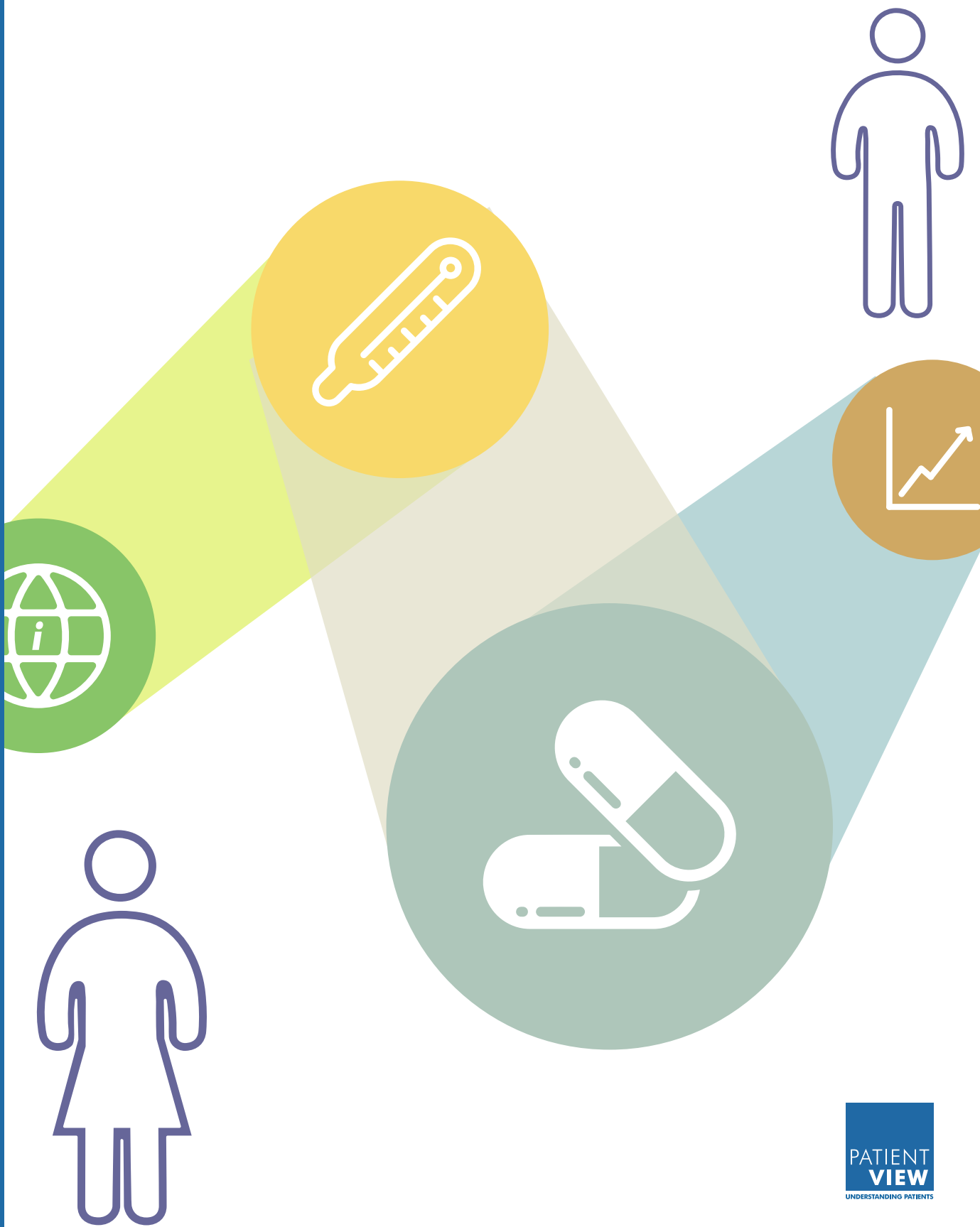
BEING PATIENT–CENTRIC

DRUG-TREATMENT INFORMATION: A PATIENT PERSPECTIVE

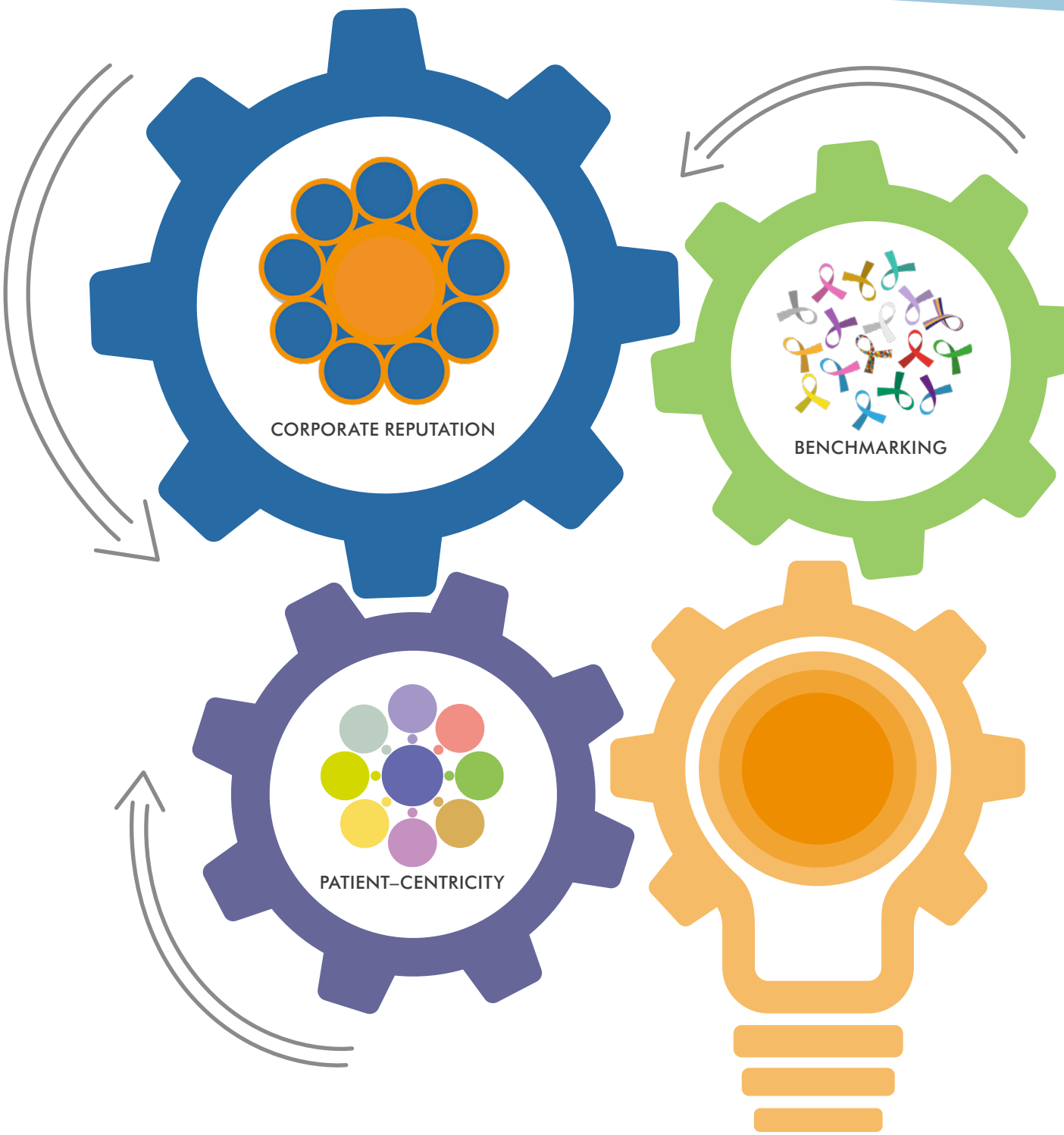
A guidance document to improve corporate reputation



PATIENT VIEW
UNDERSTANDING PATIENTS

PATIENTVIEW'S TOOLKITS

All three toolkits are supportive of one another, and are designed to yield positive advances in corporate reputation from a patient perspective.



PRECONDITIONS TO PATIENT-CENTRICITY ARE CLOSE TO THOSE OF CORPORATE REPUTATION

A company that is more patient-centric than its peers will also have a better corporate reputation than them among patient groups. Patient groups defined for PatientView the contributing indicators for patient-centricity and for corporate reputation. These evidence-based indicators are virtually the same for both corporate parameters.

BENCHMARKING THE PATIENT MOVEMENT

Benchmarking the patient movement tells you where to make the most effective investments to improve your patient group relationships.

CONTENTS

INTRODUCTION

TO A GUIDANCE DOCUMENT ON HOW TO IMPROVE CORPORATE REPUTATION IN THE PROVISION OF DRUG-TREATMENT INFORMATION

INTRODUCTION

To ensure successful participation in their healthcare, patients need clear, accurate, and helpful health information, which they can comprehend sufficiently to be able to discuss issues of importance with health professionals. The situation with prescription medicines is scarcely different. As the UK's own Medicines and Healthcare products Regulatory Agency (MHRA) stated, as recently as June 2019: "Good information helps patients to participate more fully in concordant decision-making about medicines prescribed for, or recommended to, them by healthcare professionals. Self care—a key [UK] government objective—relies heavily on patients having sufficiently high-quality information on which to base their decision-making"[1]. At issue across the world is whether the drug-treatment information currently supplied to patients is adequate, and fulfils this important purpose.

In most countries, the primary form of communication to patients about their prescribed medicines remains the mandatory Patient Information Leaflets (PILs), otherwise known as Patient Package Inserts (PPIs), found inside the packaging of prescription medicines. Each leaflet is written to conform to strict legal and scientific guidelines determined by regulators, and is typically required to provide information about the characteristics of the product; its medical purpose (therapeutic indication); when the medicine should not be used; how to take the medicine; potential side effects; how to store the drug, etc. These leaflets (which often may only be read once—if at all)

[1]User Testing Policy on Patient Information Leaflets for Parallel importers (London, MHRA, 2019)

sometimes form the only source of medicine information for many patients.

Back in 2017, a report from the European Commission recognised that information in medicines packaging suffered from many shortcomings, and did not meet the needs of Europe's patients[2]. Since then, the European Medicines Agency (EMA) has been examining how leaflets can be improved (looking particularly at the ability of patients to comprehend a leaflet's messages, and also at mechanisms for delivery of the information, including the prospect of digital communication)[3]. Numerous academic publications continue to underline the shortcomings of patients' drug-treatment information, emphasising a number of factors, such as: the need to customise information to the appropriate patient audience[4]; the possibilities of improving health outcomes through the provision of patient-decision aids[5]; and the necessity to satisfy the expectations of patients engaged in generating Real World Evidence, through feedback and support in personal treatment regimes[6]. And more.

A role for pharmaceutical companies?

The communicational shortcomings of drug-treatment information are often regarded by pharmaceutical companies as a problem that can only be dealt with by regulators. But arguments do exist to persuade companies to take a more active role, not least the high levels of medication errors resulting from the inappropriate use of prescription medicines. According to the World Health Organization (WHO), 6-7% of hospital admissions in some countries are medication related (two thirds of which are considered preventable)[7]. Another

[2]https://ec.europa.eu/health/sites/health/files/files/documents/2017_03_report_smpc-pl_en.pdf
[3]https://www.ema.europa.eu/en/news/towards-electronic-product-information-eu-medicines
[4]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6229142
[5]https://ascopubs.org/doi/full/10.1200/CCI.18.00013
[6]https://www.ncbi.nlm.nih.gov/books /NBK481618/
[7]Medication errors (Geneva, World Health Organization, 2016)

study of all drugs in the United States approved between 2001 and 2010, found that about one third of them resulted in FDA announced alerts, warnings, or recalls in the years after their approval, as knowledge about drug side effects accumulated with patient use[8]. The European pharmaceutical trade body, EFPIA, estimates that patient non-adherence to medication regimes causes 200,000 premature deaths every year in the EU[9].

A clear understanding of drug treatments is critical to all patients, as highlighted by the example of the current 'opioid crisis' in the United States, identified by the US National Institute of Drug Abuse (NIDA) in January 2019. This wide-scale problem is driven by numerous underlying causes, but a reliance on patient leaflets in medicine packaging, plus short, infrequent consultations with healthcare providers, has clearly been insufficient to prevent the gradual growth of such a health issue, according to the New York-based Center on Addiction[10]. For patients prescribed opioids for pain relief, understanding the signs and implications of opioid dependence and opioid addiction should be an intrinsic part of ensuring patient safety.

One of the reasons why pharmaceutical companies are cautious is because they have been kept by regulators at arm's length from patients for fear that their company information could quickly turn into advertising, or at least disguised promotion if not kept in check. In the EU the advertising of prescription drugs to the public is prohibited, based on the belief that doctors and healthcare professionals know best. Even in the USA, where the practice of Direct-to-Consumer Advertising (DTCA) is permitted by the pharmaceutical industry, different States are trying to find ways to rein in such promotion, because of the belief

[8]https://jamanetwork.com/journals/jama/fullarticle/2625319
[9]https://www.efpia.eu/news-events/the-efpia-view/blog-articles/110926-event-improving-the-sustainability-of-healthcare-systems-through-better-adherence-to-therapies-a-multi-stakeholder-approach/
[10]https://www.centeronaddiction.org/the-buzz-blog/understanding-difference-between-physical-dependence-and-addiction

that it has contributed to soaring drug costs[11]. However, even within these legislative limits regulators recognise the need for improvement to correct the imbalance of information that exists in healthcare between producers, providers and patients. Such reform is not only being promoted by the MHRA and the EU, but also by the US Department for Health and Human Services, Office for Civil Rights in its campaign "Information is a Powerful Medicine" which encourages patients to access their own health data and medical records, including prescription drug data.[12]

The Irish Neonatal Health Alliance (INHA) sums up the challenge at the heart of drug-treatment information when it urges industry to "find alternative methods of communication outside of the Patient Information Leaflet (PIL), to meet the needs of the patient".

Similarly, the Belgium-based blood-cancers patient group, Lymfklierkanker Vereniging Vlaanderen vzw, suggests that industry "ask [for] input from patient organisations before they make their [drug-treatment information] brochure".

So how can pharmaceutical companies legitimately do more?

Many factors are involved in the supply of drug-treatment information that go beyond content, including when, where, and how to deliver that information. The growth of digital health may give pharmaceutical companies opportunities to do more for patients, and improve treatment compliance by offering patient information through different media. Smart packaging can enable better monitoring of patient adherence to treatment. At the same time, patient groups have themselves become trusted communication channels for drug-treatment information, or wish to address a gap on behalf of their patient communities. To be effective in that role, patient groups need to be able to have transparent, consistent, and honest relationships with the pharmaceutical industry.

PatientView has already established in previous research work that the quality of a company's patient-information output has a bearing on the company's corporate reputation among patients and patient groups. The linkage is hardly

[11]http://www.ncsl.org/research/health/marketing-and-advertising-of-pharmaceuticals.aspx
[12]https://www.hipaajournal.com/?s=information+is+powerful

surprising, since the supply of drug-treatment information to patients represents one of the most important ways in which pharmaceutical companies can legitimately have direct contact with patients. Patient groups tell PatientView that they believe industry—even though it operates within a highly-regulated environment—has significant scope for improving treatment information, above and beyond the restrictions of the patient leaflet. Indeed, patient groups responding to the annual PatientView survey, 'The Corporate Reputation of Pharma—from a Patient Perspective', see a decline in the quality and usefulness of pharmaceutical-company patient information since 2015. Just 39% of the 1,500 patient groups responding to the 2018 'Corporate-Reputation' survey describe the industry as

CASE STUDY

Case studies of patient-group intervention in the provision of drug-treatment information.

Australia

Cancer Voices Australia (CVA) was responsible for convincing the Australian government in 2019 that Consumer Medicines Information (CMI) leaflets become a required, rather than an optional, issue. CMIs are printed or online drug-treatment information documents, produced by industry, and designed exclusively for patients. In addition, the Australian government announced July 2019 improvements to the format of CMIs, making them "shorter and better laid out, and featuring a one-page summary that succinctly provides people with the most critical information relating to the safe and effective use of their medicines." CMIs are also to be made available to patients on request.

Source: https://www.health.gov.au/news/improved-medicines-information-for-consumers

CASE STUDY

Case studies of patient-group intervention in the provision of drug-treatment information.

Belgium

Drawing on a grant from multiple pharmaceutical companies, the European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) mapped, in 2017-2018, the availability around the world of innovative medicines (and medical devices) for the treatment of Crohn's and colitis. Such information helps patients check which drugs are generally accessible in their countries.

Source: http://www.efcca.org/sites/default/files/Final%20Report%20Mapping%202018.pdf

Canada

The Sickle Cell Awareness Group of Ontario (SCAGO) has included pharmaceutical companies in its own projects aimed at improving treatment adherence by patients and caregivers.

Source: PatientView July 2019 Patient-Information survey.

Croatia

Koalicija udruga u zdravstvu (KUZ) [Coalition of Associations in Healthcare] acts as a form of 'clearing house', sharing treatment information with other Croatian patient groups. The KUZ also liaises with these peer groups, to try to determine which patients would benefit from the most specialised medicines currently available.

Source: PatientView July 2019 Patient-Information survey.

France

Association Pierre Enjalran Fibrose Pulmonaire Idiopathique (APEFPI) [Association Pierre Enjalran Idiopathic Pulmonary Fibrosis] consults with relevant pharmaceutical companies, and co-organises meetings with patients and patient groups, to gain input on the quality of drug-treatment information.

Source: PatientView July 2019 Patient-Information survey.

Germany

Arbeitsgemeinschaft Multiples Myelom (Plasmozytom, Morbus Kahler) Online-Netzwerk für Patienten/-innen und Angehörige (AMM-Online) [Working Group Multiple Myeloma (Plasmocytoma, Kahler's disease) Online Network for Patients and Relatives] invites doctors and other health professionals to share drug-treatment information on myeloma with its patient community. AMM-Online also invites patients with multiple myeloma who have taken different treatments to talk about their experiences on the treatments.

Source: https://www.myelom.org

CASE STUDY

Case studies of patient-group intervention in the provision of drug-treatment information.

United Kingdom

Crohn's and Colitis UK informs patients with inflammatory bowel disease (IBD) that they may be required by the UK's National Health Service to be transferred from an existing medication to a biosimilar.
Source: https://www.crohnsandcolitis.org.uk/news/new-biosimilar-drugs-for-adalimumab-to-be-made-available-on-nhs

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Epilepsy Society reports on the availability and disruption to the supply of epilepsy medications in the UK.
Source: https://www.epilepsysociety.org.uk/tags/sanofi

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Mind supplies patients who have a mental-health problem with an overview of the main characteristics of a long list of antidepressants.
Source: https://www.mind.org.uk/information-support/drugs-and-treatments/antidepressants/comparing-antidepressants/#.XYD2-W5Fy75

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The Migraine Trust provides patients with information about key drug treatments for migraine.
Source: https://www.migrainetrust.org/living-with-migraine/treatments/preventive-medicines/

*

The Multiple Sclerosis Trust runs a webpage that helps patients decide which prescription drugs best suit their personal circumstances.
Source: https://www.mstrust.org.uk/about-ms/ms-treatments/ms-decisions-aid?field_region_tid=332&field_drug_regimen_tid%5B%5D=277

*

London-based Parkinson's UK provides detailed information about different Parkinson's drugs. Parkinson's UK also reports on its website about potential supply issues for Parkinson's drugs, drawing its information from the appropriate manufacturers.
Source: https://www.parkinsons.org.uk/information-and-support/drug-treatments-parkinsons

USA

The Chicago-headquartered Depression and Bipolar Support Alliance (DBSA) runs an online Q&A forum with doctors, allowing patients and carers to ask questions about treatments. Both the queries (anonymised) and the doctors' answers are published on the DBSA site.
Source: https://www.dbsalliance.org/education/ask-the-doc/?filter=depression

CASE STUDY

Case studies of patient-group intervention in the provision of drug-treatment information.

The New York-headquartered National Multiple Sclerosis (MS) Society describes in detail the different types of MS treatments available in the USA.
Source: https://www.nationalmssociety.org/Treating-MS/Medications

*

The Virginia-based National Osteoporosis Foundation (NOF) provides information on osteoporosis treatments, and also on ways to access them.
Source: https://www.nof.org/patients/treatment

"Excellent" or "Good" at providing high-quality, useful, patient information; in 2015, the figure was 48%.

The variability in levels of health literacy among patients (plus the more frequent involvement of patients in personal treatment decisions, and an ever-greater quantity of publicly-available information on healthcare) places a significant obligation on pharma to get drug-treatment information—a critical aspect of its work—right for all patients. The patient groups participating in the PatientView July-August 2019 Information survey state that pharma has a responsibility to provide not only the basic, legally-required drug-treatment information, but to add value and context, by ensuring that the information is meaningful to sub-sections of the patient community—such as older patients, younger patients, those with co-morbidities, those with a disability, etc—and to provide this distinctive information through channels convenient to patients.

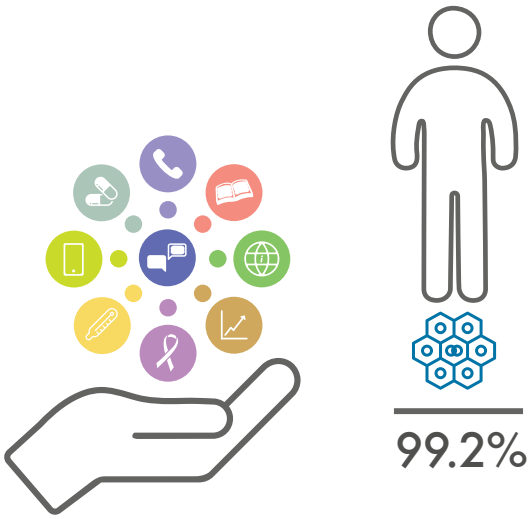
What this guidance document provides

Responding to the challenge of making drug-treatment information more patient-centred is a complex task—yet a vital one, not only to pharmaceutical companies' corporate reputations, but also because the provision of truly patient-oriented, patient-friendly, drug-treatment information adds another layer of validity to pharmaceutical-company claims of being patient-centric.

To support such efforts, therefore, PatientView has produced for industry a guidance document on how to improve drug-treatment information from a patient perspective (with the aim that treatment information becomes more patient-appropriate,

Cancer patients need to understand the science behind their treatments to better manage their medical condition

Patient and carer groups agree...Most say cancer patients want to know how their treatments work (99.2%) and that educating patients will allow them to better manage their cancer (91%).



Source: Adapted from The Use of Scientific Information about Cancer among Carers, Patients and the Public: A PatientView Survey of Patient Organisations, commissioned by AstraZeneca, 2016

and that industry accordingly enhances its corporate reputation, and is visibly seen to be more patient-centric). The document …

(1) Maps the drug-treatment-information needs of patients, across different therapy areas and different countries/regions of the world. The results are drawn from PatientView's July-August 2019 Information survey of 281 patient groups, conducted across 32 countries, in five languages, and over 34-plus disease areas. The response rate allowed for both regional and therapeutic diversity to be identified, and the findings do indeed include a wide range of opinions, according to location, disease type, and language spoken. Industry will clearly have to develop different information strategies to accommodate such significant variation (not to mention the equivalent disparity in regulations across countries' healthcare systems).

(2) Provides a detailed, evidence-based, self-evaluation toolkit of 116 questions for pharmaceutical companies. The toolkit allows companies to test the authenticity of their patient-centric drug-treatment-information strategies, and to then create further action plans. The toolkit's self-evaluation questions are drawn from the written feedback provided by patient groups responding to a number of PatientView surveys:

—281 patient groups responding to the July-August 2019 worldwide Information survey [see accompanying Appendices].

—Patient groups responding to the annual worldwide 'Corporate Reputation of the Pharmaceutical Industry' survey, 2015-2019.[13]

—119 patient groups responding to the July 2015 Europe-wide survey, 'Patient Groups' Understanding of Biosimiliars'. Results presented to the European Commission, 2015.[14]

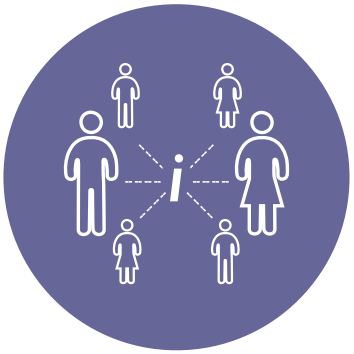
—126 cancer patient groups responding to the May 2016 worldwide survey, 'Use of Scientific Information about Cancer by Carers, Patients, and the Public'.[15]

[13] http://www.patient-view.com/bull-about-corporate-reputation-of-pharma-2018-2019.html
[14]https://alexwyke.wordpress.com/2015/12/16/patientview-study-on-biosimiliars-presented-at-european-commission-workshop/
[15]https://www.statnews.com/sponsor/2017/08/14/survey-patient-organizations-finds-cancer-science-communications-complex

Defining drug-treatment information

Drug-treatment information is a broad topic. So, interpretation of its meaning may differ, according to individual patient perspectives. The definition used in this guidance document is PatientView's own: "information provided by pharmaceutical

Why so many patients are excluded from receiving relevant drug-treatment information



NARROW CLINICAL TRIAL EVIDENCE BASE

Recruitment criteria excludes most 'real' patients

Protocol focuses on very targeted indications

Resulting evidence defines all the content of the patient information package insert

Focused even further by local treatment guidelines and restrictions

REAL WORLD PATIENTS

The limitations of current drug-treatment information risks excluding patients because they do not precisely 'match' clinical trial participants. Examples of excluded patients include:

- common co-morbidities
- common concurrent treatments
- age, gender, ethnicity
- pregnant or lactating
- weight
- motivations and concerns around treatment
- differing pharmacodynamics
- rare disease and off-label use

Information exclusion can be mitigated if there are patient-friendly channels for collecting and communicating Real World Evidence

companies relating to a licensed product". The definition should be understood to encompass two subjects of importance to patients—the distribution, and the supply, of medicines. Such information may be disseminated directly, by the originating pharmaceutical company, or indirectly, via other channels (such as through healthcare professionals or patient groups).

The importance of this 2019 guidance document

Many pharmaceutical companies today are committed to being more patient-centric. Those that have made the decision understand that such an approach benefits not only patients, but the individual pharmaceutical company's corporate reputation. Hopefully, this guidance document can provide data-driven advice on how the complex issue of providing outstanding drug-treatment information can be achieved.

Other PatientView research of possible interest

This 2019 guidance document is the third in a series that provides a 'deep dive' into the ways that companies can improve their corporate reputation through being patient-centric. The other two documents are …

—PatientView's 'Being Patient-Centric' toolkit. Published in November 2017, the toolkit is a self-assessment framework aimed at helping pharmaceutical companies move down the path to patient-centricity. The toolkit has been developed from over 10 years of work surveying the needs and perceptions of patient groups.

—PatientView's 'Patient Involvement in R&D' toolkit. Published in November 2018, this second toolkit summarises the key areas

in R&D in which pharmaceutical companies can become more patient-centric—as defined by patient groups. The toolkit has been developed from two sources: the results of an August-October 2018 PatientView survey of 104 US patient groups on the subject of patient involvement in R&D, plus the results of the November 2017-February 2018 'Corporate Reputation of Pharma' survey of 1,330 patient groups worldwide.

As an evidenced-based approach to meeting patients' needs in complex areas (and given the strong correlation between effective patient-centricity and corporate reputation), this 2019 guidance document also sits alongside PatientView's annual survey on the 'Corporate Reputation of Pharma'.

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