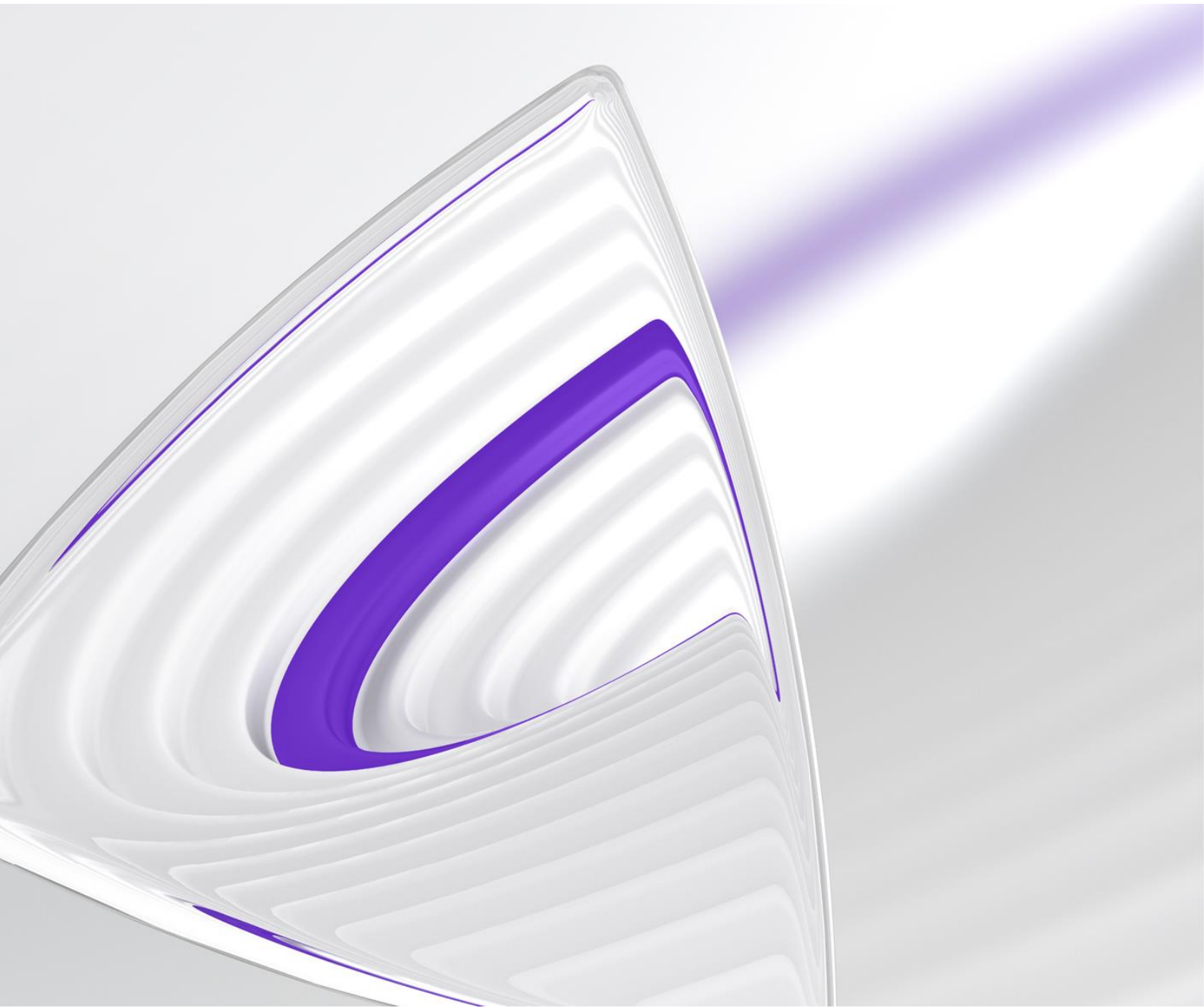
Clarivate Cortellis™

Cortellis Generics Intelligence

Help File/Glossary



Contents

Homepage

New Products

List of new Product records added to Cortellis Generics Intelligence database in the last three months. Click over the Products to be directed to their page.

New Drug Approvals EMA – US FDA (NDAs only)

Most recent approvals from either the European Medicines Agency (EMA) or US FDA (NDAs only). They are listed as brand, API and the company for whom the approval has been granted. Both the API and the company are readily accessible by clicking on their name.

Quick Search

The Quick Search bar allows fast and intuitive search of known Products or Companies. Autocomplete suggestions appear after the user has introduced three or more characters, for both Products (including US brand name, UNII and CAS number) and Companies. For Products, there is an identifier icon for Combination Products. For Companies, there is an identifier icon for Corporate Groups. The Quick Search feature is available on the homepage and in the header of all other pages.

Product View All

List of all suggested results for Product names typed in the Quick Search bar.

No. of Active API Manufacturers

Count of all API Manufacturer subsidiaries with Manufacturer Status 'Commercially Available' or 'Under Development' (see Product Key Insights section).

Company View All

List of all suggested results for Company names typed in the Quick Search bar. The first column corresponds to the Corporate Group identifier icon.

Company Type

There are two main categories:

- Corporate Group: the parent company or ultimate company holding group of a subsidiary.
- Subsidiary: specific site that is managed by a Corporate Group. There are 4 Subsidiary Types.
    - API Manufacturer: specific site to which Cortellis Generics Intelligence has linked API(s) manufacturing process.
    - Finished Dose Manufacturer: specific site to which Cortellis Generics Intelligence has linked Dose Product manufacturing process, this is API(s) and the excipients in the specific dosage form.
    - Marketer: a specific site that is connected to launched drug forms.
    - CRO: specific site to which Cortellis Generics Intelligence has linked development of bioanalytical methods as a service.
    - Other Subsidiary: all other Subsidiaries.

Corporate Group Type

Corporate Groups (and their subsidiaries) are associated to one or more of the following terms:

- API: Corporates that have API manufacturing capabilities.
- US Generic: Corporates that have a generic presence in the United States.
- US Specialty: Generic companies that have several branded products in the United States which are unique formulations.
- Small Innovator: Corporates with in-house R&D, but with a small number of innovative products and a regional sales and marketing focus.
- Biotech: Corporates associated with biologic products.
- Big Pharma: Innovative Corporates with at least $1.0B USD in annual R&D expenditures.
- Dose: This category will include OTC marketers, generics without US presence and parallel importers. It also gathers companies that do not fall in the Big Pharma, Small Innovator, US Generic or US Specialty categories.

No. of Confirmed APIs

The number of APIs Cortellis Generics Intelligence has confirmed that this company is manufacturing with 'Commercially Available' or 'Under Development' API Manufacturing statuses (see API Manufacturers Summary section).

Product Key Insights

The Key Insights view on Product Records provides a fast overview and summary of the key data available for a given product. Identifier information for the Product is displayed on top in the Product Summary and the cards below provide analytics and visualizations. Users can customize the view by dragging and dropping the sections.

Product Summary

Therapeutic Area

Products are associated to the hierarchical Anatomical Classification of Pharmaceutical Products developed by the European Pharmaceutical Market Research Association (EphMRA).

Technologies

The pharmacological mechanisms of action and all the technology terms for which the Product has been associated with based on Cortellis indexation. These includes those technologies that are in development and may not yet be available in the market.

API Availability

The API Availability Rating is a proprietary Cortellis Generics Intelligence analytic that indicates the current availability of the active ingredient for regulated markets like Europe and North America. This analytic is not displayed for Combination Products.

- No Confirmed Sources: no confirmed sources of the active ingredient exist in regulated or less regulated markets.
- Limited Sources: limited sources of the active ingredient exist in regulated and/or less regulated markets.
- Less Regulated Markets: the active ingredient is available for use in less regulated markets and may be available in limited quantities for regulated markets.
- Regulated Markets: the active ingredient can readily be found for use in regulated markets.
- Excessively Available: the active ingredient is readily available for regulated markets and supply exceeds demand.

US Generic Forecast

The US Generic Forecast is a proprietary Cortellis Generics Intelligence estimation of the likely competitiveness of a product in the US, at loss of exclusivity. This analytic is not displayed for Combination Products.

- Delayed Entry: likely delayed entry by generics because of very limited raw material availability.
- Limited Competition: few generics anticipated at loss of exclusivity; minimal and likely slow price erosion because of limited availability of raw material from qualified sources.
- Moderately Competitive: numerous generics anticipated at loss of exclusivity; moderate and likely slow price erosion because of availability of raw material from limited qualified sources.
- Highly Competitive: numerous generics anticipated at loss of exclusivity; considerable and likely rapid price erosion due to availability of raw material from many qualified sources.

Sales and API Consumption

Drug Product Sales information is licensed from IQVIA and generally reported at the base molecule level. The data refers only to retail pharmacy and hospital sales for human prescription drugs globally. IQVIA has gathered the information by auditing the distribution channels for manufacturers and wholesalers – IQVIA does not audit other channels such as sales to government institutions and other organizations. This content is only available to Cortellis Generics Intelligence Global and Premium users.

API Consumption information is also licensed from IQVIA and reported at the base molecule level. The data refers only to retail pharmacy and hospital sales for human prescription drugs globally. The data

informs of kilogram sales volume for molecule consumption. When the weight value is not useful, UI is used as a measure to indicate the biological activity of a substance. It is commonly used for vitamins, some drugs and other biologically active substances. This content is only available to Cortellis Generics Intelligence Premium users.

The Sales and API Consumption information displayed is split by Dose Form and Region, and it is exportable in Excel format.

There are 5 regions:

- USA: United States, Puerto Rico.
- EU Top 5: France, Germany, Italy, Spain, United Kingdom.
- Rest of Europe: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, Slovakia, Slovenia, Sweden, Switzerland.
- Latin America: Argentina, Brazil, Central America, Chile, Colombia, Dominican Republic, Ecuador, Mexico, Peru, Uruguay, Venezuela.
- Rest of the world: Algeria, Australia, Bangladesh, Canada, China, Egypt, French West Africa, Hong Kong, India, Indonesia, Israel, Japan, Jordan, Korea, Kuwait, Lebanon, Malaysia, Morocco, New Zealand, Pakistan, Philippines, Saudi Arabia, Singapore, South Africa, Taiwan, Thailand, Tunisia, Turkey, United Arab Emirates, Vietnam.

Altogether are summed up in Worldwide.

If NA or Not Reported is displayed for a particular region, then IQVIA did not provide data for the product in that region.

Equivalents

All other active ingredients related to the base molecule. For example, for olanzapine it would also include olanzapine form I, olanzapine form II and olanzapine polymorph. Not only is there information about the launched form, but also related APIs, providing crucial intelligence about potential alternative forms and competition.

API Manufacturers Summary

Bar chart of API Manufacturer subsidiaries count for top 5 ranked countries/territories, split by Manufacturing Status. Sixth column bundles together the remaining API Manufacturing subsidiaries regardless of their country/territory. 'Unconfirmed' and 'Not Manufacturing' statuses are excluded.

This visualization is not displayed for Combination Products.

Manufacturing Status

The current manufacturing status, or relationship, between the API and the manufacturing site, according to Cortellis Generics Intelligence.

- Commercially Available: Cortellis Generics Intelligence has confirmed with multiple sources that the site is producing or is able to produce commercial quantities of the API.
- Under Development: Cortellis Generics Intelligence has confirmed with multiple sources that the site is developing a process, has the capacity to manufacture clinical trial quantities, or is scaling up production of the API.
- Early API Activity: Cortellis Generics Intelligence has learned within the last year that there may be a connection between the API and the manufacturing site but has not yet validated this information with multiple sources.
- Innovator or Marketer: API is manufactured by the marketer and/or innovator of the branded product or by a third party for exclusive use by the innovator/marketer.
- Unconfirmed: Cortellis Generics Intelligence has not been able to confirm or has conflicting information from multiple sources concerning the status of development at this site.

- Not Manufacturing: multiple sources have confirmed that the company is not (or never was) manufacturing this API, has at some time in the past manufactured this API or is trading another company's API.

Unexpired Constraint Date Forecast and Exclusivities Summary

Table listing up to 37 countries/territories for which Constraint Date Forecast (CDF) is calculated and the rationale behind the displayed CDF. Table is sorted based on CDF, oldest to most recent.

This analysis is not available for Combination Products.

Constraint Date Forecast (CDF)

This analytic is a proprietary Cortellis Generics Intelligence algorithm that considers patents, market exclusivities and data exclusivities for a specific product in a specific country/territory and estimates when the product loses patent or exclusivity protection. The CDF is useful to consolidate patent expiry information for targeting products and should not be taken as a definitive date.

List of 37 countries/territories by alphabetical order: Albania, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, UK, USA.

Regulatory Filings Summary

Counts of the Regulatory Filings including: US DMFs, EU COS/CEPs, KR DMFs and JP DMFs. The counts only reflect the Regulatory Filings in force for the API and its Equivalents per each Regulatory Agency, this is Active US DMFs, Valid EU COS/CEP, Registered KR DMF and Registered JP DMF. In the caption of the analysis there is the total count of in force Regulatory Filings for the Product and its Equivalents.

This analysis is not available for Combination Products.

US DMF

A DMF (Drug Master File) is a confidential document covering a specific manufacturing facility, process or article used in the manufacture, processing, packaging or storing of a bulk API which is covered in an ANDA or NDA. DMFs are never approved or disapproved by the FDA. Instead, they are kept on file and only reviewed when a manufacturer files an ANDA or an NDA referencing a certain raw material supplier's DMF.

EU COS/CEP

A Certificates of Suitability (EU COS/CEP) allows the manufacturer of a substance to provide proof that the purity of the substance is suitably controlled by the monograph of the European Pharmacopoeia. It is similar to a US DMF, but it is reviewed, and a paper approval is granted.

JP DMF

A Japanese Drug Master File (JP DMF) is a file registered with the Pharmaceutical and Medical Devices Agency PMDA (Japanese regulatory agency) which provides detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and marketing of medicinal products and devices. A JP DMF also indicates that the registrant's manufacturing facilities and the management methods comply with GMP. There are the following 4 types:

- Type 1 – Active Pharmaceutical Ingredients
- Type 2 – Additives
- Type 3 – Medical Device Materials
- Type 4 – Others

KR DMF

A Korean Drug Master File (KR DMF) is a file registered with the Korea Food & Drug Administration which provides detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and marketing of medicinal products and devices. A KR DMF also indicates that the

registrant's manufacturing facilities and the management methods comply with Good Manufacturing Practices (GMP).

Approvals Summary

An analysis of US Approvals, divided by five possible Application Types for Chemical Entities (if reported); this is NDA, BLA, 505(b)(2), ANDA and aBLA Approvals. Additionally, each Application Type is split into categories based on the Approval Status.

The FDA Orange Book contains all approved NDAs and approved ANDAs along with their corresponding patent and exclusivity information. Cortellis Generics Intelligence integrates the FDA updates to the Orange Book with other FDA information such as ANDA tentative approvals and discontinuations as they become available, in addition to ANDA filings Cortellis Generics Intelligence learns about through litigation which do not appear in the online FDA Orange Book.

Listed Approvals: NDA, 505(b)(2), ANDA, BLA and aBLA.

Approval statuses: Tentative, Filed, Approved, Approved - RX, Approved - OTC, Discontinued.

The Approvals summary also provides two statuses:

- USA First Approval Date (NDA/BLA): date of first NDA, 505(b)(2) or BLA Approval reported by FDA.
- EU First Marketing Approval: country/territory/region and date of first reported First Marketing Authorization.

Unexpired Patents Summary

Analysis of patents count for top 5 ranked countries/territories/authorities, split by whether the patents are constraining or not.

This information is not available for Combination Products.

Constraining

Constraining patent(s) are those which have been identified as most likely to prevent generic competition or which may not be easily circumvented.

Product - API Manufacturers

The core of Cortellis Generics Intelligence is the proprietary and unique API manufacturing data. Cortellis Generics Intelligence has been tracking global API manufacturing activities for more than 25 years. API information is obtained from a confidential network of industry sources, including API manufacturers and their competitors, generic drug manufacturers, agents and traders, and government sources. Cortellis Generics Intelligence has an extensive network of industry contacts who are contacted on a regular basis to validate data and provide insights into the markets. Information is updated on a weekly basis as and when it has been validated and verified.

API Manufacturers table includes all the APIs and all Equivalents of the API(s). Also available is US FDA supported information such as GDUFA Fee Payment Date (fiscal year), Facility Registration Date (fiscal year), and the most recent dates for FDA Warning Letter and FDA Inspection Date, if reported.

API Manufacturer

It is the specific site to which Cortellis Generics Intelligence has linked the active ingredient manufacturing process.

Manufacturing Status

As defined in API Manufacturers Summary section.

Corporate Group Type

As defined in Quick Search section.

Corporate API Rating

It is a proprietary Cortellis Generics Intelligence analytic that indicates how capable the corporate group is of supplying bulk ingredients to regulated markets. The rating was developed by Cortellis Generics Intelligence's Research Department to provide users with an idea of how capable a corporate group is of supplying bulk ingredients to regulated markets like North America and Europe. The rating is neither product nor site specific and is not a comment on the quality of a supplier's material.

- Established: companies with years of experience supplying active ingredients to a regulated market.
- Less Established: less of a track record in supplying to regulated markets, either in terms of years of history or number of products supplied. Still considered as capable of supplying regulated markets.
- Potential Future: interest in supplying regulated markets, but with limited or no known performance.
- Local: supplying only to their local and other less-regulated markets; do not currently have the capability of passing inspections by regulatory bodies like the US FDA.
- Unrated: companies for which Cortellis Generics Intelligence has not assigned a rating.
- Big Pharma: innovative companies with at least $1.0B in annual R&D expenditures.

Cortellis Generics Intelligence attempts to track inspections for several inspection Authorities. However, only information about the US FDA inspections is available on a consistent basis and therefore it is the only inspection data that is taken into account when determining the Corporate API Rating.

Regulatory Filings

Only active Regulatory Filings are displayed. Access Regulatory Filings Summary section for a complete list that includes all Regulatory Filings regardless of their status, plus the US VMFs.

Available for Ref US DMF

Flag that identifies if an API Manufacturer has an "available for reference US DMF", which would be evidence of preparedness to enter the US market. A US DMF is available for reference when DMF GDUFA Fee is paid and the DMF passes a Completeness Assessment. Hovering on the flag provides 'Completed as of' date; if there are several US DMFs for reference, then the newest date is taken.

GMP Certificates

Good Manufacturing Practices (GMP) certification is given to API manufacturing sites upon the successful inspection of the site and manufacturing process for a specified API. Dates for certification are listed and the Certification Authorities are displayed in the tooltip. When a GMP certificate is Non-Compliant, it is specified together with the date. Certifications are provided by country/territory regulatory agencies and updated weekly.

Facility Inspections

Facility inspection certificates included in Cortellis Generics Intelligence are issued by the following agencies: Australia (TGA), Austria (AGES), Austria (BASG), Belgium (FAMHP), Brazil (ANVISA), Bulgarian Drug Agency, Canada (Health Canada), China (NMPA), Croatia (HALMED), Czech Republic (SIDC), Danish Health and Medicines Authority, Estonia Ravimiamet, EU (EDQM), Finland (Fimea), France (ANSM), Germany (BFARM), Germany Bayern (ZAB), Germany District Gov. of Cologne, Germany Lower Saxony, Germany Regional Gov. Office, Germany Regional Gov. Office, Germany Schleswig-Holstein (LAsD), Greece (EOF), Hungary (GYEMSZI), Hungary (NIPN), Hungary (OGYI), India (CDSCO), Ireland (HPRA), Italy (AIFA), Italy (DGSAFV), Japan (PMDA), Korea (MFDS), Latvia (SAM), Malta Medicine Authority, Mexico (COFEPRIS), Netherlands (IGZ), Norway (NoMA), Poland (Main Pharmaceutical Inspector), Portugal (INFARMED), Romania (NAMMD), Slovenia (JAZMP), Spain (AEMPS), Sweden (MPA, Medical Products Agency), Switzerland (Swissmedic), Taiwanese FDA, UK (MHRA), US FDA, WHO. Cortellis Generics Intelligence lists only the latest inspection dates.

Import and Manufacturing

Information from the last 5 years about which country/territory and since what date API Manufacturers may export the API. Full name of the country/territory is provided in the tooltip.

Types of Import and Manufacturing:

- Import Registration: Import Registrations are the registration of a foreign manufacturing unit and its manufactured drug for import into another country/territory. Information regarding these registrations is gathered from local regulatory agencies within the country/territory of registration.
- Manufacturing Registration: Manufacturing Registrations are the registration of a local manufacturing unit and its manufacturing activities within the country/territory. Information regarding these registrations is gathered from local regulatory agencies within the country/territory of registration.
- Import Refusal - Bulk: products entering the US through Customs that have been found to appear in violation of the Food, Drug, and Cosmetic Act. When a package is refused entry into the United States, the FDA issues an Import Refusal Report.
- DEA Import Application/DEA Import Registration: a Controlled Substance is a drug or chemical substance included in Schedule I, II, III, IV, or V of the Controlled Substances Act whose possession and use are regulated by the Drug Enforcement Administration (DEA).

Product - Regulatory Filings

The Regulatory Filings intelligence in Cortellis Generics Intelligence cover four markets: US DMFs, EU COS/CEPs, KR DMFs and JP DMFs. Their definition is in Regulatory Filings summary section. The information is displayed for the Product and its Equivalents.

Holder

The company that has requested the Regulatory Filing.

Manufacturer

The manufacturing site where the Regulatory Filing is applicable.

Date

For EU COS/CEP it is the date when filing was granted. For JP DMF and KR DMF it is the date when the filing was registered. For US DMF it is the date he filing was received by the FDA.

Number

Identifier of the Filing. For US DMFs, the records starting with N- are not true DMFs but actually Abbreviated Antibiotic Drug Applications.

Status

Current status of the Filing. JP DMF and KR DMF are Registered, US DMF either Active or Inactive, and EU COS/CEP either Valid, Expired, Suspended, Withdrawn by Holder or Withdrawn by EDQM.

Type

There are multiple “types” according to the specific Filing.

There are 5 types of US DMF:

- Type I: Manufacturing Site, Facilities, Operating Procedures, and Personnel
- Type II: Drug Substance, Drug Substance Intermediate, and Material Used in Their Preparation, or Drug Product
- Type III: Packaging Material
- Type IV: Excipient, Colorant, Flavour, Essence, or Material Used in Their Preparation
- Type V: FDA Accepted Reference Information

Type II DMFs can also be filed for intermediates and finished dose products, so not all Type II DMF holders will show up in API Manufacturers table.

There are 4 types of JP DMF:

- Type 1: Active pharmaceutical ingredients
- Type 2: Additives
- Type 3: Medical device materials
- Type 4: Others

Description

Relevant information provided by the FDA about the drug product (dose), drug substance (API), manufacturing location and manufacturing process.

AADA Type

An AADA is similar to an ANDA but reserved for antibiotics that duplicate products that were previously approved by the FDA. However, AADAs are more in line with NDAs and ANDAs from the FDAs perspective. Cortellis Generics Intelligence lists them along with the DMFs because the information they provide is similar in that they indicate when the product is approved for bulk or dose.

Complete as of

Date when US DMF GDUFA Fee was paid. According to the GDUFA legislation, a generic drug submission either referencing Type II DMF or filed after October 2012 shall be subject to a DMF fee.

Inactive as of

The quarterly posting date by the FDA when the US DMF was first listed as inactive. There are three reasons for a US DMF to be listed as Inactive:

- DMF has been closed as a result of a holder requesting that the DMF be closed.
- DMF has been closed by the FDA because the holder did not respond to an overdue notification letter within 90 days to update the DMF.
- The DMF is overdue for an update. A DMF is considered to be overdue for an update when there have been no annual reports submitted since the cut-off date. As of June 30, 2010, the cut-off date was June 30, 2007.

Product - Approvals

Cortellis Generics Intelligence contains information about Worldwide Approvals, European First Marketing Authorization and US FDA Approvals.

Worldwide Approvals

Drug Product approvals from following Regulatory Agencies:

- Brazil ANVISA
- China NMPA
- Canada HC
- Israel MOH
- Italy AIFA
- Japan PMDA
- Mexico COFEPRIS
- Saudi Arabia SFDA
- South Korea MFDS
- Turkey TITCK

There is detailed information of the Trade Name, Holder, Status, Approval Date, and Application Number. This content is only available to Cortellis Generics Intelligence Global and Premium users.

EU First Marketing Authorization Details

The first date and country/territory/region on which the Drug Product was approved for launch. These dates are the reference date for all indexed SPCs (derived from SPCs and/or Centralized Procedure data which may not be comprehensive).

35 countries/territories/regions are indexed, listed by alphabetical order: Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Germany (GDR), Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, UK.

Additionally, there are:

- EEC (European Economic Community), including Belgium, France, Germany, Italy, Luxembourg, Netherlands, Denmark, Ireland, UK*, Greece, Portugal and Spain
- EU (European Union), all the above and Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia, Sweden
- EUR Date (EU Reference Date), appears when there is no country/territory specified in the authorization, but a date is referenced.
- HB Date (Harmonized Birth Date), appears when there is no country/territory specified in the authorization, but a date is referenced.

US Filings and Approvals

The FDA Orange and Purple Books contain all approved NDAs, BLAs, ANDAs and aBLAs along with their corresponding patent and exclusivity information. Cortellis Generics Intelligence integrates the FDA updates to the Orange and Purple Books with other FDA information such as ANDA tentative approvals and discontinuations as they become available, in addition to ANDA and aBLA filings Cortellis Generics Intelligence learns about through litigation and do not appear in the online FDA Orange or Purple Books.

Approval Status

As defined in Approvals Summary section.

Filing/Approval Type

As listed in Approvals Summary section: NDA, 505(b)(2), ANDA, BLA, and aBLA. Other indexed Filings/Approvals Types:

- PMA: Premarket approval (PMA) is the FDA application for Class III Medical Devices.
- HDE: Humanitarian device exemption (HDE) application, which is similar in both form and content to a PMA application, but is exempt from the effectiveness requirements.
- 510(K): It is the FDA application for Class I and II Medical Devices, also Class III if PMA is not applicable.

TE Code

The code is based on the FDA evaluation of whether an approved Product is therapeutically equivalent to other pharmaceutically equivalent products (first letter) and provides additional information on the basis of FDA's evaluations (second letter).

All remaining fields are as listed in Orange or Purple Book, respectively.

FDA Bioequivalence Information

Direct access to FDA document with the draft guidance on how to design bioequivalence studies for the listed Drug Products (active ingredient, dosage form, strength, route of administration) to support ANDAs. FDA bioequivalence recommendations can provide insights as to the likely cost of development for a Drug Product.

US Patents & Exclusivities Associated with Approvals

This table summarizes all the information from the US FDA Orange Book, which includes Patents and Exclusivities.

Trade Name

Commercial name given to the product by the applicant.

Publication Number

The number of the US Patent as provided in the US FDA Orange Book. All Patent detailed information by clicking on the Publication Number.

Patent Use Code

Applicant designated use specified in the Patent. Information about the Use Code on hovering over.

Exclusivity Type

The type of exclusivity associated with the application. Information about the Exclusivity on hovering over.

Product - Constraint Date Forecast & Exclusivities

Table listing the countries/territories for which CDF is calculated, the rationale behind the displayed CDF and the exclusivities. This last column is depicted as a text file which summarizes the exclusivities in that given country/territory; for the US it also lists the exclusivity type associated with the application (e.g. New Chemical Entity, Orphan Drug Exclusivity) as a code. Table is sorted based on CDF, older to more recent.

This data is not available for combination products.

Constraint Date Forecast (CDF)

As defined in Unexpired Constraint Date Forecast and Exclusivities Summary section.

Data and Marketing Exclusivities

Data exclusivity protects the confidentiality of clinical trial data submitted to regulatory authorities. Data exclusivity periods may extend beyond the patent protection period of a pharmaceutical product, thus delaying the availability of lower-priced generic medicines to patients.

Data exclusivity in the US applies both to New Chemical Entities and to additional research done once the product is on the market.

- New Chemical Entities are granted 5 years of Data Exclusivity.
- Biologics that have been approved through the BLA process have 4 years of Data Exclusivity and 12 years of Market Exclusivity beginning at the BLA approval date. Data exclusivity protects the BLA product against all follow-on products, whether submitted through BLA or aBLA route. Market exclusivity protects the BLA products against follow-on products approved through the abbreviated route. It does not keep out products submitted through BLAs.

In Europe, Data Exclusivity rules depend on the filing date for the reference listed drugs:

- Before November 2005, (1) if a product was registered through the centralized procedure, it received 10 years of Data Exclusivity regardless of the country, and (2) if a product was registered through national or mutual recognition procedures, then it was covered by either 6 or 10 years of Data Exclusivity, depending on the country/territory.
- After November 2005, the new rule grants 8 years of Data Exclusivity plus an extra 2 or 3 years of Marketing Exclusivity.

The Japanese examination period is similar to the Data Exclusivity period in the US or Europe. No generic drug can be approved in Japan during this period. The length of the re-examination period is determined by Pharmaceuticals and Medical Devices Agency:

- 10 Years: Orphan Drugs and Drugs confirmed at the time of approval to require evaluation using pharmaco-epidemiological techniques.
- 8 Years: Drugs containing new active ingredients (if approved after April 1, 2001).
- 6 Years: Drugs containing new active ingredients (if approved before April 1, 2001), new combination drugs, and drugs with new administration routes.
- 4 Years: Drugs with efficacy effects different from those of previously approved drugs and drugs with uses and dosages different from those of previously approved drugs.

In South Korea, post-marketing surveillance is a period of Data Exclusivity. Generics may not launch before the exclusivity period has expired even in the absence of a protecting patent. Post-marketing surveillance is regulated by article 32 of the Korean Pharmaceutical Affairs Law and operates as follows:

- 6-year period for a New Chemical Entity drug including new API or new ratio of combination, different from the previously approved drug.
- 4-year period for a different indication from the previously approved drug in KFDA.

Product - Patents & SPCs

Cortellis Generics Intelligence analyses patents published by National Patent Offices and Authorities on a weekly basis. A summary annotation is prepared and published by our in-house research team. Proprietary algorithms are used to define Patent Families (Primary Patents) and associate with specific Patent Types.

Worldwide Patent Families

Table containing all Primary Patents linked to the Product. For Combination Products, the table contains all the Primary Patents of the individual APIs the Combination is composed of, regardless if the Primary Patent refers to the Combination itself.

Primary Patent

The Primary Patent is a Patent Cooperation Treaty (PCT) Application; this is WO Patent. If there is no PCT Application, the Primary Patent is a European Application/Patent (EP), a US Application/Patent (US) or a British Application/Patent (GB), in that order. If there is more than one Patent from the above, the document with the earliest filing date is known as the Primary Patent.

Patent Family

All records with the same Primary Patent number are considered as a Patent Family.

Patent Type

Summary of all indexed Patent Types:

- Analyte: Patents disclosing an analytical method to determine the drug, including determining its concentration in the body or body fluid.
- Component of Combination: includes all instances where the invention is primarily concerned with the use of a drug in any combination with another drug, whether synergistic or not. This term is only used if the Patent is primarily concerned with the drug combination.
- Constraining: Constraining patent(s) are those which are most likely to prevent generic competition or may not be easily circumvented.
- Delivery Device: this term is for non-consumable devices only. Delivery systems such as controlled-release tablets or suppositories would be defined as "Formulations".
- Drug target: used for receptors, enzymes, etc. which are claimed in the patent and which were used to identify a drug.
- Formulation: all types of formulation of a drug, including those where the active compound is chemically modified (e.g., prodrugs or immunoconjugates). It is only used for patents that are predominantly concerned with a particular formulation. A prodrug is an inactive form of a known drug; it has no medicinal effect itself but is activated in the body metabolism and breaks down to produce the active drug.
- General Interest: drugs not directly covered by a patent, but that are certainly of interest to someone looking for patents about the drug. Examples are patents claiming ways of overcoming resistance to a drug or claims to the drug screening method. This term is also used for biotechnology applications, where it can be difficult to decipher the relationship between a patent and its commercial application.
- New Use: methods of using a drug, usually for a new indication.
- Process: used for patents predominantly concerned with the preparation of a drug.
- Process (intermediates): used where the patent discloses a method for producing an intermediate without claiming a process for producing the drug itself.
- Product: a product Patent is usually the first one to be associated with a drug. For drug combinations, the term "Product" is assigned to each Patent claiming one of the components as well as to the patent claiming the combination.
- Product (derivative): used for patents claiming novel salts, stereoisomers, crystal form and polymorphs. The term "derivative" is not used in a chemical sense, i.e., it does not cover the

analogues of a drug that are directly chemically modified. Note that patents claiming prodrugs of a drug are linked as "Formulation" to that drug.

- Tentative: used if there is a strong likelihood that a patent refers to a compound, but the information available about that compound is not clear enough to make a decision. This is usually only applied to drugs at early development stages when the structure of the drug is not publicly available.

Priority Country and Date

The country/territory/Authority and date the Primary Patent was filed.

Opponents

Flag that identifies whether any Patent within that Patent Family has been challenged by an Opponent/Infringer. An Opponent is a company that has filed an opposition to a given Patent to block the grant of a Patent or even after the Patent has been granted. Listed under Opponent are also companies that have filed Paragraph IV challenge(s) against a Patent regardless of the outcome. An Infringer is any company that has been cited as allegedly infringing on a Patent by the Patent assignee. Opponent/Infringer relationships are obtained from company press releases, court sites, and other public sources. To find out which country/territory Patent has been challenged, refer to the Annotations in the Primary Patent.

Annotation

Our research team curates a summary Annotation for Patent Families to provide context and historical data. This includes information when patents are challenged by third parties post grant, as well as if a patent is maintained after opposition or challenge.

Worldwide Patent Families - Panel

The panel is accessible by clicking the Publication Number of the Primary Patent in the table.

Publication Number

Publication Number is a hyperlink tag to the corresponding Derwent Innovation Patent page.

Actions

The therapeutic action of a product protected by the Primary Patent.

Indication

The therapeutic indication of the product protected by the Primary Patent.

Technology

The technology terms associated to the Primary Patent.

Annotations for Patent Family

As described above.

Expiry Information for Patent Family

List of all Patents within the Patent Family listed by their Expiry Dates. Individual Patents can be accessed directly by clicking on the corresponding Publication Number.

Patents by Authority

Table containing all Patents linked to the Product. For Combination Products, the table contains all the Patents of the individual APIs the Combination is composed of, regardless if the Patent refers to the Combination itself.

Publication number

The publication number refers to either a patent number or an application number.

Orange Book Patent

Flag that identifies those Patents listed in the Orange Book.

Patent Authority

It can either refer to National Patent Offices or Organizations. The indexed Organizations are:

- EPO – European Patent Office: provides a uniform application procedure for individual inventors and companies seeking patent protection in up to 37 European countries.
- ARIPO – The African Regional Industrial Property Organization: is a central filing system comprised of members of 16 African States. The member states are Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Somalia, Sudan, Swaziland, Uganda, United Republic of Tanzania, Zambia and Zimbabwe. Potential Member states who have observer status in the meetings of ARIPO are Angola, Algeria, Burundi, Egypt, Eritrea, Ethiopia, Liberia, Libya, Mauritius, Nigeria, Rwanda, Seychelles, South Africa and Tunisia (14). These countries rely on their patent system or PCT applications.
- WIPO – The World Intellectual Property Organization: is a specialized agency of the United Nations. It was established by the WIPO Convention in 1967 with a mandate from its Member States to promote the protection of IP throughout the world through cooperation among states and in collaboration with other international organizations. Its headquarters are in Geneva, Switzerland.
- EAPO – The Eurasian Patent Office: it was created as an interstate system for the protection of industrial property in the former Soviet block and became effective in August 1995. At present, there are 9 member States - Turkmenistan, the Republic of Belarus, the Republic of Tajikistan, the Russian Federation, the Azerbaijan Republic, the Republic of Kazakhstan, the Kirghiz Republic, the Republic of Armenia and the Republic of Moldova.
- OAPI/AIPO – The African Intellectual Property Organization: is a central registration system for the French-speaking African States. The 16 current member states for OAPI are Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Republic of Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Togo. The headquarters of OAPI is based in Yaoundé, Cameroon.

Estimated Expiry Date

The estimated date when the local patent expires. It is amended by extensions for Australia, Europe (SPCs), Japan and United States. If a date is not displayed:

- NA (appl) means the Patent is in the application stage.
- NA (other) means the Patent publication does not require an expiry date such as utility model, etc.
- NA means that our research team is unable to determine the estimated expiry date at this time.

Annotations

The Annotation(s) are curated at the Patent Family(ies) level.

Patents by Authority - Panel

Both Publication Number and Primary Patent Number are hyperlink tags that link to the corresponding Derwent Innovation Patent page.

Annotations for Patent Family

As described above.

Expiry Information

Detail of Patent Expiry grouped at the level of Active Ingredients Covered in the Primary Patent. Within the Active Ingredients subsection, there is the Expiry Date for the Patent, the Status of that Expiry Date and the Countries/Territories for which it is applicable. The Status includes ‘Revoked’ when a patent has been successfully challenged and ‘Lapsed’ due to on-payment of fees. There are considered Patent

Extensions for European Countries (SPCs - see below), Australia, Canada, Israel, Japan, Russia, South Korea, Ukraine and US.

Publication History

Summary of dates and statuses that reflect the publication history for the Patent. Patent number is a hyperlink tag that directs to the corresponding Derwent Innovation Patent page.

SPCs

Table containing all SPCs linked to the Product.

SPC stands for Supplementary Protection Certificate. The EU/EEA and some associated countries developed the SPC for its members to harmonize patent extension procedures between countries and to restore the effective exclusive marketing period for drugs. An SPC comes into force only after the corresponding patent has expired. It has a maximum lifetime of 5 years and provides for a maximum of 15 years protection from first marketing approval in any member state. From the beginning of 2012 onwards, the SPC data included in Cortellis Generics Intelligence is created and managed by our research team. Data prior to 2012 was licensed from the Cabinet Alice de Pastors in Paris, France.

Patent Number

The number of the Patent upon which the SPC was applied for, granted or rejected.

SPC Status

There are 4 different statuses: Granted, Application, Rejected and Withdrawn.

Additional SPC Status

Additional details provided by our research team about the status of the SPC in a given country/territory.

Pediatric Extension Status

Status of the SPC Pediatric Extension: Granted, Application and Rejected.

Product - US Patent Challenges

US patent challenge litigation information is collected and curated by Cortellis Generics Intelligence in-house research team. There is a section for each innovator approval (either NDA, 505(b)(2) or BLA approval) with three main areas:

- Innovator approval information: brand name, approval type, approval number, dose form, route of administration, strength and Reference Listed Drug commentary
- US Patent Challenges: table detailing all challenges against the innovator approval
- View commentaries: panel with all commentaries associated to each patent challenge

Paragraph IV coverage is based on ANDA filings with Paragraph IV certification, as the source of information is the FDA's list of Paragraph IV certifications. Detailed coverage of patent challenges began in 2005, although there is some coverage of earlier challenges. Challenges to products that have been removed from the Orange Book are not covered. 505(b)(2) litigation cases are considered only if there has already been a Paragraph IV ANDA for the product.

aBLA applications are tracked by 351(k) filings and the collected information includes the dates of or announcements of those submissions, the Patents that are being challenged as part of the BPCIA or IPR, synopsis of lawsuit milestones, launch announcement or agreements, and API sources for applications.

The Small Molecule content is available to Cortellis Generics Intelligence Global and Premium users. The Biologic Product content is only available to Cortellis Generics Intelligence Premium users.

US Patent Challenges

Summary lists current Orange Book patents for Products filed under NDA, and litigated Patents for Products filed under BLA. From the Orange Book patents, those with 'Lit' green marker next to the Publication Number are those certified for Paragraph IV challenge. Those patents with IPR green marker have been subject to a petition for inter partes review.

Table containing all known challenges against the reference listed drug. The table can be shown/hidden by clicking the arrow next to the caption 'US Patent Challenges'.

Filer

Filer of the application.

Patents Litigated/Patents Associated with Disputes

Patent detailed information available by clicking over the Publication number.

Notification Date

Information displayed for Small Molecules only. The date the Paragraph IV notification letter was sent to or received by the patent owner and reference listed drug sponsor. This date is used to calculate the 30-month stay of FDA approval.

Submission Date

Information displayed for Biologic Products only. The date the submission of a biosimilar application to the FDA was announced by the filer or the date specified in the FDA approval letter.

30-Month Stay

Information displayed for Small Molecules only. If the Reference Listed Drug sponsor or patent holder files an infringement suit against the generic applicant within 45 days of receipt of Paragraph IV notification, FDA approval to market the generic drug is stayed for 30 months unless the patent expires or is judged to be invalid or not infringing before that time. The stay runs from the date of receipt of the notification by the last required recipient. If the reference listed drug is subject to a New Chemical Entity exclusivity, the stay of approval runs for 30 months beginning from the date the New Chemical Entity exclusivity expires. Because the date of receipt may be uncertain, we typically list the date to the nearest month in this field.

Approval Date

Date of the application approval.

Launch Date

Future date when the product may be launched under the terms of any settlement agreement or the date the product was launched, or launch was publicly announced.

FTF tag

First-to-file identifier tag.

For small molecules, ANDA was the first filed with Paragraph IV certification for at least one strength of the Reference Listed Drug. The first filer may be eligible for 180-days of generic drug exclusivity upon launch. If more than one ANDA is filed on the same day, eligibility for the 180-day exclusivity may be shared. For entries identified with "First to File: Assumed" in this field, first-to-file status is assumed but has not been confirmed.

For Biologic products, the first filer of a biosimilar product that receives interchangeable status. An interchangeable product may be substituted for the reference product without the involvement of the prescriber.

View Commentaries

The first text in the panel corresponds to the Reference Listed Drug commentary for the brand, approval type and approval number. Right below, there are the commentaries for each patent challenge. There is an export to PDF button and a free text search bar that allows search by keyword.

Product - Deals

Cortellis Generics Intelligence gathers all Deals related to the Product. This content is only available to Cortellis Generics Intelligence Global and Premium users.

Deal Title

Summary of the Deal. Deals detailed information provided upon clicking.

Principal Company

Primary company in the Deal, either as the licensor or the seller of the asset, or the service provider. This company receives funds or assets from the Partner Company in return. Clicking over the name will direct to the Company detail page. Next column is the country/territory of the Principal Company.

Partner Company

Partnering company in the Deal, either as the licensee or purchaser of the asset, or the service receiver. Clicking on the name will direct to the Company detail page. Next column is the country/territory of the Partner Company.

Agreement Type

The Deal Types and their definition are listed below:

- Drug – CRADA: Principal and Partner (US federal agency) establish a Cooperative Research and Development Agreement (CRADA).
- Drug – Funding: Principal receives (or receives commitment) from Partner for funding to direct towards development of drug(s). This type of agreement usually occurs between a pharma or biotech company and a charity, a non-profit organization, or a government agency. The Principal company is the one receiving the funds.
- Drug – Asset Divestment: Principal sells to Partner assets associated with drug(s).
- Drug – Discovery/Design: Principal and Partner agree to jointly or individually discover and design a drug candidate(s), with a business strategy to develop the drug(s) further.
- Drug – Screening/Evaluation: Principal agrees to screen or evaluate a drug candidate(s) against potential targets or in a particular model for Partner.
- Drug – Early Research/Development: Principal and Partner form an alliance to jointly use expertise/resources to develop drug candidates.
- Drug – Development/Commercialization License: Partner acquires a license from Principal to develop and commercialize (sell) drug(s).
- Drug – Commercialization License: Partner acquires a license from Principal to market drug(s) OR Principal agrees to promote drug(s) in collaboration with Partner.
- Drug – Manufacturing/Supply: Principal agrees to manufacture or supply drug(s) for Partner.
- Drug – Development Services: Principal agrees to perform drug development services for Partner.
- Drug – Authorized Generic: Partner acquires a license from Principal to sell a repackaged version of brand drug as authorized generic.
- Technology – Asset Divestment: Principal sells to Partner assets associated with technology (or technologies).
- Technology – Delivery/Formulation: Partner acquires a license to use Principal's delivery/formulation technology with drug(s) OR Principal agrees to work with Partner to formulate drug(s).

- Technology – Target Validation: Partner acquires a license to use Principal's technology to validate or verify a target, which a developed drug would be directed against.
- Technology – Other Proprietary: Partner acquires a license to use Principal's technology with drug(s) OR Principal agrees to use its technology with Partner's drug.
- Patent – Asset Divestment: Principal sells to Partner patent rights.
- Patent – Exclusive Rights: Partner acquires an exclusive license to use patent(s) belonging to Principal. Exclusive means that no other company has (or will have) the same rights to the patent(s).
- Patent – Non-Exclusive Rights: Partner acquires a non-exclusive license to use patent(s) belonging to Principal. Non-exclusive means that the Principal retains rights to license the same rights to other companies.
- Patent – Litigation Settlement: Principal resolves patent litigation with Partner. Principal may grant Partner a license to begin marketing its own generic version of brand drug on a specified date.
- Company – Joint Venture: Principal and Partner establish a joint venture company/branch.
- Company – M&A (in whole or part): Principal and Partner enter Merger or Acquisition activity, including equity stakes in companies and the acquisitions of business units and facilities.

Status

The current status of the deal:

- Active: Deal is in progress.
- Completed: Deal reached its proposed end-date and was not renewed. Also used for when M&As and Asset Purchases complete.
- Terminated: Deal did not reach its proposed end-date and was terminated.
- Pending: "Letter of Intent Only" Deals. It changes to "Active" when Deal is officially signed.

Deal Value ($M)

The total value of the deal in million USD.

Deal Start Date

The start date for the deal.

Deal End Date

The end date for the deal. Only deals that are completed or terminated have an end date.

Involved Products

Products involved in the Deal. Clicking on the name will direct to the Product page.

Synopsis

Click to View button to open the Deal detail panel.

Deal – Panel

Details and Information summarizes main relevant information of the Deal. There is direct link to Cortellis Competitive Intelligence Deal Report.

The Events section includes a timeline of events associated with the Deal. Each deal event listed in the timeline includes the date and the description. Entries appear listed in chronological order, from oldest to newest.

The Sources section lists the sources of information to build the Events section.

Product - Competitive Insights

Competitive Insights provides insights on those Products or Companies competing against or related to the Product of interest. This content is only available to Cortellis Generics Intelligence Global and Premium users.

Related Companies

Related Companies table summarizes all those companies that are associated to the Product and their equivalents either as Patent holders, Regulatory Filings holders or as API Manufacturers. This content is not available for Combination Products.

First Associated Date

The date when Cortellis Generics Intelligence first associated the company and the API.

Related Products

Related Products table lists all those Products that are classified under the same Therapeutic Area terms as the Product of Interest. The content is displayed for both single APIs and Combination Products, but not for single APIs equivalents.

Product - R&D

Cortellis Generics Intelligence provides clinical trials intelligence related to the Product of interest. Products with this information have reached phase III or higher and have an actual drug name, not just a development code. The table is sorted by the highest Development Status. This content is only available to Cortellis Generics Intelligence Global and Premium users.

Involved Products

All the Products identified to be related to the Clinical Trial - Development Program.

Development Program Name

Name of the Development Program as provided by Cortellis Clinical Trials Intelligence. Click to access Drug Report page for Cortellis Clinical Trials Intelligence.

Indication

Medical condition that leads to the recommendation of a treatment, test, or procedure.

Development Status

The Clinical Trials are classified under the following Development Statuses:

- Launched: the drug is being marketed.
- Registered: the relevant regulatory authority has approved the drug for marketing, but the drug is not yet available on the market.
- Pre-registration: awaiting approval; an application to market the drug (e.g. New Drug Application or Marketing Authorisation Application) has been filed.
- Phase 3 Clinical: expanded controlled and uncontrolled trials have started after preliminary evidence suggesting effectiveness of the drug has been obtained. These are intended to gather additional information to evaluate the overall relationship of the drug and provide an adequate basis for physician labelling benefit-risk.
- Phase 2 Clinical: controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks have started.
- Phase 1 Clinical: initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness have started; usually conducted in healthy volunteers.
- Clinical: for drugs which are in clinical status but the phase (i.e. Phase 1 or Phase 2) is unknown, 'Clinical' is assigned as the development status.
- Discovery: includes Discovery/Preclinical. Preclinical = in vivo testing; testing in animals has started.
- Suspended: development of the drug is temporarily halted by the company, but not discontinued (e.g., due to the emergence of side effects in a trial, issues with cash flow, or pending strategic review).
- Withdrawn: the drug license is sold, and prescription withdrawn from the market after launch.
- Discontinued: development of the drug is discontinued for the particular indication before a registration dossier has been filed (or after filing with the registration board and not gaining approval).
- No Development Reported: no change in reported development for an 18-month period
- Out licensed: the rights to develop a drug program have been transferred to a licensee, where the licensor is known, or presumed, to have no further commercial interest.

Country/Territory

The country/territory where the Development Program is taking place.

Involved Company and Corporate Group

Company and corresponding Corporate Group sponsoring the Development Program.

Last Update Date

The date the Development Program was last changed.

Product - Scientific

All scientific information associated with the Product and its Equivalents, updated on a monthly basis. This information is not available for Combination Products, please refer to individual ingredients.

Routes of Synthesis and Biological Manufacturing Processes

Cortellis Generics Intelligence illustrates Routes of Synthesis for Small Molecules, and Biologic Manufacturing Processes for Biologic Products. There can be several pathways or processes depending on the complexity and the size of the final Product. Some pathways or processes can be illustrated in one scheme (image) while other pathways or processes may require several schemes. In cases were multiple schemes are needed to depict one pathway, the same number represents each pathway while each scheme is represented by a letter (1a, 1b, etc.). Each pathway has its associated Summary.

Only one Route of Synthesis is displayed for Cortellis Generics Intelligence Sourcing and Global users. No information for Biologic Products.

All Routes of Synthesis and Biologic Manufacturing Processes and their Related Information are displayed and exportable for Cortellis Generics Intelligence Premium users. User can navigate from schema to schema using lateral arrows or the drop down available below.

Related Information for Small Molecules

The Related Information section lists Intermediates, Reagents, Patents, and Literature citations associated with the schema above.

Both the Intermediates and Reagents are listed by name and CAS number (if available). The CAS number for the Intermediates or Reagents are linked to the appropriate Product profile.

The Patents are listed by Publication Number, title and Holder. The patents numbers associated with each schema are linked (when possible) to their respective patent details panel.

Related Information for Biologic Products

The Related Information section lists Chemical Name, Sequence, Intermediates, Materials and Methods, Patents, and Literature citations associated with the schema above.

Intermediates as well as Materials and Methods are listed by name.

The Patents are listed by Publication Number, title and Holder. The patents numbers associated with each schema are linked (when possible) to their respective patent details panel.

Bioanalytical Methods

Table containing all Contract Research Organizations (CRO) subsidiaries that offer development of bioanalytical methods as a service. Bioanalytical methods are used to analyse samples to determine bioequivalence.

Technique

The precise method/technique used to analyse samples. The list of indexed techniques is as follows:

- AES = Atomic Emission Spectrometry
- AxSym® = Automated Immunoassay Instrument System
- EC = Electrochemical
- ECD = Electron Capture Detector
- ECNCI = Electron Capture Negative Chemical Ionization
- ELISA = Enzyme-linked Immunosorbent Assay
- FID = Flame Ionization Detector
- FL = Fluorescence or Fluorometric
- FPIA = Florescence Polarization Immunoassay
- GC = Gas Chromatography

- GFAA = Graphite Furnace Atomic Absorption
- HPLC = High Performance Liquid Chromatography
- HPLC - UV = High Performance Liquid Chromatography - Ultraviolet Detection
- IA = Immunoaffinity Chromatography
- ICP = Inductively Coupled Plasma
- IMMU = Immunoenzymetric Assay
- Immulite = Immulite® Automated Immunoassay Instrument System
- IRMA = Immunoradiometric Assay
- LC = Liquid Chromatography
- MS = Mass Spectrometry
- NICI = Negative Ion Chemical Ionization
- NPD = Nitrogen Phosphorous Detection
- PCR = Polymerase Chain Reaction
- Pyrosequencing = Pyrosequencing
- LC - MS - MS = Liquid Chromatography - Mass Spectrometry - Mass Spectrometry
- RIA = Radioimmunoassay
- SIM = Selected Ion Monitoring
- SPEC = Spectrometric
- TaqMan = TaqMan® PCR
- UV = Ultraviolet

Status

There are 3 different statuses: Under Development, Under Consideration and Validated.

Product - Launches & Pack Prices

Cortellis Generics Intelligence contains information about worldwide Drug Product launches and their pack prices, and the labels information for the Drug Products that have been launched in the US. This content is only available to Cortellis Generics Intelligence Global and Premium users.

Launched Drug Forms

Drug Product launches and pack prices information is licensed from IQVIA. The data refers to retail pharmacy and hospital sales and ex-manufacturer pricing for human prescription drugs globally. Launch data for Israel and Ukraine was discontinued by IQVIA in 2009.

IQVIA performs audits for both retail and hospital channels, and uses several sources to generate prices, including manufacturer lists, wholesaler lists, government price lists, and industry publications. Prices might be gathered directly from the sources of information or might be calculated using proprietary IQVIA methodology. They are always displayed for all countries/territories as average ex-manufacturer price (i.e. the manufacturer's selling price), and whether the VAT (Value Added Tax) is considered or not varies by country/territory. Prices for the retail sector will reflect price per pack, while those for the hospital sector will reflect price per dispensing unit.

For Marketers in the UK market, IQVIA has an agreement with the British Generic Manufacturers Association (BGMA) to not disclose the identity of individual companies. Generic products manufactured by BGMA members are therefore linked to the manufacturer 'UNBRANDED'. 'UNLICENSED MED' is the company that gathers all medicines that are used outside the terms of their UK license or which have no license for use in the UK. Unlicensed medicines are commonly used in some areas of medicine such as in pediatrics, psychiatry and palliative care.

For the US and Canada, there is 'PRIVATE LABEL' linked to 'LAB UNKNOWN'. The US defines this as "The term commonly used by retailers, vendors and distributors to give a product distinct identification as opposed to a nationally advertised brand name". Canada defines this as "A line of products specially manufactured and labelled for a drugstore chain". Such private label products are manufactured by more than one manufacturer.

For Latin America, unidentified Marketers will lay under the 'LAB NO INDICADO' manufacturer.

Pack Launch Date

The date on which a specific dose form and strength combination was launched by a given marketer in a specific country/territory. IQVIA does not update withdrawn or discontinued products, but an old date may not necessarily mean that the product is no longer marketed.

There might be some launch dates of '01/01/1900' as a result of how IQVIA processes the launches data. It is a dummy date for those pack prices that have not yet started accruing sales. There might also be blank launch dates for those Drug Products whose launch date is unknown, which does not imply it is not being sold or available in the market.

Launch Regions

Asia Pacific – Australia, Bangladesh, China, Hong Kong, India, Indonesia, Japan, Malaysia, New Zealand, Pakistan, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam.

Eastern Europe – Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Russia, Slovakia, Slovenia, Turkey and Ukraine.

Latin America – Argentina, Brazil, Central America, Chile, Colombia, Dominican Republic, Ecuador, Mexico, Peru, Uruguay and Venezuela.

Middle East & Africa – Algeria, Egypt, French West Africa, Israel, Jordan, Kuwait, Lebanon, Morocco, South Africa, Tunisia, UAE and Saudi Arabia.

North America – Canada and USA.

Western Europe – Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and UK.

Launches: Additional Insights

The table contains information licensed from Global Pricing Innovations and the data is complementary to that of the Launched Drug Froms table above. Each pack has detailed information regarding:

- Brand Indicator: each pack is either Generic or Branded.
- Reimbursement Status: each pack can be either Reimbursed, Non-Reimbursed or Unknown. Further details including reimbursement percentage and reimbursed price is available via the Global Pricing Trends module.
- Discontinued Status: the value is either yes or no, where “yes” indicates the pack has been discontinued in the country noted on the same table row. Note: Discontinued products are not monitored for all countries.
- Hospital Status: is either yes or no whether the pack is available in the hospital setting for the country noted on the same table row. Note: Hospital Status in not monitored for all countries.
- Parallel Import: Parallel Import status (yes/no) is available for some countries where parallel import regulations apply. A “Yes” indicates that the pack is available as via parallel import in the country noted on the same table row. Note: Parallel Import is only monitored for the following countries: Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Cyprus, Czech Republic, Denmark Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lebanon, Norway, Poland, Portugal, Russia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey, United Kingdom, USA.
- Orphan Drug Status: each pack has either yes or no value.

US Labels Information

The labels of Drug Products that have been launched in the US. The supply chain of the Drug Product manufacture can be rebuilt based on the API Source, the Manufacturer, the Analysis, the Repackager and the Labeler. There is also information about the Drug Product Approval (type, number and holder) and the corresponding NCD Code, with direct access to the DailyMed webpage. Discontinued labels records are shadowed and can be hidden from the table view with the ‘Discontinued Labels’ toggle.

Subsidiary Key Insights

A summary of the key data available for a Subsidiary is displayed in this single area within Cortellis Generics Intelligence. Identifier information for the Subsidiary is displayed on top in the Key Insights view and below it is analytics and visualizations for some of the key data.

Subsidiary Summary

Subsidiary Type

As defined in Quick Search section.

Confirmed APIs

As defined in Quick Search section.

Corporate API Rating

As defined in Product - API Manufacturers section.

Manufacturing Capabilities Summary

List of Manufacturing Capabilities associated to the Subsidiary.

Capabilities

There are 4 main Capabilities categories: Small Molecule, Biologic, Finished Dose and Other.

Regulatory Inspections Summary

Information is split in US FDA and all other indexed Regulatory Inspections as listed in Facility Inspections field in Product - API Manufacturers section.

Self Identified Registration

The US requires facilities who intend on supply the US market to register and self-identify their activities (API, Finished Dose, Analysis) annually with the US FDA.

Regulatory Filings Summary

As defined in Regulatory Filings Summary in Product Key Insights section. Information is displayed based on the Subsidiary as the Holder and/or Manufacturer of the Regulatory Filings.

Subsidiary Details

APIs

A detailed view of the APIs associated with the subsidiary.

First Associated Date

The date when Cortellis Generics Intelligence first associated the manufacturer of the API with the company.

Regulatory Filings

Information is displayed based on the Subsidiary as the Regulatory Filings Holder and/or Manufacturer.

Approvals

Information is displayed based on the Subsidiary as the Holder.

Launches & Pack Prices

Information is displayed based on the Subsidiary as the Marketer.

Patents & SPCs

Information is displayed based on the Subsidiary as the Patent Holder.

Corporate Group Key Insights

A summary of the key data available for a Corporate Group company is displayed in this single area within Cortellis Generics Intelligence. Identifier information for the Corporate Group is displayed on top in the Corporate Group Summary.

Corporate Group Summary

Group Type

As defined in Quick Search section.

Corporate API Rating

As defined in Product - API Manufacturers section.

Financial History and Sales Forecast Summary

The information is provided by Cortellis Competitive Intelligence and displayed in a chart in million USD. This content is only available to Cortellis Generics Intelligence Global and Premium users.

Sales

Net sales or revenues represent gross sales and other operating revenue less discounts, returns and allowances. The dotted line corresponds to the Sales Forecast.

Operating Income

Operating EBITDA represents the difference between sales and total operating expenses.

Net Income

Represents income before extraordinary items and preferred and common dividends, but after operating and non-operating income and expense, reserves, income taxes, minority interest and equity in earnings.

Products Summary

Confirmed APIs

As defined in Quick Search section.

Launched Dose Products

Count of the different APIs, with corresponding dose forms and strengths, launched by the Corporate Group.

Dose Forms Launched Summary

Key analytics of all Drug Products launched by the Corporate Group. This content is only available to Cortellis Generics Intelligence Global and Premium users.

Launched Dose Forms corresponds to the count of the different dose forms launched by the Corporate Group. Next, the graphical representation of the top 5 dose forms launched, based on the count of launched Drug Products per dose form.

Total count of Markets Served as the number of countries/territories where the Corporate Group has launched at least one Drug Product. Top 3 countries with their count of launched Drug Products.

API Subsidiaries Summary

Key analytics of all API Manufacturer Subsidiaries associated with the Corporate Group.

Count below API Subsidiaries is the number of all API Manufacturer Subsidiaries associated with the Corporate Group. Total counts are the sum up of metrics for individual API Manufacturer Subsidiaries.

Confirmed APIs

As defined in Quick Search section.

Active US DMF and Valid EU COS/CEP

As defined in Product Key Insights section.

Key Locations

Up to 3 main locations for the API Manufacturer Subsidiaries.

Other Subsidiaries Summary

Key analytics (see above) of all Other Subsidiaries associated to the Corporate Group.

Corporate Details

Subsidiaries

Detailed view of the API Subsidiaries and Other Subsidiaries associated with the Corporate Group.

Finished Dose Subsidiaries

Detailed view of the Finished Dose Subsidiaries associated with the Corporate Group. This content is only available to Cortellis Generics Intelligence Global and Premium users.

Marketers

Detailed view of those Subsidiaries that have launched Products and are associated with the Corporate Group. This content is only available to Cortellis Generics Intelligence Global and Premium users.

APIs

Information is displayed based on the API Manufacturer being associated to the Corporate Group.

Approvals

Information is displayed based on the Approval holder being associated to the Corporate Group.

Patents & SPCs

Information is displayed based on the Patent holder being associated to the Corporate Group.

Deals

Information is displayed based on the Corporate Group as Principal Company or Partner Company. This content is only available to Cortellis Generics Intelligence Global and Premium users.

R&D

Information is displayed based on the Corporate Group as sponsoring the Development Program. This content is only available to Cortellis Generics Intelligence Global and Premium users.

Launches & Pack Prices

Information is displayed based on the Corporate Group as Marketer of Launched Drug Forms. This content is only available to Cortellis Generics Intelligence Global and Premium users.

Advanced Search

Advanced Search helps users find:

- Patents
- Routes of Synthesis (only available to Cortellis Generics Intelligence Premium users)
- Paragraph IV Patent Challenges (only available to Cortellis Generics Intelligence Global and Premium users)
- SPCs

The search fields can be combined with Boolean operators (AND, OR, NOT). All results tables are exportable.

Patents

The available search fields are:

- Active Ingredient: with options of 'Begins with' or 'Contains'
- Publication Number: user can introduce full publication number with Cortellis nomenclature (i.e. XX-xxxxxxxx) or with digits only
- Primary Patent Number
- Patent Type
- Easliest Estimated Expiry Date
- Estimated Expiry Date: user can select date range, Patent Authority or both
- Opponents

Patents are listed at the active ingredient level by Publication Number. They include Primary Patent Number, Patent Type, Patent Holder, Estimated Expiry Date, Opponents flag and associated Annotation. Both the Publication Number and the Primary Patent Number are clickable and open a panel with detailed information. Both active ingredient and Patent Holder are clickable and user is directed to corresponding profile.

Routes of Synthesis

The available search fields are:

- Intermediate or Reagent
- Patent Authority
- Publication Number
- Number of Routes of Sythesis

Routes of Synthesis are detailed with:

- End Product and link to the Product Key Insights page
- Total count of possible Routes of Synthesis for that given End Product with direct link to Scientific page
- Which schema range contains the detailed Intermediate, Reagent or Publication Number
- Count of Intermediates, Reagents, Patents and Literature connected to that Route of Synthesis

Paragraph IV Patent Challenges

The available search fields are:

- Active Ingredient: with options of ‘Begins with’ or ‘Contains’
- Dose Form
- Approval Holder
- Paragraph IV Filer
- First ANDA Submission Date

SPCs

The available search fields are:

- Active Ingredient: with options of ‘Begins with’ or ‘Contains’
- SPC Country
- Publication Number
- SPC Expiry Date
- SPC Pediatric Extension Status
- SPC Pediatric Extension Expiry Date
- SPC Holder
- SPC Status

Product Selector

The Product Selector tool helps users identify products or markets of interest based on criteria related to capabilities and/or strategic goals. The Product Selector homepage provides the most critical criteria to quickly obtain a list of 'matching' Products in the analysis view. In this second page, there is an interactive panel to further refine the list of 'matching' products based on additional criteria including manufacturers, approvals and patents. This analysis page provides a comparison of multiple Products in a single view, which can be personalized with the "Customize Columns" feature.

The Product Selector is accessible either through the homepage, the navigation side bar or the header and it is identified by a pill icon. Both the navigation side bar and the header keep the last performed search during an active session.

Product Selector Homepage

Sales and Sales Trends

This search field is only available to Cortellis Generics Intelligence Global and Premium users.

In order to retrieve sales, the user must define the region of interest. Worldwide is selected by default. The retrieved Sales always correspond to the last available MAT (Moving Annual Total).

Sales range can be defined by *From* and *To*. The range available for the selected region is suggested in grey numbers in million USD. If either *From* and/or *To* are not filled in, then no lower and/or upper Sales limit is set, respectively.

Sales Trends is searchable by either % growth or decline, and the following options: 'More than', 'Less than', 'Between' or 'Equals'.

The search returns single ingredients only.

Launches – country/territory

This search field is only available to Cortellis Generics Intelligence Global and Premium users.

List of all countries/territories where a Product has or has not been launched. The checkbox behaves as follows:

- First click: country/territory selected as 'In' – the Product has been launched in this country/territory
- Second click: country/territory selected as 'Not in' – the Product has *not* been launched in this country/territory
- Third click: country/territory not selected

When hovering over the field, the user can see which countries/territories have been selected as 'In' and 'Not in'.

The search is connected to Dose Form, Route of Administration and Pack Launch Date.

Constraint Date Forecast

As defined in Product Key Insights section.

In Product Selector:

- User can select date ranges. If either *From* or *To* are not filled in, then no date limit to the past or future is set, respectively.
- User can select several of the available Country/Territories.
- If *From* date field is empty and the user selects a Country/Territory, then the *From* date field is automatically filled in with current day.

API Availability

As defined in Product Key Insights section.

Therapeutic Area

As defined in Product Key Insights section.

Dose Form

For Cortellis Generics Intelligence Sourcing users, it is the shortlist of available Products dose forms linked to US FDA Filings & Approvals, as listed in either Orange or Purple Books.

For Cortellis Generics Intelligence Global and Premium users, it is the shortlist of all launched dose forms.

The search is connected to Launched Country/Territory, Route of Administration and Pack Launch Date.

Route of Administration

For Cortellis Generics Intelligence Sourcing users, it is the shortlist of available Products routes of administration linked to US FDA Filings & Approvals, as listed in either Orange or Purple Books.

For Cortellis Generics Intelligence Global and Premium users, it is the shortlist of all launched Products routes of administration.

The search is connected to Launched Country/Territory, Dose Form and Pack Launch Date.

Technologies

As defined in Product Key Insights section.

Product type

This search field is only available to Cortellis Generics Intelligence Global and Premium users.

User can select to retrieve 'Small molecule' or 'Biologic product' Products in the Analysis view.

Analysis View

The interactive selector panel has 4 categories. Products displayed in the results table change according to the restrictions set based on the criteria used in both landing page and the interactive selector panel. Users can change the initial criteria by selecting Modify Criteria in the top right of the screen. Users can personalize the results table with the "Customize Columns" feature, they can show/hide the selector panel through the arrow and they can select to only see Single Ingredients or Combinations.

API Manufacturers

For Combinations Products, the fields within this category are applicable to the single APIs that compose the Combination.

No. of API Manufacturers

Number of API Manufacturer subsidiaries linked to the Product, Equivalents are excluded.

No. of Active US DMFs for API

Out of the number of the above API Manufacturer subsidiaries, how many of them have at least 1 Active US DMF.

No. of Valid EU COS/CEP for API

Out of the number of the above API Manufacturer subsidiaries, how many of them have at least 1 Valid EU COS/CEP.

API Manufactured in

Location of the API Manufacturer subsidiary site.

API Consumption

This search field is only available to Cortellis Generics Intelligence Premium users.

In order to retrieve API Consumption, the user must define the region of interest. Worldwide is selected by default. The retrieved API Consumption always correspond to the last available MAT (Moving Annual Total).

API Consumption range can be defined by *From* and *To*. The range available for the selected region is suggested in grey numbers in million USD. If either *From* and/or *To* are not filled in, then no lower and/or upper Sales limit is set, respectively.

API Consumption Trends is searchable by either % growth or decline, and the following options: 'More than', 'Less than', 'Between' or 'Equals'.

The search returns single ingredients only.

Market Performance

The category is only available to Cortellis Generics Intelligence Global and Premium users.

Pack Launch Date

This search field retrieves products that have launched drug forms within the selected date range.

The search is connected to Launched Country/Territory, Dose Form and Route of Administration.

Phase III Drugs

This category is only available to Cortellis Generics Intelligence Global and Premium users.

Highest Overall Development Status

This search field returns products that have achieved at most the selected development status.

Indications

This search field returns products that have a development status connected to the selected indication, regardless of the Highest Overall Development Status of the product.

European Approvals

User can select date ranges. If either *From* or *To* are not filled in, then no date limit to the past or future is set, respectively.

US Approvals

First US Approval Date

User can select date ranges for NDA, 505(b)(2), BLA, ANDA and aBLA Approvals. If either *From* or *To* are not filled in, then no date limit to the past or future is set, respectively.

US Approvals

Type, Status and Date searches are connected to each other.

Patents category

Because of the nature of this content set, if the user selects any of the fields available in this category, Combination Products are excluded by default.

All fields as defined in Product - Patents and SPCs section.

Compare Pack Prices View

This view is only available to Cortellis Generics Intelligence Global and Premium users.

User must select at least one Product to have access to this view. It displays all Pack Prices of the selected Products, including Dose Form, Strength, Trade Name, Marketer, Corporate Group, Launch Country/Territory, Pack Description and Ex-Manufacturer Latest Retail and Hospital Prices, as defined in Launches and Pack Prices section.

The interactive selector panel has 4 filters for Dose Form, Strength, Launch Country/Territory and Launch Region.

Company Selector

Company Selector helps users identify potential partners or competitors. Users can select the most critical criteria to quickly obtain a list of 'matching' companies in the analysis view. In this second page, there is an interactive selector panel to further refine this list of companies based on additional criteria. Furthermore, the results table allows comparison of multiple companies in a single view, which can be personalized with the "Customize Columns" feature.

Company Selector is accessible either through the homepage, the navigation side bar or the header, and it is identified by a building icon. Both the navigation side bar and the header keep the last performed search during an active session.

API Manufacturer

By selecting Company Type API Manufacturer, user will retrieve API Manufacturing sites.

Location

Location of the API Manufacturer site.

Capabilities

As defined in Subsidiary Key Insights section.

Corporate Group Location

The Corporate Group Location can be excluded.

Corporate Group Type

As defined in Quick Search section. The Corporate Group Type can be excluded.

Contract Manufacturing Organization (CMO/CDMO)

This search field in available to Cortellis Generics Intelligence Global and Premium users. It retrieves subsidiaries that have been identified as CMO/CDMOs.

API Manufacturer - Analysis View

In the Analysis View there is an interactive selector panel with 2 categories. The criteria available in this interactive panel can be adjusted to refine the analysis. Users can personalize the view of the results table with "Customize Columns" table feature. User can modify initial criteria through Modify Criteria button and can show/hide the selector panel through the arrow.

Corporate API Rating

As defined in Product - API Manufacturers section.

Latest Inspection Date

As defined in Product - API Manufacturers section.

No FDA Warning Letter

If active, then API Manufacturer subsidiaries with an FDA Warning Letter within the last 5 years are excluded from results table.

GDUFA Fees paid

If active, then API Manufacturer subsidiaries without GDUFA Fees paid within current Fiscal Year are excluded from results table.

Self Identified Registration

If active, then API Manufacturer subsidiaries without Self Identified Registration paid in current Fiscal Year are excluded from results table.

No. of Confirmed APIs

As defined in Quick Search section.

No. of Active US DMF

As defined in Product Key Insights section.

No. of Valid EU COS/CEP

As defined in Product Key Insights section.

Finished Dose Manufacturer

By selecting Company Type Finished Dose Manufacturer, user will retrieve Finished Dose Manufacturing sites. Finished Dose manufacturing data is derived from US drug label data in addition to in-house editorial curation. This search is only available to Cortellis Generics Intelligence Global and Premium users.

Location

Location of the company site.

Capabilities

As defined in Subsidiary Key Insights section.

Corporate Group Location

The Corporate Group Location can be excluded.

Corporate Group Type

As defined in Quick Search section. The Corporate Group Type can be excluded.

Contract Manufacturing Organization (CMO/CDMO)

This search field in available to Cortellis Generics Intelligence Global and Premium users. It retrieves subsidiaries that have been identified as CMO/CDMOs.

Finished Dose Manufacturer - Analysis View

In the Analysis View there is an interactive selector panel with 1 category. The criteria available in this interactive panel can be adjusted to refine the analysis. Users can personalize the view of the results table with “Customize Columns” table feature. User can modify initial criteria through Modify Criteria button and can show/hide the selector panel through the arrow.

Latest Inspection Date

As defined in Product - API Manufacturers section.

No FDA Warning Letter

If active, then API Manufacturer subsidiaries with an FDA Warning Letter within the last 5 years are excluded from results table.

GDUFA Fees paid

If active, then API Manufacturer subsidiaries without GDUFA Fees paid within current Fiscal Year are excluded from results table.

Self Identified Registration

If active, then API Manufacturer subsidiaries without Self Identified Registration paid in current Fiscal Year are excluded from results table.

Marketer

By selecting Company Type Marketer, user will retrieve Corporate Groups. The initial criteria to retrieve them are as follows:

- Markets Served: countries/territories where the Corporate Group has launched at least one Drug Product.
- Therapeutic Area: Corporate Group has launched at least one Drug Product associated to the selected Therapeutic Area term.
- Dose Form: Corporate Group has launched at least one Drug Product associated to the selected Dose Form.
- Corporate Group Location: Corporate Group Location can be excluded.
- Corporate Group Type: Corporate Group Type can be excluded.

Marketer - Analysis View

In the Analysis View, users can personalize the view of the results table with “Customize Columns” table feature. User can modify initial criteria through Modify Criteria button and can show/hide the selector panel through the arrow.

This search is only available to Cortellis Generics Intelligence Global and Premium users.

Alerts

Cortellis Generics Intelligence provides alerts on content updates for Global and Premium users only. An email is sent to the user registered email address daily for US Patent Challenges or every Friday for the remaining content areas, only if monitored changes are actually updated. Updates to content range from daily, weekly, monthly and quarterly depending on the data set. User should refer to the Content Release schedule for more information.

Setting an alert

Users can set alerts in the Product and Corporate Group pages, by clicking on the top right-hand button. A modal opens where the user sets the Alert Name and the content changes to be monitored. Changes Monitored section is split by content sets. After clicking Save, the user will receive a confirmation that the monitored changes have been properly saved, and it is additionally notified by the top right-hand button. Users can edit alerts as many times as necessary by clicking the top right-hand button.

When creating a new alert, and upon content update, users will receive an alert email with what has been updated within the last 30 days for that given record.

Managing alerts

Users can access all saved alerts through the bell sign in the left-hand navigation panel. All alerts are listed with their alert name, hyperlink to the corresponding Product record and the alert creation date. Users can edit or delete the saved alert, and they can enable/disable the email alert.

Preferences

Through Preferences, the user can select the preferred country(ies)/territory(ies) by which the content is then prefiltered in the different sections within the application. Available sections in Cortellis Generics Intelligence are:

- Product - API Manufacturers table
- Product - Patents > Patents by Authority table
- Product - Constraint Date Forecast & Exclusivities
- Subsidiary - Patents > Patents by Authority table

Preferences can be accessed either through the user account area placed top right corner or through the navigation side bar depicted as Settings icon.

US Market Share module

The US Market Share module provides quantitative information detailing the use of Brand and Generic Drugs across all products, class competing products and marketer information for the United States. The information provided is based on patient medical claims for the patient population being treated with the selected drug. The analysis is generated from raw data sourced from MarketScan from IBM Watson Health, formerly Truven Health Analytics. It covers 35 million patients under the age of 65 with employer-sponsored private health insurance and then projected out to the full US privately insured population, approximately 115 million. The content is updated on a quarterly basis.

The US Market Share module is only available as an add-on module for Cortellis Generics Intelligence Global and Premium users.

Retail Prescriptions and Retail Dose Units views

Selecting either the Retail Prescriptions or Retail Dose Units view will update many of the charts and insights on the page with that criteria.

Insights

The insights section pulls high-level, important details from the US Market Share data for a quick understanding of the product's current state in the market.

Latest Market Share

The Latest Market Share section provides recent product and dose form information which can be selected via the dropdown. The time frame is displayed under the section header.

The doughnut chart will consistently display shares of generic indicators for the product while the bar chart displays either product or dose form information in an easy-to-use chart. Export functionality offers various data breakdowns for users to choose from including:

- Product x Marketer x Generic Indicator,
- Marketer x Generic Indicator x Dose Form and
- Dose Form x Marketer x Strength

A Generic Indicator is a code identifying products as either original standard products or a generic copy of the standard product:

- Pharmaceutical Equivalents: FDA considers drug products to be pharmaceutical equivalents if they contain the same active ingredient(s), are of the same dosage form and route of administration and are identical in strength or concentration. Pharmaceutically equivalent drugs products may differ in shape, release mechanism, labelling, scoring, and excipients and may or may not be therapeutically equivalent. Only therapeutically equivalent products are interchangeable.
- Multisource brand, generic: a brand-name drug for which pharmaceutical equivalents are available. At least one of the pharmaceutically equivalent drugs is a generic.
- Multisource brand, no generic: a brand-name drug for which pharmaceutical equivalents are available. None of the pharmaceutically equivalent drugs is a generic.
- Multisource generic: a generic drug for which pharmaceutical equivalents, including other generics, are available.
- Other/unavailable: surgical devices, cosmetics, and chemicals for compounding.
- Over the counter (OTC): a pharmaceutical product available without prescription. Includes brand-name drugs, generics, and repackaged drugs.

- Single source brand: a brand-name drug with no pharmaceutical equivalents available. The drug may, however, be available via a repackager.
- Single source generic: a generic drug, including a branded generic, with no generic pharmaceutical equivalents.

Market Share History

The Market Share History chart shows the product, dose form, and marketer history in either 3, 5, and 10-year views. The view can be changed by using the button on the upper-right side of the chart. Clicking on the checkmarks in the legend will allow you to toggle lines within the chart. Each line provides more details about the year by hovering your cursor over the dots on the lines. The top items are displayed on the chart and the rest are included in an "Other" category. Details for the "Other" items can be found within the Export, available at the top of the page.

Top Competitors by Therapy Area

The Top competitors by Therapy area provides a history of the product's use within therapy areas commonly associated with the product. This is available in 3, 5, and 10-year views, accessible by the button on the right-hand side of the chart. Therapy areas can be changed using the dropdown. Hovering over the legend and bars will display tooltips with more information. The rest of the top competitors are included in an "Other" category. Details for the "Other" items can be found within the Export, available at the top of the page.

Patient Demographics

US Rx Profiles User Profile

Estimates displayed are compared to estimates for all prescription drugs. Estimated population using the product, the number of patients per 1000 of the US population, the mean (average) age of a patients taking this product, percent of the population taking this product that is female, payment cost per year per patient, number of prescriptions filled per year per patient, and days supplied per year per patient. Information displayed is for a 12-month period.

Most Frequent Diagnosis

Displays the most frequent diagnosis for patients taking this drug. This may not necessarily be the diagnosis for which this drug is indicated or being prescribed but is the most frequent diagnosis among patients who have been prescribed this drug in the past year. Information displayed is for a 12-month period.

Most Frequently Prescribed Drugs

Displays the co-prescribed drugs for the currently specified product and compares it with the most prescribed drugs to the general population. Information displayed is for a 12-month period.

LATAM (Latin American) Market Share module

The LATAM Market Share module provides best-in-class analysis and market trends for prescription drugs in Latin America (LATAM). It is available as an add-on module for subscribers of Cortellis Generics Intelligence Global and Premium only.

LATAM Market Share is based on the analysis of 5 years of historical data on sales, volume of dose units and volume of prescriptions for LATAM overall and broken down by individual countries. Additionally, the data included covers an overview of the distribution channels (retail, hospital, etc.) and top prescriber specialties by product over the last 12 months.

The data is sourced from Close-Up International, a LATAM based provider with over 50 years of experience in creating prescription audits for the pharma market. Close-Up have an extensive network of over 25K partners across retail, hospital, wholesale and government.

- The sales, volume of dose units and distribution channels is captured directly through retail, hospital and government and indirectly through wholesalers, representing 98% coverage of the total market (census data).
- The prescription counts and top prescriber specialties reflects a sample of prescriptions captured in pharmacies and is projected with a statistic model to represent the country's total prescriptions. The coverage of audited physicians in each country is between 80-99% of total active physicians in each country.
- Close-Up have robust quality control processes, audited each year by firms including PWC.

Export

Data values can be exported using the "Export" button at the top-right of the page.

Sales, Volume - Dose Units and Prescription Counts

Three metrics are available to assess market share: Sales, Volume of Dose Units and Volume of Prescriptions.

Country Coverage

Sales, volume of dose units and distribution channels is available for the following countries: Argentina, Brazil, Chile, Columbia, Ecuador, Paraguay, Peru, Uruguay. Note – Mexico and Central American countries are coming soon.

Prescription count and prescriber specialties is available for the following countries: Argentina, Bolivia, Brazil, Chile, Columbia, Costa Rica, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, R. Dominican, Uruguay, Venezuela.

Latest Market Share

The Latest Market Share section provides a 12-month analysis of the brand vs generic split and an overview of the market share based on product by dose form and dose form by strength.

Market Share History

The Market Share History chart displays the product, dose form, pack country or marketer history in either 3 or 5-year views. Clicking on the checkmarks in the legend will allow you to hide or show items within the chart. By hovering your cursor over the dots on the lines, will provide additional details.

This analysis is available by sales, volume of dose units and volume of prescription counts (available on the market access tab).

Note: Only the top 9 items for each category are displayed on the chart, with the rest grouped under "Other". Details for the "Other" items can be found within the Export, available at the top of the page.

Top Competitors by Therapy Area (EphMRA)

The Top Competitors by Therapy Area chart provides a history of the product's use within therapy areas commonly associated with the product, alongside similar products. Therapy areas can be changed using the dropdown menu. Hovering over the legend and bars will display tooltips with more information.

Note: Only the top 9 products, based on market share, are displayed with the remaining grouped under "Other". Details for the "Other" items can be found within the Export, available at the top of the page.

Channels by Sales and Volume

The Channels by Sales and Channels by Volume charts provides a comprehensive view into the different Sales and Volume channels for a given product over the last 12-months. Hovering over the legend label or channel slice will display additional details.

Top Prescriber Specialties

The Prescriber Specialties chart displays the top specialties based on prescription counts by product over the last 12-months. The top nine items are displayed, with the remaining grouped under "Other".

Brand vs Generic

The term "Brand" indicates innovator products and branded generics, whereas "Generic" indicates unbranded generics. The "B" icon displayed in charts reflects innovators

Global Pricing Trends module

The Global Pricing Trends module provides pricing and reimbursement trends for prescription drugs in 80+ countries. It is available as an add-on module for subscribers of Cortellis Generics Intelligence Global and Premium only.

Users are able to search by a single or multiple API and/or trade name, as well as categories including “country”, “dose form”, “therapeutic area”, “marketer” and even limit results to those with more than/less than a specific price or between a specific price range of interest.

Searching for multiple products will return a tabular comparison view, with pricing provided as the latest and average values based on the trade name and dose form group. Searching or selecting a single API will return visual analytics and trends focused on price evolution, country comparison and reimbursement trends.

The data is sourced from Global Pricing Innovations, a UK-based data provider that has developed an expert system to globally collect and standardise pricing from over 90 markets.

Price Points

Pricing is provided at each stage of the supply chain, including:

- Ex-manufacturer: Manufacturer’s price (without VAT), and with no margins/mark-ups applied
- Wholesale: The price at which pharmacies will purchase a drug from their wholesaler, with the wholesaler mark-up applied
- Retail: Price (without VAT) with mark-up applied by the retail pharmacist
- Hospital: Price of drug within a hospital setting

Price Types

Several price types have been provided at each stage of supply, where available for a given product, to provide complete clarity on the pricing data. This includes:

- Price (Non-Discounted): Include Listed prices which are commonly used to regulate prices, as well as calculated prices based on officilially published legislative margins; they reflect the maximum price and not necessarily the transacted price
- Price Less Discount: Is the price deducting publicly available rebates, mandatory discounts, or product-specific discounts; does not apply to all products or all markets.

Prices are available in both local currency and USD for comparison purposes.

Currency

Both local currency and standardised to USD is available for comparison purposes. Where values have been converted to USD, the conversion rate will be displayed or available on hover on the Pricing Trends chart views.

Note: Currency conversions will be available on the Pricing Overview table in early 2021.

Country Coverage

The module covers 90 countries at present, as seen below.

Countries/Territories currently covered include Albania, Algeria, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahrain, Bangladesh, Belarus, Belgium, Brazil, Bulgaria, Canada Federal, Canada Quebec, Canada Ontario, Chile, China, Colombia, Croatia, Cyprus, Czech Republic, Denmark, El Salvador, Estonia, Finland, France, Georgia, Germany, Greece, Hong Kong, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Kenya, Kuwait, Latvia, Lebanon, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malaysia, Mexico, Moldova, Montenegro, Morocco, Netherlands, New Zealand, Nicaragua,

Norway, Oman, Pakistan, Paraguay, Peru, Philippines, Poland, Portugal, Puerto Rico, Qatar, Romania, Russia, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sri Lanka, Sweden, Switzerland, Taiwan, Thailand, Tunisia, Turkey, UAE, Ukraine, United Kingdom, Uruguay, USA, Uzbekistan, Vietnam.

Latest Price and Price History

Latest price reflects current year pricing for products that are available.

Price history of up to five years is available for most countries. Where only the latest price is available for a given country, this will be indicated in the pricing trends charts in the module.

Reimbursement Trends

Reimbursement status, percentage and reimbursed price is captured for most countries.

Note: It is currently under investigation for USA and may be available in 2021. It is not available for Bangladesh, Ecuador, El Salvador, Hong Kong, Kuwait, Qatar, Singapore, Vietnam.

Exports

Data from the Pricing Overview table can be exported in excel. Underlying data from the Historical Prices and Country Comparison charts can also be exported in excel and will include values for the selected countries only.

FAQs

API Manufacturers

- **Where does Cortellis Generics Intelligence get its API intelligence?**

Our research team has been tracking global API manufacturing activities for more than 25 years. We obtain our API information from our confidential network of industry sources, including API manufacturers and their competitors, generic drug manufacturers, agents and traders, and government sources. Clarivate Research has an extensive network of industry contacts with whom we communicate on a regular basis to validate our data and provide insights into the markets.

- **Does Cortellis Generics Intelligence provide information on intermediates?**

The fundamental unit of the product is the active pharmaceutical ingredient (coverage includes vitamins, water, salts, some molecules with veterinary applications, herbal extracts etc.). We don't cover many intermediates or bulk chemicals unless they are also used as APIs. We include API manufacturers who usually produce intermediates (many steps from being an API) and may list advanced intermediates (one or two steps from being an API) in addition to APIs.

- **Does Cortellis Generics Intelligence provide information on veterinary products?**

Coverage includes only those veterinary drugs that are also used in humans. Most pharmaceutical companies in the market covered are not very involved in veterinary products. The veterinary market has a different set of requirements and regulations.

- **Why is an API listed at multiple sites for the same group?**

Companies will often list numerous sites in a DMF and many of the API manufacturers desire the flexibility of producing an active ingredient at more than one of their facilities. Cortellis Generics Intelligence does not make arbitrary decisions with regard as to which site to link the active ingredient to and therefore lists several sites.

Regulatory Filings

- **How can a company have a DMF for a product but not be listed as a manufacturer?**

Cortellis Generics Intelligence lists a company as a manufacturer only when the information can be validated. When a manufacturer files a DMF, they are supposed to have manufactured a couple of batches of the product, but that is not always the case. Since DMFs are neither approved nor disproved by the FDA, it is possible for anyone to file a DMF. So, having a DMF is not always a proof that the company can manufacture an API for commercial purposes. Companies that have filed DMFs that would not in fact be manufacturers include: traders, agents, and corporate sites that are distinct from bulk manufacturing facilities. Another cause of discrepancy is when companies stop manufacturing a product, for which they have a DMF. In cases like these the DMF can stay active until the FDA deactivates it, but the company would not have been manufacturing the product. Type II DMFs can also be filed for intermediates and finished dose products, so not all type II DMF holders will show up in our API manufacturers table.

- **Why is the number of Confirmed API by company sometimes lower than the number of Commercially Available products in the API page?**

The number of Confirmed APIs Manufactured shown in the Company Detail page is the total number of distinct APIs that are commercially available or Under Development. However, the API page shows each of the products per company site that have been confirmed as commercially available. For example, in the case of Sandoz (Novartis AG), ampicillin is listed three times because it has been confirmed as commercially available from three different API manufacturing sites.

Approvals

- **What is the Orange Book?**

The FDA Orange Book contains all approved New Drug Applications (NDAs) and approved Abbreviated New Drug Approvals (ANDAs) along with their corresponding patent and exclusivity information. Cortellis Generics Intelligence integrates the FDA updates to the Orange Book with other FDA information such as ANDA tentative approvals and discontinuations as they become available, in addition to ANDA filings we learn about through litigation. These items do not appear in the online FDA Orange Book. Product Records list all NDA/ANDA approvals (final, tentative, and discontinued for both Rx and OTC-over the counter). Filings and tentative approvals are displayed in italics and the discontinued items are greyed-out. Once the ANDA receives final approval, then the FDA will be included in the online Orange Book.

- **What are the three digits at the end of the NDA/ANDA number?**

The three digits at the end of the NDA/ANDA refer to the product number if there are multiple forms or strengths for an approved product.

- **What does "tentative" mean as a US Orange Book approval status?**

A tentative approval is issued to the applicant when the application is approvable prior to the expiration of any patents or exclusivities accorded to the reference listed drug product. A tentative approval does not allow the applicant to market the generic drug product and postpones the final approval until all patent/exclusivity issues have expired.

Launches & Pack Prices

- **Can I tell brand products from generic launches? Innovators from licensees?**

Cortellis Generics Intelligence does not distinguish between innovator and generic product launches. However, if the trade name is the same as the active ingredient, there is a strong possibility the product is a generic. Marketers other than the innovator may be licensees, and such relationships are provided in Deals. Plus, if multiple companies are selling the same branded product in different countries/territories, then it is likely that there is a licensing deal involved. If multiple companies are selling the same branded product in the same country/territory, then it is likely that some of these companies are parallel importers. Parallel importers can often be distinguished by chevron symbols (>>) next to the Marketer name and/or Trade Name.

- **How does IQVIA collect the product launch information? What channels do they use?**

IQVIA collects sales data through the traditional IQVIA network in a given country/territory. Launch details are collected as part of the MIDAS sales data collection effort. Additionally, Cortellis Generics Intelligence links another file from IQVIA that covers launch data gathered through an editorial process. By combining the two files, which are not available anywhere else, Cortellis Generics Intelligence is able to provide more complete coverage of launched products.

Once launched, IQVIA does not cover withdrawn or discontinued products. It is possible that products shown as launched are, in fact, no longer marketed by the company(s) that launched them.

- **Does IQVIA sales data include number of units sold?**

Cortellis Generics Intelligence sales data does not include number of units sold.

- **How does IQVIA collect the product launch information? What channels do they use?**

IQVIA collects sales data through the traditional IQVIA network by country/territory. Launch details are collected as part of the MIDAS sales data collection effort. Additionally, Cortellis Generics Intelligence links sales and launches data through an editorial process, which results in a more complete coverage of launched products.

- **How often is the IQVIA data updated?**

Cortellis Generics Intelligence receives IQVIA data quarterly.

Constraint Date Forecast & Exclusivities

- **Why do some products that have Paragraph IVs filed have "In litigation" as the NCD and others in the same situation do not?**

If the product patent is still present in the Orange Book, the calculated Constraint Date Forecast will be displayed, even if there is a Paragraph IV challenge on the molecule. The assumption is that the product patent will stand. However, if there is an ongoing challenge and there is no product patent standing, then it is 'In litigation'. It cannot be estimated which remaining Orange Book patent, if any, will ultimately be found constraining.

Patents & SPCs

- **What is the difference between a Publication and a Patent?**

A Publication is a document that is published by a country/territory's patent office about an application or a granted patent.

- **Does the patent data include information on patent extensions?**

Cortellis Generics Intelligence patent data covers extensions for Australia, Europe, Japan and the United States.

- **Why can the country/territory associated with the primary patent be different than the priority country/territory?**

It seems that in some small or new member countries/territories, the priority information is incomplete or inaccurate at the time of filing in the local patent office. When the patent information is submitted it does not contain the actual priority info and therefore the priority country/territory may not harmonize with the primary patent country/territory.

- **Why are some SPCs held by 'individual'?**

In some countries, SPC can be transferred from corporation to the inventor(s) and vice versa. This transfer information is not readily available, the data is incomplete or available only by specific request. Also, a transfer of ownership can take place when the patent lapses for non-payment of renewal fees.

Deals

- **What is the difference between the Deals available in Cortellis Deals Intelligence and the ones available in Cortellis Generics Intelligence?**

Cortellis Generics Intelligence includes the subset of Cortellis Deals Intelligence deals that are related to products that have reached phase III or higher development status. Occasionally, there can be a deal related to manufacturing that may involve a drug that has not reached phase III. As for companies, Cortellis Generics Intelligence covers those deals that are mainly related to generics, API manufacturers or those that are related to the early development of a drug that has reached phase III or higher. All deal types are considered, including mergers and acquisitions.

R&D

- **What is the difference between the development programs available in Cortellis Competitive Intelligence and the ones available in Cortellis Generics Intelligence?**

Cortellis Generics Intelligence includes the subset of Cortellis Competitive Intelligence development programs that are related to products that have reached phase III or higher development status, and have an actual drug name, not just a development code. These products may likely include development programs in lower phases as well.

US Market Share module

- **How can a given product have multiple generic indicators under the same manufacturer?**

It is possible that the product's generic indicator changed in the course of the year (e.g. when from "multisource brand, no generic" to "multisource brand, generic") or the manufacturer is associated with different dose forms and strengths each of which may have a different generic indicator.

- **Why are there more marketers listed in the Market Share Module than in the Dose Form Detail table?**

The data source for the Market Share Module is from MarketScan from IBM Watson Health, formerly Truven Health Analytics, and is based on patient medical claims. The Dose Form Detail table data is from IQVIA and is based on the traditional IQVIA network. There is not a direct correlation between the two.

Global Pricing Trends

- **What does the reimbursement present indicate in the Reimbursement trends chart?**

The reimbursement present is calculated by the amount the National Insurance System (NIS)/National Healthcare System (NHS) covers of the Retail + VAT price, the remaining present is covered by the patient as out-of-pocket expense or the insurer (if other than NIS).

- **What is the difference between Canada-Ontario and Canada-Federal, and why it seems Canada-Ontario to has more records than Canada-Federal?**

This is due to the following reasons:

  - For Ontario prices get extracted from "Ontario Drug Benefit Formulary" whereas for Federal from CADTH
  - Quebec publishes its own prices and therefore the need to deferential when Federal prices are not applicable across the two provinces

As Quebec and Ontario have different prices due to budget allocation Federal has less records.

System requirements

The following systems are supported, latest versions are recommended.

Devices	Desktop
	Laptop
Operating Systems	Windows
	MacOS
Browsers	Chrome
	Firefox
	Edge
	Safari*
	Internet Explorer 11**
Export	Filename.xlsx; requires spreadsheet reader such as Microsoft Excel or similar
	Filename.pdf; requires PDF reader such as Adobe Reader or similar
Additional	Pop-up blockers need to be disabled
	No plug-ins are needed

* Cortellis Generics Intelligence is tested on, but not optimized for these browsers.

** In 2021, we will be phasing out support for IE11. We recommend you experience Cortellis on any of the other supported browsers.