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Potential Patient HUB Services Opportunities in the Ex-US Drug Market: Borrowing from US Experiences

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Introduction

➢In the United States, as a single point of contact between health care practitioners (HCPs), patients and a pharmaceutical or biotech manufacturer, **a HUB Service provides comprehensive patient services to improve access, provide financial assistance pathways and increase patient adherence in a compliant manner.** Additionally , today's rapidly changing healthcare landscape requires HUBs to provide innovative HCP and patient offerings; reflective of current health policy, patient expectation and needs and adapted to payer mandates and restrictions.

➢The US digital healthcare HUB services have emerged as a vital part of the market access landscape assisting HCPs and patients overcome a multitude of obstacles to access therapies, thus achieving better patient compliance and outcomes. **These HUBs prove especially vital for patients on specialty therapies that can be complicated to understand and administer.**

➢However, due to reimbursements structures, health policy and country specific laws, many countries outside the US, do not lend themselves easily to the concept of HUB services, and **ex-US pharmaceutical and biotech firms have been uncertain about the need for these services to support their products.**

➢The aim of this study was to determine **what necessary aspects of US patient service HUBs can be adapted and integrated into the patient fulfillment infrastructure to increase patient access, education, and compliance in other geographies.**

Ex-US Patient Service Background

➢Many ex-US geographies have established a mature systematic national coverage and reimbursement process, and policy shaping opportunities are closed for major changes to the current system. **The financial support traditionally supplied by US HUBs are not needed in these markets.**

➢**Varied country-specific laws or regulations** that may prohibit patient services programs (PSPs) that could be perceived as direct- to –patient marketing, thus requiring adaptation.

➢**Certain ex-US markets, like China, have financially-focused patient assistance programs (PAPs) that are structured under market access strategy;** PAPs are setup with the help of government charitable foundations and only serve patients by providing financial assistance. HUB vendors do not currently exist in China as lowering drug prices is top-most governmental priority, and free-standing charities accept pharma funding to run such programs

➢**However, the global needs for certain patient services are now being recognized.** For example, China's central government is emphasizing improving access to rare disease treatment, and Europe recent reported €125 billion are lost each year due to medication non-adherence. In fact, APAC projected patient services CAGR is expected to grow 19% by 2030.

Methods

➢**Through secondary and primary market research (PMR), Clarivate identified the top HCP, advocacy and consumer needs and preferences for US oral-oncolytics' patient HUB service offerings** for products launched in the last 5 years. 4 main dimensions were identified: Consumer Needs, Accessibility, Satisfaction and Outreach (Fig. 1). These were then further indexed using two attributes each that were further broken down to multiple micro-services and then scored from 1 to 7.[1]

➢ **Customer experience and awareness were evaluated from PMR of HUB stakeholders that included HCPs and patient service providers.** The rest of the attributes were evaluated using HUB services offerings and drug websites by a team of marketing consultants. **The methodology illustrated in Fig 2. can easily be expanded into other therapeutic areas (TAs) and into different countries/regions.**

➢**Country-specific PSP regulations were then reviewed APAC, UK, and EU4 along with projected PSP growth** and then HUB adaptations recommendations were evaluated by each region.

➢Additionally, **Clarivate evaluated HUB non-core ancillary services that could be adapted for ex-US offerings**. (e.g., #1. Providers – dose exchange program, adverse event/reaction grading scale info, expert training videos, #2. Ease of use/Technology – Accessibility overlay suite, chat bots, editable PDFs and #3. Patients – case managers are nurse navigators, compliance support documents) These services were evaluated on consumer desire and applicability to a global program.[2]

Results

➢ Across US HCP and HCP support staff respondents to surveys and interviews, the top responses to what was most important for HUB service offerings; one being patient financial assistance (Fig. 3) which is generally not needed to the same degree outside the United States. However, **with manufacturers' support, stakeholders such as Digital Health IT companies can possibly mimic HUB offerings by tracking patient metrics such as compliance, disease tracking, caregiver support and side effect managemen**t in an ex-US market.

➢ **Researching country-specific restrictions, and laws pertaining to PSPs**, data showed that the European countries had the most country to country discrepancies in what type of PSP would be allowed.

➢ **APAC represented the best projected growth in PSP** with multiple opportunities to repurpose HUB services tools. Country-specific considerations such as Japan's widely dispersed healthcare system or China's requirement that manufacturers partner with qualified charities must be considered when developing potential opportunities.

Conclusion

➢ **Through direct evaluation of HUB services and primary research directed at end-users, essential and ancillary non-financial criteria were identified that can best support patient needs without a financial component.** Respondents identified that clearly written, easy to understand content, clear prescribing information on topics such as dosing and side effects, and access to case managers, compliance, and caregiver support were all important to a successful HUB.

➢ Unlike in the US, country-specific regulation of pharmaceutical advertising can pose a problem to launch these types of services. **The lack of standardized regulation makes implementing PSPs difficult but offers opportunities to focus on non-financial support mechanisms.** In markets where financial support is viable, like in China, specific regulation must be followed.

➢ Compared to the EU, APACs less restrictive market may offer manufacturers an easier time developing PSPs leveraging non-financial support opportunities. **Existing manufacturers should rethink their strategies and approach to PSPs supporting specialty medications and rare diseases, and targeting APAC markets is a good first step**.

Table 1: Ex-US PSP-related regulations

Country	Regulation impacting Patient Services Programs (PSP)	Impact on availability of Patient Services Programs
	Article 97 and Article 98 of Directive 2001/83/EC	Broadly governs rules for pharmaceutical marketing in EU but allows member states discretion on how to legislate PSPs[3]
	None	Lack of laws, legal precedent, guidelines, and standardized approach force manufacturers to rely on regional jurisprudence and industry standards of practice to develop PSPs[4,6]
	3rd Party Partnership	Manufacturers are required to use independent 3rd party services to manage PSPs[4,5,6]
	Country-Specific Legislation	France has passed legislation governing how PSPs are to be created and managed, with approval times taking 18 to 24 months[7]
	Agency Partnership	Manufacturers are required to follow Medicines Australia guidelines in compliance with Australia's Therapeutic Goods Association legislation[8]
	Regulatory Guidelines	Chinese regulatory oversight and PICMP guidelines govern all aspects of PSPs and require partnerships with qualified local charitable foundations in order to provide support[10]
	None	Partnerships with patient advocacy groups are allowed under JPMA code of conduct and must follow an ethical, transparent approach to develop these programs[9]

Figure 1: HUB service assessment framework

Dimension	Attribute	Description and Scoring
Consumer Needs	Patient Services	*Comprehensive education, medical, and compliant financial support for patients*
	Provider Services	*Comprehensive reimbursement, billing, and educational support for providers*
Accessibility	Ease of Use	*Accessibility to services, preferred methods, and communication for case mgmt.*
	Technology	*Availability, utilization, and quality of online resources for HUB services*
Satisfaction	Quality	*Prioritization of key programs, areas of success, areas in need of improvement*
	Customer Experience	*Consumer feedback on experience using provided services*
Outreach	Awareness	*HCP and patient awareness of program offerings, resources, and perceptions of services*
	Advocacy	*Focus on overcoming health disparities and outreach to underserved communities*

Figure 2: Oral oncolytic drug PSP target methodology

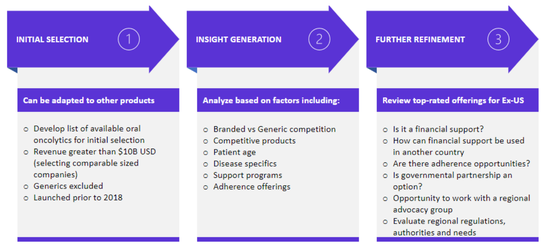

Figure 3: Summary of essentials for a HUB services Program

PSP *- Patient service program, AKA HUB services.* ***APAC-*** *Asian Pacific Countries including Japan, China, Singapore, India, Australia, and South Korea.* ***EU-*** *European Union.* ***HCPs-*** *Healthcare practitioners.*

[1]Clarivate Commercial Strategy Consulting, 2023, Data on file. [2]DRG/Clarivate Cybercitizen Health® U.S. 2021, [3]Kingham, Richard, editor. *The Life Sciences Law Review*. 5th ed., Law Business Research Ltd, 2017. [4]Global Legal Group. "International Comparative Legal Guides.", 2022. [5]Bovy, Geert. "Promoting Medical Products Globally: Handbook of Pharma and MedTech Compliance." Baker McKenzie. [6]"Are European Advertising Laws Ready for Patient Support Programmes?" Osborne Clarke, 6 Dec. 2021. [7]Upton, Julian. "Patient Support in Europe." *Pharmaceutical Commerce*, vol. 17, no. 2, Apr. 2022. [8]*Medicines Australia Code of Conduct Guidelines*. 2016, p. 95. [9]"JPMA Professional Policies and Guidelines." *Japan Pharmaceutical Manufacturers Association (JPMA)*. [10]*Yearbook of Patient Assistance in China 2021*. Deloitte, 2021.