



Femtech - Digital Health – Considerations in Early Stage Due Diligence

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What Is Legal Due Diligence and When Does It Take Place?

Legal due diligence is the process by which a potential venture capital investor (an Investor) reviews certain legal documents relating to a company (a Company or so-called “target”) prior to making an investment. The Investor does this primarily to confirm that key information provided by the Company’s management team is accurate, to help support the Investor’s valuation, and to better understand any legal risks.

Legal due diligence takes place once the Investor has completed its initial commercial and financial diligence and the parties have agreed to a term sheet (which is typically “subject to confirmatory legal due diligence”) but before the investment round has closed. Typically, an Investor will then send the Company a list of documents that it expects to review, and the Company will then make these documents available to the Investor and its advisers via an online platform (e.g., a virtual data room).

Current market trends both in Europe and the United States suggest that while the Femtech subsector continues to attract relatively high levels of investment (albeit from a low historic baseline), there has recently been a decrease in both (a) the number of digital health investments being made and (b) the value of those investments when compared with 2021. Although there are reasons to be optimistic about the 2023 outlook for this sector, we expect that Femtech and/or digital health Investors may become more selective about the investments they are willing to make and that their investment timelines may lengthen to accommodate more extensive due diligence processes (whether commercial, financial, or legal). Femtech and/or digital health companies seeking investment will therefore face more competition for funding and should be well prepared to respond to a proposed Investor’s legal due diligence requests to avoid delays or missing out on investment altogether.

Key Areas of Focus In Femtech and Digital Health Legal Due Diligence

Femtech and/or digital health Companies should be aware that Investors can (and often do) identify potentially problematic issues as part of legal due diligence, regardless of whether the relevant matter has since been rectified or the issue relates to business assets or processes that the Company no longer uses. Companies should therefore be conscious of (and seek to avoid) common pitfalls as they develop their businesses from the preseed stage.

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By experience, and in addition to the usual considerations that would apply to any venture capital or growth equity investment, Companies should expect Investors in the Femtech and/or digital health spaces to focus their legal due diligence on the following aspects:

- *Intellectual Property Rights:* Investors want to ensure that the Company owns all of the intellectual property rights embodied in its product and/or brand or, if such rights are licensed from third parties, that such licenses permit the Company to use these rights as needed. Investors will also want to ensure that the Company does not infringe any third-party rights and that the Company has a strategy for keeping its intellectual property rights (e.g., software code) confidential or for protecting patentable inventions (if applicable). This will be of critical importance, given that much of a Femtech or digital health company's valuation will be based on the utility of its proprietary software and/or hardware devices.
 - *Company considerations:* Companies should develop a clear strategy to identify and protect their proprietary intellectual property rights and perform basic searches to check whether their products and/or branding are similar to a pre-existing third party. Companies should also ensure that any third-party licenses are properly papered on arm's-length terms.
- *Data Privacy:* Investors will want to verify that the Company collects, processes, and stores personal data in compliance with applicable laws and that the Company has a suitable data privacy and cybersecurity plan in place. This is particularly important given that a Femtech or digital health Company's growth story will often hinge on its ability to successfully utilize the data generated by its products and/or devices, while the penalties for noncompliance with data privacy laws can be severe.
 - *Company considerations:* Companies should consider privacy and cybersecurity matters from the outset and look to incorporate such principles in their product development pathways (i.e., privacy by design). Companies should also be aware that additional data privacy rules may apply to any operations they have in overseas markets (most notably, General Data Protection Regulation in Europe/UK; Health Insurance Portability and Accountability Act in the United States) and in relation to cross-border transfers of data.
- *Regulatory:* Depending on the maturity of the Company, Investors will want to confirm that a Company holds all applicable licenses, authorizations, and clearances. In particular, Investors will want to understand which regulatory frameworks may apply to a Company's products and whether any authorizations or clearances (e.g., Food and Drug Administration clearance or the European CE marking) are required before such product can be

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commercialized. This step is important as the pathway to market and its related timeline will depend on the product's regulatory classification. As Investors will be generally familiar with the applicable regulatory and compliance frameworks in their jurisdictions, they also want to ensure that the Company complies with applicable labeling and advertising rules, including compliance with antikickback laws.

- *Company considerations:* Companies should look to gain a solid understanding of the regulatory frameworks applicable to their products and to factor this in to their business plan and/or product development plan — particularly if the product will require a technical file or clinical validation data to ensure timely regulatory approvals. It is important to work with competent and reputable lawyers and/or consultants in undertaking this analysis. In addition to providing expert, reliable advice, Investors will likely want to meet with such advisers and will take comfort in knowing the Company has been adequately advised, which should help expedite the diligence process and deal timing overall.
- *Quality management systems and manufacturing arrangements:* Investors will want to know that the Company has an appropriate quality management system and manufacturing plan in place, as this underpins much of a Company's regulatory compliance framework.

Company considerations: Companies will want to make sure they have a quality management system that is appropriate in the context of their business. A Company with a good compliance culture is more attractive to an Investor than one that needs an additional investment of time and energy from an Investor, who may need to assist the Company with substantive remediation and personnel training, for example.

- *Employment:* Investors based in Europe will want to ensure that the founder and other senior management or other personnel have written employment agreements that contain suitable notice periods and noncompete clauses (although this may be less of a concern for U.S.-based Investors, where employment practices are more flexible). Investors will also want to ensure that key personnel have entered into robust confidentiality and intellectual property assignment terms to ensure that any intellectual property rights developed by such persons are solely owned by the Company.
 - *Company considerations:* Companies can mitigate risks in this area by entering into robust written agreements with their employees and contractors from the outset; Investors will expect to see at least an “invention assignment agreement” for each employee or other person who provides services to the Company that may in any way touch its intellectual property. Companies should also consider taking advice

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if any of their key personnel (including the founder) works for, or is closely connected with, an academic institution or government. This will often introduce complexity into a Company's employment arrangements for various reasons and will be an area of heightened concern for Investors.

- *Commercial Arrangements:* Investors will want to review a Company's key commercial arrangements for a number of reasons — for example, to ensure that such arrangements are papered on reasonable arm's-length terms, that the investment will not trigger any adverse consequences for the Company, to help support their investment hypothesis, or to help inform other areas of diligence (e.g., commercial or financial).
 - *Company considerations:* Companies will want to ensure that prior to commencing legal due diligence, their key commercial arrangements are papered and their contract management processes are well organized. Companies should avoid agreeing to problematic commercial terms (e.g., exclusivity, change-of-control clauses, most-favored-nation clauses (e.g., preferential pricing terms), or joint ownership of IP) unless they have a strong commercial rationale for doing so and can show that such terms will not adversely affect the Company's business or a potential sale of the Company.