such duties.

### *(4) The cumulative interference*

The three mechanisms just analysed must not, however, be viewed in isolation only. Their combined operation gives rise to a further, distinct interference of its own. This fourth interference must be explained directly and separately.

The first mechanism changes the amount the notified body receives: the protected manufacturer pays less, while the notified body receives less for the same conformity-

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[44] Case C-7/97 *Oscar Bronner*, 26 November 1998, ECLI:EU:C:1998:569, paras 41 and 46.

[45] Case C-277/16 *Polkomtel*, 20 December 2017, ECLI:EU:C:2017:989, paras 50 to 55.

[46] Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others*, 19 May 2009, ECLI:EU:C:2009:316, paras 35, 39 and 40.

[47] Ibid, paras 39 and 40.

assessment activity. The second mechanism changes the time at which payment is made: the protected manufacturer pays later, while the notified body must finance the time-gap and bear the associated liquidity and default risk. The third mechanism reduces the notified body's ability to protect itself against the resulting burden by declining the request. Read together, the three measures therefore produce a cumulative shift in the economic and legal structure of the service relationship. The protected manufacturer pays less and later; the notified body receives less, receives later, bears greater risk, and may in some cases be prevented from refusing the engagement.

That cumulative effect is not exhausted by adding together the three individual interferences. It creates a fourth, composite interference of a different quality. What is affected is no longer only one contractual parameter at a time. The Proposal **restructures the economic terms** on which notified bodies must operate in relation to selected categories of manufacturers. It touches price, timing of remuneration, allocation of financial risk, contractual accessibility, and, through all of those together, the conditions on which notified bodies participate in the certification market.

That is why the combined operation of the three mechanisms must be treated separately. The Court's case-law recognises that Article 16 protects contractual freedom, the use of financial resources, and free competition.[48] Once the three components of Article 50 are read together, all of those protected elements are engaged simultaneously. The notified body is no longer simply a private undertaking operating in a regulated market. It is required, in substance, to **internalise part of the regulatory burden** which the legislature seeks to lift from protected manufacturers.

The economic and legal consequence is a **burden shift**. The Proposal does not merely provide support to SMEs, small manufacturers, and orphan-device applicants through public means. It finances part of that support by reallocating the burden of certification to notified bodies. The protected manufacturer pays less; the notified body receives less. The protected manufacturer may pay later; the notified body must carry the financing burden and the associated default risk. The protected manufacturer may, in certain circumstances, insist on access notwithstanding the notified body's contrary preference; the notified body loses the ability to avoid the transaction that generates those burdens. The combined mechanism therefore effects a transfer of cost, timing risk, and contractual disadvantage away from selected manufacturers and onto notified bodies.

This cumulative effect is especially grave because notified bodies remain private, for-profit undertakings. They are not public authorities financed from public funds. It is, of course, true that notified bodies do not provide purely private services. They form part of a regulatory system established by Union law: they act on the basis of EU legislation, their decisions condition the market access of products and manufacturers, and they are subject to designation, accreditation and supervision by public authorities. Even so, they are not themselves public authorities. They remain private, for-profit undertakings operating in competition with one another and competing for manufacturers' contracts. That institutional design serves identifiable regulatory purposes, above all efficiency and specialisation. It reflects a deliberate legislative choice to integrate private undertakings, rather than public authorities, into the conformity-assessment framework; in that sense, it is an instance of functional privatisation. Yet the combined operation of Article 50 tends to push them towards

[48] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, para 42; Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, paras 78 and 79.

a **role more characteristic of public service providers**: they must absorb revenue losses, carry financing and default risks, and in some circumstances accept the engagement notwithstanding those burdens. What remains private is the undertaking's exposure to loss and risk; what becomes quasi-public is the burden it is required to carry in the general interest.

That point bears directly on the intensity of the interference. The Proposal does not merely regulate notified bodies from outside. It tends, in substance, to transform the economic logic under which they operate. They are no longer treated simply as market actors functioning within a regulated framework in the public interest. They are required to assume burdens characteristic of public authorities while remaining private undertakings and while bearing those burdens from their own resources. The effect is to narrow, in a cumulative and systemic way, the space for genuinely market-based conduct.

At this point, the free-competition dimension of Article 16 also becomes visible in the interference analysis. The combined regime does not merely affect isolated bilateral relationships. It reallocates burdens within the market for conformity assessment in favour of selected classes of manufacturers, above all SMEs and orphan-device applicants. That does not yet decide whether the measure is justified. But it does show why the cumulative mechanism amounts to more than a set of isolated restrictions. It reshapes the competitive conditions under which notified bodies operate by requiring them, as a class, to absorb burdens from which other actors are relieved.

For those reasons, the cumulative operation of Article 50 must be characterised as a fourth, composite interference with Article 16 CFREU. It is not merely serious. It is the **most serious** of the four. It is here that the full weight of the Proposal becomes visible: the notified body may be required to charge less, to wait longer for payment, and, in certain circumstances, to accept the very engagement that generates those burdens. The resulting regime is a heavy and systemic intrusion into entrepreneurial autonomy.

### *(5) Conclusion on interference*

Each of the three operative mechanisms contained in Article 50 constitutes, taken on its own, a serious interference with Article 16 CFREU. The mandatory fee reductions seriously interfere with pricing autonomy. The mandatory payment deferral seriously interferes with the undertaking's control over the financial conditions of its activity and the use of its resources. The compelled-acceptance mechanism seriously interferes with negative contractual freedom. Their combined operation gives rise to a fourth, composite interference which is graver still, because it restructures the economic and legal terms on which notified bodies must operate in relation to selected categories of manufacturers and alters the competitive setting in which they do so.

The conclusion for the purposes of the present subsection is therefore clear: Article 50 of the Proposal entails not minor or peripheral limitations, but **serious interferences** with the freedom to conduct a business guaranteed by Article 16 CFREU.

# 2. Justification under Article 52(1) CFREU

Having established that Article 50 of the Proposal gives rise to four serious interferences with the freedom to conduct a business guaranteed by Article 16 CFREU—three individual interferences and, in addition, a fourth, composite interference resulting from their cumulative operation—the next question is whether those interferences satisfy the conditions of justification laid down in Article 52(1) CFREU.

## a) Governing Criteria and Intensity of Review

The first step is to identify the legal criteria which govern the justification of the interferences described above.

Those criteria are laid down in Article 52(1) CFREU. Any limitation on the exercise of rights and freedoms recognised by the Charter must be provided for by law, must respect the essence of the right concerned, and, subject to the principle of proportionality, must be necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others. The Court has expressly applied that structure to interferences with Article 16 CFREU.[49]

As regards proportionality in particular, the Court's settled case-law proceeds on a familiar tripartite basis. The measure must be suitable to attain the legitimate objective pursued; it must not go beyond what is necessary for that purpose; and the disadvantages caused must not be disproportionate to the aims pursued. Where several appropriate measures are available, recourse must be had to the least onerous one.[50]

The intensity with which that standard is to be applied is not uniform. In the present case, it is influenced, in particular, by four factors: first, the nature of the subjective right affected; secondly, the nature and weight of the objectives pursued; thirdly, the seriousness of the interferences identified above; and fourthly, the regulatory field in which the Proposal operates.

### *(1) Nature of the right affected*

The first relevant factor is the nature of the right with which the Proposal interferes. The right at issue is the freedom to conduct a business guaranteed by Article 16 CFREU. As already explained above, that provision is a genuine subjective right and a proper standard of legality. At the same time, the Court has consistently emphasised that it is not absolute. It "does not constitute an absolute prerogative, but must be viewed in relation to its function in society" and, by reason of its wording, it "may therefore be subject to a broad range of interventions on the part of public authorities which may, in the public interest, limit the exercise of economic

[49] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, paras 46 to 48; Case C-277/16 *Polkomtel*, 20 December 2017, ECLI:EU:C:2017:989, para 51; Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, paras 81 to 83.

[50] Case C-58/08 *Vodafone and Others*, 8 June 2010, ECLI:EU:C:2010:321, para 51.

activity".[51] That specific characteristic of Article 16 is reflected, as the Court has itself said, "in the way in which Article 52(1) of the Charter requires the principle of proportionality to be implemented".[52]

The legal consequence is therefore not that Article 16 is weakly protected, but that its protection must be worked out through a context-sensitive proportionality inquiry. The Court does not treat entrepreneurial freedom in the same way as if it were a right admitting almost no legislative interference. But neither does it relegate Article 16 to the status of a merely programmatic principle. The right remains **fully reviewable** under Article 52(1) CFREU; the point is simply that, because of its subject matter and wording, a relatively broad space for legislative regulation must be acknowledged from the outset.[53]

### *(2) Weight of the objectives pursued*

The second relevant factor is the nature and weight of the objectives pursued by the contested measure. Here, two elements matter in particular.

First, the Proposal forms part of an internal-market harmonisation measure. In that setting, the Union legislature enjoys a broad discretion as regards the method of approximation. The Court has held that, by using the expression "measures for the approximation" in Article 114 TFEU, the authors of the Treaty intended to confer on the legislature "a discretion, depending on the general context and the specific circumstances of the matter to be harmonised, as regards the method of approximation most appropriate for achieving the desired result, in particular in fields with complex technical features".[54] The Court has likewise confirmed that, in such areas, the Union legislature must be allowed a broad discretion where its action involves political, economic and social choices and requires complex assessments and evaluations.[55]

Secondly, the Proposal also pursues objectives connected with public health and the availability and safety of medical devices. That considerably increases the normative weight of the aims invoked by the Commission. The Court has repeatedly stressed the high rank of health protection in Union law. Article 114(3) TFEU "explicitly requires" that, in achieving harmonisation, "a high level of protection of human health should be guaranteed", and Article 168(1) TFEU likewise requires that such a high level of protection be ensured in the definition and implementation of Union policies and activities.[56] The Court has further made clear that, provided the conditions for recourse to Article 114 TFEU are otherwise satisfied, the Union

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[51] Case C-277/16 *Polkomtel*, 20 December 2017, ECLI:EU:C:2017:989, para 50; Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, paras 80 and 81, referring back to Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, para 46.

[52] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, para 47; Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, para 82.

[53] Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, paras 81 to 83.

[54] Case C-217/04 *United Kingdom v Parliament and Council*, 2 May 2006, ECLI:EU:C:2006:279, para 43, as quoted in Case C-58/08 *Vodafone and Others*, 8 June 2010, ECLI:EU:C:2010:321, para 35.

[55] Case C-58/08 *Vodafone and Others*, 8 June 2010, ECLI:EU:C:2010:321, para 52.

[56] Case C-210/03 *Swedish Match*, 14 December 2004, ECLI:EU:C:2004:802, para 46; Case C-380/03 *Germany v Parliament and Council*, 12 December 2006, ECLI:EU:C:2006:772, para 40.

legislature "cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made".[57]

That means that the objectives pursued here are **weighty** in two senses at once. They concern both the functioning of the internal market and the protection of health. Each of those fields, taken separately, already tends to support a relatively broad legislative margin of appreciation. Where both are engaged simultaneously, the argument for according the Union legislature substantial room for assessment becomes correspondingly stronger.

### *(3) Seriousness of the interferences*

The third factor is the seriousness of the interferences with Article 16 CFREU. This factor points in the opposite direction.

The analysis set out above has already shown that Article 50 does not contain a minor or isolated restriction. It contains three serious interferences—mandatory fee reductions, mandatory payment deferral, and compelled acceptance of requests—and, beyond them, a fourth, composite interference resulting from their cumulative operation. Those mechanisms affect core elements of entrepreneurial freedom: the freedom to determine the price of a service, the financial conditions and timing of remuneration, the allocation of liquidity and default risk, the freedom to choose one's contractual counterparties, and the broader competitive conditions under which notified bodies operate. The seriousness of the interferences found above necessarily bears on the intensity of review to be applied here.

The Court's case-law confirms that broad legislative discretion does not have the effect of neutralising rights-based review. Even where the public authority enjoys substantial room for manoeuvre, that discretion "may not have the effect of undermining the rights granted to individuals" by the Treaty provisions in which their fundamental freedoms are enshrined.[58] In other words, the more serious the interference, the less persuasive it becomes to invoke legislative discretion in the abstract as though that, by itself, resolved the problem.

In the present case, the seriousness of the interferences therefore requires a correspondingly **careful proportionality assessment**. That does not mean that the Court would abandon the deference which is ordinarily shown in complex regulatory fields. It does mean, however, that the review cannot remain at a merely formal level. A measure which seriously affects pricing autonomy, contractual freedom, financial independence and market-based operation calls for far more than perfunctory scrutiny.

### *(4) Regulatory context and legislative discretion*

The fourth factor is the regulatory field in which the Proposal operates. First, since that field confers a broad discretion on the legislature or administration, judicial review is necessarily more restrained. The Court has repeatedly emphasised that, in such fields, it is not the function of the judiciary to displace the policy choices of the legislature merely because

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[57] Case C-380/03 *Germany v Parliament and Council*, 12 December 2006, ECLI:EU:C:2006:772, para 88; see also Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health and Others*, 12 July 2005, ECLI:EU:C:2005:449, para 32.

[58] Case C-201/15 *AGET Iraklis*, 21 December 2016, ECLI:EU:C:2016:972, para 81, as quoted in Case C-674/23 *AEON NEPREMIČNINE and Others*, 27 February 2025, ECLI:EU:C:2025:109, para 62.

another solution might also have been possible or, in the Court's own view, preferable. In those circumstances, proportionality review is conducted with a measure of deference, and the contested measure will be set aside only where it is *manifestly* disproportionate to the objective pursued.[59]

That consideration is plainly relevant here. The Union legislature enjoys broad powers in the fields of internal-market harmonisation and public-health regulation under Articles 114 TFEU and 168(4)(c) TFEU. The design of the MDR/IVDR framework, and of the role assigned to notified bodies within it, involves precisely the kind of political, economic and regulatory assessment in respect of which the Court has traditionally acknowledged a wide legislative discretion.

Secondly, the regulatory field here is one in which notified bodies owe their very market position to Union legislation. The market for private, for-profit notified bodies carrying out conformity assessments for remuneration is not naturally given; it is constituted by the MDR and the IVDR. That consideration is capable of influencing the intensity of review.

The Court's case-law contains an important line of authority to the effect that economic operators **cannot normally claim a vested right to the maintenance of an existing regulatory situation**, especially in fields marked by legislative discretion and continuing adjustment. In classic terms, economic operators are "not justified in having a legitimate expectation that an existing situation which is capable of being altered by the Community institutions in the exercise of their discretionary power will be maintained".[60] The same idea appears in more recent case-law in more specific doctrinal forms: legitimate expectations require precise assurances by the Union institutions,[61] and cannot be invoked where a prudent and circumspect operator could have foreseen the adoption of the relevant measure.[62] The Court reiterated the same logic in the banking context in *Kotnik*, holding that the persons concerned had received no "precise, unconditional and consistent assurance" that burden-sharing measures would not later be introduced.[63] Finally, in the specific context of harmonising legislation, the Court has held that where a measure based on Article 114 TFEU has already removed obstacles to trade, the Union legislature cannot be denied the possibility of adapting that act to changes in circumstances or developments of knowledge, having regard to its task of safeguarding the general interests recognised by the Treaty.[64]

That line of authority is directly relevant here. It means that notified bodies cannot plausibly argue that Union law was required to preserve, unchanged, the exact market framework which Union law itself had previously created for them. They cannot claim a vested right to the indefinite maintenance of the notified-body regime in its prior form. To that extent, the Union is free to redesign the regulatory environment which it has itself brought into existence.

That, however, is not the end of the matter. The **absence of a vested right to an unchanged regulatory framework is not equivalent to the absence of Charter protection against the**

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[59] Case C-491/01 *British American Tobacco*, 10 December 2002, ECLI:EU:C:2002:741, para 123.

[60] Case C-331/88 *Fedesa*, 13 November 1990, ECLI:EU:C:1990:391, para 45; Case C-104/97 P *Atlanta*, 14 October 1999, ECLI:EU:C:1999:498, para 52.

[61] Joined Cases C-182/03 and C-217/03 *Belgium and Forum 187 v Commission*, 22 June 2006, ECLI:EU:C:2006:416, para 147.

[62] Case C-310/04 *Spain v Council*, 7 September 2006, ECLI:EU:C:2006:521, para 83.

[63] Case C-526/14 *Kotnik and Others*, 19 July 2016, ECLI:EU:C:2016:570, para 66.

[64] Case C-491/01 *British American Tobacco*, 10 December 2002, ECLI:EU:C:2002:741, paras 77 to 80; see also Case C-58/08 *Vodafone and Others*, 8 June 2010, ECLI:EU:C:2010:321, para 34.

**manner in which that framework is changed**. The Court's Article 16 case-law confirms as much. In *Sky Österreich*, the Court subjected a measure operating in a legislatively structured and highly regulated market to full review under Articles 16, 17 and 52(1) CFREU.[65] In *Polkomtel*, it expressly treated a price-control mechanism within a dense regulatory framework as an interference with Article 16 CFREU.[66] And in *AGET Iraklis*, it did the same notwithstanding the heavily regulated and crisis-sensitive nature of the field.[67] Those authorities show that undertakings do not lose Charter protection merely because their business model depends on a legislatively created and heavily regulated market.

The correct legal position is therefore more nuanced. The fact that notified bodies operate within a market created by Union law tends to support a certain restraint in review: the legislature must remain free to adapt the regime over time. But that consideration does not displace Article 16. It simply means that the real question is not whether the Union may alter the regime at all, but whether it may do so in this particular way—namely by reallocating part of a public-interest burden to a limited class of private undertakings in a manner compatible with Article 52(1) CFREU.

### *(5) Conclusion on review intensity*

These four factors thus point in different directions. The nature of Article 16, the internal-market legal basis, the weight of the health objectives pursued, and the fact that the relevant market is itself a product of Union regulation all point towards according the legislature a relatively broad margin of discretion. The seriousness and cumulative character of the interferences point towards a correspondingly careful scrutiny of how that discretion has been exercised. The present case therefore calls neither for perfunctory deference nor for the substitution of judicial policy preferences for legislative judgment. What it calls for is a **structured and exacting application of Article 52(1) CFREU to a measure adopted in a complex regulatory field but entailing serious interferences with Article 16 CFREU**.

That is the framework within which the following questions must now be examined: whether the interferences are provided for by law; whether they respect the essence of the freedom to conduct a business; whether they pursue objectives of general interest recognised by the Union; and whether, in light of the principle of proportionality, they go beyond what Article 52(1) CFREU permits.

## b) Provided for by Law

Under Article 52(1) CFREU, any limitation on the exercise of Charter rights and freedoms must be provided for by law. In the present case, that requirement appears, at first sight, to be satisfied by the proposed amending Regulation itself together with the implementing acts which the Commission would be empowered to adopt under it. The Court does not, as such,

[65] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, paras 42 to 48 and 64 to 66.

[66] Case C-277/16 *Polkomtel*, 20 December 2017, ECLI:EU:C:2017:989, paras 50 and 51.

[67] Case C-201/15 *AGET Iraklis*, 21 December 2016, ECLI:EU:C:2016:972, paras 70 to 81.

object to the fact that restrictions affecting fundamental rights may be shaped in part through implementing measures, provided that the legal basis for doing so is itself lawful.[68]

That does not, however, dispose of the matter entirely. The question remains whether, in the present case, the Union legislature may legitimately leave the relevant matters to implementing acts at all. As the analysis above has already suggested, there are reasons to doubt whether the delegation contemplated by the Proposal remains within lawful limits. Those doubts are significant not only from the perspective of the law governing delegated or implementing powers, but also for the purposes of Article 52(1) CFREU. If the legislature purports to leave to the Commission matters which, as a matter of Union law, must be determined by the legislature itself, the resulting defect is not confined to institutional law. It also affects the requirement that limitations on fundamental rights be provided for by law.

The Court itself has recognised that connection. In *Parliament v Council*, it held that the "essential elements" of a legislative act cannot be made the subject of implementing measures where the effect would be that the fundamental rights of the person concerned may be interfered with to such an extent that the involvement of the Union legislature is required.[69] The implication is clear. Where the interference with fundamental rights is sufficiently weighty, the decisive normative choices must be made at the legislative level. They cannot lawfully be displaced to implementing action.

The legality of Article 50(3) also raises a distinct institutional-law issue under Article 291 TFEU. That issue is examined separately below (infra IV.). For present purposes, however, the point can already be stated in Charter terms. Article 50(3) does not merely leave technical or procedural details to the Commission. It empowers the Commission to specify the "structure and level" of the fees charged by private notified bodies, without laying down a cost-based methodology, a rule on cost recovery, limits on the Commission's discretion, or safeguards for the economic viability and Article 16 CFREU rights of notified bodies. As will be shown below, there are therefore strong reasons to consider that Article 50(3) leaves to an implementing act matters which, under the Court's case-law on essential elements, should have been **determined by the Union legislature** itself.[70] That does not mean that every fee-related detail must be fixed in the legislative act itself. The Court has accepted that fee-setting may, in appropriate circumstances, be implemented by the Commission where the basic act has already laid down the guiding principle, conditions and criteria governing that power.[71] The difficulty with Article 50(3) is that the proposed Regulation appears not to do so. It leaves open precisely those choices which determine the economic incidence and intensity of the interference with Article 16 CFREU. For that reason, the "provided for by law" requirement cannot be treated as unproblematic. At the very least, Article 50(3) gives rise to **serious doubts** as to whether the limitation of Article 16 CFREU is sufficiently determined by the legislature itself.

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[68] Joined Cases C-92/09 and C-93/09 *Schecke and Eifert*, 9 November 2010, ECLI:EU:C:2010:662.

[69] Case C-355/10 *Parliament v Council*, 5 September 2012, ECLI:EU:C:2012:516, para 77.

[70] Ibid, paras 64 to 68 and 76 to 78.

[71] Case C-427/12 *Commission v Parliament and Council*, 18 March 2014, ECLI:EU:C:2014:170, paras 47 to 52.

## c) Essence of the Freedom to Conduct a Business

According to Article 52(1) CFREU, any limitation on the exercise of the rights and freedoms recognised by the Charter must respect the essence of those rights and freedoms.

The requirement to respect the essence of a Charter right is conceptually distinct from the proportionality test. Article 52(1) CFREU first requires that the essence of the right be respected and only then provides that, subject to the principle of proportionality, limitations may be made where they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others. The Court has treated that structure as meaningful. In *Digital Rights Ireland*, it examined separately whether the essence of Articles 7 and 8 CFREU was affected before turning to proportionality.[72] In *Schrems*, it went further and held that legislation permitting public authorities to have access on a generalised basis to the content of electronic communications compromises the essence of Article 7 CFREU, and that legislation providing no possibility of effective legal remedies does not respect the essence of Article 47 CFREU.[73]

The position is, however, more restrained in relation to Article 16 CFREU. The Court's case-law shows that the threshold for finding an infringement of the essence of the freedom to conduct a business is very high. In *Sky Österreich*, the Court held that Article 15(6) of Directive 2010/13 did not affect the core content of Article 16 because it did not prevent a business activity from being carried out as such by the holder of exclusive broadcasting rights and did not prevent that holder from making use of those rights by broadcasting the event itself for consideration, by granting the right to another broadcaster for consideration, or by granting it to another economic operator.[74] The decisive point was therefore not that the undertaking retained its full contractual autonomy. It plainly did not. The decisive point was that the undertaking could still carry on its business activity as such and could still exploit the relevant economic asset in a commercially meaningful way.

The same approach appears in *Bank Melli Iran*. There, the Court recalled that any limitation must respect the essence of the right and then stated that the essence of the freedom to conduct a business is potentially infringed, in particular, where an undertaking is deprived of the opportunity to assert its interests effectively in a contractual process.[75] On the facts of *Bank Melli Iran*, however, the Court found that the annulment of a contractual termination would not deprive Telekom of the possibility of asserting its interests generally in the contractual relationship, but would merely limit that possibility where the termination had been effected in order to comply with third-country sanctions[76].

Those authorities are important for the present case. They show, first, that an interference with price-setting, counterparty choice or contractual freedom does **not automatically** affect the essence of Article 16 CFREU. Much more is required. Secondly, however, they also show that the essence of Article 16 is **not irrelevant**. It protects, at a minimum, the continued

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[72] Joined Cases C-293/12 and C-594/12 *Digital Rights Ireland and Seitlinger and Others*, 8 April 2014, ECLI:EU:C:2014:238, paras 39 and 40.

[73] Case C-362/14 *Schrems*, 6 October 2015, ECLI:EU:C:2015:650, paras 94 and 95.

[74] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, para 49.

[75] Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, paras 83 and 87; Case C-201/15 *AGET Iraklis*, 21 December 2016, ECLI:EU:C:2016:972, para 87.

[76] Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, para 88.

possibility of carrying on the business activity as such and of asserting one's interests effectively in the contractual and economic framework within which that activity takes place.

Measured against that standard, the present case is **difficult**. It cannot simply be said that Article 50 of the Proposal prevents conformity-assessment activities from being carried out as such. Nor does it formally prevent notified bodies from charging fees for those activities. If the matter were limited to a single mandatory discount, the conclusion under the essence limb would therefore be doubtful, and the analysis would more naturally belong to proportionality.

The problem, however, is that Article 50 of the Proposal does not operate through one isolated measure. It operates through a cumulative regime (supra III.1.b)(4)). Article 50(2) imposes mandatory fee reductions. The same provision imposes mandatory payment deferral. Article 50(6) may, in certain circumstances, compel acceptance of a request. Article 50(3), finally, empowers the Commission to specify the structure and level of notified-body fees by implementing act. These elements interact. The notified body may be required to charge less, to receive payment later, to bear the associated liquidity and default risk, and, in certain circumstances, to accept the very engagement that generates those burdens. At the same time, the broader structure and level of its fees may be specified by the Commission without the Proposal itself laying down a cost-based methodology, a rule on cost recovery, or safeguards for economic viability.

That cumulative structure is what gives the essence question its force. The notified body does not merely lose one incident of contractual autonomy. It risks losing, in relation to a significant part of the market, the **effective ability to assert its interests in the contractual process**. The amount of remuneration is constrained by mandatory reductions and potentially by Commission implementing acts. The timing of remuneration is constrained by mandatory deferral. The decision whether to accept the contractual engagement may be overridden by the competent authority. The ordinary market-based means by which a private undertaking protects itself against uneconomic transactions are therefore narrowed simultaneously.

That distinguishes the present case from *Sky Österreich*. In that case, the holder of exclusive broadcasting rights remained able to exploit the rights commercially in other ways; the Court expressly relied on the fact that the undertaking could still broadcast the event itself for consideration or grant the right to other operators for consideration.[77] Here, by contrast, the cumulative regime may affect precisely the economic conditions under which the relevant activity is carried out: the price, the timing of payment, the assumption of financing risk, the freedom to refuse the engagement, and, through Article 50(3), the broader fee architecture. It is therefore not merely a case in which one economic opportunity is restricted while the undertaking remains otherwise free to organise the commercial exploitation of its activity. It is a case in which the legal framework may substantially **replace market-based contractual ordering with public determination of the essential economic terms**.

The case is also different from *Bank Melli Iran*. There, the Court considered that the limitation did not deprive Telekom of the possibility of asserting its interests generally in the contractual relationship, but only limited that possibility where the termination was linked to compliance with third-country sanctions.[78] Under Article 50, by contrast, the limitation is not confined to a specific abusive or externally induced motive for termination. It is built into the **regulatory structure itself**. The notified body's ability to assert its interests is not merely

[77] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, para 49.
[78] Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, para 88.

restricted in a particular exceptional situation; it is structurally curtailed by the combined operation of mandatory rebates, deferred payment, possible compelled acceptance, and possible Commission determination of fee structure and level.

That point must, however, be formulated with care. Since the implementing act under Article 50(3) has not yet been adopted, the full extent to which notified bodies will be deprived of market-based fee-setting cannot be determined in advance. The essence analysis therefore cannot rest on speculation about the future implementing act alone. It must rest on the structure of the Proposal itself. That structure already gives rise to serious doubts because the legislative act does not itself secure cost recovery, reasonable remuneration, or any meaningful space for notified bodies to protect their economic interests through contract. It leaves central features of the remuneration framework to the Commission while simultaneously imposing mandatory discounts, deferred payment and potential compelled acceptance.

The consequence is that the respect of the essence of Article 16 CFREU cannot be treated as plainly satisfied. The Court may ultimately be reluctant to find a breach of the essence of Article 16, given the high threshold in its case-law and the fact that notified bodies would not, formally, be prevented from carrying out conformity-assessment activities or charging fees. For that reason, the principal objection to Article 50 remains the proportionality analysis. Nevertheless, there are **serious reasons to doubt** whether the Proposal respects the essence of the notified bodies' freedom to conduct a business if Article 16 is understood to preserve at least some effective space for market-based contractual autonomy and for the undertaking to assert its interests in the contractual process.

In substance, Article 50 risks leaving too little of the economic autonomy that constitutes the freedom to conduct a business. Notified bodies remain private, for-profit undertakings. Yet the Proposal may require them to perform conformity-assessment activities on economic terms whose key elements are no longer the result of market-based contracting: remuneration is reduced by law, payment is postponed by law, acceptance may be compelled by public authority, and the structure and level of fees may be specified by the Commission. If those elements are taken together, the notified body is pushed towards the position of a public service provider, but without the public financing and institutional protections which that position would ordinarily entail.

For those reasons, there is a credible argument that Article 50 **comes close to, and may cross, the boundary** at which a limitation no longer merely restricts Article 16 CFREU but affects its essence. At the very least, the essence requirement reinforces the need for an especially strict proportionality assessment. Even if the Court were to conclude that something formally remains of the notified bodies' freedom to conduct a business, what remains is so substantially hollowed out by the cumulative regime that the same considerations must carry decisive weight in the necessity and excessive-burden stages of the proportionality test.

## d) Legitimate Objectives of General Interest

Under Article 52(1) CFREU, limitations on the exercise of Charter rights and freedoms are permissible only if they **genuinely meet objectives of general interest recognised by the Union** or the need to protect the rights and freedoms of others. At this stage of the analysis, the question is not yet whether the measures are suitable, necessary or proportionate in the

strict sense. The question is more limited: whether the aims pursued by the Union legislature are, in principle, capable of justifying limitations on Article 16 CFREU.

That question must be approached with some precision. It is necessary to distinguish between, first, the general objectives of the Proposal as a whole and, secondly, the more specific objectives pursued by the individual mechanisms contained in Article 50. Those two levels are connected, but they are not identical. The general objectives explain the regulatory context in which Article 50 is adopted. The specific objectives explain why Article 50 interferes with notified bodies' entrepreneurial freedom in the particular ways identified above.

### *(1) General objectives of the Proposal*

At the general level, the Proposal seeks to respond to perceived structural weaknesses in the operation of the MDR and IVDR framework. The Commission identifies, in particular, high compliance costs, lengthy and unpredictable certification procedures, capacity constraints affecting notified bodies, increased administrative burden, reduced predictability, and possible negative effects on innovation, competitiveness and device availability. The Proposal therefore aims to simplify and reduce regulatory burdens, to improve the functioning of the medical-device regulatory framework, to support innovation and competitiveness, and to preserve the availability of safe medical devices in the Union market.

Those objectives are capable, in principle, of falling within recognised Union interests.

First, the Proposal is located within the **internal-market framework**. Article 114 TFEU confers on the Union legislature the power to adopt measures for the approximation of national provisions which have as their object the establishment and functioning of the internal market. The Court has consistently held that recourse to that legal basis is permissible where differences between national rules are liable to obstruct the fundamental freedoms or create appreciable distortions of competition and thereby have a direct effect on the functioning of the internal market; it may also be used to prevent the emergence of future obstacles to trade, provided that their emergence is likely and that the measure is designed to prevent them.[79] That internal-market dimension is particularly concrete here. The Commission states that the Proposal aims to improve the functioning of the current regulatory framework, in particular as regards the smooth functioning of the single market, while preserving a high level of health protection for patients.[80] It also identifies as a continuing problem the lack of sufficiently predictable certification timelines and diverging practices across the Union, which undermine the efficiency of the CE-marking process.[81] The Targeted Evaluation gives that diagnosis greater specificity. It states that perceptions of unclear requirements and divergent interpretations across Member States and notified bodies limit predictability and hinder the smooth functioning of the internal market;[82] that operational clarity and harmonisation remain insufficient and that increased consistency in the interpretation and application of the Regulations by actors across Member States is needed;[83] and that notified-body designation and oversight remain uneven, while conformity-assessment

[79] Case C-380/03 *Germany v Parliament and Council*, 12 December 2006, ECLI:EU:C:2006:772, paras 37 and 38; Case C-210/03 *Swedish Match*, 14 December 2004, ECLI:EU:C:2004:802, paras 30 to 33.

[80] Proposal, COM(2025) 1023 final (supra note 1), at 4.

[81] Ibid, at 3.

[82] Evaluation, SWD(2025) 1051 final (supra note 2), at 14.

[83] Ibid, at 16.

processes are perceived as unpredictable and inefficient.[84] More specifically, the Targeted Evaluation explains that, although some fragmentation can be expected in a decentralised certification system, the increased harmonisation of conformity-assessment activities sought by the Regulations has not yet been achieved, partly because of divergent interpretation of requirements and divergent oversight capacity of notified bodies by authorities.[85] It further identifies poor harmonisation in the designation process, variation in national processes, insufficient coordination of notified-body oversight, differences in interpretation and application of notified-body requirements, diverse monitoring outcomes and, ultimately, a lack of harmony in the activities of notified bodies across the Union.[86] Finally, it records a negative evolution in the perception of harmonisation of notified bodies' conformity-assessment activities and identifies inconsistencies in how notified-body fees are presented as hampering the formation of a level playing field across Member States.[87] The Proposal responds to that diagnosis while retaining the decentralised structure of the MDR/IVDR regime: notified bodies remain under the responsibility of the Member States, but the Proposal seeks to improve oversight and regular monitoring through the involvement of Commission experts and experts from other Member States, to strengthen coordination between notified bodies through NBCG-Med, and to improve coordination between competent authorities with the support of EMA, in particular as regards borderline and classification issues, derogations, clinical evaluations and investigations, vigilance and market surveillance.[88] Measures designed to improve the functioning of that decentralised regulatory framework, to reduce divergences in application, and to ensure more predictable and more uniform access to conformity assessment may therefore, in principle, pursue an internal-market objective.

Secondly, the Proposal pursues objectives linked to **public health and patient safety**. Those objectives carry particular weight in Union law. Article 114(3) TFEU expressly requires a high level of protection of human health to be guaranteed in harmonisation measures, and Article 168(1) TFEU likewise requires a high level of human-health protection to be ensured in the definition and implementation of Union policies and activities. The Court has repeatedly recognised the normative importance of that requirement.[89] It has also made clear that, where the conditions for recourse to Article 114 TFEU are fulfilled, the Union legislature cannot be prevented from relying on that legal basis merely because public-health protection is a decisive factor in the choices to be made.[90] That legal assessment is reinforced by the Commission's own materials. The Proposal states that medical devices play a key role in ensuring the functioning of Member States' healthcare systems and in achieving a high level of public-health protection.[91] It further recalls that the MDR and IVDR aim to ensure a high level of safety and health, and that stricter clinical-evidence requirements and a more robust conformity-assessment system were introduced in order to check the quality, safety and performance of devices placed on the Union market.[92] The Targeted Evaluation likewise

[84] Ibid, at 19.
[85] Ibid, at 19.
[86] Ibid, at 20-21.
[87] Ibid, at 22.
[88] Proposal, COM(2025) 1023 final (supra note 1), at 4.
[89] Case C-210/03 *Swedish Match*, 14 December 2004, ECLI:EU:C:2004:802, para 46; Case C-380/03 *Germany v Parliament and Council*, 12 December 2006, ECLI:EU:C:2006:772, para 40.
[90] Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco*, 10 December 2002, ECLI:EU:C:2002:741, para 62; Case C-380/03 *Germany v Parliament and Council*, 12 December 2006, ECLI:EU:C:2006:772, para 88.
[91] Proposal, COM(2025) 1023 final (supra note 1), at 1.
[92] Ibid, at 2-3.

states that medical devices and IVDs have a "fundamental role in saving lives" and that the Regulations aim to ensure that only safe and performant devices are placed on the Union market, to protect patient safety and public health while supporting innovation.[93] It also explains that weaknesses in the earlier framework had led to an uneven level of protection of patients, users and public health, and that the Regulations maintained the general objective of ensuring a high level of protection of health for patients and users.[94] The Proposal therefore does not invoke public health merely as an abstract Treaty value. It presents the preservation of patient safety, public-health protection and device availability as central reasons for the revision itself, including the concern that excessive burdens may lead manufacturers, especially SMEs, to discontinue supplying devices or delay their launch, with potential negative consequences for patient care and public health.[95]

Thirdly, the Proposal pursues objectives of **industrial competitiveness, innovation and support for SMEs**. Those objectives are also recognised by Union primary law. Article 3(3) TEU refers to a highly competitive social market economy and to the promotion of scientific and technological advance; Article 173(1) TFEU expressly refers to conditions favourable to the development of undertakings, particularly SMEs; and Articles 179 et seq. TFEU recognise research and technological development as Union objectives. The Commission's materials connect those Treaty objectives directly with the medical-device sector. The Proposal describes that sector as innovative and economically significant, notes that SMEs represent around 90 % of the industry, and identifies competitiveness, innovation and the position of micro, small and medium-sized companies as central concerns of the reform.[96] The Targeted Evaluation similarly treats innovation, competitiveness, costs and administrative burdens, especially for SMEs, as central issues in the functioning of the MDR/IVDR framework.[97] Measures seeking to reduce regulatory barriers for SMEs, preserve innovative capacity and support the competitiveness of Union industry are therefore capable, in principle, of serving recognised Union interests.

At this general level, therefore, the objectives of the Proposal are plainly legitimate. The proper functioning of the internal market, the protection of health and patient safety, the availability of medical devices, the support of innovation, and the competitiveness of Union industry all qualify as objectives of general interest recognised by the Union.

### *(2) Specific objectives of Article 50*

The more difficult and legally more important question is how those general objectives translate into the specific mechanisms contained in Article 50. The justification analysis must not remain at the level of broad regulatory aspirations. It must identify the objectives pursued by the particular interferences with Article 16 CFREU.

First, the mandatory fee reductions in Article 50(2) seek to **reduce the immediate financial burden** of conformity assessment for micro enterprises, small enterprises and orphan-device applicants. That objective follows directly from the operative text of Article 50(2), which requires notified bodies to apply reductions of at least 50 % for micro enterprises, 25 % for small enterprises, and 50 % for orphan-device applications.[98] It also reflects the broader

[93] Evaluation, SWD(2025) 1051 final (supra note 2), at 2.
[94] Ibid, at 6-8.
[95] Proposal, COM(2025) 1023 final (supra note 1), at 4.
[96] Proposal, COM(2025) 1023 final (supra note 1), at 1 and 3-4.
[97] Evaluation, SWD(2025) 1051 final (supra note 2), at 2-3, 7, 23-24.
[98] Proposal, COM(2025) 1023 final (supra note 1), at 59-60.

diagnosis in the Proposal that costly and unpredictable conformity-assessment procedures affect device availability, the competitiveness of Union manufacturers, especially SMEs, and innovation in medical technology.[99] The Targeted Evaluation likewise identifies costs and administrative burdens, especially for SMEs, as a central focus of the evaluation, and states that the complexity and uncertainty of the regulatory framework have constrained innovation and competitiveness, particularly for SMEs, with particular effects on niche and orphan devices.[100] The specific objective of the fee-reduction mechanism is therefore to make conformity assessment less costly for categories of manufacturers which the Commission regards as particularly vulnerable to the costs of the MDR/IVDR framework.

Secondly, the payment-deferral mechanism in Article 50(2) pursues a related but distinct **liquidity objective**. It does not reduce the nominal amount of the fee. Instead, it allows micro and small enterprises to defer payment until the relevant conformity-assessment activity has been finalised.[101] The Commission does not appear to use the technical language of "liquidity pressure" in the operative explanation. Nevertheless, the objective follows from the structure of the measure: the manufacturer is relieved of the need to pay at the outset of the procedure. That objective is consistent with the Commission's broader finding that compliance costs, lengthy procedures and regulatory complexity create particular difficulties for SMEs and may affect market access, innovation and device availability.[102] The payment-deferral mechanism is therefore aimed at reducing the immediate cash-flow burden of conformity assessment for micro and small manufacturers.

Thirdly, Article 50(3) pursues an **objective of fee predictability, comparability and affordability**. It empowers the Commission to specify the structure and level of notified-body fees, taking into account quality and safety, device availability, SME interests, innovation and competitiveness.[103] That mechanism must be read against the Commission's broader concern that the certification process lacks sufficiently predictable timelines and that diverging practices across the Union undermine the efficiency of obtaining CE marking.[104] The Targeted Evaluation similarly identifies unpredictable conformity-assessment processes, time and costs as barriers, divergent approaches by notified bodies and national authorities, and an uneven playing field linked to inconsistencies in interpretation, implementation and costs across Member States and notified bodies.[105] The specific objective of Article 50(3) is therefore not merely transparency in the narrow sense, but the creation of a more predictable and more uniform economic framework for access to conformity assessment.

Fourthly, Article 50(4), (5) and (6) pursue an **access objective**. Article 50(4) requires notified bodies to ensure that SMEs have access to conformity-assessment activities on terms no less favourable than those offered to other manufacturers; Article 50(5) requires notified bodies to deal with any request and respond within 15 days; and Article 50(6) permits the responsible authority, where duly justified in the interest of public health or patient health or safety, to instruct a notified body to accept a request.[106] That objective corresponds to the Proposal's concern that insufficient predictability, capacity constraints and diverging practices in the

[99] Ibid, at 3-4.
[100] Evaluation, SWD(2025) 1051 final (supra note 2), at 2-3 and 23.
[101] Proposal, COM(2025) 1023 final (supra note 1), at 59-60.
[102] Proposal, COM(2025) 1023 final (supra note 1), at 3-4; Evaluation, SWD(2025) 1051 final (supra note 2), at 2-3 and 23.
[103] Proposal, COM(2025) 1023 final (supra note 1), at 60.
[104] Ibid, at 3-4.
[105] Evaluation, SWD(2025) 1051 final (supra note 2), at 19, 146 and 172.
[106] Proposal, COM(2025) 1023 final (supra note 1), at 60.

certification process may lead to delay, discontinuation or non-launch of devices, with potential negative consequences for patient care, public health and competitiveness.[107] The Targeted Evaluation likewise records that capacity constraints, fragmented oversight and uneven evidence requirements reduce efficiency and predictability, and that current regulatory complexity and uncertainty have led to longer timelines and limited device availability, especially for niche and orphan devices.[108] The access mechanisms in Article 50 are therefore directed at ensuring that manufacturers, especially SMEs and orphan-device applicants, are not effectively prevented from entering or completing the conformity-assessment pathway.

These specific objectives are also **legitimate** in principle. Reducing the conformity-assessment cost burden for SMEs and orphan-device applicants, easing immediate payment pressure, increasing the predictability and comparability of fees, and securing access to notified bodies may all serve recognised Union interests where they are linked to the functioning of the internal market, innovation, competitiveness, device availability and health protection. But the distinction between objective and means must be preserved. The objective is to support selected categories of manufacturers and to improve the functioning of the medical-device regulatory system. The method chosen is to impose mandatory rebates, deferred payment and possible compelled acceptance on private notified bodies. Whether that method is suitable, necessary and proportionate remains a separate question.

### *(3) Relative weight of the objectives*

It follows from the foregoing that the objectives pursued by Article 50 are not artificial or extraneous. They are anchored in recognised Union interests. That matters for the justification analysis. The protection of public health and patient safety is an objective of particularly high rank. The functioning of the internal market is likewise a central Treaty objective. Innovation, competitiveness and SME support are also recognised Union interests, especially in light of Articles 3(3), 173(1) and 179 et seq. TFEU.

Nevertheless, the weight of those objectives must be assessed at the correct level of abstraction. The objective of protecting health and ensuring the availability of safe medical devices is very weighty. But Article 50 does not pursue that objective directly by laying down safety standards for devices or by improving the substantive quality of conformity assessment. It pursues it **indirectly**, by reducing or postponing the costs borne by certain manufacturers and by seeking to secure their access to notified bodies. The same is true of innovation and competitiveness. Those objectives are important, but the connection between them and mandatory fee reductions or payment deferral is mediated through several steps: lower certification costs are expected to reduce burdens on SMEs; that, in turn, is expected to support market participation; that, in turn, is expected to preserve innovation, competitiveness and device availability.

That does not deprive the objectives of legitimacy. Article 52(1) CFREU does not require the objective to be attained by the most direct possible route. But it does mean that the legitimacy analysis **must not overstate** what has been established. The more indirect the connection between the measure and the final objective, the more important the later proportionality analysis becomes.

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[107] Ibid, at 3-4.

[108] Evaluation, SWD(2025) 1051 final (supra note 2), at 7-8 and 23.

A further distinction is essential. The support of SMEs, orphan-device applicants, innovation and device availability may constitute legitimate objectives. The particular method chosen to finance that support does not itself constitute an objective. It is a **means**. In other words, the Union may legitimately seek to reduce the burden borne by SMEs. It may also legitimately seek to improve access to conformity assessment. But it does not follow from that premise that the Union may achieve those aims by shifting the corresponding economic burden onto notified bodies. That burden allocation is precisely what must be justified under the proportionality test.

This point is decisive for the structure of the analysis. The objective pursued by Article 50 is not, and could not be, the extraction of economic value from notified bodies as such. The objective is to support selected categories of manufacturers and to improve the functioning of the medical-device regulatory system. The imposition of mandatory rebates, deferred payment and possible compelled acceptance on notified bodies is the chosen means of pursuing that objective. Whether that means is suitable, necessary and proportionate in the strict sense remains a separate question.

### *(4) Conclusion on legitimate objectives*

The requirements of Article 52(1) CFREU concerning legitimate objectives are therefore **satisfied in principle**. Article 50 pursues objectives of general interest recognised by the Union: the functioning of the internal market, the protection of health and patient safety, the availability of medical devices, the support of innovation and competitiveness, and the reduction of regulatory burdens on SMEs and orphan-device applicants.

That conclusion must, however, be **carefully confined** to the present stage of the analysis. It establishes only that the objectives invoked by the Commission are capable of justifying limitations on Article 16 CFREU. It does not establish that the specific interferences created by Article 50 are proportionate. In particular, it does not answer the central question whether those objectives may lawfully be pursued by requiring private, for-profit notified bodies to finance part of the support granted to selected categories of manufacturers. That question belongs to the proportionality analysis which follows.

## e) Proportionality under Article 52(1) CFREU

Under Article 52(1) CFREU, any limitation on the exercise of rights and freedoms guaranteed by the Charter must comply with the principle of proportionality. In its settled case-law, the Court states that proportionality requires that measures adopted by the Union institutions do not exceed the limits of what is appropriate and necessary to attain the objectives legitimately pursued by the legislation in question; where there is a choice between several appropriate measures, recourse must be had to the least onerous; and the disadvantages caused must not be disproportionate to the aims pursued.[109]

That formula contains three analytically distinct elements. First, the measure must be suitable or **appropriate** to attain the objective pursued. Secondly, it must be **necessary**, in the sense that the objective could not be attained by an equally effective but less onerous measure. Thirdly, even if the measure is suitable and necessary, the disadvantages caused to the right-

[109] Case C-58/08 *Vodafone and Others*, 8 June 2010, ECLI:EU:C:2010:321, para 51.

holder must not be **disproportionate** to the aims pursued. The proportionality analysis must therefore proceed in three stages: **appropriateness, least onerous means, and excessive burden**.

The **intensity of review** at each of those stages is not uniform. It depends on the legal and factual context. In fields involving political, economic and social choices and requiring complex assessments, the Union legislature enjoys a broad discretion. In such fields, the Court has often held that the legality of the measure is affected only if it is *manifestly* inappropriate having regard to the objective pursued by the competent institution.[110] That consideration is relevant here, since the Proposal concerns the functioning of the internal market in medical devices, public health, device availability, innovation and the organisation of a complex regulatory framework.

That broad discretion, however, does not remove the need for a structured proportionality assessment. Nor does it mean that the Court's review is confined, at every stage and for every question, to a merely formal search for manifest inappropriateness. The Court has also made clear that legislative or administrative discretion may not have the effect of undermining rights protected by Union law.[111] In the present case, that qualification is important. Article 50 does not merely involve technical regulation in a complex field. It interferes seriously with Article 16 CFREU by affecting pricing autonomy, the timing and financial conditions of remuneration, negative contractual freedom and the competitive conditions under which notified bodies operate.

The proportionality inquiry must therefore hold two considerations together. On the one hand, the Union legislature must be allowed a **substantial margin of assessment** in designing the MDR/IVDR framework and in pursuing internal-market, public-health, innovation and SME-support objectives. On the other hand, that discretion remains **subject to Charter review**, especially where the measure places serious and cumulative burdens on a limited class of private undertakings. The question is therefore not whether the Court or any external observer would have chosen a different regulatory model. The question is whether the specific burden-allocation mechanism chosen by Article 50 remains within the limits of what Article 52(1) CFREU permits.

It is against that standard that the three stages of proportionality must now be examined.

## *(1) Appropriateness*

### *(a) Standard of review*

The first question is whether the measures chosen are appropriate to attain the objectives pursued. Article 52(1) CFREU itself requires that limitations on rights and freedoms "genuinely meet" objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others. In the Court's case-law, the appropriateness test is **not** generally understood in an **unduly demanding** sense. Where a measure pursues several

[110] Ibid, para 52.

[111] Case C-201/15 *AGET Iraklis*, 21 December 2016, ECLI:EU:C:2016:972, para 81; Case C-674/23 *AEON NEPREMIČNINE and Others*, 27 February 2025, ECLI:EU:C:2025:109, para 62.

objectives, it is sufficient that it be suitable for achieving at least one of them.[112] Nor is it necessary, at this stage, that the measure by itself fully attain the objective in question; it is enough, in principle, that it be capable of making a genuine contribution to its attainment.[113].

That is especially so in fields involving political, economic and social choices and requiring complex assessments. In such fields, the Union legislature enjoys a broad discretion, and the Court will normally find a measure inappropriate only if it is manifestly inappropriate having regard to the objective pursued by the competent institution.[114] That standard is relevant here. The Proposal concerns the functioning of the internal market in medical devices, the availability of devices, public-health protection, innovation, competitiveness, and the organisation of a complex regulatory framework.

At the same time, appropriateness must be assessed by reference to the particular mechanisms chosen and the specific objectives they pursue. Article 50 does not contain a single measure. It contains several mechanisms: mandatory fee reductions, mandatory payment deferral, the power to specify the structure and level of fees, and access mechanisms culminating in possible compelled acceptance. The suitability inquiry must therefore ask, in a differentiated way, whether each mechanism is capable of contributing to the objectives identified above, and then whether the package as a whole is suitable in light of its cumulative effects.

*(b) Mandatory fee reductions*

The first mechanism is the system of mandatory fee reductions in Article 50(2). Notified bodies must apply at least a 50 % fee reduction for micro enterprises, at least a 25 % fee reduction for small enterprises, and at least a 50 % fee reduction for orphan-device applications.

In one respect, that mechanism is **plainly suitable**. Its immediate objective is to reduce the financial burden of conformity assessment for categories of manufacturers which the Commission regards as particularly vulnerable to the costs of the MDR/IVDR framework. In that regard, the connection between the measure and the objective is direct. Fees form part of the compliance costs associated with conformity assessment. A mandatory reduction in those fees therefore lowers, in immediate financial terms, one component of the cost of entering or remaining in the market. To that extent, there is a close and intelligible fit between the instrument chosen and the objective pursued.

The measure is also capable of making some contribution to broader objectives such as device availability, innovation and competitiveness. The Commission proceeds on the basis that costly and unpredictable conformity-assessment procedures may affect device availability, the competitiveness of Union manufacturers, especially SMEs, and innovation in medical technology.[115] The Targeted Evaluation likewise identifies costs and administrative burdens, especially for SMEs, and the availability of innovative, niche and orphan devices as central concerns.[116] It is therefore not implausible to assume that reducing one element of the

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[112] Case C-296/93 *France and Ireland v Commission*, 29 February 1996, ECLI:EU:C:1996:65, paras 36 et seq.

[113] Case C-280/93 *Germany v Council*, 5 October 1994, ECLI:EU:C:1994:367, para 86.

[114] Case C-58/08 *Vodafone and Others*, 8 June 2010, ECLI:EU:C:2010:321, para 52.

[115] Proposal, COM(2025) 1023 final (supra note 1), at 3-4.

[116] Evaluation, SWD(2025) 1051 final (supra note 2), at 2-3 and 23.

conformity-assessment burden may help some smaller manufacturers maintain products on the market, bring new products to market, or retain resources for innovation.

That contribution should, however, **not be overstated**. Fees constitute only a relatively small component of the overall regulatory burden; existing estimates place their share at approximately 7 %.[117] The Commission's materials identify a much broader set of difficulties, including lengthy and unpredictable certification procedures, divergent practices, capacity constraints, clinical-evidence requirements, administrative complexity and regulatory uncertainty.[118] Those factors are likely to be more structurally significant for market access, innovation and device availability than the level of notified-body fees alone. Market exit by SMEs is therefore not plausibly explained by fee levels in isolation. It is more plausibly explained by the cumulative effect of cost, delay, uncertainty and administrative burden.

The same is true of innovation and competitiveness. Lower conformity-assessment fees may assist some manufacturers. But innovation in a highly regulated market depends more decisively on predictable timelines, clear requirements, sufficient assessment capacity and coherent regulatory practice. A reduction in fees may therefore be supportive, but it is unlikely to be transformative. It does not by itself increase notified-body capacity, shorten assessment timelines, improve the quality of regulatory coordination, or remove divergences in interpretation and practice.

For those reasons, the mandatory fee reductions are **suitable in a narrow and immediate sense**. They are capable of reducing one component of the cost burden borne by micro enterprises, small enterprises and orphan-device applicants. Their contribution to the broader objectives of innovation, competitiveness, device availability and public health is, however, **indirect and limited**.

*(c) Mandatory payment deferral*

The second mechanism is the payment-deferral requirement in Article 50(2). Notified bodies must provide micro and small enterprises with the possibility to defer payment of fees until the relevant conformity-assessment activity has been finalized.

This mechanism pursues a distinct liquidity objective. Unlike the fee reductions, it does not reduce the nominal amount of the fee. Its purpose is to change the timing of payment. It relieves micro and small manufacturers of the need to pay at the outset of the conformity-assessment procedure and postpones the financial outflow until the relevant activity has been completed. In that respect, the measure is suitable for reducing immediate cash-flow pressure on micro and small manufacturers.

That objective is not artificial. The Commission's materials identify compliance costs, lengthy procedures and regulatory complexity as particular difficulties for SMEs.[119] In a sector in which regulatory expenditure may arise before any commercial return materialises, a deferral of payment can make it easier for smaller undertakings to enter or remain in the conformity-

[117] MedTech Europe, *MDR/IVDR Survey Report Highlights*, March 2025, available at: https://www.medtecheurope.org/wp-content/uploads/2025/01/mte-ivdr-mdr-survey-report-highlights-march.2025.pdf.

[118] Proposal, COM(2025) 1023 final (supra note 1), at 3-4; Evaluation, SWD(2025) 1051 final (supra note 2), at 19 and 23.

[119] Proposal, COM(2025) 1023 final (supra note 1), at 3-4; Evaluation, SWD(2025) 1051 final (supra note 2), at 2-3 and 23.

assessment pathway. The measure is therefore **capable of contributing** to SME support, and indirectly to market participation, innovation and device availability.

Again, however, the contribution is **limited**. Payment deferral does not reduce the final cost of conformity assessment. It merely postpones that cost. It may therefore assist manufacturers facing short-term liquidity constraints, but it does not address the total economic burden of compliance. Nor does it remove the broader structural causes of delay, uncertainty or capacity shortage. It is therefore suitable only for a **narrower objective**: easing the immediate financing burden at the beginning of the procedure.

Moreover, the measure contains an obvious **countervailing risk**. The liquidity pressure is not eliminated; it is shifted. What the manufacturer does not have to pay immediately, the notified body must finance temporarily from its own resources. If that financing burden becomes significant, especially in combination with mandatory fee reductions, it may impair the notified body's capacity to invest in personnel, expertise, infrastructure and assessment capacity. That may in turn undermine, rather than promote, timely access to conformity assessment.

The payment-deferral mechanism is therefore appropriate in a narrow sense: it is capable of relieving immediate cash-flow pressure for micro and small manufacturers. Its contribution to the Proposal's broader objectives is indirect, and it may generate countervailing effects on the notified-body side.

*(d) Fee predictability under Article 50(3)*

The third mechanism is Article 50(3), which empowers the Commission, in consultation with the MDCG, to adopt implementing acts specifying the structure and level of notified-body fees. In exercising that power, the Commission is to take account of quality and safety, device availability, SME interests, innovation and competitiveness.

From the perspective of appropriateness, that mechanism is capable of contributing to fee predictability, comparability and affordability. The Targeted Evaluation identifies divergent approaches by notified bodies and national authorities, unpredictable conformity-assessment processes, time and costs as barriers, and an uneven playing field linked to inconsistencies in interpretation, implementation and costs across Member States and notified bodies.[120] It also records inconsistencies in the way notified-body fees are presented and indicates that such inconsistencies may hamper the formation of a level playing field. Against that background, a power to specify fee structure may make fees more transparent, more comparable and more predictable for manufacturers.

That is a legitimate and intelligible regulatory aim. If manufacturers, and especially SMEs, cannot foresee the likely costs of conformity assessment, the regulatory pathway becomes less predictable. A more uniform fee structure may therefore contribute to reducing uncertainty and improving access to conformity assessment. To that extent, Article 50(3) is capable of making a genuine contribution to the objectives pursued by the Proposal.

The suitability of Article 50(3) should nevertheless be **formulated carefully**. A power to specify the structure and level of fees may improve predictability and comparability. It does not necessarily follow that it will improve device availability, innovation or competitiveness

[120] Evaluation, SWD(2025) 1051 final (supra note 2), at 19, 146 and 172.

in any strong or direct sense. Much depends on how that power is exercised. If the resulting fee structure is transparent, balanced and cost-sensitive, it may support the functioning of the system. If, however, it suppresses fees without regard to notified bodies' costs and economic viability, it may impair notified-body capacity and thereby weaken the same objectives it seeks to promote.

It is also essential to keep the present analysis distinct from the separate institutional-law issue addressed below (infra IV.). The fact that Article 50(3) may be suitable for increasing fee predictability and comparability does not answer the question whether the legislature may lawfully confer on the Commission the power to specify the structure and level of private notified-body fees by implementing act. Suitability under Article 52(1) CFREU does not cure a possible defect under Article 291 TFEU. The two questions must remain analytically separate.

For the limited purposes of the appropriateness test, Article 50(3) is therefore capable of contributing to the objectives of predictability, comparability and affordability. That conclusion does not prejudge either the Article 291 TFEU issue or the later questions of necessity and excessive burden.

*(e) Access mechanisms and compelled acceptance*

The fourth set of mechanisms concerns access to conformity assessment. Article 50(4) requires notified bodies to ensure that SMEs have access to conformity-assessment activities on terms no less favourable than those offered to other manufacturers. Article 50(5) requires notified bodies to deal with any request and to respond within 15 days. Article 50(6) then permits the authority responsible for notified bodies, where duly justified in the interest of public health or patient health or safety, to instruct a notified body to accept a manufacturer's request for conformity-assessment activities falling within that body's scope of designation.

Those mechanisms are, in principle, **suitable** to pursue an access objective. If manufacturers cannot obtain access to notified bodies, they cannot complete the conformity-assessment pathway. That may delay market entry, discourage innovation, lead to discontinuation or non-launch of devices, and ultimately affect device availability. The Proposal expressly identifies lack of predictability, capacity constraints and diverging practices in the certification process as factors capable of producing negative consequences for patient care, public health and competitiveness.[121] The Targeted Evaluation similarly links capacity constraints, fragmented oversight, uneven requirements and regulatory uncertainty with longer timelines and limited device availability, especially for niche and orphan devices.[122]

Article 50(4) and (5) are particularly easy to understand from that perspective. A non-discrimination rule in favour of SMEs and a duty to respond within a defined period may improve procedural access, reduce uncertainty and prevent manufacturers from being left without any timely indication of whether a notified body will take on their file. Those mechanisms are capable of contributing to a more predictable and accessible conformity-assessment process.

Article 50(6) is more intrusive, but it too can be regarded as suitable in a narrow sense. If a manufacturer cannot obtain a notified body and the case is duly justified in the interest of

[121] Proposal, COM(2025) 1023 final (supra note 1), at 3-4.
[122] Evaluation, SWD(2025) 1051 final (supra note 2), at 7-8 and 23.

public health or patient health or safety, a power to instruct acceptance may ensure that the conformity-assessment process can begin or continue. In such cases, the measure is capable of **contributing** to device availability and public-health protection.

The **limits** of that suitability must, however, be recognised. Compelled acceptance does not create additional assessment capacity. If the reason for refusal is that the notified body has exhausted its capacity, forcing the notified body to accept the request may simply redistribute scarcity rather than remove it. It may delay other files, overstretch personnel, and increase pressure on the assessment process. Similarly, if the reason for refusal is that the manufacturer or the product dossier does not sufficiently meet the requirements of the MDR or IVDR, compelled acceptance does not make the file compliant. It merely obliges the notified body to process a file that may still fail.

For that reason, Article 50(6) is suitable only in a **limited and conditional** sense. It may secure access in individual cases. But it does not, by itself, solve capacity shortages, improve the quality of applications, or remove structural causes of delay. Its contribution to the broader objectives of device availability and public health is therefore contingent and potentially ambivalent.

*(f) Cumulative suitability and countervailing effects*

The appropriateness of Article 50 must finally be assessed as a package. The individual mechanisms are not unrelated. Mandatory fee reductions reduce the cost burden for protected manufacturers. Payment deferral reduces their immediate liquidity burden. Article 50(3) seeks to make the fee framework more predictable and comparable. Article 50(4) to (6) seek to improve access to notified bodies. Taken together, those mechanisms are capable of contributing to the Commission's objectives of SME support, device availability, innovation, competitiveness and the functioning of the internal market.

That conclusion, however, must be qualified. The package does not merely support manufacturers. It does so by shifting part of the burden onto notified bodies. The manufacturer pays less and later; the notified body receives less, receives later, bears greater financing and default risk, and may in some circumstances be compelled to accept the engagement. Article 50(3) may further restrict the notified body's ability to offset those burdens through autonomous fee structuring. The suitability of the package is therefore **structurally ambivalent**.

The risk is that Article 50 may impair the very objectives it pursues. If notified bodies are required to absorb mandatory reductions and payment deferrals, they may seek to **recover losses elsewhere**. They may cross-subsidise through higher fees for other manufacturers, prioritise economically more attractive files, reduce investment in capacity, limit their exposure to SME files where possible, or devote fewer resources to individual assessments. More seriously, if the combined burden is substantial, some notified bodies may reduce capacity or withdraw from parts of the market altogether. Such reactions would be liable to undermine the availability, speed and reliability of conformity assessment.

That **risk** is **particularly important** because the Proposal itself is concerned with capacity, predictability and the functioning of the conformity-assessment system. Measures that weaken notified bodies' economic position may make those problems worse. A measure designed to facilitate access for SMEs and orphan-device applicants may therefore become

counterproductive if it reduces the willingness or ability of notified bodies to maintain or expand assessment capacity.

There is also a **quality and independence dimension**. Articles 53(5) MDR and 49(5) IVDR require notified bodies and their personnel to be free from pressures and inducements, particularly financial, which might influence their judgment or the results of conformity assessment. A package that reduces remuneration, postpones payment and may compel acceptance creates financial and organisational pressure on the very actors whose independence and technical reliability the system requires. That does not mean that Article 50 is incapable of contributing to the objectives pursued. But it does mean that its contribution is not one-directional. It is accompanied by risks that may run counter to public-health protection, device availability and the proper functioning of the conformity-assessment system.

Those countervailing effects do not necessarily cause Article 50 to fail the appropriateness test. Given the broad discretion enjoyed by the Union legislature in this field, it would be difficult to say that the mechanisms are manifestly inappropriate. They do address real concerns identified by the Commission, and they are capable of making some contribution to the objectives pursued. But they do so in a **limited and ambivalent** way. Their suitability is strongest in relation to the narrow objectives of reducing immediate financial and liquidity burdens for protected manufacturers and improving formal access. It is weaker and more indirect in relation to innovation, competitiveness, device availability and public health.

*(g) Conclusion on appropriateness*

Article 50 therefore satisfies the appropriateness test, but only in a qualified sense.

The mandatory fee reductions are **suitable** to reduce one component of the conformity-assessment cost burden for micro enterprises, small enterprises and orphan-device applicants. The payment-deferral mechanism is suitable to reduce immediate liquidity pressure on micro and small manufacturers. Article 50(3) is capable of improving fee predictability and comparability. The access mechanisms in Article 50(4) to (6) are capable of improving access to conformity assessment, at least in individual cases.

That is sufficient to pass the relatively deferential appropriateness test. The measures **cannot be characterised as manifestly inappropriate**. But their contribution to the Proposal's broader objectives is **limited, indirect and structurally ambivalent**. Article 50 does not itself increase notified-body capacity, shorten assessment timelines, improve the quality of applications, or remove the deeper causes of regulatory uncertainty. At the same time, it may create countervailing pressures on notified bodies which risk impairing the same objectives of device availability, innovation, competitiveness and public-health protection that the Proposal invokes.

The proper conclusion at this stage is therefore narrow. Article 50 is capable of making a contribution to legitimate objectives and therefore passes the appropriateness test. But it does not do so in a particularly compelling way. The decisive questions are whether the same objectives could have been attained by less onerous means and whether the burden imposed on notified bodies remains proportionate in the strict sense. Those questions arise in the following stages of the analysis.

## *(2) Necessity: Less Onerous Means*

### *(a) Standard: equally effective, less restrictive means*

The next question is whether the interferences with Article 16 CFREU are necessary within the meaning of Article 52(1) CFREU. Under the Court's settled formula, the principle of proportionality requires that measures adopted by the Union institutions do not exceed what is appropriate and necessary to attain the objectives legitimately pursued; where several appropriate measures are available, recourse must be had to the least onerous one; and the disadvantages caused must not be disproportionate to the aims pursued.[123]

That requirement remains applicable even in fields involving complex economic, technical and social choices. Legislative discretion does not eliminate the necessity test. It affects the intensity of judicial review, but it does not authorise the legislature to disregard less intrusive means that would attain the same objective with equivalent effectiveness. The Court's case-law therefore requires the analysis to distinguish carefully between the importance of the objectives pursued and the necessity of the particular means chosen.

This is particularly important where the measure interferes with a Charter right. The Court has repeatedly held that Article 16 CFREU protects freedom of contract, the freedom to determine the price of a service, the freedom to choose one's contractual counterparties, and the undertaking's ability to use its economic, technical and financial resources.[124] The task of the necessity test is therefore not to ask whether the Union may regulate notified bodies at all. It plainly may. Nor is the question whether the Union may pursue SME support, orphan-device support, innovation, device availability or public-health objectives. It plainly may. The narrower question is whether the specific interferences created by Article 50 were necessary, or whether the same objectives could have been achieved by equally effective but less onerous means.

### *(b) What must be justified: private burden-shifting*

The necessity inquiry must be framed by the structure of Article 50 as already analysed above. Article 50 seeks to reduce the effective conformity-assessment burden on selected manufacturers, to ease immediate payment pressure for micro and small enterprises, to improve predictability and comparability of fees, and to secure access to conformity assessment in cases where access is considered important for public health or patient health or safety.

The method chosen to pursue those objectives is, however, a specific **burden-allocation mechanism**. Article 50 does not merely provide public support to SMEs or orphan-device applicants. It requires private notified bodies to grant mandatory rebates, to carry the financing burden of deferred payment, and, in certain circumstances, to accept requests which they would otherwise not accept. In addition, Article 50(3) may restrict the ability of notified

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[123] Case C-58/08 *Vodafone and Others*, 8 June 2010, ECLI:EU:C:2010:321, para 51; Case C-477/14 *Pillbox 38 (UK)*, 4 May 2016, ECLI:EU:C:2016:324, para 48.

[124] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, para 42; Case C-277/16 *Polkomtel*, 20 December 2017, ECLI:EU:C:2017:989, paras 50 and 51; Case C-124/20 *Bank Melli Iran*, 21 December 2021, ECLI:EU:C:2021:1035, para 80.

bodies to offset those burdens through autonomous fee structuring, because it empowers the Commission to specify the structure and level of notified-body fees.

The necessity question is therefore not whether the objectives of Article 50 are important. They are. Nor is it whether the measures are capable of making some contribution to those objectives. As shown above, they are. The question is whether the Union legislature had to pursue those objectives by shifting the economic burden onto notified bodies, or whether equally effective alternatives were available which would have reduced costs, eased liquidity pressure, improved predictability and secured access without imposing uncompensated and cost-blind burdens on private undertakings protected by Article 16 CFREU.

*(c) Benchmark of equal effectiveness*

For the least-onerous-means test to be applied properly, it is necessary to identify the relevant benchmark of equal effectiveness. An alternative is not less onerous in the legally relevant sense merely because it is more favourable to notified bodies. It must also be capable of achieving the objectives pursued by Article 50 with comparable effectiveness. The Court's case-law is strict on this point: a proposed alternative must be realistic and capable of attaining the relevant objective, not merely conceivable in the abstract.[125]

In the present case, an **equally effective alternative** would therefore have to do **four things**. First, it would have to reduce the effective conformity-assessment cost burden for micro enterprises, small enterprises and orphan-device applicants. Secondly, it would have to address the liquidity problem which Article 50(2) seeks to address by allowing micro and small enterprises to defer payment until completion of the relevant conformity-assessment activity. Thirdly, it would have to improve fee predictability, comparability and transparency in a decentralised system of notified bodies. Fourthly, it would have to improve access to conformity assessment, especially where access problems may affect device availability, patient safety or public health.

The crucial point is that **none** of those objectives logically requires the **economic burden to be borne by notified bodies themselves**. Reducing the manufacturer's effective cost burden does not require reducing the notified body's remuneration. Easing the manufacturer's liquidity constraint does not require imposing financing and default risk on the notified body. Improving fee predictability does not require an open-ended power to determine the structure and level of private notified-body fees without legislative cost-recovery criteria. Securing access in cases of public-health need does not necessarily require uncompensated compelled acceptance by private undertakings.

This last point is especially important because the MDR and IVDR already contain **exceptional public-law mechanisms** for situations in which patient health, patient safety or public health require access to a device notwithstanding the absence of completed conformity assessment. Article 59 MDR and Article 54 IVDR allow competent authorities, on a duly justified request, to authorise for a limited period the placing on the market or putting into service of a specific device for which the applicable conformity-assessment procedures have not been carried out, where use of the device is in the interest of public health, patient safety or patient health. The Proposal itself confirms the relevance of that route by amending Article 59 MDR and Article 54 IVDR and by adding further derogation mechanisms for public-health

[125] Case C-477/14 *Pillbox 38 (UK)*, 4 May 2016, ECLI:EU:C:2016:324, paras 72 and 127.

emergencies, disasters and crises.[126] That existing public-law architecture matters for necessity. Where the problem is truly exceptional and health-related, Union law already contains a mechanism that addresses the issue through public authority decision-making rather than through a duty imposed on a private notified body to enter into a contract.

The benchmark must also take account of the fact that Article 50 uses **SME status** as the trigger for substantial legal consequences imposed on third parties. Commission Recommendation 2003/361/EC contains important safeguards. It distinguishes autonomous, partner and linked enterprises, requires aggregation of data in respect of partner and linked enterprises, and takes account, in appropriate cases, of relationships through natural persons in the same or adjacent markets.[127] Those rules are designed to ensure that only undertakings which genuinely require SME advantages benefit from them. Nevertheless, Article 50 attaches mandatory rebates and payment deferral to SME status without itself adding any specific verification mechanism, anti-avoidance rule, or allocation of the risk of incorrect classification. That matters for necessity. Where a measure imposes the cost of SME support on private notified bodies, the legislature must ensure that the class of beneficiaries is tightly and reliably defined. Otherwise the measure risks burdening notified bodies even in cases where the manufacturer does not, in economic substance, require the support.

Finally, the benchmark must be set against the existing proportionality logic of the MDR/IVDR framework. That framework already contains **multiple forms of calibration**. Manufacturer obligations, conformity-assessment procedures, technical-documentation assessment, surveillance and notified-body involvement are structured by reference to factors such as risk class, device type, technical complexity, manufacturing structure, suppliers, subcontractors, range and classes of devices, and the availability of post-market information. The Proposal itself also seeks to reduce notified-body involvement for certain lower and medium-risk devices and to make surveillance activities proportionate to risk class.[128] Against that background, a flat statutory rebate of 25 % or 50 % risks operating as an additional and uncalibrated layer of preferential treatment. It does not ask whether the fee charged by the notified body already reflects the smaller scale, lower complexity or reduced assessment burden of the manufacturer or device concerned. That reinforces the necessity objection: if the objective was to make existing proportionality more effective, the less onerous solution would have been to refine the existing risk-, complexity- and cost-based mechanisms, not to impose a second, flat-rate burden on notified bodies.

That distinction between the objective and the financing method is decisive. Article 50 selects one particular method: private burden shifting. The least-onerous-means test asks whether that method was necessary.

*(d) Pharmaceutical comparator*

The comparison with Union pharmaceutical law is instructive because Union law has long addressed a structurally similar problem in that field. Smaller innovators may face high regulatory costs at an early stage, whereas commercial returns, if they materialise at all, arise only later. Union pharmaceutical law responds to that problem through fee reductions,

[126] Proposal, COM(2025) 1023 final (supra note 1), at 30, 67 and 110-111.
[127] Commission Recommendation 2003/361/EC, recitals 9 and 12; Annex, Articles 3 and 6.
[128] Proposal, COM(2025) 1023 final (supra note 1), at 28 and 67.

waivers, deferrals and administrative support. But it does so within a public, centralised and cost-based institutional framework.

The first layer was the general EMA fee system established by Council Regulation (EC) No 297/95. That Regulation laid down the basic system of fees payable to the Agency for obtaining and maintaining Community marketing authorisations and for other Agency services. It contained differentiated fee categories, allowed for reductions, exemptions and deferrals in specific cases, and required fee review to be based on an evaluation of the Agency's costs and of the costs of the services provided by Member States.

The second layer was Regulation (EC) No 2049/2005. That Regulation created a specific SME support regime within the EMA framework. It provided for deferral of certain fees, including fees connected with marketing-authorisation applications and inspections, until later procedural stages. It also provided for substantial fee reductions, including 90 % reductions for inspections, scientific advice and scientific services, and supplemented those financial measures with administrative assistance, including translations, procedural guidance, training and support through the SME Office.

The orphan-medicinal-products regime confirms the same logic. Regulation (EC) No 141/2000 expressly states that, in order to facilitate the granting or maintenance of a Community authorisation, fees payable to the Agency should be waived at least in part and that the Community budget should compensate the Agency for the resulting loss of revenue. That provision makes explicit the financing principle underlying the pharmaceutical model: the applicant receives relief, but the public institutional body performing the regulatory function is not simply required to absorb the loss without compensation.

The current EMA fee regime, laid down in Regulation (EU) 2024/568, systematises that approach. It describes EMA as a public authority, emphasises the need for adequate and sustainable financing, and establishes cost-based fees and charges together with cost-based remuneration for the competent authorities of the Member States. It provides for cost monitoring, inflation adjustment and revision mechanisms. Even where fee reductions or waivers apply, the overall architecture remains one of public, cost-based and institutionally secured financing.

The pharmaceutical comparison is therefore relevant not because the medical-device regime should simply copy the EMA model. It is relevant because it shows that **Union law itself recognises a less intrusive way of supporting SMEs, orphan products and innovation in a highly regulated health market**. The Union may reduce the effective burden on applicants without requiring the regulatory actor performing the assessment to bear the loss from its own resources.

*(e) Why the comparator does not justify Article 50*

Article 50 appears to **borrow** visible instruments from the pharmaceutical model: fee reductions, payment deferral, and support for smaller or particularly vulnerable applicants. The decisive point, however, lies in what it **omits**. It adopts the relief mechanisms without reproducing the public institutional and financing structure that makes those mechanisms sustainable in the pharmaceutical field.

In pharmaceutical law, the fee-charging body is EMA, a public Union authority. The system is built around a **public institutional framework**. Fee reductions and waivers are embedded

in a **cost-based financing model**. In the orphan-medicinal-products regime, lost fee revenue is expressly **compensated by the Union budget**. In the current EMA fee Regulation, the legislature itself lays down a cost-based architecture and provides mechanisms for monitoring and adjustment.

Article 50 proceeds differently. It applies comparable instruments to a decentralised system of private, for-profit notified bodies. The manufacturer pays less or later; the notified body receives less or later. The manufacturer's liquidity burden is eased; the notified body carries the financing burden and default risk. The manufacturer may, in certain circumstances, obtain compelled access; the notified body may lose the ability to avoid the engagement. The support is therefore **not publicly financed**. It is financed by the private undertaking required to perform the conformity-assessment activity.

That difference is **structural**. In pharmaceutical law, support is publicly organised. Under Article 50, support is achieved through **private-sector burden shifting**. The fact that notified bodies exercise functions in the public interest does not remove that difference. They are not public authorities. They remain private undertakings operating in competition and bearing their own costs, risks and losses.

This makes the transplantation both unfair and unstable.

It is **unfair** because the Proposal imposes on private undertakings a burden that, in the closest Union-law comparator, is borne within a public institutional framework. If the Union wishes to support SMEs, orphan-device applicants, innovation and device availability, it may do so. But it does not follow that the costs of that policy may be **placed on notified bodies without compensation and without cost-based calibration**.

It is **unstable** because the design risks undermining the conformity-assessment system itself. Notified bodies facing mandatory rebates, deferred payment and possible compelled acceptance may seek to recover losses elsewhere, prioritise economically more attractive files, reduce investment in capacity, limit exposure to SME files where legally possible, or withdraw from parts of the market. Such reactions would impair the very objectives of predictability, access, device availability, innovation and public health which Article 50 seeks to promote.

The existing independence clauses in the MDR and IVDR do not cure that problem. Article 53(5) MDR and Article 49(5) IVDR require notified bodies and their personnel to be free from pressures and inducements, particularly financial, which might influence their judgment or the results of their conformity-assessment activities. Those provisions are protective standards. They cannot justify a legislative design which itself creates the relevant financial pressure. On the contrary, they reinforce the criticism. If Union law requires notified bodies to be free from financial pressure capable of influencing assessment, then a regime that reduces remuneration, postpones payment and may compel acceptance sits uneasily with the institutional logic of the MDR and IVDR.

The Court's reasoning in *Apothekerkammer des Saarlandes* supports that point by analogy. The Court accepted that, in a public-health field, legal rules may seek to ensure that the relevant activity is exercised under conditions of genuine professional independence and may reduce the risk that such independence is prejudiced, because that prejudice may affect the

reliability and quality of the service provided.[129] The same logic applies here. A conformity-assessment system that depends on the independent judgment of notified bodies should not be organised in a way that subjects those bodies to **avoidable financial pressure**.

*(f) Less onerous alternatives*

Once the measure is understood in those terms, the less intrusive alternatives become clear. They correspond to the specific objectives pursued by Article 50.

First, as regards mandatory fee reductions, the legislature could have used a **public compensation model**. It could have required the same effective rebates for micro enterprises, small enterprises and orphan-device applicants, while providing that the reduced share of the fee be reimbursed to the notified body from Union funds, Member State funds, or a dedicated regulatory support mechanism. That would have achieved the same result for protected manufacturers: they would still have paid less. But it would have been materially less intrusive for notified bodies, because the revenue loss would not have been imposed on them.

A closely related alternative would have been a **voucher or reimbursement scheme** for protected manufacturers. Under such a model, the notified body would charge its ordinary fee, while the manufacturer would receive a public voucher or reimbursement covering the relevant share. The manufacturer's effective certification burden would be reduced to the same extent as under Article 50(2), but the notified body's pricing autonomy and economic position would remain substantially intact. That alternative would therefore be equally effective for the manufacturer and less onerous for the notified body.

Such an approach would also fit better with the existing proportionality structure of the MDR/IVDR system. The current framework already differentiates regulatory intensity by reference to risk class, device type, technical documentation, quality-management systems, suppliers, subcontractors and other features affecting the actual assessment burden. A reimbursement or voucher scheme could be calibrated to those factors. Article 50(2), by contrast, adds flat-rate rebates on top of the existing structure without asking whether the fee charged by the notified body already reflects the scale or complexity of the assessment. That is precisely what makes the chosen measure less necessary than a calibrated support mechanism.

Secondly, as regards payment deferral, the legislature could have adopted a **secured or compensated deferral model**. If the objective is to relieve micro and small enterprises of immediate payment pressure, it is not necessary to make the notified body bear the financing cost and default risk alone. The same liquidity relief could be achieved through a public guarantee, escrow arrangement, interest-compensation mechanism, or public bridge-financing system. The manufacturer would still be relieved of upfront payment. But the notified body would not be required to finance the procedure from its own resources without compensation or security.

Thirdly, as regards fee predictability and comparability, the legislature could have **strengthened the existing transparency and enforcement regime** rather than conferring an open-ended power to determine the structure and level of private notified-body fees. Articles 50 MDR and 46 IVDR already require notified bodies to establish lists of their standard fees

[129] Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others*, 19 May 2009, ECLI:EU:C:2009:316, paras 19 and 30 to 35.

for the conformity-assessment activities that they carry out and to make those lists publicly available. The difficulty identified by the Commission is therefore not the absence of any publication duty, but the insufficient comparability, standardisation and effective supervision of the information published. The Targeted Evaluation indicates that notified bodies present their fees inconsistently and that most notified bodies do not appear to follow the MDCG template list of standard fees.[130] A less intrusive response would therefore have been to reinforce the existing Articles 50 MDR and 46 IVDR mechanism: mandatory use of a harmonised fee template, standardised categories of conformity-assessment activities, clearer rules on how fees must be presented, notification of fee lists to the Commission, publication through a central Commission portal, reporting obligations, oversight by designating authorities, and effective enforcement of the publication and presentation duties. Those measures would improve transparency, comparability and predictability without empowering the Commission to determine the structure and level of private notified-body fees.

If the legislature considered some degree of fee regulation necessary, it could also have laid down the essential cost-based criteria itself. It could have required that any specification of fee structure preserve cost recovery, reasonable remuneration, differentiation according to complexity and resource intensity, and safeguards for notified bodies' economic viability. Such a model would be less intrusive than Article 50(3) because it would constrain any later implementing measure by legislative standards protecting the economic position of notified bodies. It would also be more consistent with the Article 291 TFEU concerns addressed below.

Recital 28 of the Proposal points in the same direction. To the extent that the problem is insufficient transparency or comparability, it can be addressed through templates, publication, reporting and enforcement. To the extent that the problem is abusive pricing or anticompetitive conduct by particular notified bodies, Articles 101 and 102 TFEU provide a targeted framework. Article 50(3), by contrast, replaces targeted control and transparency-based regulation with a general ex ante power to specify the structure and level of private fees.

Fourthly, as regards access problems, the legislature could have used **coordination and allocation mechanisms** that do not impose uncompensated compelled acceptance. It could have strengthened capacity mapping, public triage, referral mechanisms between notified bodies, coordination through competent authorities, or transparent waiting-list rules. It could also have required a more structured review of the reasons for refusal, distinguishing between lack of notified-body capacity, incompleteness of the application, wrong classification, lack of scope of designation, and genuinely exceptional patient- or public-health need. That distinction matters because compelled acceptance is not an effective solution where the reason for refusal is lack of capacity or an incomplete or non-compliant file.

In cases in which the problem is genuinely one of public health, patient safety or patient health, the MDR and IVDR already contain a **less intrusive public-law mechanism**. Article 59 MDR and Article 54 IVDR allow competent authorities, on a duly justified request, to authorise for a limited period the placing on the market or putting into service of a specific device for which the applicable conformity-assessment procedures have not been carried out, where use of the device is in the interest of public health, patient safety or patient health. The Proposal itself confirms the importance of that route by amending those provisions and by introducing further derogation mechanisms for public-health emergencies, disasters and

[130] Evaluation, SWD(2025) 1051 final (supra note 2), at 22.

crises.[131] Those mechanisms address exceptional health needs through public authority decision-making rather than by compelling a private notified body to enter into a contract. They are therefore directly relevant to the necessity of Article 50(6).

If, exceptionally, a notified body is nevertheless to be required to accept a request in the public interest, the legislature could at least have coupled that duty with **compensation, safeguards against overcapacity**, and criteria ensuring that the file is sufficiently complete and capable of assessment. It could also have provided that the competent authority must first examine whether the case can be dealt with by coordination, referral, prioritisation, or the existing derogation mechanisms in Article 59 MDR and Article 54 IVDR. That would have been a less onerous and more coherent model than uncompensated compelled acceptance.

Fifthly, if the legislature wished to impose public-service-type duties on notified bodies because they perform functions in the public interest, it could have adopted a **compensated public-service-obligation model**. Such a model would align the public-interest duty with a corresponding financial framework. It would acknowledge the quasi-public function invoked by the legislature without simply transferring the cost of that function onto private undertakings.

Sixthly, the legislature could have added more **precise verification and anti-avoidance mechanisms for SME status**. This is not a marginal point. Article 50 makes SME classification the gateway to substantial legal advantages for manufacturers and corresponding burdens for notified bodies. Recommendation 2003/361/EC already contains safeguards against artificial fragmentation by requiring the position of partner and linked enterprises to be taken into account, including relationships through natural persons in the same or adjacent markets. But Article 50 does not specify how notified bodies are to verify SME status, who bears the risk of incorrect declarations, or what happens where the classification later proves wrong. A less onerous design would have placed verification on a public authority or a public support scheme, rather than requiring notified bodies to absorb the economic consequences of possible misclassification or strategic restructuring by manufacturers. Such a mechanism would not reduce the effectiveness of SME support for genuine SMEs. It would make that support more accurate and less burdensome for notified bodies.

These alternatives are not merely abstract possibilities. They would preserve the practical benefit for protected manufacturers: lower effective certification costs, reduced immediate liquidity pressure, better fee predictability, improved access, and support in genuine public-health cases. What they would avoid, or at least materially reduce, is the interference with notified bodies' pricing autonomy, financial resources, freedom to refuse engagements and ability to manage economic risk. They are therefore less onerous means within the meaning of Article 52(1) CFREU.

*(g) Conclusion on necessity*

The necessity analysis leads to a **clear conclusion**. Article 50 pursues legitimate objectives: reducing the regulatory burden on SMEs and orphan-device applicants, easing liquidity constraints, improving fee predictability, securing access to conformity assessment, and thereby supporting device availability, innovation, competitiveness and public health. But the

[131] Proposal, COM(2025) 1023 final (supra note 1), at 30, 67, and 110-111.

method chosen is **not necessary**. The Proposal pursues those objectives by shifting cost, financing risk and contractual disadvantage onto notified bodies.

Equally effective but less intrusive alternatives were available. Public compensation, vouchers or reimbursement schemes could have reduced the effective cost burden for manufacturers without reducing notified-body remuneration. Public guarantees, escrow arrangements, bridge financing or interest compensation could have relieved manufacturer liquidity pressure without imposing financing and default risk on notified bodies. Fee templates, publication duties, reporting obligations and legislative cost-based criteria could have improved predictability and comparability without granting an open-ended power to determine the structure and level of private notified-body fees. Capacity coordination, public triage, structured refusal review, targeted derogation mechanisms under Article 59 MDR and Article 54 IVDR, and compensated public-service obligations could have addressed access problems without uncompensated compelled acceptance. Public verification and anti-avoidance mechanisms could have ensured that SME advantages benefit only those undertakings which genuinely qualify for them, without placing the risk of misclassification on notified bodies.

The pharmaceutical comparison confirms the point. Union law already contains a model for supporting smaller and vulnerable applicants in a highly regulated health market. That model is public, cost-based and institutionally secured. Article 50 reproduces selected instruments from that model while omitting its financing logic. It therefore chooses private burden shifting where public or cost-based support mechanisms were available.

The same conclusion follows from the internal logic of the MDR/IVDR system itself. That system already contains risk-, complexity- and procedure-based forms of proportionality. The Proposal itself seeks to refine some of those mechanisms. Article 50, by contrast, superimposes flat and mandatory economic advantages for certain manufacturers on notified bodies without cost-based calibration, without sufficient verification safeguards, and without first exhausting less intrusive public-law mechanisms for exceptional access cases.

For those reasons, **Article 50 does not satisfy the least-onerous-means requirement** under Article 52(1) CFREU. The legislature did not choose the measure that interfered least with notified bodies' freedom to conduct a business. It chose a design that burdens private notified bodies directly, even though the same objectives could have been attained through mechanisms that would have been equally effective for protected manufacturers and materially less restrictive of Article 16 CFREU.

### *(3) Proportionality stricto sensu: Excessive burden?*

#### *(a) Standard: final balancing and fair balance*

The final stage of the proportionality inquiry is whether Article 50 imposes an **excessive burden** on notified bodies in relation to the objectives pursued. This is a distinct stage of the analysis. Even a measure which is suitable, and even a measure which could not be replaced by an equally effective but less onerous alternative, may still fail proportionality if the disadvantages caused to the right-holder are disproportionate to the aims pursued.

The Court's settled formula expresses that final stage clearly. The principle of proportionality requires that measures adopted by the Union institutions do not exceed what is appropriate

and necessary to attain the legitimate objectives pursued; where several appropriate measures are available, recourse must be had to the least onerous one; and the disadvantages caused must not be disproportionate to the aims pursued.[132] The final limb of that formula is concerned with the **maintenance of a fair balance between the public-interest objective and the burden imposed on the holder of the right**.

That balancing exercise remains necessary even where the Union legislature enjoys a broad discretion. It is true that, in areas involving political, economic and social choices and requiring complex assessments, the Court accords the legislature a substantial margin of assessment. It is also true that the field at issue here — the regulation of medical devices, the functioning of the internal market, public-health protection, device availability, innovation and competitiveness — is one in which such discretion is relevant. But broad discretion is not unlimited discretion. The Court has made clear that even substantial public discretion may not have the effect of undermining rights protected by Union law.[133]

That point is particularly important in relation to Article 16 CFREU. The freedom to conduct a business is not absolute and must be viewed in relation to its social function; it may therefore be subject to a broad range of public-interest interventions.[134] But the same case-law also confirms that Article 16 is a genuine Charter right and that limitations on it must satisfy Article 52(1) CFREU.[135] The task at this final stage is therefore not to deny legislative discretion, but to determine whether the specific burden placed on notified bodies remains tolerable in light of the objectives pursued.

*(b) Object of the balance: cumulative burden allocation*

The object of the final balance is not an isolated transparency rule. Nor is it merely an ordinary adjustment of the regulatory framework for notified bodies. Article 50 operates as a cumulative burden-allocation mechanism.

The first element is the mandatory fee-reduction mechanism in Article 50(2). It requires notified bodies to grant mandatory rebates of at least 50 % for micro enterprises, at least 25 % for small enterprises, and at least 50 % for orphan-device applications. The second element is the payment-deferral mechanism in the same paragraph. It requires notified bodies to allow micro and small enterprises to defer payment until the relevant conformity-assessment activity has been finalised. The third element is the access mechanism culminating in Article 50(6), under which the competent authority may, where duly justified in the interest of public health or patient health or safety, instruct a notified body to accept a manufacturer's request for conformity-assessment activities falling within that notified body's scope of designation. The fourth element is Article 50(3), which may further restrict notified bodies' residual economic room for manoeuvre by empowering the Commission to specify the structure and level of notified-body fees.

Those elements interact. The manufacturer pays less and later. The notified body receives less and later. The manufacturer obtains financial and liquidity relief. The notified body bears the corresponding revenue loss, financing burden and default risk. In certain circumstances, the manufacturer may obtain access despite the notified body's unwillingness to accept the

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[132] Case C-58/08 *Vodafone and Others*, 8 June 2010, ECLI:EU:C:2010:321, para 51; Case C-477/14 *Pillbox 38 (UK)*, 4 May 2016, ECLI:EU:C:2016:324, para 48,

[133] Case C-201/15 *AGET Iraklis*, 21 December 2016, ECLI:EU:C:2016:972, para 81.

[134] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, paras 45 and 46.

[135] Ibid, paras 47 and 48.

engagement. The notified body may then lose the ordinary contractual means by which a private undertaking would otherwise protect itself against an uneconomic, capacity-consuming or otherwise unsuitable transaction. Article 50(3) may further limit the possibility of offsetting those burdens through autonomous fee structuring.

It is that **cumulative structure** which must be balanced against the objectives pursued. The Union may legitimately seek to reduce regulatory burdens for SMEs and orphan-device applicants. It may legitimately seek to support innovation, competitiveness, device availability and public health. But the specific method chosen by Article 50 is to require a limited class of private undertakings to finance part of that policy through mandatory rebates, deferred payment, possible compelled acceptance and potentially constrained fee autonomy. The final proportionality question is whether that burden remains fair and tolerable.

*(c) Concentrated burden on notified bodies*

The first reason why the burden is **excessive** lies in its concentrated and distributive character.

Article 50 pursues objectives directed at the system as a whole. It seeks to support SMEs, orphan-device applicants, innovation, competitiveness, access to conformity assessment, device availability and public health. Those are general-interest objectives. But the economic burden of pursuing them is not distributed across the system. It is not borne by the public purse. It is not spread across all economic operators benefiting from a functioning medical-device market. It is **concentrated** on notified bodies.

That concentration matters. All undertakings operate under regulatory constraints. Regulation may impose duties, costs and administrative burdens. But Article 50 does more than regulate the framework within which notified bodies operate. It uses notified bodies as the financing vehicle for a policy directed primarily at relieving other undertakings. The protected manufacturer receives a direct economic benefit. The system is expected to receive an indirect public-interest benefit. The notified body bears the immediate cost.

This may be described, analytically, as a **special burden**. That terminology should not be misunderstood. Union law has not developed a freestanding doctrine of *Sonderopfer* as an autonomous test under Article 52(1) CFREU.[136] The point is not to import a separate national-law doctrine into Union law. The point is more limited and more directly relevant to proportionality stricto sensu: where a measure pursues system-wide public objectives but concentrates the economic sacrifice on a small class of private undertakings, that concentration is a central factor in the final balance.

The burden is especially problematic because Article 50 does not merely reduce future profit opportunities. It requires notified bodies to internalise part of the cost of a distributive policy. The fee reductions transfer part of the certification cost from protected manufacturers to notified bodies. The payment deferral transfers liquidity and financing risk from protected manufacturers to notified bodies. The compelled-acceptance mechanism may prevent notified

[136] However, Advocate General Poiares Maduro expressly referred to the German *Sonderopfertheorie* [special sacrifice theory] and observed that the relevant idea was "not very far removed" from the theory according to which persons who, by reason of lawful public action, suffer a "special sacrifice" may be entitled to reparation: Opinion of AG Maduro, Joined Cases C-120/06 P and C-121/06 P *FIAMM*, 20 February 2008, ECLI:EU:C:2008:98, para 63.

bodies from avoiding the engagement that generates those burdens. Article 50(3) may then restrict the ability to rebalance the economic consequences through the broader fee structure.

The result is not simply regulation in the public interest. It is **private financing of a public-interest support policy**. That distinction is decisive at the final balancing stage.

*(d) Institutional asymmetry and quasi-public burdens*

The second reason why the burden is excessive lies in the institutional asymmetry created by Article 50.

Notified bodies are integrated into a regulatory framework established by Union law. They perform functions of public importance. Their decisions are relevant for market access, device availability and patient safety. They are designated, supervised and monitored by public authorities. None of that can be denied.

But notified bodies are **not public authorities**. They are private, for-profit undertakings operating in a market environment. They bear their own costs. They finance their own personnel, technical expertise, infrastructure, accreditation and designation-related obligations. They compete for manufacturers' business. Regulatory integration into a public-health framework does not eliminate the private economic character of the operator.[137]

Article 50 blurs that distinction. It treats notified bodies, in important respects, as if they were public-service providers. They must grant rebates in the public interest. They must finance deferred payment in the public interest. They may be compelled to accept an engagement in the public interest. Yet they do not receive the institutional status, public financing or cost-recovery safeguards normally associated with public-service obligations.

That **asymmetry** is particularly visible in relation to Article 50(6). The MDR and IVDR already contain public-law mechanisms for exceptional cases in which patient health, patient safety or public health require access to a device despite the absence of completed conformity assessment. Article 59 MDR and Article 54 IVDR allow competent authorities, on a duly justified request, to authorise for a limited period the placing on the market or putting into service of a specific device for which the applicable conformity-assessment procedures have not been carried out, where use of the device is in the interest of public health, patient safety or patient health. The Proposal itself confirms the relevance of that public-law route by amending Article 59 MDR and Article 54 IVDR and by adding further derogation mechanisms for public-health emergencies, disasters and crises.

That public-law architecture matters for the final balance. If the problem is genuinely exceptional and health-related, Union law already knows how to address it through public authority decision-making. Article 50(6) adds a different instrument: a power to compel a private notified body to accept the contractual engagement. That does not merely fill a regulatory vacuum. It superimposes a quasi-public duty to contract on private undertakings. That makes the burden more **one-sided** and more difficult to justify in proportionality stricto sensu.

[137] Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others*, 19 May 2009, ECLI:EU:C:2009:316, para 37.

The pharmaceutical comparator points in the same direction. In pharmaceutical law, fee relief for SMEs and orphan medicinal products is embedded in a public institutional framework. The EMA fee system is public, centralised and cost-based. The orphan-medicinal-products regime expressly states that, in order to facilitate the granting or maintenance of a Community authorisation, fees payable to the Agency should be waived at least in part and that the Community budget should compensate the Agency for the resulting loss in revenue. The protected applicant receives relief, but the regulatory institution is not simply required to absorb the loss without compensation.

Article 50 proceeds differently. It **reproduces some of the visible instruments of that model — rebates, deferral and support for vulnerable applicants — but omits the public financing logic that makes the model sustainable**. What is publicly organised in pharmaceutical law becomes privately financed in Article 50. That institutional asymmetry is a major factor in the final balance.

*(e) Lack of compensation and cost-based calibration*

The third reason why Article 50 imposes an excessive burden is the **absence of compensation** and **cost-based calibration**.

The Proposal fixes mandatory rebates of 25 % and 50 % without linking those percentages to the actual cost of the conformity-assessment activity. It does not require an assessment of the notified body's cost structure. It does not distinguish between simple and complex files. It does not take account of the resources required for a particular assessment, the expertise needed, the duration of the procedure, the number of sites, suppliers or subcontractors involved, or the overhead costs of maintaining designation. It does not require that the reduced fee remain cost-covering. It does not provide compensation where the mandatory reduction pushes the assessment below cost.

That is a **serious defect** in proportionality stricto sensu. The burden is not merely heavy; it is legally crude. It is imposed in flat-rate terms. It is detached from the economic reality of the service that the notified body must provide. It may therefore require notified bodies to perform conformity-assessment activities at a loss, or at least on terms that do not reflect the actual cost and risk of the procedure.

The same is true of the payment-deferral mechanism. The Proposal does not provide for statutory interest, a public guarantee, escrow protection, reimbursement of financing costs, or compensation for default risk. The liquidity burden is simply moved from the manufacturer to the notified body. That shift may be tolerable if it is limited, secured or compensated. Article 50 does none of those things.

Article 50(3) does not cure the problem. On the contrary, it may **aggravate** it. The criteria listed in Article 50(3) concern quality and safety, device availability, SME interests, innovation and competitiveness. Those criteria are important. But they do not include cost recovery, reasonable remuneration, the economic viability of notified bodies, or protection of their Article 16 CFREU rights. The provision therefore allows the broader structure and level of notified-body fees to be specified without anchoring that power in cost-based safeguards. That matters not only for Article 291 TFEU, but also for the excessive-burden test. If notified bodies are required to absorb mandatory rebates and deferred payment, their ability to offset those burdens becomes crucial. Article 50(3) may restrict that ability without ensuring that the resulting fee structure remains economically sustainable.

The systemic overbreadth of the mechanism is reinforced by the internal logic of the MDR/IVDR framework itself. That framework already contains multiple forms of calibration. Manufacturer obligations, conformity-assessment procedures, technical-documentation assessment, surveillance and notified-body involvement are structured by reference to factors such as risk class, device type, technical complexity, manufacturing structure, suppliers, subcontractors, range and classes of devices, and post-market information. This calibration logic is also reflected in IAF MD 9, which provides that audit time for ISO 13485 certification depends, inter alia, on the audit scope, applicable regulatory requirements, the range, class and complexity of the devices, and the size and complexity of the organisation, and which uses the effective number of personnel as the starting point for determining initial audit time.[138] The Proposal itself seeks in certain respects to refine that proportionality logic, including by reducing notified-body involvement for certain lower and medium-risk devices and by making surveillance activities more proportionate to risk class.

Against that background, flat statutory rebates of 25 % and 50 % risk operating as a **second and uncalibrated layer of preferential treatment**. They do not ask whether the fee already reflects lower complexity, lower risk, smaller scale or reduced assessment effort. They do not ask whether the notified body's existing fee already incorporates the proportionality inherent in the MDR/IVDR system. They simply add a mandatory economic reduction on top. That may produce an uncalibrated double advantage for the manufacturer and a corresponding uncalibrated burden for the notified body.

The **SME-status trigger** creates an additional imbalance. Recommendation 2003/361/EC contains safeguards against artificial fragmentation. It distinguishes autonomous, partner and linked enterprises, requires aggregation of data in respect of partner and linked enterprises, and takes account, in appropriate cases, of relationships through natural persons in the same or adjacent markets.[139] Those rules are designed to ensure that only undertakings which genuinely require SME advantages benefit from them.

Nevertheless, Article 50 makes SME status the gateway to substantial legal advantages for manufacturers and corresponding burdens for notified bodies **without itself specifying a robust verification**, correction or risk-allocation mechanism. It does not say how notified bodies are to verify SME status. It does not say who bears the economic consequence if SME status is wrongly claimed. It does not specify what happens if a manufacturer's corporate structure has been arranged so as to obtain SME treatment despite economic links that undermine the substance of that classification. That matters for proportionality stricto sensu. The risk is not merely that public support may be misdirected. The risk is that a private third party — the notified body — is made to finance the consequence of misclassification or strategic structuring. That further aggravates the imbalance.

*Altmark Trans* supports the same cost-calibration concern by analogy, though it does not directly govern the present case. In *Altmark Trans*, the Court held that public-service compensation must not exceed what is necessary to cover all or part of the costs incurred in discharging public-service obligations, taking into account the relevant receipts and a reasonable profit.[140] That is a State-aid rule, not a direct Article 52(1) CFREU rule. But its underlying logic is relevant. Where Union law deals with private undertakings performing public-interest functions, it treats cost-based calibration as legally significant. Article 50

[138] IAF_MD9_Issue_4_010220221.pdf, pp. 11–12 and Annex D, pp. 30–31.

[139] Commission Recommendation 2003/361/EC, recitals 9 and 12; Annex, Articles 3 and 6.

[140] Case C-280/00 *Altmark Trans and Regierungspräsidium Magdeburg*, 24 July 2003, ECLI:EU:C:2003:415, para 92.

moves in the opposite direction. It imposes public-interest burdens without ensuring cost recovery, reasonable remuneration, or compensation.

That **lack of calibration** is central to the excessive-burden analysis. Article 50 does not merely ask notified bodies to participate in a regulated system. It requires them to bear a distributive burden whose amount is fixed abstractly, whose incidence may be substantial, whose interaction with deferral and compelled acceptance is cumulative, and whose relationship to actual costs is not secured by the Proposal.

*(f) Counterarguments: regulation, public-interest function and no vested right*

There are, of course, serious counterarguments. First, notified bodies operate in a heavily regulated market. Their role exists because Union law created the MDR/IVDR conformity-assessment architecture. They cannot claim that their commercial position is naturally given or immune from **legislative adjustment**.

Secondly, notified bodies perform a **public-interest function**. The conformity-assessment system is not an ordinary private services market. Notified bodies contribute to the safety, quality and performance of medical devices and to the functioning of the internal market. The legislature may therefore subject them to regulatory obligations more intensive than those applicable in ordinary commercial sectors.

Thirdly, economic operators do **not** normally have a **vested right to the maintenance of an existing regulatory situation**. The Court has held that operators are not justified in having a legitimate expectation that an existing situation which is capable of being altered by the Union institutions in the exercise of their discretionary power will be maintained, especially in fields involving ongoing regulatory adjustment.[141] Legitimate expectations require precise, unconditional and consistent assurances, and cannot be inferred merely from the continuation of an existing regulatory environment.[142]

Those points are correct. Notified bodies have no right to an immutable MDR/IVDR framework. They cannot insist that Union law preserve indefinitely the precise market conditions under which they previously operated. The Union legislature remains free to alter the regime, to simplify it, to make it more efficient, to improve oversight, to reduce unnecessary burdens, and to support SMEs and orphan-device applicants.

But those concessions do not decide the present issue. The absence of a vested right to an unchanged regulatory environment is not equivalent to the absence of Charter protection against the manner in which that environment is changed. The Court's Article 16 case-law confirms that point. In *Sky Österreich*, the Court subjected a measure operating in a legislatively structured and highly regulated market to review under Articles 16 and 52(1) CFREU.[143] In *Polkomtel*, the Court treated a price-control mechanism within a regulated telecommunications framework as an interference with Article 16 CFREU.[144] In *AGET Iraklis*, the Court likewise insisted that discretion may not undermine rights protected by Union law.[145]

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[141] Case C-310/04 *Spain v Council*, 7 September 2006, ECLI:EU:C:2006:521, para 81.
[142] Case C-526/14 *Kotnik and Others*, 19 July 2016, ECLI:EU:C:2016:570, paras 62 to 65.
[143] Case C-283/11 *Sky Österreich*, 22 January 2013, ECLI:EU:C:2013:28, paras 42 to 48.
[144] Case C-277/16 *Polkomtel*, 20 December 2017, ECLI:EU:C:2017:989, paras 50 and 51.
[145] Case C-201/15 *AGET Iraklis*, 21 December 2016, ECLI:EU:C:2016:972, para 81.

The correct legal position is therefore more nuanced. The Union may redesign the notified-body regime. It may regulate notified bodies intensively. It may take account of their public-interest function. But it must still respect Article 16 CFREU. The question is not whether the Union may alter the framework at all. It plainly may. **The question is whether it may alter it in this particular way: by concentrating an uncompensated, cost-blind, potentially compulsory and economically significant burden on a limited class of private undertakings**.

That is precisely where the counterarguments lose their force. They justify regulation. They do not justify using private **notified bodies as the financing vehicle for a public-interest support policy** without compensation, without cost-based calibration, without adequate safeguards for economic viability, and without first respecting the existing public-law architecture for exceptional health-related access cases.

*(g) Final balance*

The final balance must therefore weigh substantial public-interest objectives against a serious, concentrated and uncalibrated burden.

On one side of the balance, the objectives are important. Article 50 seeks to support SMEs and orphan-device applicants, reduce regulatory burdens, facilitate access to conformity assessment, improve predictability, support innovation and competitiveness, preserve device availability and protect public health. Those objectives are recognised and weighty.

On the other side of the balance, however, the burden imposed on notified bodies is unusually **severe**. It affects core elements of Article 16 CFREU: pricing autonomy, the timing and financial conditions of remuneration, the use of economic resources, negative contractual freedom and competitive market participation. It operates cumulatively. It reduces remuneration, postpones payment, shifts financing and default risk, may compel acceptance of the relevant engagement, and may restrict the possibility of offsetting losses through autonomous fee structuring.

The burden is also **concentrated**. The Proposal does not finance SME and orphan-device support through public funds or a general sectoral mechanism. It places the immediate economic cost on notified bodies. That is especially problematic because notified bodies remain private, for-profit undertakings even though they perform functions in the public interest.

The burden is **uncompensated**. There is no public reimbursement of the mandatory rebates. There is no compensation for deferred payment. There is no guarantee against default risk. There is no compensation mechanism if Article 50(6) requires a notified body to accept a file that it would otherwise have refused.

The burden is **cost-blind**. The percentages of 25 % and 50 % are not linked to the cost of the assessment. The payment deferral is not linked to the financing cost imposed on the notified body. Article 50(3) does not require cost recovery or reasonable remuneration to be preserved. The SME trigger is not accompanied by sufficiently clear verification, correction and risk-allocation mechanisms. The mechanism is therefore not tailored to the actual economic burden borne by the undertaking required to bear it.

The burden is also **systemically overbroad**. The MDR/IVDR framework already contains risk-, complexity- and procedure-based forms of proportionality. Article 50 superimposes flat mandatory economic advantages on top of that structure without asking whether the existing fee already reflects reduced complexity, lower risk, smaller scale or reduced assessment effort. That makes the measure not only heavy, but insufficiently calibrated to the logic of the system into which it is inserted.

Finally, the burden is **institutionally asymmetric**. Where genuinely exceptional health needs arise, the MDR and IVDR already contain public-law derogation mechanisms in Article 59 MDR and Article 54 IVDR. Yet Article 50(6) adds a mechanism of private contractual compulsion. Where the Union's pharmaceutical regime supports SMEs and orphan products, it does so through a public, cost-based and institutionally secured model. Article 50 instead transfers the economic burden to private notified bodies.

Taken together, those factors tip the balance. The Union legislature may support SMEs. It may seek to preserve orphan devices. It may pursue innovation, competitiveness, device availability and public health. But Article 50 pursues those objectives by imposing on notified bodies a burden that is concentrated, uncompensated, cost-blind, cumulative and institutionally asymmetric. Even allowing for the legislature's broad discretion, that burden is **not fairly balanced** against the objectives pursued.

*(h) Conclusion on proportionality stricto sensu*

Article 50 therefore fails the final limb of the proportionality test.

The point is not that notified bodies are immune from regulation. They are not. Nor is the point that the Union legislature must preserve the existing MDR/IVDR framework unchanged. It need not. The point is narrower and more fundamental: Article 50 does not merely regulate notified bodies in the public interest. It makes them finance, from their own resources, a support policy for selected categories of manufacturers.

That burden is excessive. It is imposed on a limited class of private undertakings for the benefit of other market participants and the system as a whole. It is not accompanied by public compensation. It is not calibrated to actual costs. It is aggravated by deferred payment and possible compelled acceptance. It may be reinforced by Commission specification of fee structure and level without cost-recovery safeguards. It is layered on top of an already differentiated MDR/IVDR framework. It attaches significant private burdens to SME status without sufficient verification and risk-allocation safeguards. And it imposes quasi-public burdens on private notified bodies notwithstanding the existence of public-law mechanisms for exceptional health-related access cases.

For those reasons, even if Article 50 is suitable, and even if some of its objectives are weighty, it imposes an **excessive burden** on notified bodies. It therefore **does not satisfy proportionality stricto sensu** under Article 52(1) CFREU.

# 3. Conclusion on Article 16 CFREU

Article 50 of the Proposal gives rise to **serious interferences** with the freedom to conduct a business guaranteed by Article 16 CFREU. The mandatory fee reductions interfere directly with notified bodies' pricing autonomy. The payment-deferral mechanism interferes with the financial conditions of service provision and shifts liquidity and default risk onto notified bodies. The power to compel acceptance of requests interferes with negative contractual freedom. Taken together, those mechanisms produce a further, composite interference: notified bodies may be required to charge less, receive payment later, bear greater financial risk, and accept the very engagement that generates those burdens. Article 50(3) may intensify that cumulative effect by restricting the notified bodies' ability to offset those burdens through autonomous fee structuring.

Those interferences pursue **legitimate objectives**. The Union may seek to improve the functioning of the medical-device regulatory framework, support SMEs and orphan-device applicants, preserve innovation and competitiveness, secure access to conformity assessment, and protect device availability and public health. Nor is Article 50 manifestly inappropriate for those purposes. In a narrow sense, the measures are capable of contributing to the objectives pursued.

The difficulty lies elsewhere. Article 50 does not merely regulate notified bodies in the public interest. It uses private notified bodies as the financing mechanism for a policy designed to relieve selected categories of manufacturers. That design is **not necessary**, because equally effective but less intrusive alternatives were available, including public compensation, reimbursement or voucher schemes, secured payment-deferral mechanisms, reinforced transparency and enforcement of existing fee-publication duties, cost-based legislative criteria, public coordination mechanisms, targeted use of existing derogation regimes, and compensated public-service obligations.

In any event, Article 50 imposes an **excessive burden** on notified bodies. The burden is concentrated on a limited class of private undertakings, uncompensated, insufficiently cost-calibrated, and cumulative in its operation. It is imposed despite the fact that notified bodies remain private, for-profit actors, and despite the existence of public-law mechanisms for exceptional health-related cases. It also sits uneasily with the independence logic of the MDR and IVDR, which require notified bodies to remain free from financial pressures capable of influencing conformity assessment.

The conclusion is therefore that Article 50, in its proposed form, cannot be regarded as a proportionate limitation of Article 16 CFREU within the meaning of Article 52(1) CFREU. While the objectives pursued by the Proposal are legitimate and weighty, the chosen mechanism shifts public-interest burdens onto private notified bodies in a manner that goes beyond what the Charter permits.

On that basis, Article 50 of the Proposal constitutes a disproportionate interference with Article 16 CFREU and therefore **violates** the notified bodies' fundamental right to conduct a business.

The legal consequence follows from that conclusion. If Article 50 were enacted in its proposed form, the provisions giving rise to the unjustified interference with Article 16 CFREU would be **invalid and unenforceable**. Since the Charter has the same legal value as the Treaties, secondary Union legislation which infringes Article 16 CFREU and cannot be

justified under Article 52(1) CFREU cannot be lawfully maintained. The result would not be merely a duty to interpret Article 50 restrictively. The relevant provisions **could not be relied upon by Union institutions, Member State authorities or manufacturers against notified bodies**. That applies, in particular, to the mandatory fee reductions, the mandatory payment-deferral mechanism and the compelled-acceptance mechanism.

# IV. Article 50(3) of the Proposal and Article 291 TFEU

Article 50(3) of the Proposal raises a separate institutional-law question. That question is connected with the fundamental-rights analysis set out above, but it is not reducible to it. It concerns the division of normative responsibility between the Union legislature and the Commission under Article 291 TFEU.

Article 50(3) empowers the Commission, in consultation with the MDCG, to adopt implementing acts specifying "the structure and level" of the fees charged by notified bodies for conformity-assessment activities. In doing so, the Commission is to take into account the need to establish and maintain high standards of quality and safety of devices, to ensure the availability of devices, to protect the interests of micro, small and medium-sized enterprises, and to support innovation and competitiveness.

The question is whether a power of that breadth may lawfully be conferred on the Commission as an implementing power, or whether the relevant choices must instead be made by the Union legislature itself. Recital 28 of the Proposal is relevant also for that analysis. The Proposal itself recognises that notified bodies' price-setting and economic activities may fall within the potential scope of Articles 101 and 102 TFEU. The matter left to the Commission is therefore not a merely technical question of administrative formatting. It concerns the structure and level of prices charged by private undertakings in a regulated market.

## 1. Limits of implementing powers under Article 291 TFEU

Article 291(2) TFEU allows implementing powers to be conferred on the Commission where uniform conditions for implementing legally binding Union acts are needed. The function of an implementing act is therefore executive. It is to ensure the uniform implementation of rules already laid down in the basic act. It is not to determine the essential normative content of the measure.

The Court's case-law draws the relevant constitutional boundary with some clarity, the leading case being *Parliament v Council*. The essential rules governing the matter in question must be laid down in the basic legislation and may not be delegated. Provisions which, in order to be adopted, require political choices falling within the responsibilities of the Union legislature cannot be delegated to the executive. The identification of such essential elements is not left to the discretion of the legislature alone, but must be based on objective factors

amenable to judicial review, taking account of the characteristics and particular features of the field concerned.[146]

The same judgment is particularly important for the present context because it links the concept of essential elements to the intensity of the interference with the legal position of the persons concerned. In *Parliament v Council*, the Court held that provisions permitting coercive measures against individuals in the context of sea-border surveillance required political choices falling within the responsibilities of the Union legislature and therefore could not be adopted as implementing measures.[147] The principle is not confined to that factual setting. It expresses a broader constitutional rule: where a measure determines **rights-sensitive and politically significant choices**, the legislature must itself lay down the essential elements.

At the same time, the Court's judgment in *Commission v Parliament and Council* concerning biocidal products confirms that this does not mean that fee-related matters can never be specified by implementing act. In that case, the Court accepted that the Union legislature could confer on the Commission an implementing power to set fees payable to ECHA under Regulation (EU) No 528/2012.[148] That judgment is important, but it must be read in its context. The Court emphasised that both the guiding principle of the system of fees and the conditions and criteria governing the exercise of the Commission's power had been laid down by the legislature itself.[149] The Commission was therefore called upon to provide further detail for the implementation of a framework whose basic normative choices had already been made by the legislative act.

The decisive question is therefore not whether fees may ever be the subject of implementing acts. They may. The question is whether the basic act itself lays down the **essential choices and criteria**, leaving only technical or uniform implementing detail to the Commission. Where the basic act leaves the Commission to determine the substantive economic architecture of the regime, and where that determination requires distributive and rights-sensitive choices, Article 291 TFEU is not satisfied.

## 2. Application to Article 50(3)

Measured against that standard, Article 50(3) is constitutionally problematic.

The provision does not merely authorise the Commission to adopt technical rules on the publication, format, or comparability of fee lists. Nor is it confined to procedural arrangements designed to ensure transparency. It empowers the Commission to specify the "structure and level" of the fees themselves. That language is **broad**. It covers not only the presentation of fees, but their substantive architecture and amount. It may therefore determine whether notified bodies may recover their costs, whether they may include a margin, how different types of conformity-assessment activities are to be priced, whether cross-

[146] Case C-355/10 *Parliament v Council*, 5 September 2012, ECLI:EU:C:2012:516, paras 64 to 68.
[147] Ibid, paras 76 to 78.
[148] Case C-427/12 *Commission v Parliament and Council*, 18 March 2014, ECLI:EU:C:2014:170, paras 38 to 42 and 46 to 52.
[149] Ibid, paras 47 to 52.

subsidisation is possible, and how the burden of discounts for protected manufacturers is to be absorbed.

Those are not merely implementing details. They concern the economic structure of the conformity-assessment market. They determine the financial terms on which private notified bodies provide services to manufacturers. They also interact directly with the mandatory fee reductions in Article 50(2), the payment-deferral obligation, and the possibility of compelled acceptance under Article 50(6). In substance, Article 50(3) empowers the Commission to decide, on its own, whether notified bodies retain any meaningful capacity to manage the economic consequences of the new burden-allocation regime.

The difficulty is aggravated by the absence of sufficiently determinate legislative criteria. Article 50(3) instructs the Commission to take account of quality and safety, device availability, SME interests, innovation and competitiveness. Those are important objectives, but they are all oriented towards the functioning of the system and the interests of manufacturers, patients and the market. The provision does not require the Commission to take account of the actual costs incurred by notified bodies, the need for cost recovery, their economic viability, the financing burden created by payment deferral, the risk of loss-making assessments, or the fundamental-rights position of notified bodies under Article 16 CFREU. Nor does it lay down any methodology for translating the listed objectives into fee levels. It contains no upper or lower limits, no cost-based formula, no rule on reasonable remuneration, no compensation principle, and no distinction according to the complexity or resource intensity of the assessment.

That is a serious omission. The choice between a cost-based fee model, a capped fee model, a redistributive model, a cross-subsidisation model, or a model designed primarily around SME affordability is **not "technical"** within the meaning of *Parliament v Council*. It requires a political and distributive judgment about who should bear the costs of conformity assessment in a market deliberately organised around private notified bodies. That judgment affects private undertakings' freedom to determine the price of their services, their ability to recover costs, and their capacity to participate in the market on economically viable terms. It therefore belongs to the kind of choice which, under the Court's case-law, must be made by the Union legislature itself.

The problem is not that Article 50(3) seeks uniformity. Uniformity may properly be pursued by implementing acts. The problem is that the provision leaves to the Commission the central normative question of how the conformity-assessment fee system is to be economically structured. The Commission would not merely fill in technical details; it would determine the concrete level and architecture of the remuneration payable to private undertakings for services which they perform in a regulated market and in the public interest.

It follows that Article 50(3), in its present form, goes beyond what can safely be treated as an implementing power under Article 291 TFEU. The Commission may properly be empowered to adopt rules ensuring uniform presentation of fee information, common templates, procedural arrangements for publication, or technical methodologies applying legislative criteria already fixed in the Regulation. But the substantive determination of the structure and level of private notified-body fees, in the absence of legislative cost-recovery criteria and fundamental-rights safeguards, appears to involve essential elements of the regime. Those elements should be laid down by the legislature.

# 3. Pharmaceutical fee regime as comparator

The comparison with Union pharmaceutical law, from which the Commission in its Proposal seems to be borrowing (supra III.2.e)(2)(d)), reinforces that conclusion.

In the pharmaceutical field, the Union legislature has not left the essential architecture of the EMA fee regime to an open-ended implementing power. Regulation (EU) 2024/568 was adopted by the European Parliament and the Council through the ordinary legislative procedure. It states that EMA plays a key role in ensuring that only safe, high-quality and efficacious medicinal products are placed on the Union market and that adequate financing must be provided to ensure the sustainability of its operations. It further states that the Regulation should establish cost-based fees and charges to be levied by the Agency, as well as cost-based remuneration to competent authorities of the Member States for the services they provide for the completion of the Agency's statutory tasks. The fees payable to EMA are to be proportionate to the work carried out and based on a transparent evaluation of workload and related costs.

The same Regulation then lays down, in its operative provisions and annexes, the types of fees and charges, the amounts of the fees and charges, the corresponding remuneration, the rules on payment, working arrangements, cost monitoring, transparency, inflation adjustment and later revision. The amounts are set in euro in detailed annexes. Even where fee reductions or waivers apply, the Regulation preserves the logic of cost-based remuneration and institutional financing.

That legislative design is instructive for two reasons. First, the legislature itself fixed the central elements of the fee system: categories, amounts, remuneration, cost basis and adjustment logic. Secondly, where flexibility is needed, it is embedded within a cost-monitoring and cost-adjustment framework. The Regulation expressly provides for monitoring of costs and for objective, fact-based mechanisms capable of supporting later changes.

The older SME regime points in the same direction. Regulation (EC) No 2049/2005 laid down specific rules regarding reduced fees, deferred payment and administrative assistance for SMEs. It identified the relevant circumstances, specified the fee deferrals, fixed the time of payment, and provided for 90 % reductions for inspections, scientific advice and scientific services. It is true that Regulation No 2049/2005 was a Commission Regulation adopted under the pre-Lisbon framework. It should therefore not be transposed mechanically into the Article 291 TFEU analysis. But it nevertheless illustrates the level of normative specification that the pharmaceutical regime contains. The fee-support mechanism is not left to an open-ended power to determine the structure and level of fees by reference only to broad policy objectives.

Article 50(3) of the Proposal is markedly different. It does not establish a public, cost-based fee system comparable to Regulation (EU) 2024/568. It does not set the fee levels itself. It does not set the permissible structure. It does not require cost recovery. It does not provide a cost-monitoring system for notified bodies. It does not preserve remuneration for those who perform the assessment when reductions apply. It does not define how the Commission is to balance SME support against the economic viability of notified bodies. Instead, it confers on the Commission the power to specify the structure and level of private conformity-assessment fees, while listing only broad objectives that largely point towards affordability, availability and competitiveness.

That contrast is legally significant. In the pharmaceutical field, the legislature itself made the essential choices and created a public, cost-based, institutionally secured fee architecture. In Article 50(3), by contrast, the legislature would leave to the Commission the central choice of how private notified bodies' fees are structured and set, and thus how the economic burden of the new regime is allocated. That strongly supports the conclusion that Article 50(3), as drafted, does not merely confer implementing power. It risks transferring essential legislative choices to the Commission.

# 4. Fundamental-rights implications

This institutional-law defect also has implications for the Article 16 CFREU analysis. If the structure and level of fees are left to the Commission without adequate legislative criteria, the problem is not only that Article 291 TFEU may be infringed. The same defect also affects the requirement in Article 52(1) CFREU that limitations on Charter rights be provided for by law.

The point is not that every detail affecting a fundamental right must appear in the legislative act itself. Union law permits implementing measures, including in fields touching fundamental rights, provided that the basic act lays down the essential choices and sufficiently determines the framework within which the executive acts. But where the executive is empowered to determine matters which themselves define the intensity and economic incidence of the interference, and where those matters involve political choices about the distribution of burdens between private undertakings and protected manufacturers, the legislative basis becomes **constitutionally insufficient**.

That is the position here. Article 50(3) concerns one of the core elements of the interference with Article 16 CFREU: the level and structure of the remuneration which notified bodies may receive for their services. It may determine whether the mandatory rebates remain economically manageable or become loss-making; whether cost recovery is possible; whether cross-subsidisation is available; and whether notified bodies retain any effective space for market-based pricing. Those are not peripheral details. They are central to the interference itself. If they are left to an implementing act without sufficiently precise legislative criteria, the limitation of Article 16 is not adequately determined by law.

The conclusion is therefore twofold. As a matter of institutional law, Article 50(3) is vulnerable because it appears to confer on the Commission decisions which go beyond uniform implementation within the meaning of Article 291 TFEU. As a matter of fundamental-rights law, the same defect reinforces the doubts under Article 52(1) CFREU, because essential features of the limitation of entrepreneurial freedom are not determined by the legislature itself.

# 5. Conclusion on Article 291 TFEU

Article 50(3) should therefore be treated as a serious and independent legal problem. A narrower implementing power would likely be unobjectionable: the Commission could be empowered to harmonise the presentation of fee lists, specify reporting templates, define technical units of comparison, or adopt procedural rules ensuring transparency and comparability. Such matters concern uniform implementation.

The power actually proposed is broader. It extends to the structure and level of notified-body fees. In the absence of legislative criteria securing cost recovery, economic viability and an appropriate balance between SME support and notified-body autonomy, that power appears to leave **essential distributive and rights-sensitive choices** to the Commission. Large parts of the matter should therefore be determined by the **Union legislature itself**. At the very least, the legislative act would need to define the substantive fee methodology, the cost-based principles, the limits of Commission discretion, and the safeguards protecting notified bodies before any implementing power under Article 291 TFEU could lawfully be used.

The legal consequence follows from that conclusion. If Article 50(3) were enacted in its proposed form, that empowerment would be **invalid and unenforceable**. The **Commission could not lawfully rely on Article 50(3) to adopt implementing acts specifying the structure and level of notified-body fees**. **Any implementing act adopted on that basis would itself be vulnerable, because the basic act would not validly confer the necessary implementing power.** The defect would **remove the legal basis for Commission fee-setting** and require the Union legislature itself either to determine the essential fee criteria in the legislative act or to replace Article 50(3) with a narrower implementing power confined to genuinely technical matters such as templates, reporting formats, publication mechanisms and comparability tools.