Key Topic	Description
Regulatory Data Protection (RDP)	RDP period of 7.5 years. 1 additional year may be granted for addressing unmet medical need, 6 months if a significant portion of the R&D has been performed in the EU, but a cap of 8.5 years is in place. Note: Pan-European launch requirement for additional RDP has been dropped as proposed in earlier drafts.
Antimicrobial Resistance (AMR)	Introduction of transferable data exclusivity voucher for priority antimicrobial enabling a maximum of 12 months additional data protection. 'One Health Approach' – provisions put in place to ensure prevention and minimisation of environmental risks throughout the supply chain, use and disposal, awareness raising among patients, consumers, and healthcare professionals, and prudent and responsible use of antimicrobials. Dispensing limits to counter AMR. Tightening of prescription status of antimicrobials, with additional limits on amounts and duration of treatment. Introduction of an antimicrobial stewardship and access plans. Introduction of educational materials to inform use of antimicrobials, and introduction of appropriate disposal systems. Introduction of 'awareness cards' in packaging of antimicrobials to guide patients on AMR and appropriate use and disposal.
Real World Data	The use of real-world data to support regulatory decision making, including data generated via in silico methods, such as computational modelling and simulation, molecular modelling, mechanistic modelling, digital twin and artificial intelligence, where appropriate, could also be used to support regulatory decision-making.
Animal testing	Only to be used as necessary, focus on alternative methods and on replacement, reduction, and refinement.
Electronic product information (EPI)	Introduction of EPI complementary to paper leaflets.
Unmet medical need	The establishment of a criteria-based definition of 'unmet medical need' to incentivise the development of medicinal products in therapeutic areas that are currently underserved, including the definition of morbidity.
Pricing and reimbursement	In order to increase the availability of medicines and contribute to reducing access inequalities within the Union, the marketing authorisation holders of medicinal products should submit an application for pricing and reimbursement in Member States upon request.
Environmental Risk Assessment (ERA)	Marketing authorizations can be refused if ERAs are incomplete or insufficiently substantiated, and the reason for the incomplete nature of the environmental risk assessment is not duly justified and substantiated. The ERA should include the risk associated with production. ERAs may be required for products previously authorized without one.
Orphan Drugs	Orphan designation valid for 7 years (i.e. one can avail of orphan incentives in this period). Market exclusivity periods: • 9 years – 'standard' orphans • 11 years – drugs addressing high unmet medical need • 4 years – well established use orphan drugs Designation criterion on the basis of return on investment has been abolished. Mandates sponsors to seek protocol assistance before MA submission.
Reduced administrative burden	MA review times reduced from 210 to 180 days. Broaden scope of centralised procedure – open to medicines addressing significant therapeutic, scientific, or technical innovation; includes products of public health interest including antimicrobials. Simplified and reduced structure of EMA committees - the Committee for Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC) will remain; other committees will be retained in working parties/pool of experts. Possibility of phased or 'rolling review' for very select products that offer exceptional therapeutic advancement in the diagnosis, prevention or treatment of a life-threatening, seriously debilitating, or serious and chronic condition, or that are expected to be of major interest from the point of view of public health, or intended for conditions with no authorised alternatives in the Union.
Enhanced scientific and regulatory support	Likely expansion of the Priority Medicines (PRIME) scheme. Introduction of a regulatory 'sandbox' on a case-by-case basis.
Temporary emergency marketing authorization	Introduction of the possibility for the Commission to grant temporary emergency marketing authorisations to address public health emergencies.