

### What does TARIUS® provide?

#### Easy access to regulatory FAQ's and national authorities' guidances

The <http://parabio.tarius.com> web-portal created by Tarius® consolidates Human Drug and Biologics information into a single, searchable interface providing you with immediate access to information

#### "Google-like" ease of use.

Tarius® offers the power and user-friendly functionality to help you quickly find, use and share the exact information you need.

Paragon Biomedical has an enterprise-wide subscription to the contents detailed in this Tip Card. This insures unlimited access for all Paragon Biomedical staff.

### What you need to know

#### News Services

Receive Weekly Newsletter by Email:  
You will find the link to sign up for the newsletter on the front page of the <http://parabio.tarius.com> web-portal.

#### Personalize Your Newsletter:

You may personalize your email by selecting the topic areas of your interest. You will then receive your newsletter every Monday morning.

#### Contents and updates

#### National authorities' regulations, guidelines, forms, etc:

Tarius monitors national governments' and relevant national authorities' websites to provide organized compilations of acts, regulations, directives, codes, decisions, policy papers, guidelines, forms and more.

The authorities' documents are provided in the national language and English metadata are added to each document (title, keywords, abstract, etc), enabling effective search.

All reference documents are monitored continuously and updates are uploaded to the web portal on a daily basis.

#### Expert summaries:

The summaries are written by Tarius' global network of independent experts. This information is reviewed and updated systematically on a monthly basis. See list of topics covered on page 2.

#### Link to Experts:

You will find a link to the expert's names, emails and websites on the front page of the <http://parabio.tarius.com> web-portal.

### Training Resources

#### e-Learning

Free web-based tutorial on the <http://parabio.tarius.com> web-portal.

#### Other Support

Tarius staff offer support via LiveMeeting or, if in the area, for groups. In addition technical support and a Help feature are available thru the web portal.

### Organization of Documents by Region & Country

National Authorities' reference documents and Tarius Expert Summaries concerning

USA, Canada, Argentina, Australia, Chile, India, Russia

European countries: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, The Netherlands, Poland, Romania, Slovak Republic, Spain, Sweden, Switzerland and United Kingdom

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### Symbols

**Status: Current** When displayed, the legal status of the document is clearly indicated by the color code.  
**Status: Draft** Documents with no legal status or for which a legal status is irrelevant display the status indication NOT APPLICABLE.  
**Status: Archive**

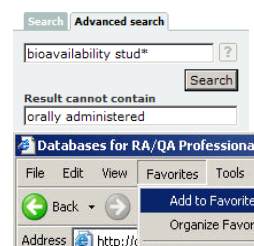
**News** = Displays most recent documents added to product

**Topic** = Displays a set of pre-defined searches. Select a topic and sub-topics to narrow your focus.

**A-Z** = Displays all documents in the product by title

### Save Favorite Searches

Insert your search expression using either the basic or the advanced search function in Tarius. Select the browser's menu 'Favorites, Add to favorites'. Rename the favorite as you wish in order to identify the document. Organize your favorite shortcuts in folders as you wish.



### Shortcuts to Favorites

Use your Internet Browser to create shortcuts to favorite documents.

Rename the bookmark as you wish in order to identify the document.

### Open in New Window

Click 'Ctrl+N' or use 'File, New Window' in the browser's menu bar of Internet Explorer to open multiple windows at the same time.

Alt., hit the 'Shift' key while clicking on a hyperlink. This opens the next document in a separate window

## Searching

In the Tarius web portal you can choose between *simple search* and *advanced search*. *Simple search* is used for broad searches and usually followed by sorting the search result. *Advanced search* is used to make a more precise search, i.e. for a particular document or within a particular period of time. The principles below apply to both *simple* and *advanced search*.

Principle	Explanation	Example
<b>word</b>	Key in a single word followed by <i>Enter</i> or clicking on the <i>search</i> button.	<b>toxic</b> This will find all the documents which contain the word toxic.
<b>space</b>	When searching for more than one word, separate them with a space.	<b>toxic substance</b> This will find all the documents which contain both words. Documents in which the words are found beside or near each other will be listed at the top. Note: all words matter - each additional word limits the results.
<b>"..."</b>	Search for a phrase by using quotation marks.	<b>"toxic substance"</b> This will find all the documents containing the phrase toxic substance.
<b>*</b>	Truncating a word.	<b>substance*</b> This will find documents that contain the words substance or substances. <b>authori*ation, labe*ing, p*diatric</b> will find documents with British or American spellings in one search. Note: You cannot truncate words in a phrase surrounded by quotation marks.
<b>-</b>	Excluding a word.	<b>toxic substance -hazardous</b> This will find documents containing the words toxic and substance, but not those containing the word hazardous.
<b>title:</b>	The word must be found in the document title.	<b>title:toxic</b> This will only find documents which contain the word toxic in the title.
<b>body:</b>	The word must be found in the text of the document.	<b>body:toxic</b> This will find documents which contain the word toxic in the document text.
<b>combinations</b>	Combination of search expressions.	<b>title:clinical p*diatric -safety</b> This will find documents that contain the word clinical in the title, the word pediatric or paediatric anywhere in the document and that do not contain the word safety.

## Comments or questions?

Your input is important to us! If you have problems, comments or suggestions for further improvements, please contact:

**Kimberley Mihalovich,**  
Direct phone: (1) 949.224.2895  
Email: [kmihalovich@parabio.com](mailto:kmihalovich@parabio.com)

If you are having any technical problems (for example login issues), please contact Tarius via email: [support@tarius.com](mailto:support@tarius.com). If possible, please also attach a screen dump which illustrates your problem, any related error message, etc.

## National Expert Summaries

Original documents written by Tarius' national experts following the same table of contents about the practical implementation of the international regulations, guidelines and "best practices" in a particular country. They cover all major aspects of the drug product life cycle from product development to the post-marketing period. The summaries are reviewed on a monthly basis.

### Topics covered:

#### *National Authorities*

- Ministry for Health Products
- National Health Product Authorities
- Other National Authorities

#### *Drug Development*

- Scientific Advice
- Conduct of Clinical Trials

#### *Mktg Authorisation Applications*

- The National Procedure
- Electronic Submissions
- Products Requiring Mktg Authorizations
- Orphan Drug Designation
- Format & Content of Applications
- Packaging & Labeling Requirements

#### *Exemptions*

- Parallel Import
- Compassionate Use / Temporary Us
- Import of Products Manu in Foreign Countries*
- Import of Health Products

#### *Maintenance of Mktg Authorizations*

- Variations, Renewals, Line Extensions
- Transfers, Withdrawals
- OTC Switch (Changes of Legal Status)

#### *Pricing & Reimbursement*

#### *The Post Mktg Period*

- Adverse Event Reporting
- Advertising
- Inspection of Manufacturing Sites
- Sale to Consumers

#### *National Fees*

#### *National Industry Associations*