



# USE IDRAC TO RETRIEVE REGULATORY INFORMATION SPECIFIC TO THE EUROPEAN UNION

Listed below are a few different ways to access information. Make sure you have the **European Union** selected as your region in the drop down list.

## 1. How do I find the comparative table on Fees for the Decentralized Procedure?

<b>IDRAC EXPLANATORY</b> European Union Region	<b>ADVANCED SEARCH</b> European Union Region
<ul style="list-style-type: none"><li>• IDRAC Comparative Tables</li><li>• Comparative Tables on Fees</li><li>• Fees for Decentralized Procedure</li></ul>	<b>Keyword Field:</b> "Fee" AND "Decentralized Procedure" <b>Click 'Search'</b>

## 2. Where do I find the latest documents of the Notice to Applicants about the CTD?

<b>REFERENCE TEXTS</b> European Union Region	<b>ADVANCED SEARCH</b> European Union Region
<ul style="list-style-type: none"><li>• Commission</li><li>• Notices to Applicants</li><li>• Table 2B-1</li></ul>	<b>Keyword Field:</b> "NTA" AND "CTD" <b>Click 'Search'</b>

## 3. How do I find information about the CHMP's main tasks, composition, membership and meeting schedule?

<b>IDRAC EXPLANATORY</b> European Union Region	<b>ADVANCED SEARCH</b> European Union Region
<ul style="list-style-type: none"><li>• EU Committees &amp; Working Group Overview</li><li>• EMEA Committee for Medicinal Products for Human Use (CHMP)</li></ul>	<b>Title Field:</b> "Committee for Medicinal Products for Human Use" <b>Click 'Search'</b> <b>Click 'Filter' drop down list:</b> Select <i>IDRAC Explanatory</i> . The results page will automatically be refreshed displaying only <i>IDRAC Explanatory Documents</i>

## 4. How do I find the documents issued by the Committee for Paediatric Drugs (PDCO)?

<b>REFERENCE TEXTS</b> European Union Region	<b>ADVANCED SEARCH</b> European Union Region
<ul style="list-style-type: none"><li>• Paediatric Committee (PDCO)</li></ul>	<b>Keyword Field:</b> "PDCO" <b>Click 'Search'</b>

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TURN THE CARD OVER TO VIEW SEARCHES FOR THE UNITED STATES





# USE IDRAC TO RETRIEVE REGULATORY INFORMATION SPECIFIC TO THE UNITED STATES

Listed below are a few different ways to access information. Make sure you have the **United States** selected as your region in the drop down list.

## 1. How do I find the final guidance for industry regarding Pharmacogenetic data submissions?

<b>REFERENCE TEXTS</b> USA Region	<b>ADVANCED SEARCH</b> USA Region
<ul style="list-style-type: none"> <li>Guidelines/Guidances</li> <li>Procedural</li> </ul>	<b>Keywords:</b> "Guidance for Industry" AND "Pharmacogenomics"  <b>Click 'Search'</b>

## 2. Where can I find the guidelines pertaining to Generics?

<b>REFERENCE TEXTS</b> USA Region	<b>ADVANCED SEARCH</b> USA Region
<ul style="list-style-type: none"> <li>Guidelines/Guidances</li> <li>Generics</li> </ul>	<b>Abstract Field:</b> "Current Version"  <b>Keyword Field:</b> "Generic" AND "Guidance for Industry"  <b>Click 'Search'</b>

## 3. Which documents explain the process for the import of investigational new drug (IND) products for use in clinical trials?

<b>IDRAC EXPLANATORY</b> USA Region	<b>ADVANCED SEARCH</b> USA Region
<ul style="list-style-type: none"> <li>Clinical Research</li> <li>Investigational Products</li> </ul>	<b>Keyword Field:</b> "Clinical Trial" AND "IND" AND "Import"  <b>Click 'Search'</b>  <b>From the Results Page, Click 'Filter' drop down list:</b> Select <i>IDRAC Explanatory</i> . The results page will automatically rerun displaying only <i>IDRAC Explanatory Documents</i>

## 4. How do I find Advisory Committee documents including the AdComm Bulletin, AdComm Profiles, and AdComm Voting?

<b>IDRAC EXPLANATORY</b> USA Region	<b>ADVANCED SEARCH</b> USA Region
<ul style="list-style-type: none"> <li>Advisory Committees</li> <li>AdComm Bulletins</li> <li>AdComm Profiles and Voting Histories</li> </ul>	<b>Keywords:</b> "AdComm Bulletin" OR "AdComm Profile" OR "AdComm Voting"  <b>Click 'Search'</b>

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