

EUDAIMONIA comparative table of institutional design obligations

<p>Health law (1):</p> <ul style="list-style-type: none"> - Medicinal products: Directive 2001/83 on Community code on medicinal products, integrated with Regulation 726/2004 on Community procedures for authorization of medicinal products, Directive 2001/20 on good clinical practices, and Directive 2011/62 on falsified medicines. [first column] - Medical devices: Regulation 2017/745 on medical devices integrated with Regulation 2017/746 on in vitro diagnostic medical devices. [second column] 	<p>Obligations flowing from EU primary law and/or secondary legislation</p>	
<p>Legal form ?</p>	<p>Competent authority – no specific legal form.</p> <p>Establishment of ethics committees (Article 6 (1)) that should be independent bodies (Article 1 (k) Dir. 2001/20).</p> <p>Establishment of a coordination group (Article 26 Dir. 2001/83), which is composed of one representative per Member State accompanied by an expert. (Article 27(2) Dir. 2001/83). Rules on transparency and independence apply (Article 27(2) last paragraph Dir. 2001/83).</p>	<p>Designation of competent authority or authorities entrusted with the powers, resources, equipment, and knowledge necessary for the proper performance of their tasks (Article 101 Reg. 2017/745 – Article 96 Reg. 2017/746).</p> <p>In addition, choice to designate an authority responsible for notified bodies - can be different from national authority responsible for medical devices - and might consist of separate constituent entities under national law (Article 35 (6))</p>

		second subparagraph Reg. 2017/745 and Article 31 Reg. 2017/746).
Composition ?	<p>To ensure independence and transparency, members of the staff, rapporteurs, and experts must have no financial or other interest in the pharmaceutical industry and thereby, make an annual declaration of their financial interests (Article 126b Dir. 2001/83).</p> <p>No conditions attached to the appointment of (key) officials.</p>	<p>Authority responsible for notified bodies should have sufficient number of competent personnel (Article 35 (6) Reg. 2017/745 and Article 31(6) Reg. 2017/746), be established, organized and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies. (Article 35 Reg 2017/745 and Article 31 Reg. 2017/746).</p> <p>No conditions attached to the appointment of (key) officials.</p>
Process ?	<p>Requirements as to the structure, outcome and review of decision-making: various examples, among the others, time limit applies to marketing authorization, manufacturing authorization and authorisation of wholesale distribution (respectively Articles 17(1), 43(1), and 77(1) Dir. 2001/83).</p> <p>Marketing authorization must be made publicly available without delay (Article 21(3) Dir. 2001/83).</p>	<p>Requirements as to the structure, outcome and review of decision-making:</p> <p>competent authorities for medical devices - specific obligations for disclosure of information and documentation (Article 10 (14) third and fourth subparagraphs Reg. 2017/745).</p>

	<p>Every decision shall state in detail the reasons on which it is based, be notified to the party concerned, and made publicly available (Article 125 Dir. 2001/83).</p> <p>Competent authority should make publicly accessible its rules of procedure and those of its committees, agendas and records of its meetings, accompanied by decisions taken, details and explanations of votes, including minority opinions (Article 126b second paragraph Dir. 2001/83).</p> <p>System of supervision in place. Officials representing the competent authority can carry out inspections when suspecting non-compliance. The content of the inspection must be communicated, and the receiving entity can submit comments. If necessary, the authority can impose effective, proportionate, and dissuasive penalties. (Article 111 Dir. 2001/87).</p> <p>Cooperation and coordination: Communicate with each other (Articles 122 and 124 Dir. 2001/83), with the Commission in case of investigation for potential failure to comply with Regulation 726/2004 (Article 84a Reg. 726/2004). Exchange of information and measures (Recital 34 Dir. 2011/62). The European Medicines Agency is established to coordinate existing scientific resources put at its disposal by Member</p>	<p>Harmonized procedures, for instance, market surveillance activities (Article 93 et ss Reg. 2017/745 and also Article 88 Reg. 2017/746).</p> <p>Such measures should state the exact grounds on which they are based, notify without delay to the person interested by the measure, and inform that person of the remedies available under the law or the administrative practice of the Member State concerned (Article 99 (1) Reg. 2017/745 and Article 94 Reg. 2017/746).</p> <p>In that context, also coordination among authorities (Article 93 (9) Reg. 2017/745) and cooperate (Article 93 (10) Reg. 2017/745).</p> <p>Cooperation among competent authorities (Article 102 Reg. 2017/745 and Article 96 Reg. 2017/746). To that end, the medical devices coordination group (MDCG) is established, and each Member State shall appoint a representative (Article 103 Reg. 2017/745). Independence and impartiality of members of the</p>
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	<p>States (Article 55 Reg. 726/2004).</p> <p>Member States should take measures to ensure cooperation between competent authorities for medicinal products and customs authorities (Article 118c Dir. 2011/62)</p> <p>Members of the coordination group and experts shall, for the fulfilment of their tasks, rely on the scientific and regulatory resources available to national competent authorities (Article 27 Dir.2001/83). Best endeavors of the members to reach an agreement in case of initial disagreement over an assessment report (Article 29 Dir. 2001/83).</p> <p>Harmonized procedures for ethics committees' activities (Article 6 Dir. 2001/20).</p>	<p>MDCG (Article 107 Reg. 2017/745 and similar in Article 97 reg. 2017/746)</p> <p>Authority responsible for notified bodies:</p> <p>respect confidentiality of the info obtained.</p> <p>Harmonized procedures (for instance, on the procedure on the conformity assessment of notified bodies, Articles 39 Reg. 2017/745)</p> <p>At the same time, it shall exchange info with other Member States and the Commission and other regulatory authorities (Article 35 (5) Reg. 2017/745).</p> <p>Exchange of experience between authorities responsible for notified bodies and coordination of administrative practice among them (Article 48 (1) and 49 (1) Reg. 2017/745).</p> <p>Development of mechanisms of peer review (Article 48 (1) (f) Reg. 2017/745).</p>
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<p>Modus operandi (judicial review) ?</p>	<p>No specific judicial review mechanism.</p>	<p>No specific judicial review mechanism.</p>
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<p>Health law (2):</p> <ul style="list-style-type: none"> - Cross-border healthcare: Directive 2011/24/EU. [first column] - Tobacco: Directive 2014/40/EU on tobacco products. [second column] - Cross-border threats to health: Regulation 2022/2371. [third column] 	<p>Obligations flowing from EU primary law and/or secondary legislation</p>		
<p>Legal form ?</p>	<p>Obligation to designate one or more national contact point (Article 6 (1) Directive 2011/24) – free to decide on the form and number of them (recital 49). However, they should be established in an efficient and</p>	<p>Designate competent authorities (Article 26 Directive 2014/40).</p>	<p>Designation of a competent authority responsible for epidemiological surveillance (Article 13 (9) Regulation 2022/2371), which will participate in the network for the epidemiological surveillance of communicable diseases (Article 13 (1)).</p>

	<p>transparent way (recital 49).</p> <p>Encouraged the creation of European reference networks between health providers and centers of expertise in the Member States based on voluntary participation (Article 12).</p>		<p>Designation of competent authorities responsible within their territory for the services supporting the use of substances of human origin, which will participate to the network for substances of human origin (Article 16).</p> <p>Designation of the competent authority or authorities responsible at national level for notifying alerts and determining the measures required to protect public health, for the purposes of early warning and response (Article 18 (3))</p>
Composition ?	No conditions attached to the appointment of (key) officials.	No conditions attached to the appointment of (key) officials.	No conditions attached to the appointment of (key) officials.
Process ?	<p>Only suggestion as to the structure, outcome and review of decision-making: administrative procedures on the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State - based on objective, non-discriminatory criteria which are necessary and</p>	<p>No suggestion or requirement as to the structure, outcome and review of decision-making.</p> <p>Competent authorities shall cooperate with each other and the Commission (Article 23 (4)).</p>	<p>No suggestion or requirement as to the structure, outcome and review of decision-making.</p> <p>Obligation to consult each other and coordinate in case of alert (Article 21 (1) (2)).</p>

	<p>proportionate, accessible, information publicly available (Article 9; see also recital 47).</p> <p>Close cooperation among contact points (Article 6 (2)).</p> <p>Mutual assistance between Member States and cooperate (Article 10).</p> <p>EU's support to cooperation among Member States in different areas (see Chapter IV).</p> <p>Encouraged the creation of voluntary networks connecting national authorities. For instance, among national bodies responsible for health technology assessment - based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations. (Article 15 (1) (2) (b); Recital 58). See also, Articles 13 and 14)</p>		
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<p>Modus operandi (judicial review) ?</p>	<p>Obligation to guarantee transparent complaints procedures and mechanisms in place for patients, in order for them to seek remedies (Article 4 (2) (c) and recital 24)</p> <p>Individual decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are properly reasoned and subject, on a case-by-case basis, to review and are capable of being challenged in judicial proceedings (Article 9 (4))</p> <p>The Commission should draw up a report which includes information on the functioning of national contact points (Article 20 (2)).</p>	<p>Obligations imposed by the Directive should respect fundamental rights and principles, proportionate (Recital 59)</p>	<p>No specific judicial review mechanism.</p>