

AMENDMENT APPLICATION FOR A LICENCE TO MANUFACTURE/ASSEMBLE THERAPEUTIC PRODUCTS

You may wish to print a copy of this application guide for easy reference before proceeding with the application submission.

Please also note that companies must register with CRIS and applicants must have valid CRIS user rights in order to be able to submit applications on behalf of the company via PRISM@HSA.

For information and application for CRIS account, you can click [here](#). For enquiry relating to CRIS, you can contact us at HSA_CRIS@hsa.gov.sg.

1. The online form is estimated to take an average of 20 minutes to fill in. The time taken varies depending on the number and sizes of the file attachments, configurations of your computer and network system, internet performance etc. The recommended computer and network configurations are as described at http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/PRISM_e-services/system-requirements-for-prism.html.

Please note that the time stated above excludes the preparatory work in relation to filling the online form (e.g. scanning documents for file attachments).

2. You may need the following information/item(s) to fill the form:
 - Updated Site Master File, if applicable. Please note that the Site Master File should be prepared in accordance with the PIC/S Explanatory Notes for Pharmaceutical Manufacturers on the Preparation of a Site Master File which is available from HSA website at <http://www.hsa.gov.sg>.
 - Certificate of Accreditation of the contract testing laboratory, if applicable.
 - Letter of approval issued by the agency/institution that approves the use of the premises for the manufacturing and storage of health products, if applicable.
 - Details of the dosage forms and products (i.e. name, strength and product licence number, if applicable) manufactured and/or assembled. Please also indicate if your company is acting as a contractor acceptor (i.e. manufactures partially/wholly for others) for these products.
3. The applicant will require a CorpPass or SingPass* before he/she can login to PRISM to retrieve the application form. A person who drafts an application on behalf of his/her company and is not a Singaporean Citizen, Permanent Resident or Employment Pass holder can apply for a HSA PIN to login to PRISM. The CorpPass / SingPass* or HSA PIN login is necessary for authentication and authorisation purposes.

** During the transition period from now to 31 August 2018, both SingPass and CorpPass can be used to login to PRISM. However, as CorpPass will eventually replace SingPass for business transactions with the government, companies / business entities are encouraged to familiarise themselves with the usage of CorpPass.*

** With effect from 1 September 2018, the applicant will require a CorpPass before he/she can login to PRISM.*

For more information, please refer to http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/CRIS_Updates.html

For more information on CorpPass, please refer to
<http://www.corppass.gov.sg/>

For more information on HSA PIN, please refer to
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/HSA_PIN.html

4. Mode of payment

Please note that there will be no refund of any payment made in relation to applications submitted through PRISM.

The mode of payment available is as follows:

- Non-GIRO: eNETS (Credit/Debit Card)
- GIRO (Preferred mode of payment)

Payment by GIRO requires pre-registration. The [GIRO application form](#) is required to be submitted by post to the HSA Finance Department. The correspondence address can be found in the application form. The registration process will take around 3 to 4 weeks after the submission of the application form.

Application Form

Part Zero – Licence/Permit/Certificate/Listing Summary

The applicable Licence No, the effective and expiry dates of the existing licence will be displayed for your information.

PQ1001 AMENDMENT FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

Fill in the application form					Guideline	Help
0. Licence Summary	3. Pharmaceutical Dosage Form	6. Warehouse Particulars	9. Personnel Particulars	12. Confirmation		
1. Company Particulars	4. Forensic Classification	7. Other Products Manufactured in Same Premise	10. Licence Duration	Special Symbol		
2. Applicant Particulars	5. Manufacturing Particulars	8. Contract Testing Laboratories Particular	11. Supporting Attachments	Attach Save		

1. Licence/Permit/Certificate/Listing Summary	
1.1 Licence/Permit/Certificate/Listing No.:	<input type="text"/>
1.2 Start Date:	<input type="text"/>
1.3 Expiry Date:	<input type="text"/>
1.4 Amendment Details:	<input type="text"/>
1.5 Site Inspection (Please refer to the guidelines, available at the top right hand corner, before selection)	<input type="radio"/> This amendment requires site inspection <input type="radio"/> This amendment does not requires site inspection

[Next](#) [Reset](#)

The applicant would need to furnish the following information:

- 1) Amendment Details (Please provide in this entry the reason for the amendment)

The applicant has to make amendment(s) to the licence when the following changes occur:

A) Examples of changes which may require on-site audit:

- Addition or amendment of manufacturing site address
 - Please note that each Manufacturer's Licence is issued to each company with a specific manufacturing address and postal code. If your company is relocating the manufacturing premise to a different address (i.e. postal code), please submit a new application.
 - Your company may file for amendment application if there is addition or relocation of manufacturing activities within the approved building (e.g. addition of unit or floor) and/or postal code.
- Addition or amendment of warehouse address, including addition of third party logistic warehouse.
- Addition of cold-chain activities.
- Addition or amendment of manufacturing activities (i.e. manufacture or primary assembly or secondary assembly) for approved dosage form(s)

- Addition of manufacturing activities of product comprising highly sensitizing materials (e.g. penicillins, cephalosporins, hormones, steroids, etc.) and/or biologicals (including vaccines, blood products, preparations containing viruses and other micro-organisms) and/or cytotoxic substances.

B) Examples of changes which do not involve on-site audit. The appropriateness of such changes would be assessed in the next audit.

- Amendment of company name or business address (Note: Such amendment has to be made via the "Change of Company Information" module)
- Amendment of applicant
- Amendment of person in-charge of production or quality control
- Addition or amendment or deletion of contract testing laboratory address or type of analytical test performed
- Deletion of approved manufacturing site address
- Deletion of approved warehouse address
- Deletion of approved manufacturing activities
- Deletion of approved dosage form
- Addition of new dosage forms for secondary assembly

If you are in doubt or encounter a situation which is not found in the above lists of examples, please contact us before submission.

Part One - Company Particulars

The company name and address will be pre-populated based on the registered CRIS records. If you need to make changes to this information, please submit the change via the "[Amend Company Information](#)" module.


Part Two – Applicant Particulars

The section requires the applicant to furnish this information

- 1) Applicant's Name
- 2) Applicant's NRIC/Fin
- 3) Applicant's Designation
- 4) Contact Details like Telephone/Fax/Handphone/Pager number and E-mail address
- 5) Preferred Contact mode

(Please note that your preferred contact mode is the delivery mode of which you will receive the final notification of this application. During the course of this application, you will receive our input requests (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)

PQ1001 AMENDMENT FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

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[Previous](#) [Next](#)

Fields marked with an asterisk * are mandatory.

2. Applicant Particulars	
2.1 Name : *	<input type="text"/> (as in NRIC/FIN)
2.2 NRIC/FIN : *	<input type="text"/> (Example: S1234567A, F1234567A)
2.3 Designation : *	<input type="text"/>
2.4 Contact Details	
2.4.1 Tel : *	<input type="text"/> 2.4.2 Fax : <input type="text"/>
2.4.3 Handphone :	<input type="text"/> 2.4.4 Pager : <input type="text"/>
2.4.5 Email :	<input type="text"/>
2.5 Preferences	
2.5.1 Preferred Contact Mode : *	<input type="radio"/> Email <input type="radio"/> Fax <input type="radio"/> SMS (Please ensure that the relevant contact details above is entered for your preferred contact mode. Please note that this preferred contact mode is the mode which you will receive the final notification of this application. During the course of this application, you will receive our input requests (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)

[Previous](#) [Next](#) [Reset](#)

Part Three – Pharmaceutical Dosage Form

The section requires the applicant to furnish the following information if there is an amendment to the details. **Otherwise, please do not amend any details at this section.**

To amend the dosage form, you will just have to click on the dosage form of interest, and the page will refresh to display the particulars of the dosage form. Click on “Update” to update any changes you have made. You may also choose to add or remove any of the previously applied dosage forms.

To add new dosage form(s):

1) **Dosage form.**

You can select the dosage form(s) your company is dealing with from the list provided. If a dosage form you are dealing with is not included in the list provided, please select the option “Others” from the list provided, and give details of the dosage form in section 3.2

Dosage forms	
Active Pharmaceutical Ingredient (API)	Non-sterile semi-solid preparations
Admixtures for intravenous infusion	Oral Liquid Preparations
Beads	Oral powders and granules
Dental Liners	Pastilles
Dry powder inhalers	Pessaries
Ear drops	Pills
External Liquid Preparations	Powder Preparations for inhalation
Foams	Powders and granules for oral liquid preparations
Hard Capsules	Reconstituted cytotoxic preparations
Implants	Soft Capsules
Injectable admixtures containing pencillins or cephalosporins	Sterile non-injectable liquid preparations
Injectable reconstituted preparations containing cytotoxic medical products	Sterile powders for injection
Injections	Sterile powders for irrigations
Injections (Radiopharmaceuticals)	Sterile semi-solid preparations
Intracular drug delivery systems	Sterile strips
Liquid Preparations for nasal administration (non-sterile)	Suppositories
Liquid preparations for inhalation (non-sterile)	Tablets for external administration
Medicated Gums	Tablets for oral administration
Medicated Tampons	Total parenteral nutrition preparations
Medicated Soap bars	Transdermal patches
Medicinal Gases	Others
Non sterile powders for topical applications	

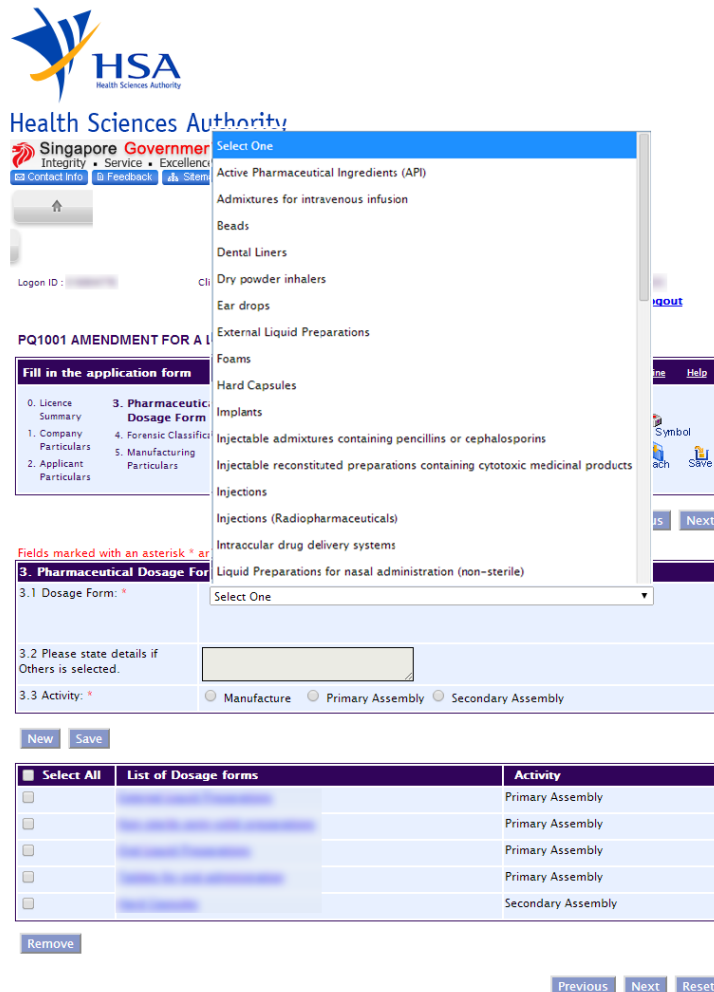
2) Activity

Please select the relevant activity for each dosage form you are dealing with, and save the entry. You will see the page refreshes, and the refreshed page will display the details of the dosage form with its associated activity you have added

- Manufacture (i.e. manufacturing of the bulk product only or as well as primary and/or secondary assembly of the selected dosage form).
- Primary Assembly (select this if your company is conducting primary assembly or both primary and secondary assembly for the selected dosage form only).
- Secondary Assembly (select this if your company is conducting secondary assembly for the selected dosage form only).

To remove the manufacturing activities for each dosage form(s), please select the correct dosage form and activity displayed in the list and click the 'Remove' button.

Please note that for addition of new dosage form, relevant manufacturer/assembler information is also required to be filed/updated in the product licence with the Therapeutic Products Branch of Pre-Marketing Division for each product in the dosage form selected, if applicable.



3. Pharmaceutical Dosage Form

3.1 Dosage Form: *

3.2 Please state details if Others is selected.

3.3 Activity: * Manufacture Primary Assembly Secondary Assembly

Select All	List of Dosage forms	Activity
<input type="checkbox"/>	[blurred]	Primary Assembly
<input type="checkbox"/>	[blurred]	Primary Assembly
<input type="checkbox"/>	[blurred]	Primary Assembly
<input type="checkbox"/>	[blurred]	Primary Assembly
<input type="checkbox"/>	[blurred]	Secondary Assembly

Part Four – Forensic Classification

The section requires the applicant to furnish the following information if there is an amendment to the details. **Otherwise, please do not amend any details at this section.**

- 1) Forensic classification. Please select the relevant forensic classification(s) of the products you manufacture or assemble. You can select more than one option.

PQ1001 AMENDMENT FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

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Fields marked with an asterisk * are mandatory.

4. Forensic Classification	
4.1	<input type="checkbox"/> Prescription Only
4.2	<input type="checkbox"/> Pharmacy Only
4.3	<input type="checkbox"/> General Sale List

[Previous](#)
[Next](#)
[Reset](#)

Part Five – Manufacturing / Assembly Particulars

The section requires the applicant to furnish the following information if there is an amendment to the manufacturing site particulars. **Otherwise, please do not amend any details at this section.**

All manufacturing or assembly addresses where the manufacturing and/or primary or secondary assembly activities are performed should be detailed, providing the Level and Unit number, where applicable.

To amend the manufacturing site address, click on the manufacturing site of interest, and the page will refresh to display the details of the manufacturing/assembly address. After you have amended the address, Click on the “Save” button.

To add new Manufacturing/Assembly Address, click on the “New” button. Please remember to click the ‘Save’ button after updating the address.

To remove manufacturing address, please select the address of interest from the Manufacturer List and click the ‘Remove’ button.

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[Previous](#) [Next](#)

Fields marked with an asterisk * are mandatory.

5 Manufacturing/Assembly Address	
5.1 Address Type : *	Local
5.2 Postal Code : *	<input type="text"/> Retrieve Address
5.3 Block / House No :	5.4 Level - Unit : # <input type="text"/> - <input type="text"/>
5.5 Street Name :	
5.6 Building Name :	
5.7 Country :	SINGAPORE

[New](#) [Save](#)

<input type="checkbox"/> Select All	Manufacturer List
<input type="checkbox"/>	[Link]

Part Six – Warehouse Particulars

The section requires the applicant to furnish the following information if there is an amendment to the warehouse particulars. **Otherwise, please do not amend any details at this section.**

All storage and handling addresses for raw and bulk materials, packaging materials and finished products should be detailed, providing the Level and Unit number, where applicable. To amend the warehouse address, click on the warehouse of interest, and the page will refresh to display the details of the warehouse address. After you have amended the address, click on the “Reset” button.

To add new warehouse address, update the detail and click on the “Add Warehouse” button.

To remove warehouse address, please select the warehouse of interest and click the ‘Remove’ button.

PQ1001 AMENDMENT FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

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[Previous](#) [Next](#)

Fields marked with an asterisk * are mandatory.

6. Warehouse Particulars	
6.1 Warehouse Address	
6.1.1 Address Type : *	Local
6.1.2 Postal Code : *	<input type="text"/> Retrieve Address
6.1.3 Block / House No :	6.1.4 Level - Unit : # <input type="text"/> - <input type="text"/>
6.1.5 Street Name :	
6.1.6 Building Name :	
6.1.7 Country :	SINGAPORE
6.2 Storage Condition of Warehouse	
6.2.1 Temperature: *	<input type="checkbox"/> 15C to 30C (Room Temperature) <input type="checkbox"/> 8C to 15C (Cool) <input type="checkbox"/> 2C to 8C (Refrigerate, Do not freeze) <input type="checkbox"/> -10C to -20C (Freeze) Others <input type="text"/>
6.2.2 Relative Humidity:	Min <input type="text"/> % - Max <input type="text"/> %
6.2.3 Approved By:	Select One <input type="text"/>

[Add Warehouse](#)

SN	<input type="checkbox"/> Select All	Warehouse List
1	<input type="checkbox"/>	

[Remove](#)

[Previous](#) [Next](#) [Reset](#)

Part Seven – Other Products Manufactured in Same Premise

The section requires applicant to furnish the following information if there is an amendment to the details. Otherwise, please do not amend any details at this section:

- Categories of products. Please select from the list provided the substance(s) your company is also manufacturing/assembling. You can select more than one option.

PQ1001 AMENDMENT FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

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[Previous](#) [Next](#)

Fields marked with an asterisk * are mandatory.

7. Other Products Manufactured in Same Premise	
7.1 Categories of Products: *	
<input type="checkbox"/> Penicilins	<input type="checkbox"/> Cytotoxics
<input type="checkbox"/> Steroids	<input type="checkbox"/> Biological
<input type="checkbox"/> Cephalosporins	<input type="checkbox"/> Not Applicable
<input type="checkbox"/> Hormones	<input type="checkbox"/> Non-medical products
7.2 If non-medical products, state whether contain hazardous or toxic substances	
<input type="text"/>	

[Previous](#) [Next](#) [Reset](#)

Part Eight – Contract Testing Laboratories Particulars

The section requires applicant to furnish the following information if there is an amendment to the details. **Otherwise, please do not amend any details at this section**

- 1) Is a contract testing laboratory engaged to conduct laboratory tests for your company? If your answer to the question is “No”, you can proceed to the next Part. If your answer is “Yes”, you will be required to give details of the contract testing laboratory in the following sections.
- 2) Name and address of the contract testing laboratory.
- 3) Type of analytical test performed by the laboratory based on your contract. You will only need to give a brief description of the test(s) performed.
- 4) If the contract testing laboratory is accredited to any international quality system standards, and the scope of accreditation. You will only need to give a brief description of the scope of accreditation.
- 5) Add the contract testing laboratory by clicking on the “Save” button. You will see the page refreshes, and the refreshed page will display the details of the contract testing laboratory you have added.

To remove Contract Testing Laboratories, select the laboratory and click on the ‘Remove’ button.

PQ1001 AMENDMENT FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

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[Previous](#) [Next](#)

Fields marked with an asterisk * are mandatory.

8. Contract Testing Laboratories Particulars	
Is a contract testing lab engaged? :*	<input type="radio"/> Yes <input type="radio"/> No

[New](#) [Save](#)

[Previous](#) [Next](#) [Reset](#)

Part Nine – Personnel Particulars

The section requires the applicant to furnish the following information if there is an amendment to the personnel. **Otherwise, please do not amend any details at this section.**

To amend the personnel, you will just have to click on the personnel of interest, and the page will refresh to display the particulars of the personnel. Click on “Update” to update any changes you have made. You may also choose to add or remove any of the previously approved personnel.

To add personnel:

- 1) Particulars of the persons in-charge of production/assembly AND quality operations. The name, identity number, designation, experience, and the designation of the supervisor to whom they directly report to should be furnished. Add the record by clicking on the “Save” button. You will see the page refreshes, and the refreshed page will display the details of the personnel you have added. You can add more than one record.

To remove Personnel, select the personnel and click on the ‘Remove’ button.

PQ1001 AMENDMENT FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

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[Previous](#) [Next](#)

Fields marked with an asterisk * are mandatory.

9. Personnel Particulars	
9.1 Person in Charge*	<input type="radio"/> Production/Assembly <input type="radio"/> Quality Operations
9.2 Name as in NRIC/Passport :*	<input type="text"/>
9.3 NRIC/FIN No :*	<input type="text"/>
9.4 Designation :*	<input type="text"/>
9.5 Experience:*	<input type="text"/>
9.6 Directly report to:*	<input type="text"/>

[New](#) [Save](#)

<input type="checkbox"/> Select All	Personnel List	
<input type="checkbox"/>		Production/Assembly
<input type="checkbox"/>		Quality Operations




[Remove](#)

[Previous](#) [Next](#) [Reset](#)

Part Ten – Licence Duration

The default licence duration is 1 year; this meant for information only and cannot be changed. Please click the “Next” button to proceed to the next section.




PQ1001 AMENDMENT FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

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2. Applicant Particulars	5. Manufacturing Particulars	8. Contract Testing Laboratories Particular	11. Supporting Attachments			
10. Licence Duration						
10.1 Duration of licence: * 1 Year						

[Previous](#)
[Next](#)
[Reset](#)

Part Eleven – Supporting Attachments

PQ1001 AMENDMENT FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

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1. Company Particulars	4. Forensic Classification	7. Other Products Manufactured in Same Premise	10. Licence Duration			
2. Applicant Particulars	5. Manufacturing Particulars	8. Contract Testing Laboratories Particular	11. Supporting Attachments			

[Previous](#)
[Next](#)

[Click here to encrypt documents](#)

Fields marked with an asterisk * are mandatory.

11. Supporting Attachments	
To add an attachment, type in the path or hit the browse button. Then hit the Attach Files button to save the attachment to the list below.	
Please click here for guideline on document attachment.	
Documents	
11.1	<input type="button" value="Choose File"/> No file chosen
11.2	<input type="button" value="Choose File"/> No file chosen
11.3	<input type="button" value="Choose File"/> No file chosen
11.4	<input type="button" value="Choose File"/> No file chosen
<input type="button" value="Attach Files"/>	

[Previous](#)
[Next](#)
[Reset](#)

Part Twelve – Declaration

Declaration	
1.	I have been authorised to make this application
2.	I undertake to carry out manufacture of medicinal products in accordance with current Good Manufacturing Practices
3.	I declare that the particulars given in this application are true and that the documents enclosed are authentic or true copies and undertake to notify the licensing authority within one week of any change in the particulars submitted in this application
4.	I, on behalf of my company, declare that there are no additional amendments made to this application, including attachment, other than those requested by the Health Sciences Authority. (This is only applicable for re-submission of application)
Accept <input type="radio"/> Decline <input type="radio"/>	

Payment Advice
No payment is required at this point of application. Payment may be advised later.

[Previous](#) [Validate](#) [Submit](#) [Reset](#)

Other useful information

1. You may check on the status of your application upon submission at track@prism.
2. Kindly contact HSA Helpdesk at the following contact details if you encounter any technical issues (IT problems) during the application submission or any enquiry relating to your CRIS account:

Hotline : 6776 0168 (from 7:00 am to midnight daily)
Fax : 6872 3054
Email : helpdesk@hsahelp.gov.sg
3. For general enquiries or questions related to licences and certificates of manufacturers, importers and wholesalers, please contact the Audit and Licensing Division at Tel: 6866 1111 or write to <https://crm.hsa.gov.sg/event/feedback.aspx>