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Short communication

Licensing strategies for future challenges

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Introduction

The pharmaceutical industry is changing fast. Companies face high research and development costs, long development time, strict rules, complex supply chains and strong global competition. These challenges can make it harder to bring safe and high-quality medicines to patients (Paul et al., 2010; DiMasi et al., 2016; European Medicines Agency, 2023).

Licensing is one useful answer to these challenges. Through in-licensing, a company can get access to products, technology or knowledge from another company. Throughout-licensing, a company can share its own products with a partner and reduce risk. In this way, licensing supports innovation, growth and wider market access (European Commission, 2011; U.S. Food and Drug Administration, 2012; Schuhmacher et al., 2025).

Materials and methods

This paper is based on a short narrative review. Scientific papers, regulatory documents and professional guidance were reviewed. Most sources were published between 2010 and 2025. The main search words were pharmaceutical licensing, in-licensing, out-licensing, external innovation, R&D productivity, technology transfer, GMP, digitalization and Pharma 4.0.

Around 20 sources in English were checked. Peer-reviewed papers and official regulatory or professional documents were preferred. Only sources that were relevant to licensing, R&D, GMP, manufacturing or digital tools were used in the final text.

Results and discussion

Licensing models and strategic value

Licensing may include in-licensing, out-licensing, co-development, regional licensing and strategic alliances. In-licensing helps companies fill portfolio gaps and enter markets faster. Out-licensing helps companies gain value from their own products when they cannot develop or sell them alone.

These models are useful because pharmaceutical R&D is costly and risky (Paul et al., 2010; DiMasi et al., 2016). Licensing can share costs, tasks and risks between partners. It can also connect innovative products with companies that have regulatory, manufacturing and market experience.

Regulatory, manufacturing and CMO integration

Before a licensing deal, companies should check the regulatory status, product quality and manufacturing options. Good manufacturing practice (GMP) requires clear responsibilities, strong quality systems and controlled transfer of knowledge (European Commission, 2011; European Medicines Agency, 2023).

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Contract Manufacturing Organizations (CMOs) can support licensing by helping with technology transfer, scale-up and supply. Clear quality agreements and good communication are important. For drug substances, development and manufacturing should be planned with product quality in mind (U.S. Food and Drug Administration, 2012).

Digitalization and partner selection

Digital tools can make licensing work faster and better. They can help companies find opportunities, compare partners, review risks and manage products during their lifecycle. Pharma 4.0 supports digital use in development, manufacturing and quality systems (International Society for Pharmaceutical Engineering, 2025).

Still, digital tools should support expert judgment, not replace it. Companies must also check the science, intellectual property, regulatory pathway, manufacturing strength, market value and partner fit. Good planning can make complex development programs easier to manage (U.S. Food and Drug Administration, 2023).

Key risks and success factors

Licensing also has risks. These include weak due diligence, intellectual property problems, unclear regulatory results, manufacturing-transfer problems, supply issues and financial risk. International deals can be more complex because each market may have different rules and expectations.

Success depends on careful due diligence, fair valuation, clear contracts, defined quality and safety duties, good governance and shared goals. Strong partnerships can help companies adapt to future scientific, technological and market changes (Schuhmacher et al., 2025).

Conclusion

Innovative licensing strategies are important for the future pharmaceutical industry. They help companies access external innovation, share risk, renew product portfolios and reach more markets. Future-ready licensing should be based on good scientific review, regulatory and GMP compliance, smooth technology transfer, digital support and long-term cooperation between partners.

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