The pharmaceutical composition described herein comprises an anti-IL-12/IL-23p40 antibody specifically engineered to target cytokines implicated in inflammatory pathways. This antibody is characterized by distinct variable regions in both the heavy and light chains, each containing unique complementarity determining regions (CDRs) essential for antigen binding specificity and affinity.

The heavy chain variable region consists of three CDRs, each defined by specific amino acid sequences. CDRH1, identified by SEQ ID NO:1, facilitates initial antigen contact. CDRH2, with SEQ ID NO:2, enhances binding stability and specificity. CDRH3, defined by SEQ ID NO:3, is crucial for determining overall binding affinity and specificity due to its strategic position at the antibody binding site.

Similarly, the light chain variable region comprises three CDRs. CDRL1, with SEQ ID NO:4, initiates antigen interaction. CDRL2, identified by SEQ ID NO:5, provides additional contact points to stabilize the antigen-antibody complex. CDRL3, defined by SEQ ID NO:6, further refines specificity and contributes to binding strength.

An alternative structural configuration includes a heavy chain variable region represented by SEQ ID NO:7 and a light chain variable region by SEQ ID NO:8, offering a different binding profile that may enhance therapeutic efficacy or stability.

Another embodiment features a heavy chain with SEQ ID NO:10 and a light chain with SEQ ID NO:11, potentially offering advantages in manufacturing efficiency or pharmacokinetic properties.

The composition is accompanied by packaging containing drug product label elements informed by data from a rigorous clinical study. This study, a randomized, double-blind, placebo-controlled trial, was conducted in pediatric patients with moderate to severe psoriasis. The inclusion of such data ensures the composition is supported by robust clinical evidence, enhancing its credibility and utility in therapeutic applications.

The antibody's structural design is optimized to achieve high specificity and affinity for the IL-12/IL-23p40 cytokine, providing a targeted therapeutic approach for inflammatory conditions such as psoriasis. The technical implementation involves precise engineering of the antibody's variable regions to maximize therapeutic potential while ensuring safety and efficacy.

The pharmaceutical composition undergoes evaluation through a clinical study targeting a pediatric demographic aged 6 to less than 12 years, specifically those diagnosed with moderate to severe plaque psoriasis. This condition, marked by inflamed, scaly skin lesions, necessitates advanced therapeutic interventions such as phototherapy or systemic treatments due to its severity.

Stringent inclusion criteria are implemented in the study design to select participants most likely to benefit from the treatment. The methodology involves a thorough assessment of the safety and efficacy of the antibody composition within this young population. Parameters including dosage optimization, pharmacokinetics, and pharmacodynamics are meticulously evaluated to tailor the treatment to the unique physiological characteristics of pediatric patients.

To monitor therapeutic response and disease progression, advanced imaging techniques and biomarker analyses are employed. These tools provide quantitative data on lesion reduction and skin clearance, offering insights into the composition's impact on the underlying pathophysiology of psoriasis.

The study also addresses the psychosocial aspects of pediatric psoriasis, acknowledging the importance of enhancing quality of life alongside clinical outcomes. Patient-reported outcomes and caregiver feedback are integral to the evaluation process, ensuring a holistic approach to treatment assessment.

In conclusion, the clinical study rigorously tests the antibody composition's potential as a viable treatment option for young patients with severe psoriasis, emphasizing both clinical efficacy and patient-centered outcomes.

The antibody composition is specifically formulated for subcutaneous administration, selected for its practicality and enhanced patient compliance, particularly among pediatric populations. This administration route facilitates absorption into systemic circulation via subcutaneous tissue, enabling controlled release and extended therapeutic effect.

Formulation efforts focus on optimizing the antibody's stability and solubility to ensure efficacy upon administration. The composition is engineered to preserve structural integrity under physiological conditions, thereby preventing degradation or aggregation that could undermine therapeutic action.

The subcutaneous delivery system is meticulously designed to minimize discomfort and enhance ease of use, which is critical for pediatric patients. Needle gauge and injection volume are strategically chosen to reduce pain and anxiety associated with injections, thereby improving adherence to the treatment regimen.

Pharmacokinetic studies are conducted to ascertain the absorption rate, bioavailability, and half-life of the antibody when administered subcutaneously. These studies guide the development of dosing schedules that maximize therapeutic benefits while minimizing potential side effects.

Furthermore, the formulation may incorporate excipients that enhance the antibody's stability and absorption, ensuring consistent therapeutic levels. The packaging and delivery device are crafted to be user-friendly, with clear instructions to assist caregivers in administering the treatment effectively.

In summary, the subcutaneous administration of the antibody composition is tailored to address the needs of pediatric patients, balancing efficacy, safety, and ease of use to optimize therapeutic outcomes.

The disclosed method presents a comprehensive strategy for the commercialization of a drug product containing ustekinumab, specifically targeting healthcare professionals who treat pediatric patients with moderate to severe plaque psoriasis. Initially, the method involves the precise manufacturing of ustekinumab, ensuring compliance with rigorous quality control standards to produce a biologically active and stable product.

Following the manufacturing process, strategic promotional activities are implemented to convey the safety and efficacy of ustekinumab therapy. These activities aim to educate healthcare professionals on the clinical benefits and therapeutic potential of the drug for young patients eligible for phototherapy or systemic treatment. The promotional strategy may include the distribution of peer-reviewed clinical study results, emphasizing the drug's efficacy, safety profile, and patient outcomes.

Educational seminars, webinars, and workshops are organized to provide healthcare professionals with comprehensive insights into the drug's mechanism of action, dosing regimens, and administration techniques. These initiatives are designed to build confidence in the drug's therapeutic value and support informed decision-making.

Furthermore, the method includes the development of detailed informational materials, such as brochures and digital content, tailored to address common queries and concerns of healthcare providers. These materials serve as a resource for understanding the drug's role in managing pediatric psoriasis and its integration into existing treatment protocols.

Ultimately, these efforts culminate in the engagement of healthcare professionals, leading to the procurement of the drug product. By fostering a thorough understanding of ustekinumab's clinical advantages, the method effectively supports the decision-making process, resulting in the acquisition and utilization of the drug product within clinical settings.

The disclosed method addresses moderate to severe chronic plaque psoriasis in pediatric patients through the precise subcutaneous administration of an anti-IL-12/IL-23p40 antibody. Tailored to the patient's body weight, this therapeutic approach ensures the delivery of a safe and effective dosage, maximizing clinical benefits while minimizing potential adverse effects.

For patients weighing less than 60 kg, the antibody is administered at a dosage ranging from approximately 0.5 mg/kg to 1.0 mg/kg, with an optimal target of 0.75 mg/kg. This weight-based dosing strategy ensures sufficient antibody concentration to exert therapeutic effects without exceeding safety thresholds.

In pediatric patients weighing between 60 kg and 100 kg, a fixed dosage ranging from about 35 mg to 55 mg is recommended, with a preferred dose of approximately 45 mg. This regimen maintains consistent therapeutic levels across a broader weight range, accommodating variations in patient metabolism and antibody clearance rates.

For patients exceeding 100 kg, the method prescribes a dosage between 80 mg and 100 mg, with 90 mg being the preferred amount. This higher dosage accounts for the increased volume of distribution and potential alterations in pharmacokinetics associated with greater body mass, ensuring the antibody maintains its efficacy in larger patients.

The administration process requires careful preparation and handling of the antibody to preserve its biological activity. Healthcare providers are trained to perform subcutaneous injections with precision, minimizing discomfort and ensuring accurate delivery of the prescribed dose.

Overall, this method emphasizes a personalized treatment approach, adjusting the antibody dosage based on individual patient characteristics to optimize therapeutic outcomes in managing chronic plaque psoriasis in pediatric populations.